

Nursing, Midwifery and Allied Health Professions Research Unit Scientific Review 2010-2017

Volume

2



Contents

PART 1: PROJECT SUMMARIES - COMPLETED AND IN-PROGRESS

Long Term Conditions Management

LTCM01 - Improving mental health and wellbeing	16
LTCM01.1 A feasibility study for a trial of Recovery versus Mindfulness models for depression (ReMoDe).....	17
LTCM01.2 Patient Centred Assessment Method (PCAM): improving nurse led biopsychosocial assessment of patients with long term conditions and co-morbid mental health needs.....	19
LTCM01.3 Keep Well: Minnesota-Edinburgh complexity assessment method (MECAM) to assess mental health and wellbeing.....	21
LTCM01.4 Solution Development for the challenges faced by people with dementia and their carers.....	23
LTCM01.5 Preventing Depression and Improving Awareness through Networking in the EU (PREDI-NU).....	24
LTCM01.6 Feasibility of a multi-site RCT exploring the effectiveness of mindfulness-based cognitive therapy to improve emotional wellbeing and glycaemic control among adults with type 1 diabetes.....	27
LTCM01.7 Is there anybody out there? An exploration of policy and practice in relation to addressing suicidality in children in Scotland.....	29
LTCM01.8 Finding the right ingredients: Improving mental health and wellbeing through food centred activities.	31
LTCM01.9 Exploring links between low literacy and poor health: an investigation of the experiences of people with low literacy of health service use and self-care.....	33
LTCM02 - Improving outcomes and experiences after cancer	35
LTCM02.1 Improving quality of life and swallowing function in patients with head and neck cancer: development and feasibility of a swallowing intervention package (SIP).....	36
LTCM02.2 Working after cancer: a systematic review and meta-synthesis of qualitative studies exploring experience, problems and strategies in relation to employment and return to work.....	38
LTCM02.3 Development of a sarcoma-specific patient-reported outcome measure.....	40
LTCM02.4 A qualitative evaluation of the late effects clinic at the Beatson West of Scotland Cancer Centre.....	42
LTCM02.5 Cancer diagnosis as an opportunity for increasing uptake of smoking cessation services among families: an exploratory study of patients, family members and health professional's views.....	44
LTCM02.6 Scottish cancer patient experience survey – free text analysis.....	46
LTCM02.7 TreatWELL - a feasibility study to assess the delivery of a lifestyle intervention for colorectal cancer patients undergoing curative treatment.....	48
LTCM02.8 Exploring the experiences of patients undergoing treatment and surviving with bone cancer.....	50

LTCM03 - Interventions to improve self-management of long term conditions.....	51
LTCM03.1 (Phase I) Development of interventions to increase physical activity among inactive young people with long-term conditions: MRC complex intervention framework phase 1 using asthma as an exemplar.....	52
LTCM03.2 Can eliciting and addressing health-related goals improve asthma control and asthma-related quality of life? Feasibility Phase II pilot randomised controlled trial of a brief intervention.....	55
LTCM03.3 Development of Interventions to reduce patient delay with symptoms of Acute Coronary Syndrome: identifying optimal content and mode of delivery.....	57
LTCM03.4 Development of an intervention to increase physiotherapy adherence among young children with cystic fibrosis: A Medical Research Council complex intervention framework development and feasibility study.....	59
LTCM03.5 Podiatry interventions to reduce falls in older people – a systematic review.....	61
LTCM03.6 Assessing the appropriateness and acceptability of a new multi-level taxonomy of asthma plan terms.	63
LTCM03.7 A podiatry intervention to reduce falls in care home residents: development, feasibility and acceptability study with exploratory randomised controlled trial.....	65
LTCM03.8 Exploring decision making and patient involvement in prosthetic prescription.....	68
LTCM03.9 A Phase 2 randomised controlled trial of Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy versus control in Parkinson’s disease (PD COMM pilot).....	71
LTCM03.10 A multi-centre randomised controlled trial to compare the clinical and cost effectiveness of Lee Silverman Voice Treatment versus standard NHS speech and language therapy versus control in Parkinson’s disease (PD COMM II).....	72

Pelvic health

PVH01 Prolapse.....	75
PVH01.1 Multicentre Randomised Controlled Trial of Pelvic Floor Muscle Training to Prevent Pelvic Organ Prolapse in Women (PREVPROL).....	76
PVH01.2 Surgery and physiotherapy for prolapse to avoid recurrence: a feasibility study – SUPER.....	78
PVH01.3 VUE: Vault or Uterine prolapse surgery Evaluation: two parallel randomised controlled trials of surgical options for upper compartment (uterine or vault) pelvic organ prolapse.....	80

Contents

PVH01.4	PROSPECT: Clinical and cost-effectiveness of surgical options for the management of anterior or posterior vaginal wall prolapse, pragmatic evaluation by multicentre randomised controlled trial - PROlapse Surgery, Pragmatic Evaluation and randomised Controlled Trial.....	82
PVH01.5	Mind the Gap – making pessary use for prolapse woman-centred and evidence –based.....	84
PVH01.6	NIHR HS&DR Project: 14/04/02 - Implementation of an evidence based pelvic floor muscle training intervention for women with pelvic organ prolapse (PROlapse and PFMT: implementing Evidence Locally - PROPEL).....	86
PVH02 Bladder.....		88
PVH02.1	A prospective exploration of the experiences and factors affecting the continuity of use of intermittent self-catheterisation in people with MS – COSMOS.....	89
PVH02.2	A pilot trial of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in older adults in residential care.....	91
PVH02.3	Development and clinical trial of a mixed (multi/single-use) catheter management package for users of intermittent catheterisation - MULTICATH.....	93
PVH02.4	OPAL – Optimal PFMT for Adherence Long Term: Multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence.....	95
PVH02.5	A Feasibility And Acceptability Study For A Randomised Controlled Trial Of Urinary Catheter Wash out Solutions To Prevent Blockage In Long-Term Catheter Users.....	97
PVH02.6	Development and validation of a clinical prediction rule to guide and improve the treatment of female stress urinary incontinence.....	98
PVH02.7	(Phase I) Identifying messages for physiotherapists treating female urinary incontinence: a Cochrane overview of the evidence - CRUISE.....	99
PVH02.8	(Phase III) Antibiotic Treatment for Intermittent Bladder Catheterisation: A Randomised Controlled Trial of Once Daily Prophylaxis (The AnTIC study).....	101

PVH02.9	ELECTric Tibial nerve stimulation to Reduce Incontinence in Care homes: ELECTRIC.....	103
PVH02.10	Promoting continence following stroke – developing and evaluating the implementation of a stroke rehabilitation intervention for urinary incontinence.....	104
PVH02.11	A feasibility study for a randomised controlled trial of transcutaneous posterior tibial nerve stimulation to alleviate stroke-related urinary incontinence.....	107
PVH03	Bowel.....	109
PVH03.1	(Phase 1) Feasibility of abdominal massage for the alleviation of symptoms in people with Parkinson’s Disease – SCAMP.....	110
PVH03.2	Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis – AMBER...	112

Contents

Stroke

STROKE01 Communication.....	115
STROKE01.1 Cochrane review of speech and language therapy for aphasia following stroke.....	116
STROKE01.2 Collaboration of Aphasia Trialists (Phase 1).....	118
STROKE01.3 Collaboration of Aphasia Trialists [Phase 2].....	122
STROKE01.4 REhabilitation and recovery of peopLE with Aphasia after StroKE (RELEASE): Utilizing secondary data to enhance speech and language therapy interventions for people with aphasia after stroke.....	124
STROKE01.5 Clinical and cost effectiveness of aphasia computer therapy compared with usual stimulation or attention control long term post stroke (Big CACTUS).....	128
STROKE01.6 Aphasia telerehabilitation early post stroke.....	130
STROKE01.7 A family-centred approach to the management of lifestyle risk factors for recurrent stroke.....	131
STROKE01.8 Mindfulness based stress reduction to support self management of anxiety and depression following stroke: a development study.....	134
STROKE01.9 Peer support for people with aphasia following stroke.....	136
STROKE01.10 Long term consequences and recovery from stroke: what is important to stroke survivors and health professionals?.....	138
STROKE01.11 Improving stroke clinical trial design and conduct through investigations using a clinical trials resource.....	140
STROKE01.12 Hearing after stroke.....	142
STROKE01.13 Fluoxetine Or Control Unlocks Stroke (FOCUS).....	143
STROKE01.14 Living with dysarthria: evaluation of the feasibility of the implementation of a group intervention programme for stroke patients and carers, addressing the impact of dysarthria.....	145
STROKE01.15 Can an arts based creative engagement intervention following stroke improve psychosocial outcomes? A feasibility trial of a creative engagement intervention for in-patient rehabilitation.....	147
STROKE01.16 Factors associated with fatigue in non-depressed stroke patients.....	149
STROKE01.17 Nottingham Fatigue After Stroke (NotFAST study): Understanding the nature of the clinical problem and determining factors associated with fatigue in stroke patients without depression...	150
STROKE01.18 Exploring the barriers and facilitators to maintaining engagement in physical activities after the end of post-stroke rehabilitation: a qualitative study of stroke survivors, caregivers and stroke physiotherapists.....	152
STROKE01.19 Too much sitting in extended bouts in stroke survivors: a qualitative study to inform novel interventions.....	154
STROKE01.20 Life after stroke - nurse research priorities.....	155

STROKE02 Arm Function		157
STROKE02.1	Quality of Life and Health Utilities at 3 Months after Acute Ischaemic Stroke	158
STROKE02.2	A Cochrane overview of interventions to improve upper limb function after stroke (OSCAR)	160
STROKE02.3	Physical rehabilitation treatment approaches following stroke: Cochrane systematic review of the evidence (SPRUCE)	162
STROKE02.4	Development of the Standardisation of Measurements in Arm Rehabilitation Trials (SMART) toolbox	164
STROKE02.5	Adherence diaries: How can they be optimised for use in home-based rehabilitation?	166
STROKE02.6	Practical methods for meta-analysis of continuous outcomes in stroke rehabilitation trials (MASK)	168
STROKE02.7	VISTA-Rehab	170
STROKE02.8	Recruitment to stroke rehabilitation trials	172
STROKE02.9	Goal setting in community based stroke rehabilitation: A feasibility and acceptability study of implementing a goal setting and action planning practice framework	174
STROKE02.10	Optimising stroke survivor recovery through effective goal setting practice in community based rehabilitation settings: implementing research to enhance practice and improve outcomes	176
STROKE02.11	Executive function in people with stroke	177
STROKE02.12	Commercial gaming devices for stroke upper limb rehabilitation	179
STROKE02.13	LYCRA. Lycra orthosis for therapy in upper limb Rehabilitation after Stroke: The LOTUS Study	
STROKE02.14	Early VERsus Later Augmented Physiotherapy (EVERLAP) compared with usual upper limb physiotherapy: an exploratory RCT of arm function after stroke	183
STROKE02.15	Physical activity for non-ambulatory stroke survivors living at home: developing a feasible and acceptable intervention	184
STROKE03 Vision		185
STROKE03.1	Visual scanning training after stroke: dissemination to facilitate translation of evidence into practice	186
STROKE03.2	Visual scanning training interventions for people with visual field loss after stroke	188
STROKE03.3	A pilot RCT to compare the clinical and cost effectiveness of prism glasses, visual search training and standard care in patients with hemianopia following stroke (VISION trial)	190
STROKE03.4	Writing group to develop proposals aimed at evaluating the effectiveness of visual scanning training on activity and participation in patients with visual problems after stroke	192

Contents

STROKE04 Oral Health Care	194
STROKE04.1 Cochrane review of staff-led interventions for improving oral hygiene in patients following stroke.....	195
STROKE04.2 A multi-centred, stepped wedge, cluster randomised controlled trial to compare the clinical and cost effectiveness of a complex oral health care intervention and standard oral health care in stroke care settings: a Phase II pilot trial (SOCLE II).....	197
STROKE04.3 DORIS Guidelines Project.....	199

Health and Behaviour Change

HBC01 Primary prevention of ill health through behaviour change	202
HBC01.1 Feasibility study of how best to engage obese men in narrative SMS (Short Message System) and incentive interventions for weight loss, to inform future effectiveness and cost-effectiveness trial.....	203
HBC01.2 Feasibility study for a weight loss intervention for women treated for breast cancer (PhD Studentship).....	206
HBC01.3 Reducing alcohol-related harm in disadvantaged men: development and feasibility assessment of a brief intervention delivered by mobile.....	208
HBC01.4 (Phase I) Community-based health improvement for disadvantage women: could a physical activity/healthy eating intervention be delivered in Bingo clubs in Scotland?.....	210
HBC01.5 HBC01.5 - Ways to intervene and support engagement of older adults weight loss study (WISE OWLS).....	212
HBC01.6 Systematic reviews and integrated report on the quantitative and qualitative evidence base for the management of obesity in adult men ROMEO.....	213
HBC01.7 Reducing alcohol consumption in obese men: development and feasibility testing of a complex community-based intervention (MACRO).....	216
HBC01.8 Reducing binge drinking among disadvantaged men through a brief intervention delivered by mobile phone: A multi-centre randomised controlled trial.....	217
HBC01.9 Adapting and piloting an informal school-based peer-led intervention for smoking prevention in Scotland (ASSIST-Scotland): an exploratory trial.....	219
HBC01.10 Improving physical activity levels of older people living in care homes.....	221
HBC01.11 Knowledge, attitudes and current practice of health professionals regarding the use of e-cigarettes and other smoking cessation interventions by cancer survivors.....	223

HBC01.12	A systematic literature review of population level interventions to improve health, happiness and wellbeing in the transition from adolescence to adulthood.....	224
HBC01.13	Promoting smoking cessation during pregnancy: a combined feasibility and pilot trial of a theory-based intervention using narrative, images and embedded behaviour change techniques, delivered via text-messaging (SKIP-IT).....	226
HBC01.14	We Can Quit2: a randomised pilot trial of a community-based smoking cessation intervention for women in disadvantage areas of Ireland.....	228
HBC02	Incentive interventions to change health related behaviours.....	230
HBC02.1	Benefits of incentives for breastfeeding and smoking cessation. A platform study for a trial. (BIBS)...	231
HBC02.2	CPIT III trial. Cessation of smoking in pregnancy incentives trial.....	236
HBC02.3	Use of breast pumps to improve breastfeeding outcomes: development and feasibility testing of novel incentive intervention. Short name: BABI 1: Breastfeeding And Breast-pumps Intervention.....	238
HBC02.4	Breastfeeding And Breast-pumps Intervention (BABI 0). Opinions on breast pumps: an on-line survey.....	239

Contents

Maternal and Child Health

MCH01 Maternal and Infant Mental Health and Wellbeing.....	242
MCH01.1 The development and initial validation of a screening scale for antenatal anxiety.....	243
MCH01.2 Aberlour Perinatal Befriending Support Service: An evaluation of the pilot delivery.....	244
MCH02 Maternity Services Policy and Quality of Care Delivery.....	245
MCH02.1 Developing and implementing a decision support tool for redesign of postnatal care: PRAM	246
MCH02.2 Right from the Start. A scoping study of the implementation of the GIRFEC practice model within Maternity Care in three contrasting sites across Scotland.....	248
MCH02.3 Early years interventions to improve child health and wellbeing: what works, for whom and in what circumstances? A realist review (Scottish National Midwifery Research Programme).....	250
MCH02.3 The Scottish Midwifery Research Collaboration: SMART.....	252
MCH02.4 The Scottish National Maternity Experience Programme.....	254
MCH02.5 Achieving Seamless Services for Scotland's Children.....	256
MCH02.6 Is there a relationship between ultrasound scanning ability and the visuospatial perception or psychomotor ability.....	259
MCH02.7 Improving maternal and child health in Malawi: Rotary scholarship.....	260
MCH02.8 Making a difference for Mothers and babies: Midwifery Research in Scotland.....	261
MCH03 Supporting Healthy Choices and Behaviours for Maternal and Child Health.....	262
MCH03.1 Development of a theory and evidence informed intervention to promote smoking cessation during pregnancy using narrative, text-messages and images as modes of delivery.....	263
MCH03.2 Antenatal physical activity: women's experiences and the acceptability of antenatal walking groups..	265
MCH03.3 PETER-FEST: Proactive telephone care for breastfeeding women delivered by a dedicated feeding support team in a rural community.....	267
MCH03.4 A randomised controlled trial of proactive breastfeeding telephone support for mothers of preterm infants.....	269
MCH03.5 Assets-based feeding help Before and After birth (ABA): feasibility study for improving breastfeeding initiation and continuation.....	271
MCH03.6 (Phase II) A women-centred, tailored SMS-delivered multi-component intervention for weight loss and maintenance of weight loss in the postpartum period: intervention adaptation and pilot RCT.....	273

Innovations in Services, Systems and Roles

ISSR01	Pre-hospital emergency care	276
ISSR01.1	A national prevalence survey of impaired awareness of hypoglycaemia in patients who have been attended by the Scottish Ambulance Service due to a severe hypoglycaemic event.....	277
ISSR01.2	Impact of Hypoglycaemia on healthcare services.....	278
ISSR01.3	Using record linkage analysis to inform the development of an improved care pathway(s) for psychiatric and self-harm emergencies currently transferred by ambulance to Emergency Departments.....	279
ISSR01.4	Consensus on the items and quantities of clinical equipment required to deal with a mass casualties big bang incident: an national Delphi study.....	281
ISSR02	Development and evaluation of innovations in developing services, systems and roles	282
ISSR02.1	Scottish Person Centredness Improvement Collaboration (Scopic).....	283
ISSR02.2	A qualitative evaluation of the Govan SHIP: a social and health integration partnership project.....	286
ISSR02.3	The Evaluation of the Implementation of Advanced Nurse Practitioner Roles in Primary Care.....	288
ISSR02.4	Qualitative baseline evaluation of community hub pilots in NHS Fife and NHS Forth Valley..	289
ISSR02.5	Using “Good Goals” to improve children’s occupational therapy services: a feasibility study of a multifaceted intervention.....	291
ISSR02.6	Evaluating the impact of mental health nursing initiatives in Scotland: the 3 R’s.....	293
ISSR02.7	Revolutionising psychological trauma care: providing the final details for an NIHR application for a robust evaluation of effectiveness, reach and context dependence of a novel Scottish government funded model of care.....	295
ISSR02.8	(Phase I) Shared decision-making in treatment evaluation.....	296
ISSR02.9	(Phase IV) Evaluation of the Scottish Recovery Indicator tool.....	298
ISSR02.10	(Phase IV) A theoretically informed exploration of practice change in speech and language therapy..	299
ISSR02.11	Development and Validation of the ‘valuing people as individuals scale’ VPAIS.....	301
ISSR02.12	ECCO oncopolicy project: Systematic review.....	302

Contents

Methods

M01.1	Developing meta-ethnography reporting guidelines and standards for research (eMERGE).	305
M01.2	Identifying and assessing different approaches to developing complex intervention (INDEX study)	307
M01.3	A Scottish improvement science research, development and knowledge translation collaborating centre (SISCC).....	309
M01.4	(Phase 1) Guidance to optimise pilot study design and conduct: a joint HTMR and NIHR HTA 'research on research' proposal.....	311
M01.5	Developing theory based behaviour change interventions to minimise drop-out in randomised trials (Systematic Techniques to Enhance Retention in RCTs: The STEER Project).....	312
M01.6	(Phase II) ConDuCT-II Hub. Collaboration and innovation for difficult and complex randomised controlled trials in invasive procedures.....	313
M01.7	Methods and strategies for the development of optimised complex health interventions: exploring existing and potential new approaches.....	315
M01.8	ACTIVE - Authors and consumers together impacting of evidence.....	317

NMAHP Policy & Practice Development & Research Career Development

PPRC01.1	Clinical Academic Nursing & Midwifery Research Careers for Scotland.....	320
PPRC01.2	Carnegie Centenary Professorship.....	322

PART 2: PUBLICATIONS

NMAHP-Research Unit Publications 2010-2017.....	325
Details of publications in the top 5% of all research outputs scored by Altmetric.....	365
Publications cited in online policy documents.....	377
Publications reported in high-profile online news outlets.....	383



1

PART 1:
PROJECT SUMMARIES –
COMPLETED AND
IN-PROGRESS

LONG TERM CONDITIONS MANAGEMENT



IMPROVING MENTAL HEALTH AND WELLBEING



We believe that there is strategic value to SG and NHS Scotland from funding the NMAHP unit. It is well recognised that the lack of a robust evidence base for many NMAHP delivered interventions results in significant variation in the processes and outcomes of care disadvantaging sections of the patient population and creating challenges for policy makers. The NMAHP unit has a significant role to play in producing high quality research in a number of these therapeutic interventions



Project Number:	LTCM01.1
Status:	Complete
Project Title:	A feasibility study for a trial of Recovery versus Mindfulness models for depression (ReMoDe)
Source of funding and total value of award:	Chief Scientist Office, £224,995
Value of funding to NMAHP RU:	£201,114
Principal investigator/co-applicants:	Maxwell M (PI) (University of Stirling), Mercer S (University of Glasgow), Williams C (University of Glasgow), Donaldson C (Glasgow Caledonian University), Dougall N (University of Stirling), Bradstreet S (Scottish Recovery Network), MacGregor A (ScotCEN), Ettershank C (Action on Depression), McHugh G (Edinburgh University), Calveley E (University of Stirling).
NMAHP RU investigators:	Maxwell M, Dougall N, Calveley E.
Workstream:	Long Term Conditions Management
Start date:	December 2012
Duration:	22 Months

Aim(s):

To establish whether it would be feasible and worthwhile to conduct a community based full-scale randomised trial of the effectiveness and cost-effectiveness of two group-based interventions for people with recurrent depression, namely the recovery-based Wellness Recovery Action Planning (WRAP) versus Mindfulness Based Cognitive Therapy (MBCT).

Summary:

The study attracted 148 potential participants, against a target of 120 (69 from Edinburgh, 49 from Glasgow and 25 from Inverness-shire). 109 of these were screened for eligibility and 67 (61%) of were deemed eligible to take part before recruitment was closed. Of these, 57 were randomly allocated to one of the trial arms. 37% of these withdrew from the study before the end of the

group sessions, 41% from the MBCT arm and 32% from the WRAP arm. 67% of those who dropped out did so before the groups started, mainly for pragmatic or logistical reasons. Participants generally found the groups and the methods used acceptable. Descriptive analysis of the pre/post intervention data suggested that WRAP was no worse than MBCT across outcome measures. The pilot economic evaluation suggested the methods could be used effectively to calculate costs and economic impacts of the interventions.

Community-based recruitment was highly efficient, allowing recruitment targets for eligible participants to be met quickly and effectively. The interventions and research methods used were acceptable to participants. A full scale community based trial can be efficiently run with minor modifications.

Outcomes/Impact:

Beyond studies on the qualitative impact of the Recovery approach, there is little evidence for its effectiveness across a range of potential outcomes. This study indicates that a community based randomised full-scale trial of WRAP V MBCT is feasible; and a non-inferiority design would be appropriate for comparing WRAP with MBCT. There are current deficits in evidence based non-pharmacological interventions for people who experience recurrent depression.

WRAP may provide additional community based options and this study, alongside a future definitive trial, can add to the required evidence base. This study was submitted to NIHR HTA and then to NIHR Public Health as a full proposal but was unsuccessful.

Publications:

Andy MacGregor, Susan McConville and Margaret Maxwell. WRAP groups within a Feasibility Study: Qualitative report. ScotCen Social Research, 2014.

Other dissemination activity:

- RCN Network of Psychiatric Nurses Research Conference, Coventry UK, September 2014. M Maxwell, E Calveley, A MacGregor, S Mercer, N Dougall, S Bradstreet. From feasibility to full scale trial: using the ADePT model to help identify protocol changes.
- RCN Network of Psychiatric Nurses Research Conference, Coventry, September 2014. E Calveley, M Maxwell, S Mercer, N Dougall, A MacGregor, S Bradstreet. Recruitment made easy: A feasibility study for a community based trial of Wellness Recovery Action Planning (WRAP) versus Mindfulness Based Cognitive Therapy (MBCT) for Depression.
- NHS Scotland Annual Public Health Conference, Aviemore UK, Nov 2014. A MacGregor, S McConville, M Maxwell, E Calveley. A Feasibility RCT of Wellness Recovery Action Planning (WRAP) versus Mindfulness-Based Cognitive Therapy (MBCT) interventions.
- Royal College of Nursing's Research Conference, Glasgow, April 2014 M Maxwell, E Calveley, N Dougall, S Mercer, A MacGregor, S Bradstreet Recruitment made easy: A feasibility study for a community based trial of Wellness Recovery Action Planning (WRAP) versus Mindfulness Based Cognitive Therapy (MBCT) for Depression.
- Scottish Mental Health Research Network's Annual Scientific Meeting, Glasgow, 2013. Maxwell, M., Williams, C., Mercer, S., Dougall, N., Bradstreet, S., McGregor, A., Donaldson, C., Mason, H., Day, I. and Calveley, E. Recruitment Made Easy: A feasibility study for a community based trial of Wellness Recovery Action Planning (WRAP) versus Mindfulness Based Cognitive Therapy (MBCT) for Depression.
- NatCen Social Research Newsletter article: New Scottish research adds to growing WRAP evidence base. Tuesday, 18 November 2014

Project Number:	LTCM01.2
Status:	Complete
Project Title:	Patient Centred Assessment Method (PCAM): improving nurse led biopsychosocial assessment of patients with long term conditions and co-morbid mental health needs.
Source of funding and total value of award:	NIHR HS&DR, £278,053
Value of funding to NMAHP RU:	£200,000
Principal investigator/co-applicants:	Maxwell M (PI), Hibberd C, Dougall N (All University of Stirling), Mercer S (University of Glasgow) Pratt R (University of Edinburgh/ University of Minnesota), Cameron I (University of Aberdeen), Hoy C (The Health and Social Care Alliance Scotland).
NMAHP RU investigators:	Maxwell M, Hibberd C, Dougall N.
Workstream:	Long Term Conditions Management
Start date:	April 2015
Duration:	20 Months

Aim(s):

1. To assess the acceptability and implementation requirements of the Patient Centred Assessment Method (PCAM) for use in UK primary care, particularly with practice nurses in the context of annual reviews for people with LTCs.
2. To examine fidelity of use of PCAM by practice nurses in routine annual reviews of LTCs.
3. To assess the feasibility of conducting a full-scale trial of effectiveness of the PCAM based on 2 potential units of analysis, namely intermediate level nurse behaviour and longer term patient wellbeing.

Summary:

Four Practitioner and two patient focus groups explored acceptability and implementation requirements of the PCAM which was then tested in a feasibility cluster

randomised controlled trial aiming to recruit eight GP practices and 16 Nurses. Baseline data collection was conducted with nurses prior to randomisation for a cohort of ten patients per nurse including: patient demographics, patient evaluation of consultation and patient completed outcomes (CARE, PEI, WEMWBS, GHQ, SF12); and nurse referrals/signposting to services. Patient follow-up questionnaires were completed at 8 weeks. Practices were then randomised to the PCAM intervention or care as usual (CAU). Data collection was repeated for a second cohort of patients. Fidelity was tested by comparing a sample of recorded consultations pre and post PCAM training. Qualitative interviews with PCAM nurses and a sample of patients were conducted.

From approaches to 159 eligible practices, six practices (10 nurses) were recruited with 5 practices (7 nurses) completing both data collection phases.

At baseline, nurses collected data on 113 patients and 71 (53%) completed follow-up questionnaires. Five practices were randomised: three practices (six nurses) to the PCAM arm and two practices (four nurses) to the CAU arm. In phase 2, 7 nurses collected data on 77 patients with 40 (52%) completing follow-up. Only four PCAM nurses agreed to recording consultations with five pre- and four post-PCAM recordings obtained. Post-PCAM training, there was evidence of more attention being given to patients' mental wellbeing and social issues.

Outcomes/Impact:

The PCAM intervention warrants further exploration as an effective mechanism for improving care for people with LTCs: this could be conducted within an implementation study.

The PCAM was fairly easily integrated into consultation, although some nurses reflected that this benefited from early support. Patients were not always aware of its use but most were happy to have their needs assessed. The PCAM is feasible and acceptable for use by primary care nurses and may have potential for encouraging biopsychosocial assessment of patients. Efforts required to recruit and retain staff indicate that a full trial is not feasible or cost effective at this time.

Publications:

NIHR Report due to be published August 2017

Other dissemination activity:

- RCN International Research Conference. 5-7th April 2017 Oxford. Oral presentation. Can primary care nurses improve integrated care and self-management for long-term conditions – a feasibility trial process evaluation of the person centred assessment method (PCAM). C Hibberd, M Maxwell, E Calveley, S Mercer, R Pratt, I Cameron.
- Scottish School of Primary Care Annual Conference. 18th May 2017 Edinburgh. Oral presentation. Can primary care nurses improve integrated care and self-management for long-term conditions – a feasibility trial process evaluation of the person centred assessment method (PCAM). M Maxwell, C Hibberd, S Mercer, E Calveley, R Pratt.
- Society for Academic Primary Care Annual Conference. 12-14th July 2017 Warwick. Accepted oral presentation. Patient Centred Assessment Method (PCAM): Experiences of adding the Psychosocial to the Clinical in Annual Reviews for patients with Long Term Conditions in Primary Care: A Process Evaluation of a Feasibility Randomised Controlled Trial. S Mercer, C Hibberd, M Maxwell, E Calveley, I Cameron
- BPS Division of Health Psychology. 6-8th Sept. 2017 Cardiff. Accepted oral presentation. Can primary care nurses improve biopsychosocial care and self-management for long-term conditions – a feasibility trial/ process evaluation of the person centred assessment method (PCAM). E Calveley, C Hibberd, M Maxwell, S Mercer.
- 45th North American Primary Care Research Group (NAPCRG) Annual Meeting. 17-21st November, Montreal. Accepted oral presentation. Can Primary Care Nurses Improve Integrated Care and Self-Management for Long-Term Conditions? A Feasibility Trial and Process Evaluation of the Person Centered Assessment Method (PCAM). C Hibberd, M Maxwell, E Calveley, R Pratt, S Mercer, I Cameron.

Project Number:	LTCM01.3
Status:	Complete
Project Title:	Keep Well: Minnesota-Edinburgh complexity assessment method (MECAM) to assess mental health and wellbeing
Source of funding and total value of award:	NHS Health Scotland, £65,000
Value of funding to NMAHP RU:	£4,713
Principal investigator/co-applicants:	Pratt R (PI) (University of Edinburgh/ University of Minnesota), Maxwell M (University of Stirling), Hibberd C (University of Edinburgh/University of Stirling), Cameron I (University of Aberdeen), Mercer S (University of Glasgow).
NMAHP RU investigators:	Maxwell M, Hibberd C.
Workstream:	Long Term Conditions Management
Start date:	July 2010
Duration:	15 Months

Aim(s):

The Minnesota Edinburgh Complexity Assessment Method (MECAM) has been developed to provide a practical tool for nurses conducting Keep Well health checks to assess mental wellbeing and biopsychosocial need in patients. The MECAM is a verbal assessment of patient need (conducted by trained practitioners), and uses a form to support identification of any required action.

The key aim of the research was to develop and establish face validity of the professional version of MECAM, specifically in its ability to identify mental health-related needs.

Secondary aims of the research were to:

- conduct preliminary external validity testing of the MECAM
- establish how best to integrate the MECAM into existing Keep Well health checks
- evaluate the implementation and perceived value of MECAM in a Keep Well setting.

Summary:

Developing the MECAM as a tool with high face validity was achieved through a four stage process. This included focus groups with nurses from two Keep Well teams with additional input from clinical, social science and health services academics, and an NHS Health Scotland steering group. Patient vignettes were also used to identify face validity issues and comprehensiveness of the tool. The subsequent draft version (D4) of the MECAM had four key domains:

- health and wellbeing
- social environment
- health literacy and communication
- actions

Two Keep Well health teams were trained on how to use the MECAM and then implemented the MECAM into their health checks.

Preliminary testing of the impact of the MECAM (D4) and an evaluation of the process of implementation within the Keep Well health checks were conducted via a prospective cohort study. Baseline data (phase one) were collected to assess patient satisfaction of the Keep Well health checks as well as recording of the actions (referrals and signposting) initiated by Keep Well nurses. Patient outcomes were assessed using the Client Satisfaction Questionnaire (CSQ) and the Consultation and Relational Empathy measure (CARE).

Post-implementation data were also collected (phase two), which involved repeating the same data collection as at baseline but including an additional general health scale for patients (the SF-36vs2) and the completed

MECAM forms by nurses. The SF-36vs2 was included to conduct preliminary external validity testing of the MECAM. Qualitative interviews were conducted with all participating nurses to evaluate the process of implementation, and to identify any perceived advantages and difficulties in the MECAM's use which could be addressed in the training. Finally a case study of the MECAM's use in populations with known high complexity (Gypsy Traveller and homeless) was undertaken, to consider the feasibility of using MECAM with these patient groups.

A final version of the MECAM was developed in response to the findings of this study.

Outcomes/Impact:

The MECAM was fully integrated into the Keep Well health check in NHS Lanarkshire with over 40 nurses being trained in its use. The MECAM has subsequently been developed for use in primary care by nurses conducting annual health checks for those with LTCs (see PCAM study: LTCM01.2).

Publications:

- Rebekah Pratt, Carina Hibberd, Isobel Mary Cameron, Stewart W. Mercer, Margaret Maxwell. The Patient Centered Assessment Method (PCAM): integrating the social dimensions of health into primary care. *Journal of Co-morbidity*. 2015; 5:110–119
- M Maxwell, C Hibberd, R Pratt, I Cameron, S Mercer. Development and Initial Validation of the Minnesota and Edinburgh Complexity Assessment Method for Use Within the Keep Well Health Check.

Other dissemination activity:

- www.pcamonline.org/
- R Pratt, M Maxwell. Nurse led screening for depression: what the QOF doesn't tell you. UK Primary Care Mental Health Conference. Manchester, March 2010
- C Hibberd. QOF Screening for depression in long-term conditions - Pandora's box or tick-box? How well is screening currently working in Scottish General Practices? ADEG (Academic Departments of General Practice) Conference. Dundee, January 2010
- M Maxwell Mental Health in Long Term Conditions: Complexity and how to manage this. Highland Health Conference, Inverness March 2011
- M Maxwell "A tick box exercise": Nurse led screening for depression in high risk groups. Highland Health Conference, Inverness March 2011

Project Number:	LTCM01.4
Status:	Complete
Project Title:	Solution development for the challenges faced by people with dementia and their carers
Source of funding and total value of award:	Internal university funds, £1182
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Ietswaart M (PI), Ryde G (University of Stirling).
NMAHP RU investigators:	France E.
Workstream:	Long Term Conditions Management
Start date:	June 2015
Duration:	2 Months

Aim(s):

To formulate innovative solutions to the challenges faced by people with dementia, their families and carers, health professionals, policy makers, and other end-users and stakeholders.

Summary:

On 3 June 2015 researchers from across the university came together for a full day to explore whether they could develop a multidisciplinary answer to the societal challenge of dementia. It was attended by four Crucibilists (3 from Biological and Environmental Sciences and 1 from sport) and a Stirling Crucible founding member. There were 22 delegates in total from almost every schools at Stirling University: six professors, ten academics, and six contract staff. Core to the Stirling Dementia Connections meeting was the process of rapid innovation cycles aimed at formulating innovative solutions that draw on the research expertise of the cooperative. To facilitate this, each participant first

introduced themselves and their research background, expertise, activity and dementia research interests (prospective or current). Stirling's Dementia Chair Prof Reynish had set the scene in an introductory talk describing the dementia landscape prior to this. The day was concluded by pitching the different innovation proposals to Professors Andrews and Bowes. The outcome of the meeting was a range of initial ideas for collaboration in the following four themes: 1) Assistive technology for dementia; 2) Diagnosis of dementia; 3) Animal models of dementia; 4) Lifestyle dementia prevention.

Project Number:	LTCM01.5
Status:	Complete
Project Title:	Preventing Depression and Improving Awareness through Networking in the EU (PREDI-NU)
Source of funding and total value of award:	European Commission in the Framework of the Health Programme - Consumer, Health and Food Executive Agency, CHAFEA (formerly EAHC - European Agency for Health and Consumers).
Value of funding to NMAHP RU:	£68,342
Principal investigator/co-applicants:	Hegerl U (University of Leipzig, Germany), Maxwell M, Harris F (University of Stirling), Arensman E (National Suicide Research Foundation, Cork, Ireland), Audenhove C (Catholic University of Leuven, Belgium), Gusmao R (Universidade Nove de Lisboa, Lisbon), Pull C (University of Leipzig), Sola VP (University of Leipzig, Germany), Szekely A (Semmelweis University, Hungary), Varnik A (Estonian-Swedish Mental Health and Suicidology Institute (ERSI), Estonia).
NMAHP RU investigators:	Maxwell M, Harris F.
Workstream:	Long Term Conditions Management
Start date:	September 2011
Duration:	36 Months

Aim(s):

Although effective treatments for mood disorders exist, there are still major gaps in the provision and availability of such resources for depression. The demand for effective treatments for depression is increasing, which subsequently leads to limited availability. Additional interventions for people suffering from depression are therefore needed, to complement the resources that are available. Computerised Cognitive Behavioural Therapy (cCBT) is one type of an intervention recommended for the treatment of mild to moderate depression, that has the potential to complement existing treatments for depression. Such interventions often incorporate the concept of 'self-management'. This is an important

aspect to the management of longer-term illnesses and has been successfully applied to chronic physical diseases (such as asthma, diabetes and arthritis) and is now increasingly being applied to mental health. With this mind, the PREDI-Nu project aimed to promote mental health and prevent depression and suicidal behaviour through information and communication technologies.

Specifically, it aimed to:

1. Develop an online, guided self-management programme for mild to moderate depression (the iFightDepression tool);
2. Develop a website to increase knowledge and awareness of depression and suicidal behaviour

3. Implement and evaluate the use of the iFightDepression tool in a number of European countries – Ireland, Germany, Spain, Hungary, Estonia.
4. All materials to be available in at least 7 European languages.

Summary:

The iFightDepression tool and the website were developed according to a consensus process involving the following steps:

Preparatory steps:

- Extensive and systematic review of existing resources and the literature on internet-based programmes based on Cognitive-Behavioural Therapy.
- Development of content for the iFightDepression tool and website and programming of the resources as technical platforms.
- Discussion of these materials involving a consensus process among the consortium members, and involving a wider international panel of experts and representatives from patient and family organisations.
- Simultaneous development of training awareness modules for general practitioners (GPs) and mental health professionals (MHPs).

Pilot phase:

- Introduction of the iFightDepression tool to GPs and MHPs via three-hour training and depression awareness workshops.
- Recruitment of patients using the iFightDepression tool and subsequent guidance of patients by trained professionals.
- Evaluation of the acceptability of the tool and feasibility of its use, via standardised questionnaires and focus groups.

Enhancement and further implementation:

- Enhancement of the iFightDepression tool (in terms of content, layout and technical features) based on the results from the pilot study.
- Dissemination of the iFightDepression results via regional launch events and further professional depression awareness workshops in the intervention regions, an international symposium in Brussels (April 1st, 2014), followed by the go-online of the website and a subsequent virtual launch via a google ad campaign.

Outcomes/Impact:

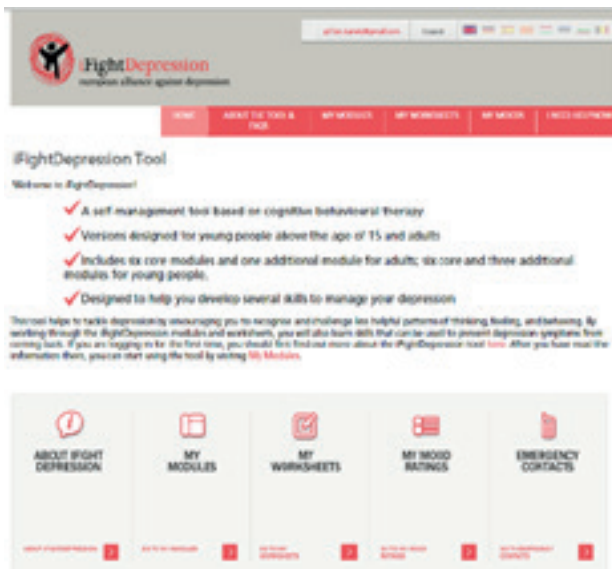
PREDI-Nu contributed to the European Commission's Second Programme of Community Action in the Field of Health (2008-2013). PREDI-Nu's objectives are in line with a number of points outlined in the "eHealth Action Plan 2012-2020", published by the European Commission in December 2012. The iFightDepression tool and website represent concrete resources that will continuously contribute to the promotion of health and distribution of health knowledge. They will also continue to be implemented in the European regions that were involved in PREDI-Nu, and will be further developed by the European Alliance against Depression (a non-profit organisation dedicated to the improvement of depression care and prevention of suicidal behaviour).

The multilingual iFightDepression website allows for large-scale implementation of the tool among European citizens who do not speak languages other than their native language. It also allows them to have access to high quality, accurate information about depression. The multilingual internet-based iFightDepression self-management tool represents a major asset because in many countries the vast majority of depressed people have very limited or no access to psychotherapy at all.

Publications:

- Ella Arensman, Nicole Koburger, Celine Larkin, Gillian Karwig, Claire Coffey, Margaret Maxwell, et al. Depression awareness and self-management through the internet: An internationally standardised approach. JMIR Res Protoc 2015, vol. 4: iss. 3; e99. <http://www.researchprotocols.org/2015/3/e99/>

Other dissemination activity:



- Approximately 50 presentations at scientific proceedings, professional workshops and public and press events, which were tailored to specific audiences;
- The development of distinct logos to increase the visibility and awareness of PREDI-NU and iFight-Depression as separate brands and to visually communicate the meaning of each;
- The development of both the iFightDepression website and PREDI-NU project website;
- The development, publication and circulation of a wide range of media (press releases, articles, factsheets, leaflets, News Bulletins, flyers, posters, invitations, announcements and reports, culminating in the distribution of over ten thousand media overall);
- The organisation, conduction and broadcasting of interviews on a number of radio and television channels;
- The organisation of an international Symposium and various local launch events;
- The organisation of a professional web launch to increase visibility and awareness of the project resources, and
- The use and enhancement of regional and international professional networks.

Project Number:	LTCM01.6
Status:	In Progress
Project Title:	Feasibility of a multi-site RCT exploring the effectiveness of mindfulness-based cognitive therapy to improve emotional wellbeing and glycaemic control among adults with type 1 diabetes.
Source of funding and total value of award:	Chief Scientist Office, £216,424
Value of funding to NMAHP RU:	£5,020
Principal investigator/co-applicants:	Keen A (PI), de Bruin M (University of Aberdeen), Mercer S (University of Glasgow), Maxwell M (University of Stirling) Gold A (NHS Grampian)
NMAHP RU investigators:	Maxwell M.
Workstream:	Long Term Conditions Management
Start date:	September 2015
Duration:	24 Months

Aim(s):

Type 1 diabetes is a uniquely challenging condition to manage. Anxiety and depression appear significant barriers to effective self-management. We are bereft of studies examining the effectiveness of psychological interventions designed to reduce depression and/or anxiety, and improve diabetes control among adults with Type 1 diabetes with difficulties in both these areas.

The aim of this study is to establish if a large scale, definitive RCT of a specifically designed mindfulness-based group intervention, with self-management activation embedded within the programme structure, for adults with Type 1 diabetes and significant emotional distress is feasible, justified, and potentially cost-effective.

Summary:

Participants will be adults (over the age of 18 years) with Type 1 diabetes, with mild to moderate levels of anxiety and/or depression (ie, HADS scores of ≥ 8) and a most recent HbA1c value of ≥ 80 mmol/mol. Potential participants must have been diagnosed with Type 1 diabetes for at least 1 year to allow for a period of stabilization. Exclusion criteria will include severe mental health problems such as severe depression with suicidal ideation, psychosis, personality disorder; terminal illness; inability to give informed consent in English, and inability to understand written and spoken English. We will recruit participants from secondary care clinics in Aberdeen and Glasgow. These will include diabetes outpatient clinics at the JJR Macleod Centre for Diabetes, Endocrinology and Metabolism, Aberdeen as well as the Victoria Infirmary; Southern General, and Gartnavel General Hospitals in Glasgow.

The MBCT intervention has been tailored for adults with Type 1 diabetes.

Outcomes will be collected via brief, self-report inventories at baseline, post-treatment and at 6 months follow-up to establish participants' level of mindfulness (Cognitive and Affective Mindfulness Scale-Revised); diabetes-specific distress; anxiety and depression (HADS); positive emotional wellbeing (Warwick-Edinburgh Mental Wellbeing Scale); satisfaction with treatment provision (Diabetes Treatment Satisfaction Questionnaire); health-related quality of life (EQ-5D-5L), and the Fear of Hypoglycaemia Scale. During the intervention, we will also ask participants to keep a diary of the number of times they completed the formal mindfulness exercises (see below), and keep a record of attendance at group sessions. Details of the frequency of severe hypoglycaemia (defined as occasion they needed help to correct blood glucose levels); mild-moderate (self-corrected) hypoglycaemia, and the number of admissions for diabetic ketoacidosis in the 6 months preceding the beginning of the MBCT course and for the period between the end of treatment and follow-up will be collected. Baseline and 6 month HbA1c values will be recorded. Finally, we will ask participants to keep a diary of their health care use during the previous 6 months at baseline and follow-up. In addition, we will use NHS Scotland; NHS Grampian, and NHS Glasgow electronic systems (eg, SCI-Diabetes and SCI-Store) to obtain an accurate account of contact with secondary health professions. One-to-one qualitative interviews will be conducted with 10-15 participants, with equal numbers from the MBCT group and the control group, about 1 month after the end of the intervention.

Outcomes/Impact:

The design of effective treatments that improve depression and anxiety among adults with Type 1 diabetes, and which also considers important aspects of self-management of the condition itself, may not only be helpful to emotional wellbeing and general quality of life, but may also result in improved diabetes control in the shorter-term and the associated health benefits of better control in the longer-term. The results therefore are potentially important to the many 1000s of adults with Type 1 diabetes in Scotland; diabetes services involved in their care, and to NHS Scotland inpatient and outpatient costs.

Project Number:	LTCM01.7
Status:	In Progress
Project Title:	Is there anybody out there? An exploration of policy and practice in relation to addressing suicidality in children in Scotland.
Source of funding and total value of award:	ESRC Pathway studentship (1+ 3), £55,000
Value of funding to NMAHP RU:	£55,000
Principal investigator/co-applicants:	Maxwell M (PI), Gilmour L (University of Stirling)
NMAHP RU investigators:	Maxwell M, Gilmour L, Duncan E
Workstream:	Long Term Conditions Management
Start date:	Aug 2016
Duration:	48 Months

Aim(s):

This PhD seeks to explore what is known about children (aged <16) in Scotland who are considering suicide. It will explore current policy and health service responses to children referred for suicidal ideation, or attempted suicide, and establish whether there is a gap in service response/provision. Concerned with capturing the experiences and documenting the journey of these children, it will inform best practice in this field.

Research Questions:

1. How does current policy and practice address the issue of suicidality in children (aged<16)?
2. What are the current pathways of care for children who are identified as expressing suicidal behaviours?
3. What is the experience and outcomes for children referred to CAMHS in Scotland for help with suicidal ideation/behaviours?
4. What specific responses, and interventions does this research tell us children presenting with suicidal behaviours (including ideation) need?

Summary:

This study will involve mixed methods and the following linked studies:

Narrative Literature Review using research questions as a framework for analysis.

Purpose: Identify, assess and interpret what is known about children and suicide, service provisions and responses in Scotland, and internationally. Identify gaps in policy and research. Use findings to inform development of research tools; structured interviews, questionnaires etc.

Data Source: Web and bibliographic databases:

Google Scholar, TRIP database, Applied Social Science Index and abstracts, International Bibliography of Social Sciences, Science Direct, Medline, PubMed, PsychInfo.

Study 1. Longitudinal Study of CAMHS referrals for suicidality:

Purpose: Map care pathways and experiences of children referred to CAMH's where there is suicidal ideation and/or suicidal behaviours.

Data Source: Two different NHS board CAMH's teams. Track referrals to CAMHS over 6 months where main reason for referral is suicidal ideation or DSH. Record referral outcome (e.g. treatments initiated, no treatment, signposting to other services).

Study 2. Exploration of: attitudes, beliefs and opinions of practitioners, policy makers and social researchers towards suicidality in children; CAMHS perspectives on the management of these referrals.

a) Semi-structured interviews:

Data Source: CAMHS professionals and those working with children at risk of suicide outwith CAMHS; policy makers and leading suicidality researchers in Scotland (n=12-15).

b) On-line questionnaires:

Data Source: CAMH's practitioners across all 12 NHS boards (n=4x staff per CAMHs team=48)

Study 3. Exploration of perspectives of children who have considered and or attempted suicide, regards their suicidality and care.

a) Semi Structured interviews; by telephone, on-line via skype or face to face (n=10-15)

Purpose: Document views of children who were referred to CAMH's following attempted suicide or suicidal ideation.

Data Source: With consent of family, follow-up after 6 months; 10 children who had treatment initiated; 10 where no CAMHS interventions offered.

b) On line survey / questionnaire; utilise websites such

as Childline / Mood Juice (n=50 approx)

Purpose: Document perspective of wider population of children where suicidality is an issue who may/may not have contact with services.

Data Source: Self-selected users of support websites. (82% of Childline counselling about suicide occurs online).

Outcomes/Impact:

This PhD will provide knowledge and acumen to improve best practice, and responses for children who experience suicidal ideation or engage in suicidal behaviours. Its findings will be of relevance to social researchers, policy makers, and practitioners across health and social care services, locally, nationally and internationally, articulating the need for evidence based interventions for managing suicidality in children.

Project Number:	LTCM01.8
Status:	Complete
Project Title:	Finding the right ingredients: Improving mental health and wellbeing through food centred activities
Source of funding and total value of award:	Wellcome Trust, £45,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Estrade M (PI) (University of Edinburgh), Jepson R, Frank J (University of Edinburgh), Maxwell M(University of Stirling)
NMAHP RU investigators:	Maxwell M.
Workstream:	Long Term Conditions Management
Start date:	July 2015
Duration:	12 Months

Aim(s):

The aim of this project is to develop an intervention in the form of a food and nutrition education program that addresses the unique needs of an underserved at-risk population in Scotland, with the potential for widespread delivery at the community level. It will be grounded upon the idea that the potential for food-based activities to impact one's quality of life goes beyond teaching about good nutrition or cooking skills, by addressing the community context in which these activities take place and the skills participants develop. While educational at its surface, the envisaged mechanism of action on mental health will be through the opportunities afforded for positive social interaction and improvements in self-esteem through skill-building.

This early phase study is required to ensure that the intervention is relevant and acceptable to both the people receiving the intervention and those delivering it.

Summary:

The proposed project makes use of a novel theoretical model for intervention development, called Six Steps in Quality Intervention Development (6SQUID) [15], which employs an evidence-based framework in six defined steps to develop an effective intervention:

1. Defining and understanding the problem
2. Clarifying the causal or contextual factors that are malleable and have greatest scope for change in particular contexts
3. Identifying how to change them: at which point and by what means (change mechanism, with an explicit "theory of change")
4. Designing the intervention
5. Implementing the pilot intervention
6. Evaluating the pilot intervention

The first step was completed in previous work by members of the team (RJ, ME), with steps 2-4 carried out in the current study. The fifth and sixth steps will be carried out in a future study funded through a subsequent grant application.

What we learned:

- People want to learn to cook economically- money is a concern for people
- People are aware of how important food and eating properly can be for general and mental health, or how mental health can affect eating habits.
- When taking part in any activity, it is important to feel safe and secure. The Stafford centre is a place where people generally feel safe and the staff do a good job.
- Learning new skills and being able to use those skills to help yourself as well as others, builds confidence and self-esteem.
- Taking part in activities at the Stafford centre is an opportunity to socialise and see friends.

Outcomes/Impact:

This project has laid the foundations for the development of a food based intervention for promoting wellbeing among those experiencing, or in recovery, from mental health problems.

Project Number:	LTCM01.9
Status:	Complete
Project Title:	Exploring links between low literacy and poor health: an investigation of the experiences of people with low literacy of health service use and self-care
Source of funding and total value of award:	Chief Scientist Office, £33,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Easton P (PI) (NHS Tayside), Entwistle V (University of Aberdeen).
NMAHP RU investigators:	Williams B.
Workstream:	Long Term Conditions Management
Start date:	July 2010
Duration:	36 Months

Aim(s):

To explore the implications of poor literacy skills for health-care use, self care and health.

Research questions:

1. What is the epidemiological evidence for relationships between literacy problems, health status and other possible mediating/confounding variables?
2. How (via what mechanisms) does literacy affect access to and use of health services and self care practices?
3. What kinds of strategies do people with literacy problems adopt in their dealings with health services?
4. How does literacy affect uptake of health services and self care in people with chronic disease?

Summary:

Background: Low literacy is a significant problem across the developed world. A considerable body of research has reported associations between low literacy and less appropriate access to healthcare services, lower likelihood of self-managing health conditions well, and poorer health outcomes. There is a need to explore the previously neglected perspectives of people with low literacy to help explain how low literacy can lead to poor health, and to consider how to improve the ability of health services to meet their needs.

Methods: Two stage qualitative study. In-depth individual interviews followed by focus groups to confirm analysis and develop suggestions for service improvements. A purposive sample of 29 adults with English as their first language who had sought help with literacy was recruited from an Adult Learning Centre in the UK.

Results: Over and above the well-documented difficulties that people with low literacy can have with the written information and complex explanations and instructions they encounter as they use health services, the stigma of low literacy had significant negative implications for participants' spoken interactions with healthcare professionals.

Participants described various difficulties in consultations, some of which had impacted negatively on their broader healthcare experiences and abilities to self-manage health conditions. Some communication difficulties were apparently perpetuated or exacerbated because participants limited their conversational engagement and used a variety of strategies to cover up their low literacy that could send misleading signals to health professionals.

Participants' biographical narratives revealed that the ways in which they managed their low literacy in healthcare settings, as in other social contexts, stemmed from highly negative experiences with literacy-related stigma, usually from their schooldays onwards. They also suggest that literacy-related stigma can significantly undermine mental wellbeing by prompting self-exclusion from social participation and generating a persistent anxiety about revealing literacy difficulties.

Conclusion: Low-literacy-related stigma can seriously impair people's spoken interactions with health professionals and their potential to benefit from health services. As policies increasingly emphasise the need for patients' participation, services need to simplify the literacy requirements of service use and health professionals need to offer non-judgemental (universal) literacy-sensitive support to promote positive healthcare experiences and outcomes.

Outcomes/Impact:

Engagement with NES <http://www.healthliteracyplace.org.uk/blog/?a=Dr%20Phyllis%20Easton> and a health literacy demonstrator project in NHS Tayside

Publications:

- Easton, P, Entwistle V, Williams B. Low literacy and health in the "hidden population." A systematic review of the literature. BMC Public Health. 2010, 10:459doi:10.1186/1471-2458-10-459 2011
- Easton, P, Entwistle, V, Williams B. (2013) How the stigma of low literacy can impair patient-professional spoken interactions and affect health: insights from a qualitative investigation. BMC Health Services Research. 2013 13:319 DOI: 10.1186/1472-6963-13-319.

Other dissemination activity:

- Can't read but won't say: the challenges of the hidden population with low literacy in healthcare contexts. PM Easton1, VA Entwistle, B Williams. European Association for Communication in Healthcare. St Andrews, UK, 2012

IMPROVING OUTCOMES AND EXPERIENCES AFTER CANCER



Having a Scottish centre of excellence from which to draw NMAHP academic expertise for government led and more local NHS work to improve the quality of care is essential. Recent policy drivers including e.g. improving person-centred care, delivering realistic medicine and integrating health and social care can only benefit from the conceptual thinking and evidence development that academic enterprise produces.



Project Number:	LTCM02.1
Status:	Complete
Project Title:	Improving quality of life and swallowing function in patients with head and neck cancer: development and feasibility of a swallowing intervention package (SIP)
Source of funding and total value of award:	Chief Scientist Office, £200,875
Value of funding to NMAHP RU:	£200,875
Principal investigator/co-applicants:	Wells M (PI) (University of Stirling), MacAulay F (NHS Tayside), Patterson J(City and Sunderland NHS Trust/University of Newcastle), McGarva J (NHS Forth Valley), Boa S (Strathcarron Hospice), Cowie J (University of Stirling), Philp J (NHS Fife), Toft K (NHS Lothian), Slaven E (NHS Greater Glasgow and Clyde), Niblock P (NHS Tayside), Dougall N (Edinburgh Napier University)
NMAHP RU investigators:	Wells M, King E, Boa S, Dougall N and Cowie J (all previously NMAHP RU)
Workstream:	Long Term Conditions Management
Start date:	January 2015
Duration:	26 Months

Aim(s):

1. Identify and model the optimal characteristics of a patient-focused, practical and evidence-based swallowing intervention package (SIP) for patients with head and neck cancer (HNC) who are having chemoradiotherapy (CRT).
2. Understand the barriers and facilitators to adherence and fidelity to the SIP.
3. Examine the feasibility and potential impact of the SIP for patients and head and neck cancer teams
4. Develop and conduct preliminary psychometric analysis of a self-report measure of rehabilitation intervention beliefs
5. Pilot the use of an e-support system (e-SIP) with potential to support patients to perform their exercises and for collecting patient-reported data through video-diaries
6. Assess the feasibility and acceptability of study process and outcome measures in order to inform a future multi-centre trial.

Summary:

Swallowing difficulties have a significant impact on quality of life and affect up to two thirds of patients undergoing chemo-radiotherapy (CRT) for head and neck cancer. Effective interventions to improve swallowing outcomes are urgently needed. There is some evidence that prophylactic swallowing exercises may improve a range of short- and long-term outcomes, as they increase the blood flow to muscles, reducing or preventing fibrosis, and maintaining the range and speed of swallowing movements.

This feasibility study aimed to develop and test a practical Swallowing Intervention Package (SiP) for patients undergoing CRT for head and neck cancer, in partnership with patients and SLTs. Phase 1 included focus groups with 23 patients and carers and consensus work with 17 clinicians, culminating in the development of an evidence-based SiP. Phase 2 recruited 36 patients to the intervention and 17 patients to a usual care (comparison) group, from 5 different health boards. The intervention was largely feasible to deliver, and outcome measures were generally well completed, although not all patients were willing to undergo a Fibre-optic Endoscopic Evaluation of Swallowing (FEES). Less than half of those eligible wanted to take part, and patients struggled to adhere to the full exercise regime once treatment side-effects became severe. Setting up and recruiting to usual care sites was also challenging.

Outcomes/Impact:

The SiP manual and materials were developed in Phase 1. Analysis of Phase 2 data provides evidence of retention and drop-out rates, treatment fidelity, adherence to, and impact of the SiP on quality of life, swallowing outcomes and service use. The study will provide the evidence needed to refine intervention and study processes in order to inform a definitive multi-centre trial.

Publications:

- Wells, M. and King, E. (2017) Patient Adherence to Swallowing Exercises in Head and Neck Cancer. *Current Opinion in Otolaryngology & Head & Neck Surgery* (e-Pub Ahead of Print) Doi: 10.1097/MOO.0000000000000356.
- Wells, M., King, E., Toft, K., MacAulay, F., Patterson, J., Dougall, N., Hulbert-Williams, N., Boa, S., Slaven, E., Cowie, J., McGarva, J., Niblock, P., Philp, J. and Roe,

J. (2016) Development and feasibility of a Swallowing intervention Package (SiP) for patients receiving radiotherapy treatment for head and neck cancer—the SiP study protocol. *Pilot and Feasibility Studies*, 2, pp. 40.

Other dissemination activity:

The study has been presented by different members of the research team at several National and International meetings, including the British Association of Head & Neck Oncology (BAHNO) in 2016 and 2017, the British Psycho-Oncology Society (BPOS) in 2016 and 2017, Medical Sociology Conference (2015), RCN International Nursing Research Conference (2016), European Cancer Conference (ECCO) in 2015, Scottish Health Council Research Network (2017), International Clinical Trials Methodology (ICTM) 2017, IPOS 2017. At BAHNO 2016 the study team won the best AHP/nursing poster prize for their presentation on Phase 1 of SiP. Aspects of the study e.g. methods, progress and preliminary results have also been incorporated into a number of plenary talks on treatment consequences in head and neck cancer over the past three years, including BAHNON and ECCO in 2015, Nordic Association of Otolaryngology in 2017.

Project Number:	LTCM02.2
Status:	Complete
Project Title:	Working after cancer: a systematic review and meta-synthesis of qualitative studies exploring experience, problems and strategies in relation to employment and return to work
Source of funding and total value of award:	Chief Scientist Office, £49,932
Value of funding to NMAHP RU:	£267.34
Principal investigator/co-applicants:	Wells M (PI) (University of Dundee) Kroll T, MacGillivray S, Coyle J, Lang H, Firnigl D (University of Dundee).
NMAHP RU investigators:	Williams B
Workstream:	Long Term Conditions Management
Start date:	August 2010

Aim(s):

To identify, appraise and synthesize the available evidence relating to the value and impact of cancer nursing on patient experience and outcomes.

Summary:

There are more than 2 million cancer survivors currently in the UK. Growing evidence indicates that they experience a range of disadvantages in the labour market during and after cancer treatment and that they receive little work-related advice and support from clinicians and employers. A detailed understanding of the complex interplay of social, clinical and work related factors influencing patients' workplace related experiences and behaviours is important for the development of employment-promoting interventions. Two systematic reviews were conducted to explore cancer survivors', family/carers', and employers' attitudes, experiences, problems and strategies in relation to employment, retention and/or return to work. Review A synthesised

qualitative studies and Review B updated a recent meta-analysis of quantitative studies. Twenty-five papers were included in the qualitative review and 3 in the quantitative review.

The integration of our reviews found substantial gaps in the theoretical and conceptual foundations of our understanding of employment experiences in people with cancer. Our findings have led to the development of a conceptual model to guide future studies in this field, providing direct evidence of the individual meaning and experience of work in the context of cancer and the importance of mid-level variables such as organisational support, family and interpersonal aspects of work culture.

Outcomes/Impact:

This work was cited by the European Agency for Safety and Health at Work on 04 Feb 2017 Rehabilitation and return to work after cancer: Literature review, 2017, <https://osha.europa.eu/en/tools-and-publications/publications/rehabilitation-and-return-work-after-cancer-literature-review/view>. It led to the development of a multi-disciplinary group – CAN-WORK, several members of whom have developed further studies in this field as well as an ESRC Seminar Series on Cancer and Work.

Publications:

- Wells M, Williams B, Firnigl D, Lang H, Coyle J, MacGillivray S, Kroll T Supporting “work-related goals” rather than “return to work” after cancer? A systematic review and meta-synthesis of 25 qualitative studies *PsychoOncology*. 2013 Jun;22(6):1208-19. doi: 10.1002/pon.3148.
- Wells M, Amir Z, Cox T, Eva G, Greenfield D, Hubbard G, McLennan S, Munir F, Scott S, Sharp L, Taskila T, Wiseman, T. (2014). Time to act: The challenges of working during and after cancer, initiatives in research and practice (Editorial). *European Journal of Oncology Nursing*, 18(1), 1-2. doi:10.1016/j.ejon.2014.01.001.

Other dissemination activity:

Oral presentations were given at The International Rehabilitation and Participation conference in Dundee, May 2011, and the Alliance for Self Care conference 2012.

Posters were presented at the European Cancer Conference (ECCO) in Stockholm, September 2011, and the American Society of Public Health in 2012.

Project Number:	LTCM02.3
Status:	In Progress
Project Title:	Development of a sarcoma-specific patient-reported outcome measure
Source of funding and total value of award:	Sarcoma UK, £119,464
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Taylor R (PI) (UCLH NHS Foundation Trust), Whelan J (UCLH NHS Foundation Trust), Bennister L (Sarcoma UK), Storey L (Queens University Belfast), Gerrand C (Newcastle upon Tyne Hospitals NHS Foundation Trust), Fern L (Teenage Cancer Trust/National Cancer Research Institute), Windsor R(UCLH NHS Foundation Trust), Woodford J (Royal National Orthopaedic Hospital).
NMAHP RU investigators:	Wells M.
Workstream:	Long Term Conditions Management
Start date:	January 2017
Duration:	18 Months

Aim(s):

1. To develop and validate a sarcoma-specific PROM and to develop a strategy for its incorporation into practice.

Summary:

Sarcomas are a rare and diverse group of cancers arising from connective tissue, including soft tissue sarcoma (STS) and bone tumours. They are characterised by considerable clinical heterogeneity in presenting symptoms, morbidity and success rates of treatment. For a significant proportion of patients with sarcoma, the physical burden of the disease and of treatment is very high and is in many cases accompanied by low expectations of survival. Subsequently poorer patient-reported outcomes (PRO) are recorded in comparison to patients with other cancer types.

Currently there are no sarcoma-specific PROMS with which to evaluate physical and psychosocial outcomes in research and clinical practice. This is a mixed methods study based on recommended methodology for developing a PROM, comprising of three stages: (i) Developing the PROM using literature and qualitative interviews to generate items (ii) Psychometric testing of the PROM in up to 400 patients (iii) Developing a strategy to implement the PROM into clinical practice, using workshops with patients, clinicians and other stakeholders.

Outcomes/Impact:

The benefits of using PROMS in clinical practice and research are well known. The S-PROM will be useable for needs assessment, shared decision making, symptom management, outcome assessment and quality improvement.

Other dissemination activity:

A poster has been presented at the British Sarcoma Group conference in 2017. Regular dissemination of progress through Sarcoma UK.

Project Number:	LTCM02.4
Status:	Complete
Project Title:	A qualitative evaluation of the late effects clinic at the Beatson West of Scotland Cancer Centre
Source of funding and total value of award:	Macmillan Cancer Support, £7,600
Value of funding to NMAHP RU:	£7,600
Principal investigator/co-applicants:	Harris F (PI) (University of Stirling), Jepson R (CCRC), Meehan L (Beatson West of Scotland Cancer Centre).
NMAHP RU investigators:	Harris F.
Workstream:	Long Term Conditions Management
Start date:	April 2010
Duration:	13 Months

Aim(s):

To evaluate the 'Late Effects Clinic' in haemato-oncology in order to:

- identify the strengths and weaknesses of the service
- explore the reach of the service
- explore views related to different ways of delivering the service in order to maximise or extend the reach of the Late Effects Clinic.

Summary:

The Late Effects Clinic at the Beatson West of Scotland Cancer Centre was established in April 2008 in order to provide follow-up care to people who have received treatment for haematological cancers. The core aim of the Clinic was to reduce the number and severity of possible problems brought on by previous treatments for haematological cancers, via early detection and treatment. 15 qualitative interviews with health professionals and patients who attend the Clinic were conducted in order to find out their views of the service. The reach of the service

was explored via data on Clinic attendance provided by the Information Services Division, NHS Scotland.

Key Results:

1. The importance of the care provided by Clinic staff was emphasised by patients and other health professionals who refer to this service. The expertise in Late Effects of treatment, with the holistic approach (including both physical and mental health) that this entails was particularly praised by health professionals.
2. Clinic staff are perceived in an extremely positive light and the care that they provide is regarded as being very thorough. Waiting times are low and the physical environment of the Clinic was also regarded positively.
3. Although satisfaction with the service was extremely high, this appeared to be in inverse proportion to travel time to the Clinic (although this was not an issue for all patients who had a long distance to travel).
4. Many patients lamented the lack of sufficient parking for patients, although this would appear to be something that Clinic staff have no control over.

1. The blood testing area (outwith the Clinic) was mentioned by a few patients as a source of distress owing to the lack of privacy or contact with patients who were in active treatment.
2. Patients on the whole find visits to the Clinic a means to reassure themselves about any health anxieties and welcome the face-to-face contact with staff.
3. Patients who have a range of health problems that entail a range of hospital appointments may be less satisfied with attending the Clinic, although they were still appreciative of the service provided by the Late Effects Clinic staff.
4. In order to widen the reach of the service, possible alternative approaches were discussed. Face-to-face consultations and the potential for establishing satellite clinics were regarded favourably.
5. The qualitative data supports the conclusion that the Late Effects Clinic provides a high quality service that is highly regarded by both patients and health professionals alike.

Other dissemination activity:

- Meehan L. A qualitative evaluation of the late effects clinic at the Beatson West of Scotland Cancer Centre, Bone Marrow Transplant, Annual conference, 2011.

Outcomes/Impact:

Although this was a small study, it was important to the Clinic staff to receive service user and health professional feedback on this relatively new service. The lead nurse for the Clinic (Meehan) took the results of the evaluation forward to inform CPD events and other dissemination activity.

Publications:

- Harris F, Jepson R (2011) A qualitative evaluation of the late effects clinic at the Beatson West of Scotland Cancer Centre, A report to Macmillan Cancer Support.

Project Number:	LTCM02.5
Status:	Complete
Project Title:	Cancer diagnosis as an opportunity for increasing uptake of smoking cessation services among families: an exploratory study of patients, family members and health professional's views
Source of funding and total value of award:	Chief Scientist Office, £161,149
Value of funding to NMAHP RU:	£153,069
Principal investigator/co-applicants:	Wells M (PI), Williams B, Bauld L (University of Stirling), Entwistle V (University of Andrews), Haw S (University of Stirling), Ozakinci G (University of St. Aberdeen), Radley A (NHS Tayside), Munro A (University of Dundee).
NMAHP RU investigators:	Wells M, Williams B, Harris F, Aitchison P.
Workstream:	Long Term Conditions Management
Start date:	August 2013
Duration:	22 Months

Aim(s):

To explore patients', family members' and health professionals' views of the key factors likely to increase uptake of current smoking cessation services, within the context of a recent cancer diagnosis.

To develop the theoretical and empirical basis for an intervention to increase the uptake of smoking cessation services in family members as well as patients with cancer.

Summary:

Cancer diagnosis can promote behaviour change in patients and their relatives who smoke, however, uptake of smoking cessation services is low. We explored patients', family members' and health professionals' views of the key factors likely to increase uptake of current smoking cessation services, in relation to a recent cancer diagnosis.

We did a qualitative study (stage 1 of the MRC complex interventions framework): 67 interviews with patients with cancer, relatives, and health professionals. Key findings and potential approaches were discussed at public engagement sessions.

Individual, relationship and system factors may limit opportunities for cessation discussion and support. Improving uptake of smoking cessation therefore requires targeting systems and individuals. Interventions should be person-centred, non-judgemental, enabling and future-orientated.

Study findings are consistent with other research, adding insights to specific issues within a Scottish/UK context. Smoking cessation is currently insufficiently integrated into cancer care. NICE guidance provides a clear care pathway from identification to referral for treatment; however, training, support and tailored materials are required so that the guidance can be implemented in oncology.

Outcomes/Impact:

Smoking cessation support is insufficiently integrated into cancer care. Timely and future health-promoting action should be given as much priority as early diagnosis and world-class cancer treatment. Advice and support for smoking cessation needs to be part of the cancer care pathway. Interventions to improve uptake of smoking cessation must target systems as well as individuals. NICE guidance for smoking cessation in acute services provides a clear care pathway from identification to referral for treatment; however, training, support and tailored materials are required for the guidance to be implemented in oncology.

Publications:

- Wells, M., Aitchison, P., Harris, F., Ozakinci, G., Radley, A., Bauld, L., Entwistle, V., Munro, A., Haw, S., Culbard, B. and Williams, B. (2017) Barriers and facilitators to smoking cessation in a cancer context: A qualitative study of patient, family and professional views. *BMC Cancer*, 17, pp. 348.

Other dissemination activity:

- Two public engagement events held in Dundee 2015. Short articles were published on the School of Health Sciences blog (World Cancer Day) and in NMAHP-RU's newsletter Presentations at International Psycho-Oncology Society conference Dublin 2016, European Association of Communication in Healthcare (EACH) conference Heidelberg 2016.

Project Number:	LTCM02.6
Status:	Complete
Project Title:	Scottish cancer patient experience survey – free text analysis
Source of funding and total value of award:	Scottish Government £10,000, Macmillan £3500
Value of funding to NMAHP RU:	£13,500
Principal investigator/co-applicants:	Wells M (PI) (University of Stirling).
NMAHP RU investigators:	Cunningham M, Aitchison P, Wells M.
Workstream:	Long Term Conditions Management
Start date:	January 2016
Duration:	9 Months

Aim(s):

To analyse free-text responses from the first Scottish Cancer Patient Experience Survey to understand patients' experiences of care, identify valued aspects and areas for improvement.

Summary:

Patient experience is recognised as one of the critical elements of high quality health care, along with clinical effectiveness and safety. National Cancer Patient Experience Surveys have been carried out annually in England since 2010. The first Scottish survey was conducted in 2015/16. The quantitative results of the SCPES were published by the Scottish Government, and NMAHP RU researchers were commissioned to analyse 6961 free-text responses from 2663 respondents. Data were analysed thematically and differences in the proportion of positive to negative comments by demographic were analysed using chi-squared tests. Participants made more positive than negative comments overall. Analysis produced two key themes, highlighting the importance to

patients of Feeling that Individual Needs Are Met and Feeling Confident Within the System, and providing insight into how the way care is processed and structured can negatively impact on patients' experience.

Outcomes/Impact:

The free-text analysis of the Scottish Cancer Patient Experience Survey has been used by Health Boards, Macmillan Cancer Support and Scottish Government, to underpin improvements in cancer care.

Publications:

- Cunningham, M. and Wells, M. (2017) Qualitative Analysis of 6961 free-text comments from the first National Cancer Patient Experience Survey in Scotland. BMJOpen (e-Pub Ahead of Print) Doi: 10.1136/bmjopen-2016-015726.
- Cunningham, M. and Wells, M. (2016) Scottish Cancer Patient Experience Survey 2015/16: Analysis of Free-text Comments <http://www.gov.scot/Publications/2016/10/1882>.

Other dissemination activity:

- Invited presentation to Cross Party Cancer Group, Scottish Government.
- Oral presentations at European Oncology Nursing Society (EONS10) conference, Dublin, 2016 and British Psycho Oncology Society conference, Oxford, 2017.
- Poster presented at PHE Cancer Data and Outcomes Conference 2017.
- Press article in The Herald, Interviewed on Radio Scotland, University of Stirling press video.

Project Number:	LTCM02.7
Status:	Complete
Project Title:	TreatWELL - a feasibility study to assess the delivery of a lifestyle intervention for colorectal cancer patients undergoing curative treatment
Source of funding and total value of award:	Chief Scientist Office, £132,392
Value of funding to NMAHP RU:	£1496
Principal investigator/co-applicants:	Anderson AS (PI), Steele R and Munro A (University of Dundee), O'Carroll R, Stead M, Wells M (University of Stirling), Campbell A (Edinburgh Napier University), Rodger J (NHS Tayside).
NMAHP RU investigators:	Wells M.
Workstream:	Long Term Conditions Management
Start date:	December 2013
Duration:	19 Months

Aim(s):

To assess the feasibility of delivering and evaluating a lifestyle intervention (smoking, alcohol, physical activity, diet and weight management) programme (TreatWELL) for colorectal cancer (CRC) patients undergoing potentially curative treatments.

Summary:

Colorectal cancer (CRC) survival has improved, but, in Scotland, survivors still have excess mortality within the first year post diagnosis compared to other European countries. This lifestyle programme was delivered in 3 face to face sessions (plus phone calls) by lifestyle counsellors over three phases: 1: Pre-habilitation, 2: Surgical recovery 3: Post therapy recovery. Feasibility outcomes were recruitment rates, phase length, ease of programme implementation, time required for intervention procedures, collection of measurements, patient acceptability, factors

influencing adherence and retention. During the study period, 84 patients were diagnosed, 22 (26%) were recruited and 15 (18%) completed the study. The median time in phase 1 was 15 days, but was often shorter and only 6 participants completed end of phase 1 measures. The median time in phase 2 was 36.5 days and phase 3 was 102 days but was frequently extended by clinical problems. Median time for intervention delivery by lifestyle counsellors was 5 hours 29 with >70% of components reported as being successfully delivered. Acceptability of the intervention was rated highly. Although programme adherence was endorsed by many NHS staff, further support could have been provided. Further work is needed to optimise recruitment. Timing of measurements needs reconsideration in phase 1 and 3. Protocols for phase 2 and 3 need to be flexible to allow for variation in clinical progress. Ways for NHS staff to support and facilitate the programme aims should be explored.

Outcomes/Impact:

The work highlights the importance of clinical staff in endorsing, facilitating implementation and supporting positive health behaviours in patients with colorectal cancer.

The resources utilised and behavioural techniques used have highlighted the gaps in training and practice that are needed to improve care and outcomes in patients diagnosed with curable bowel cancer.

Other dissemination activity:

Presentations at Scottish Cancer Prevention Network (Edinburgh, Feb 2015) - Patient experiences in the TreatWELL study- Morag Gudmunsen and UK Society for Behavioural Medicine (Newcastle, Dec 2015) - TreatWELL – the challenge of lifestyle change in patients with colorectal cancer.

Project Number:	LTCM02.8
Status:	In Progress
Project Title:	Exploring the experiences of patients undergoing treatment and surviving with bone cancer
Source of funding and total value of award:	Bone Cancer Research Trust, £8,010
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Taylor R (PI), Whelan J, Windsor R (University College Hospitals NHS Trust), Fern L (Teenage Cancer Trust/National Cancer Research Institute), Bennister L (Sarcoma UK), Storey L (Queens University Belfast), Gerrand C (Newcastle upon Tyne Hospitals NHS Foundation Trust), Woodford J (Royal National Orthopaedic Hospital).
NMAHP RU investigators:	Wells M.
Workstream:	Long Term Conditions Management
Start date:	January 2017
Duration:	15 Months

Aim(s):

To understand the experience of being diagnosed and surviving with bone cancer.

Summary:

This cross sectional qualitative study is an adjunct to stage 1 of another project (LTCM02.3) to develop a sarcoma specific patient reported outcome measure (S-PROM). This will be developed directly from patient-reported experiences to accurately reflect the issues that are important to them. Sarcomas are a group of rare cancers of the bone and soft tissue. In this project, approximately 20 patients with primary bone cancer (PBC) will be purposefully sampled and interviewed to understand their experience of living with this type of sarcoma. Data will be analysed using thematic analysis.

Outcomes/Impact:

A detailed understanding of patients' experiences of PBC and outcomes most relevant and important to patients, which will confirm the relevance of the S-PROM and underpin a subsequent grant application to apply the strategy.

Other dissemination activity:

A poster has been presented at the British Sarcoma Group conference in 2017. Regular dissemination of progress through Sarcoma UK.

INTERVENTIONS TO IMPROVE SELF-MANAGEMENT OF LONG TERM CONDITIONS



We now have an established group of experts able to undertake high quality research that underpins NMAHP practice. NMAHPs throughout the UK and beyond can access robust systematic reviews to support the development of clinical guidelines and pathways which are used as the basis of service improvement and service redesign across Scotland.



Project Number:	LTCM03.1
Status:	Complete
Project Title:	(Phase I) Development of interventions to increase physical activity among inactive young people with long-term conditions: MRC complex intervention framework phase 1 using asthma as an exemplar
Source of funding and total value of award:	Chief Scientist Office Scotland, £224,118
Value of funding to NMAHP RU:	£108,415
Principal investigator/co-applicants:	Williams B (PI) (University of Stirling), Treweek S (University of Dundee), Sniehotta F (Newcastle University), Sheikh A (University of Edinburgh), McGhee J (University of Dundee), Hoskins G (University of Stirling), Hagen S (Glasgow Caledonian University), Cameron L (University of California), Jones C (University of Dundee), Brown G (Asthma UK Scotland)
NMAHP RU investigators:	Williams B, Hagen S, Hoskins G.
Workstream:	Long Term Conditions Management
Start date:	November 2011
Duration:	24 Months

Aim(s):

This project developed a theoretically based visual intervention to increase uptake and ongoing engagement in physical activity in inactive young people with asthma aged 12-18 years consisting of an interactive educational component with motivational and skill developing elements to create intentions to engage in increased activity and an activity plan to facilitate the translation of those intentions into changes in behaviour.

Summary:

Regular physical activity improves aerobic fitness and well-being. For people with asthma the benefits also include reduced hospital admissions, absenteeism, medication use, and improved ability to cope with the disease. However, although children and young people with asthma can exercise safely they are less likely to be

physically active than their peers. We developed a theoretically-informed interactive animation to encourage young people aged 12-18 years with asthma to engage in physical activity. The study took a two-stage approach using qualitative and quantitative methods. In Stage 1 we recruited 23 people to a consultative user group (young people with asthma, parents, health professionals) and used highly iterative online consultation to inform intervention development (modelling). After refining the theoretical basis we converted this into a 3D animation by creating a narrative structure and visual aesthetic. An action plan and volitional help sheet was also created. In Stage 2 the intervention was piloted through in-depth interviews and a web based intervention modelling experiment (wIME) to assess recruitment, baseline activity and psychological characteristics, retention/attrition, and provide data for future sample size calculations.

Outcomes/Impact:

We successfully developed an interactive 3D animation that embeds behavioural theory and is regarded as meaningful, acceptable and potentially effective by parents, young people, health professionals and teachers. Our results indicate that addressing perceptions around safety, capability and motivation positively impacts on intention to engage in physical activity. Health professionals felt it could be potentially very useful within a clinical consultation/asthma review. The consultative user group was highly engaged and fundamental to the success of the project. If successful in a large-scale study it could increase the intentions of young people with asthma to become more active reducing health burden and costs for them and for the NHS.

Publications:

- Williams B, Treweek S, Hagen S, Sheikh A, Cameron A, Sniehotta F, Hoskins G, McGhee J; Brown G, Jones C. (2014) Consulting on the development of a novel visual intervention and activity plan to increase physical activity among inactive young people with asthma: Can visualisation encourage physical activity in patients with asthma? CSO Report reference number: CZH/4/664.
- Murray J, Williams B, Hoskins G, Skar S, McGhee J, Treweek S, Sniehotta F, Sheikh A, Brown G, Hagen S, Cameron L, Jones C, Gauld D. An interdisciplinary approach to developing visually mediated interventions to change behaviour; an asthma and physical activity intervention exemplar. *Pilot and Feasibility Studies* (2016) 2:46 DOI 10.1186/s40814-016-0091-x <https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-016-0091-x>
- Murray, J., Williams, B., Hoskins, G., Skar, S., McGhee, J., Gauld, D., Brown, G., Treweek, S., Sniehotta, F., Cameron, L., Sheikh, A., Hagen, S. (2014). Can a theory-informed interactive animation increase inten-

tions to engage in physical activity in young people with asthma?

- In M. Kurosu (Ed.), *Human-Computer Interaction, Part III, HCII 2014, Lecture Notes in Computing Science*, 8512, 289-300. Switzerland: Springer International Publishing.
- Murray, J., Williams, B., Hoskins, G., McGhee, J., Gauld, D., Brown, G. (2013). Developing a theory-informed interactive animation to increase physical activity among young people with asthma.
- In R. Shumacker (Ed.), *Virtual, Augmented and Mixed Reality held as part of Human-Computer Interaction (VAMR/HCII) 2013, Part II, LNCS 8022*, pp60-65, 2013.

Other dissemination activity:

- Murray, J., Todoran, A., Williams, B., Hoskins, G., & McClatchey, K. (2016). Evaluating the acceptability of a novel visual intervention designed to increase safe physical activity amongst young people with asthma. Poster presented at 4th Annual Research Symposium: Mobilising Evidence to Drive Improvement, Health Improvement Scotland. COSLA Conference Centre, Edinburgh, March 17th, 2016.
- Murray, J., Williams, B., Hoskins, G., & Todoran, A. (2016). Embedding theory into complex visual interventions: Using an asthma and physical activity animation as an exemplar.
- Research in Progress Seminars, Edinburgh Napier University, February 23rd.
- Hoskins G, Williams B, Murray J, Skar S, McGhee J, Gauld D, Brown G, Treweek S, Sniehotta F, Cameron L, Sheikh A, Hagen S. Developing a theory-informed interactive animation to increase engagement in physical activity in young people with asthma. RCN International Nursing Research Conference and exhibition, Edinburgh International Conference Centre, April 3rd-6th, 2016.

- Hoskins G, Williams B, Murray J, Skar, S, McGhee J, Gauld D, Brown G, Treweek S, Sniehotta F, Cameron L, Sheikh A, Hagen S. (2014). 'Can a Theory-Informed Interactive Animation Increase Intentions to Engage in Physical Activity in Young People with Asthma?' British Thoracic Society Winter Meeting, 3rd-5th December 2014, London. 10.1136/thoraxjnl-2014-206260.250
- Murray J, Williams B, Hoskins G, Skar S, McGhee J, Gauld D, Brown G, Treweek S, Sniehotta F, Cameron L, Sheikh A, Hagen S. (2014). Can a theory-informed interactive animation increase intentions to engage in physical activity in young people with asthma? Invited paper presented at Human Computer Interaction International 2014, Creta Maris, Crete, Greece, June 22-26.
- Murray J, Williams B, Hoskins G, McGhee J, Gauld D, Brown G. (2013). Developing a theory-informed interactive animation to increase physical activity among young people with asthma. Invited Paper presented at Human Computer Interaction International 2013, Mirage, Las Vegas, Nevada, July 21-26.

Project Number:	LTCM03.2
Status:	Complete
Project Title:	Can eliciting and addressing health-related goals improve asthma control and asthma-related quality of life? Feasibility Phase II pilot randomised controlled trial of a brief intervention.
Source of funding and total value of award:	Chief Scientist Office Scotland, £144,528
Value of funding to NMAHP RU:	£110,694
Principal investigator/co-applicants:	Hoskins G (PI), Williams B, Duncan E (University of Stirling), Sheikh A (University of Edinburgh), Pinnock H (University of Edinburgh), Donnan P (University of Dundee), van der Pol, M (HERU University of Aberdeen).
NMAHP RU investigators:	Hoskins G, Williams B, Duncan E
Workstream:	Long Term Conditions Management
Start date:	October 2012
Duration:	24 Months

Aim(s):

To assess the acceptability, effectiveness and cost-effectiveness of a goal-setting intervention in the management of asthma in a primary care setting.

Summary:

Despite being a core component of self-management, goal setting is rarely used in routine care. The use of a goal elicitation tool in asthma holds the potential for substantial impact. This study piloted a primary care, nurse-led intervention (GOAL) for adults with asthma that had already shown promise in development/scoping studies. Patients were invited to identify and prioritise their goals in preparation for discussing and negotiating an action/coping plan with the nurse at a routine asthma review. The results showed an improvement in asthma related quality of life in the intervention group compared to the standard review

group but costs were higher. Data from the embedded qualitative study, however, suggested that while the goal-elicitation tool was welcomed by patients as it provided them an opportunity to raise a wide range of issues that otherwise remain unexplored, made them more conscious about their health and enabled them to take an active part in their care, the healthcare professionals found the intervention impacted unreasonably on their time.

Outcomes/Impact:

Self-management is important for improving health and well-being and reducing the economic burden of asthma. Goal-setting is increasingly recognised as an effective behavioural technique for improving health-related self-management behaviour.

This study showed that although the intervention is theoretically sound and would be welcomed by patients there are major challenges in introducing it in its present form in primary care. Benefits to the NHS will only happen if evidence from this type of study is provided and then acted upon. The intervention is likely to be beneficial to people with asthma but there are practical issues which need to be addressed before progressing to a full trial. If the NHS is to benefit from such innovation then the intervention must be less burdensome and where possible championed at a locality level.

Publications:

- Hoskins Gaylor, Abhyankar Purva, Taylor D Anne, Duncan Edward, Sheikh Aziz, Pinnock Hilary, van der Pol Marjon, Donnan T Peter, Williams Brian. Goal-setting intervention in patients with active asthma: protocol for a pilot cluster-randomised controlled trial. *Trials*.2013, 14:289. DOI: 10.1186/1745-6215-14-289. URL: <http://www.trialsjournal.com/content/14/1/289>
- Gaylor Hoskins, Brian Williams, Edward Duncan, Aziz Sheikh, Hilary Pinnock, Peter Donnan, Marjon van der Pol. (2014) Can eliciting and addressing health-related goals improve asthma control and asthma-related quality of life? Feasibility Phase II pilot randomised controlled trial of a brief intervention. CSO Report reference number: CZH/4/697.
- Gaylor Hoskins, Brian Williams, Purva Abhyankar, Peter Donnan, Edward Duncan, Hilary Pinnock, Marjon van der Pol, Petra Rauchhaus, Anne Taylor, Aziz Sheik. Achieving Good Outcomes for Asthma Living (GOAL): mixed methods feasibility and pilot cluster randomised controlled trial of a practical

intervention for eliciting, setting and achieving goals for adults with asthma. *Trials*.2016, 17:584 DOI: 10.1186/s13063-016-1684-7 URL: <http://www.trialsjournal.com/content/17/1/584>

Other dissemination activity:

- Abhyankar P, Hoskins G, Duncan E, Donnan P, Sheikh A, Pinnock H, van der Pol M, Taylor A, Williams B. 2014. Enabling patient-centred self-management support- Is a goal setting intervention feasible and useful? 12th International Conference on Communication in Healthcare, September 28 – October 1, Amsterdam, The Netherlands.
- Gaylor Hoskins, Purva Abhyankar, Anne D Taylor, Edward Duncan, Aziz Sheikh, Hilary Pinnock, Marjon van der Pol, Peter T Donnan, Brian Williams. Goal setting in the management of asthma: the challenges of a trial in primary care. International Primary Care Respiratory Conference, 21st – 24th May 2014, Athens, Greece.
- Gaylor Hoskins, Purva Abhyankar, Anne D Taylor, Edward Duncan, Aziz Sheikh, Hilary Pinnock, Marjon van der Pol, Peter T Donnan, Brian Williams. Goal-setting intervention in patients with active asthma – Is it acceptable? Is it useful? International Primary Care Respiratory Conference, 21st – 24th May 2014, Athens, Greece.
- Gaylor Hoskins, Purva Abhyankar, Anne D Taylor, Edward Duncan, Aziz Sheikh, Hilary Pinnock, Marjon van der Pol, Peter T Donnan, Brian Williams. Cluster RCT of an asthma goal setting intervention in primary care: the highs and lows of project recruitment. Royal College of Nursing International Research Conference 2nd-4th April 2014, Glasgow.

Project Number:	LTCM03.3
Status:	Complete
Project Title:	Development of Interventions to reduce patient delay with symptoms of Acute Coronary Syndrome: identifying optimal content and mode of delivery
Source of funding and total value of award:	Chief Scientist Office, £221,668
Value of funding to NMAHP RU:	£158,204.00
Principal investigator/co-applicants:	Farquharson B (PI) (University of Stirling) Johnston M, Williams B (University of Stirling), Dombrowski S (University of Stirling), Rowland C (University of Dundee), McGhee J, Treweek S (University of Aberdeen), Dougall N (University of Stirling), Jones C (University of Dundee), Pringle S (University of Dundee).
NMAHP RU investigators:	Farquharson B, Williams B, Dougal N.
Workstream:	Long Term Conditions Management
Start date:	May 2014
Duration:	21.5 months

Aim(s):

Overall aim: To develop an intervention to reduce patient delay with symptoms of ACS.

Aim 1 (Stage 1): To identify the specific content most likely to be effective in changing peoples' help-seeking behaviour when experiencing symptoms of ACS.

Aim 2 (Stage 2): To develop an intervention (content specified by Stage 1) and evaluate the effectiveness of two modes of delivery (text+visual and text-only).

Summary:

Acute Coronary Syndrome (ACS) is serious and delay to treatment, in particular patient decision time, is a critical factor in reducing mortality and achieving optimal benefit from current treatment strategies. Previous interventions to

reduce patient decision time have been largely unsuccessful. However, most interventions have failed to incorporate relevant psychological theory or to use established behaviour change techniques (BCTs). We propose to develop a theory-based intervention by (i) identifying the content (i.e. BCTs) most likely to be effective, based on existing evidence (Systematic Review) and consensus amongst subject experts (Delphi study) and (ii) identifying the most effective way of delivering that content by comparing two modes of delivery (text only and text+visual) with a control in an intervention modelling experiment, measuring effect on intention to seek help immediately. Such an intervention has the potential to achieve significant reductions in mortality and morbidity for this group.

Outcomes/Impact:

Systematic Review is complete and has been submitted for publication. The Delphi study has been completed. The intervention has been developed and testing in the IME is ongoing.

Publications:

- Farquharson B, Johnston M, Smith K, Williams B, Treweek S, Dombrowski S, Dougall N. and Abhyankar P. (under review) Reducing delay in patients with Acute Coronary Syndrome: a systematic review to identify the behaviour change techniques associated with effective interventions. *Open Heart*
- Farquharson B, Johnston M, Smith K, Williams B, Treweek S, Dombrowski S, Dougall N. and Abhyankar P. (2016) Reducing patient delay in Acute Coronary Syndrome (RAPiD): Research protocol for a web-based Randomised Controlled Trial examining the effect of a behaviour change intervention. *J Adv Nurs*. Accepted Author Manuscript. doi:10.1111/jan.13191
- Farquharson B. (2016) Are heart attack symptoms sexist? *The Conversation*. Available at: <http://the-conversation.com/are-heart-attack-symptoms-sexist-58669>, last accessed 28/10/2016.
- Farquharson B, Pollock A, Johnston M, Smith K, Williams B, Dombrowski S, Treweek S, Jones C, Dougall N and Pringle S. (2014) Reducing patient delay with symptoms of Acute Coronary Syndrome (ACS): A research protocol for a systematic review of previous interventions to investigate which behaviour change techniques are associated with effective interventions. *Open Heart* 1:e000079.doi:10.1136/openhrt-2014-000079

Other dissemination activity:

- Dombrowski S et al. Selecting BCTs for Intervention in Acute Coronary Syndrome Delay: Combining Systematic Review and Delphi Methods presented at European Health Psychology Conference 2015.
- Farquharson et al. Selecting Behaviour Change Techniques for inclusion in an intervention to reduce patient delay in Acute Coronary Syndrome presented at Royal College of Nursing International Research Conference 2016.

Project Number:	LTCM03.4
Status:	Complete
Project Title:	Development of an intervention to increase physiotherapy adherence among young children with cystic fibrosis: A Medical Research Council complex intervention framework development and feasibility study.
Source of funding and total value of award:	Chief Scientist Office, £132,194
Value of funding to NMAHP RU:	£94,568
Principal investigator/co-applicants:	France E (PI) (University of Stirling), Hoskins G (University of Stirling), Hagen S (Glasgow Caledonian University), Dhouieb E (NHS Lothian), Cunningham S (NHS Lothian), Main E (University College London), Rowland C, Treweek S (University of Aberdeen), McGhee J (University of New South Wales), Glasscoe C (University of Liverpool), Allen JM (Cystic Fibrosis Trust), Hoddinott P (University of Stirling), Williams B (University of Stirling).
NMAHP RU investigators:	Williams B, Hoskins G, Hoddinott P, Hagen S.
Workstream:	Long Term Conditions Management
Start date:	May 2014
Duration:	20 months

Aim(s):

This project designed and tested an intervention (film and action plan) intended to improve adherence to home Chest physiotherapy (CPT) among young children with cystic fibrosis (CF) and their parents/carers.

Summary:

CF is an inherited, life-threatening disorder of the lungs and digestive system affecting approximately 1 in 2,500 children. CPT is a major component in the respiratory management of CF to help prevent lung damage. Adherence in young children is important because damage occurs rapidly and can be irreversible. However, only 50% of parents and young children adhere to their recommended regimen. Interventions to address this significant problem are lacking.

The study took a two-stage approach using qualitative and quantitative methods.

Stage 1. A cyclical qualitative action research approach was used to develop a documentary film, including a lung computer animation, and action plan in partnership with paediatric CF clinicians and parents of young children with CF. Twenty-nine participants - 18 parents and 11 clinicians - took part in online interaction and telephone interviews over 8 months.

Stage 2. A before-and-after repeated measures feasibility study of the intervention with 20 parents in the UK. Quantitative data on adherence (primary outcome), parental depression/anxiety and burden of care (secondary outcomes) were collected from parents (the main family caregiver) by telephone at baseline, 4 weeks and 8 weeks post intervention. Post-intervention, in-depth qualitative interviews explored experiences and acceptability of the intervention.

Outcomes/Impact:

The study suggests that the documentary film and accompanying action plan is an inexpensive, acceptable, appealing and supportive intervention that could potentially enhance CPT adherence. If it proves successful after a future large-scale study, it has the potential to decrease the likelihood of lung damage and medical complications, reducing both health burden and costs to families and the NHS. A future study should: target low-moderate adherent parents, collect outcomes data from all caregivers who administer home CPT, and modify the action plan to improve its salience and use.

Publications:

- Emma France, Shaun Treweek, Gaylor Hoskins, Suzanne Hagen, Brian Williams, Elaine Dhouieb, John McGhee, Steve Cunningham, Claire Glasscoe, Eleanor Main, Janet Marjorie Allen, Chris Rowland, Pat Hoddinott. (2016) Development of an intervention to increase physiotherapy adherence among young children with cystic fibrosis: A Medical Research Council complex intervention framework development and feasibility study. CSO Report reference number: CZH/4/1021.
- Two papers in preparation on 1) the intervention development and 2) the feasibility study for submission to Pilot and Feasibility Studies have been delayed due to maternity leave.
- Semple, K, France, EF, Grindle, M., Duncan, K., Rowland C., Hoskins, G. Developing an audio-visual intervention to increase adherence to home chest physiotherapy in young children with cystic fibrosis. Target journal: Pilot and feasibility Studies.
- France, EF, Semple, K, Hagen, S. Feasibility and preliminary effectiveness of an audio-visual intervention to increase adherence to home chest physiotherapy in young children with cystic fibrosis. Target journal: Pilot and feasibility Studies.

Other dissemination activity:

Conference Papers

- E.F France, Semple, K, M Grindle, et al. Developing an audio-visual intervention to support children's adherence to home chest physiotherapy for cystic fibrosis. 38th European Cystic Fibrosis Conference, Brussels, Belgium, 10th-13th June 2015.
- France, E.F, Semple, K, Mark Grindle et al. Using a novel action research approach to develop an audio-visual resource to support children's adherence to home chest physiotherapy for cystic fibrosis. Oral presentation at the International Institute for Qualitative Methods 14th Annual Qualitative Methods Conference, Melbourne, Australia, April 28-30 2015.
- E.F France, Semple, K, M Grindle, et al. Using action research to develop an intervention to increase children's adherence to physiotherapy for cystic fibrosis. RCN International Nursing Research Conference and exhibition, Edinburgh International Conference Centre, April 3rd-6th, 2016. Accepted at Royal College of Nursing Annual Conference April 2016.

Project Number:	LTCM03.5
Status:	In Progress
Project Title:	Podiatry interventions to reduce falls in older people – a systematic review
Source of funding and total value of award:	Chief Scientist Office, £27,573
Value of funding to NMAHP RU:	£26,377
Principal investigator/co-applicants:	Morris J (PI) (University of Stirling), Witham MD (University of Dundee), Campbell P (Glasgow Caledonian University), Frost H (University of Stirling), Wylie G (University of Dundee).
NMAHP RU investigators:	Morris J, Campbell P.
Workstream:	Long Term Conditions Management
Start date:	March 2017
Duration:	6 months

Aim(s):

To undertake a systematic review and relevant meta-analyses to determine the most effective podiatry interventions for prevention of falls in older people.

Summary:

We systematically searched MEDLINE, AMED, EMBASE, CINAHL, PEDro, Cochrane Central Register of Controlled Trials, CDSR, DARE, HTA, ZETOC, WHO ICTRP, EThOS and Google Scholar (from inception to 30 March 2017, with no language restrictions). We hand-searched reference lists and contacted experts. We included all RCTs or quasi-RCT studies that documented podiatry interventions in older people (aged 60+). Two reviewers independently applied selection criteria and assessed methodological quality using the Cochrane risk of bias tool. Data were extracted in accordance with TiDieR guidelines and tabulated and summarised in a narrative format.

We identified 32717 titles and screened 3118 abstracts for eligibility. Nine studies met our inclusion criteria, trials generally were judged as potentially low risk of bias. Total sample size was 6518, range 40-3727 participants. Most podiatry interventions were multi-faceted although 2 were single component interventions (e.g. insoles or footwear). The majority of interventions were conducted with older people in the community (n=5). Five trials reported beneficial effects on falls rate (n=1) and falls risk (e.g. proportion of fallers, balance, foot pain) (n=4) and improvements in fall-related consequences (n=1).

Outcomes/Impact:

This is the first study to synthesise the available evidence of podiatry interventions for falls prevention in older people living in care homes or in the community. The evidence is limited, in particular in care homes, however there is some indication that that multifaceted/ multiple component interventions have the potential to be successful in falls prevention. Meta-analysis is ongoing and the outcomes will be refined once that is complete.

Outcomes/Impact:

This study will inform the development of an application to NIHR HTA for a future definitive trial of a podiatry intervention to prevent falls in care homes.

Other dissemination activity:

- Gavin Wylie, Claire Torrens, Pauline Campbell, Helen Frost, Miles Witham, Jacqui Morris. A systematic review of podiatry interventions to reduce falls in older people. Abstract Submitted to Falls, Frailty and Bone Health 2017, Dublin.

Project Number:	LTCM03.6
Status:	Complete
Project Title:	Assessing the appropriateness and acceptability of a new multi-level taxonomy of asthma plan terms.
Source of funding and total value of award:	Queen's Nursing Institute Scotland, £25,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Ring N (PI) (University of Stirling).
NMAHP RU investigators:	Hoskins G.
Workstream:	Long Term Conditions Management
Start date:	February 2012
Duration:	9 months

Aim(s):

To obtain the views of patients with asthma and their health professionals on the promotion and use of written asthma plans and to determine whether a proposed hierarchy of asthma plan terms with standardised definitions was appropriate and acceptable.

Summary:

Written action plans provided within an asthma self-management programme can improve clinical outcomes and are recommended as good practice internationally. However, despite evidence of their effectiveness, action plans are issued infrequently by professionals and under-used by patients, with only about a quarter of those with asthma owning or using one. Using a case study design we interviewed 11 patients, 7 GPs, 10 PNs and one hospital respiratory nurse. Case studies varied in size from three to six participants. All the practice case studies (CS1-5) consisted of at least one patient, one PN and one GP. Three 'independent' PNs and 2 'independent' GPs were also interviewed.

This approach provided a rich data set for exploring the complexities of asthma action plan use and the terminology associated with it.

Outcomes/Impact:

Whilst written action plans were seen as beneficial in some circumstances patients did not always remember having one and if they did, rarely referred to it. Although the health professionals were able to provide more detailed insight into the concept of self-management and to action plan terminology, a wide range of asthma plan formats and terms were used. Not all professionals considered written asthma plans as central to asthma management and their inflexible format was considered a barrier to professional use. Where written asthma plans were being issued professional review occurred infrequently and was superficial in nature. However, written asthma action plans are a practical tool for operationalising the concept of self-management and while the variation in type and nature of action plan may 'encourage' poor practice, the differences highlighted may also imply that a professional has thought

LTCM03.6 Assessing the appropriateness and acceptability of a new multi-level taxonomy of asthma plan terms.

about and selected the plan which seems right for them to issue and for individual patients to receive.

The study highlighted that the present format of written asthma plans and the organisational processes for issue and review are 'not fit for purpose'. There is currently a mismatch between patients understanding of self-management plans to that of the health professional use of plans. To increase the use of written asthma plans and make them fit for contemporary clinical care there needs to be an integrated approach with greater team working between patients, PNs and GPs. Going forward we need to take the concept of self-management and encourage diversity in how it is delivered rather than assume we can select/shoe horn the patients in to existing action plans. This approach impacts on the training and support provided to health professionals and the resources for implementing the self-management process in practice.

Publications:

- Nicola Ring, Hazel Booth, Caroline Wilson, Gaylor Hoskins, Hilary Pinnock, Aziz Sheikh, Ruth Jepson. Assessing the appropriateness and acceptability of a new multi-level taxonomy of asthma plan terms. Final Report. QNIS 2013.
- Nicola Ring, Hazel Booth, Caroline Wilson, Gaylor Hoskins, Hilary Pinnock, Aziz Sheikh, Ruth Jepson. The 'vicious cycle' of personalised asthma action plan implementation in primary care: a qualitative study of patients and health professionals' views. BMC Family Practice (2015) 16:145; DOI 10.1186/s12875-015-0352-4

Project Number:	LTCM03.7
Status:	Complete
Project Title:	A podiatry intervention to reduce falls in care home residents: development, feasibility and acceptability study with exploratory randomised controlled trial
Source of funding and total value of award:	Chief Scientist Office, £184,152
Value of funding to NMAHP RU:	£1,971
Principal investigator/co-applicants:	Wylie G (PI) Morris J (University of Dundee), Williams B (University of Stirling), Sullivan F (University of Dundee), Ogston S (University of Dundee), Menz H (La Trobe University).
NMAHP RU investigators:	Williams B, Morris J.
Workstream:	Long Term Conditions Management
Start date:	March 2013
Duration:	26 months

Aim(s):

Falls in the care home (CH) settings are common. However, delivering interventions and conducting trials in CHs is challenging. The purpose of this project was to (i) establish the feasibility of implementing and testing, in CHs, an existing podiatry intervention designed to reduce falls, (ii) remodel the intervention and subsequent trial in light of the feasibility findings to suit the CH context, and (iii) estimate the effect size of the remodelled intervention on balance related outcomes and falls.

Summary:

Common foot problems are independent risk factors for falls in older people. There is evidence that podiatry can prevent falls in community-dwelling populations. The feasibility of implementing a podiatry intervention and trial in the care home population is unknown. To inform a potential future definitive trial, we performed a pilot randomised controlled trial to assess: (i) the feasibility of a trial of a podiatry

intervention to reduce care home falls, and (ii) the potential direction and magnitude of the effect of the intervention in terms of number of falls in care home residents. The study was informed by Medical Research Council guidance on developing and evaluating complex interventions and conducted in 2 phases. Phase 1 – care home residents and staff were recruited to take part in a 12-week feasibility and acceptability study of a 4-component multifaceted podiatry intervention (toe and ankle strengthening exercises, footwear, and foot orthoses provision) trial in the CH setting. Semi structured qualitative interviews were conducted to elicit participants' and care home staff views on experiences, barriers, and facilitators, and possible changes to the intervention, prior to its examination in an exploratory randomised controlled trial. The proportion of care home residents eligible for inclusion in an MPI trial was recorded. We also recorded and evaluated participant recruitment and selection of appropriate outcomes.

Phase 2 – we conducted a single blind, pilot randomised controlled trial in six care homes in the East of Scotland. Participants were randomised to either: (i) a three month podiatry intervention comprising core podiatry care, foot and ankle exercises, orthoses and footwear provision or (ii) usual care. Falls-related outcomes (number of falls, time to first fall) and feasibility-related outcomes (recruitment, retention, adherence, data collection rates) were collected. Secondary outcomes included: generic health status, balance, mobility, falls efficacy, and ankle joint strength.

Outcomes/Impact:

Phase 1 results - from 288 care home residents, 7% (n=21) met the initial inclusion criteria because of disability and cognitive impairment in the selected homes. For those participants, the MPI was feasible in the care home setting. Staff reported finding the MPI straightforward to implement, and devised flexible ways of delivering the exercise component of the intervention to CH residents to fit around existing CH routines. Staff suggested ways of improving the intervention, mainly in terms of delivery and staff training. We tailored the recruitment methods prior to commencing the phase 2 RCT.

Phase 2 results - 474 care home residents were screened. 43 (9.1%) participants were recruited: 23 to the intervention, 20 to control. Nine (21%) participants were lost to follow-up due to declining health or death. It was feasible to deliver the trial elements in the care home setting. 35% of participants completed the exercise programme. 48% reported using the orthoses 'all or most of the time'. Completion rates of the outcome measures were between 93% and 100%. No adverse events were reported. At the nine month follow-up period, the intervention group per-person fall rate was 0.77 falls vs. 0.83 falls in the control group. The negative binomial model indicated no significant difference between the groups: incidence rate ratio 0.605, 95% CI 0.243 to 1.502, p = 0.3.

Conclusions: A podiatry intervention to reduce falls can be delivered to care home residents within a pilot randomised controlled trial of the intervention. Although not powered to determine effectiveness, these preliminary data provide justification for a larger trial, incorporating a full process evaluation, to determine whether this intervention can significantly reduce falls in this high-risk population.

Next steps: This work has led to the formation of a team to develop an application to the NIHR for a large multicentre RCT of the intervention. In support of this application, a catalytic grant application to the Chief Scientist Office in March 2017 to conduct a systematic review of podiatry interventions to reduce falls in older people was successful. This is due to report at the end of August 2017.

Publications:

- Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, Young Z, Morris J. Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study). *BMC Geriatr. BMC Geriatrics*; 2017;17(1):143.
- Wylie G, Young Z, Littleford R, Sullivan F, Coyle J, Williams B, Morris J. Finding your feet : The development of a podiatry intervention to reduce falls in care home residents. *J Foot Ankle Res. BioMed Central Ltd*; 2015;8(Suppl 1):A7.
- Wylie G, Young Z, Littleford R, Sullivan F, Williams B, Menz H, Young Z, Morris J. Reflecting on the methodological challenge of recruiting older care home residents to podiatry research. *J Foot Ankle Res. BioMed Central Ltd*; 2015;8(Suppl 1):A10.
- Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, Young Z, Morris J. A podiatry intervention to reduce falls in care home residents demonstrates benefits: results from a pilot randomised controlled trial - The College of Podiatry Annual Conference 2015: meeting abstracts. *J Foot Ankle Res. 2016 Apr 27*;9(S1):12.

LTCM03.7 A podiatry intervention to reduce falls in care home residents: development, feasibility and acceptability study with exploratory randomised controlled trial

Other dissemination activity:

- 8-9 June 2017: Royal College of Physicians and Surgeons (Glasgow), Excellence in Healthcare Conference. Third prize poster presentation - A podiatry intervention to reduce falls in care home residents demonstrates benefits: results from a pilot randomised controlled trial.

Project Number:	LTCM03.8
Status:	Complete
Project Title:	Exploring decision making and patient involvement in prosthetic prescription
Source of funding and total value of award:	£10,000 SOTA Prosthetics Group, £40,000 Scottish Government (funded before 2010)
Value of funding to NMAHP RU:	£50,000
Principal investigator/co-applicants:	Semple K, Cheyne H, Maxwell M (All University of Stirling)
NMAHP RU investigators:	Semple K, Cheyne H, Maxwell M
Workstream:	Long Term Conditions Management
Start date:	May 2011
Duration:	48 Months

Aim(s):

To explore aspects of prosthetic care provision in the UK including clinical decision making, patient experience and the transition of prosthetic care from the Ministry of Defence (MOD) to the NHS.

Summary:

Recent conflicts have seen an increase in trauma related military amputees who incur complex injuries. In many cases these amputees have been provided with state of the art (SOTA) components with the expectation that they will transfer into NHS care after military discharge. However, there is a lack of knowledge around how prosthetic prescriptions are made in both the MOD and NHS, including patient involvement.

Design: A qualitative study informed by decision making and patient involvement theory. Semi-structured interviews were carried out with nineteen clinical staff involved in prosthetic provision, six civilian and five veteran trauma amputees.

Thematic analysis was used to analyse the data.

Findings: Prosthetists used a wide range of factors in making prescription decisions, including physical characteristics, patients' goals, and predicted activity levels.

Prescription decision making varied depending on the prosthetists' level of experience and the different 'cues' identified. In some cases there was a lack of transparency about drivers for the prescription choice. Prescription decisions are influenced by long term relationships between prosthetist and patient, allowing a trial and error approach with increasing patient involvement over time. Patient experiences of their trauma amputation influenced their approach to rehabilitation. Patients reported wanting different levels of involvement in their prosthetic care, however, communication was essential for all. Veteran amputees benefited from peer support opportunities which NHS services were less conducive to. However, NHS amputees were more likely to have been 'involved' in care decisions. The expectations that MOD patients had of inferior care in the NHS were not realised in the majority of veteran cases.

Other dissemination activity:

- Semple K (2013) Decision Making in Prosthetic Prescription for Traumatic Amputees. British Association of Prosthetists and Orthotists Conference, Telford

Project Number:	LTCM03.9
Status:	Complete
Project Title:	A Phase 2 randomised controlled trial of Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy versus control in Parkinson's disease (PD COMM pilot)
Source of funding and total value of award:	Dunhill Medical Trust, £240,000
Value of funding to NMAHP RU:	£9,940.00
Principal investigator/co-applicants:	Sackley C (PI) (University of Birmingham), Brady MC (Glasgow Caledonian University), Clark C, Ives N, Meek C (University of Birmingham), Patel R (Parkinson's UK), Roberts H (University of Southampton), Smith C (University College London), Wheatley K (University of Birmingham).
NMAHP RU investigators:	Brady MC.
Workstream:	Long Term Conditions Management
Start date:	July 2010
Duration:	3 years

Aim(s):

To assess the feasibility of comparing Lee Silverman Voice Treatment (LSVT) with traditional SLT and control in PD, and to determine the sample size and primary outcome measure for a main trial.

Research questions:

1. What is the eligibility, recruitment and retention, participant acceptability and treatment compliance within the proposed trial design?
2. Can we improve our estimated sample size and refine the choice of outcome measures including those used for the economic evaluation for the main trial?

Summary:

Although over two thirds of people with Parkinson's disease (PD) report speech problems the evidence base for speech and language therapy (SLT) in PD is limited and inconclusive. Speech problems are often a key concern for people with PD and many believe they will benefit from SLT. Despite this, referral rates are low and services are often underfunded and overstretched. We conducted two systematic reviews on the topic and found a lack of evidence to support clinical practice. Our study was the first step towards an adequately powered definitive RCT (LTCM03.10) that will provide clear information on the clinical and cost effectiveness of SLT for PD, and also identify which SLT approach is more effective.

A total of 89 people with PD reporting problems with speech were recruited from elderly care/ neurology clinics from across the UK, and randomised to receive community-delivered LSVT (a technique focused on improving vocal loudness), or standard NHS SLT, or no SLT for 6 months. Outcome measures were recorded at baseline, three and six months, and included the Assessment of Intelligibility of Dysarthric Speech, Voice Handicap Index, vocal loudness, PDQ-39, Voice-Related Quality-of-Life Scale, Living with Dysarthria Questionnaire. Adherence and adverse events were also monitored.

Outcomes/Impact:

Of the 89 participants, 90 per cent in the therapy arms and 100 per cent in the control arm completed the trial. Our findings were used to inform the development and submission of an application to the HTA for a definitive Phase III trial. This trial is currently underway (LTCM03.10). Our study findings will be used by commissioners to correctly shape the services provided for people with PD, channelling funding into approaches to SLT delivery that will lead to optimum gains in health and wellbeing. The evidence may also provide support for referral to these services, helping move towards all patients having access to SLT as required, as advocated in national PD guidelines.

Publications:

- Sackley CM, Smith CH, Rick C, Brady MC, Ives N, Patel R, Roberts H, Dowling F, Jowett S, Wheatley K, Patel S, Kelly D, Sands G and Clarke C. Lee Silverman Voice Treatment versus standard NHS Speech and Language Therapy versus control in Parkinson's Disease (PD COMM Pilot): Study protocol for a randomised controlled trial. *Trials*, 15(213) doi:10.1186/1745-6215-15-21.
- Clarke C, Sackley C, Smith C, Rick C, Brady MC, Ives N, Patel S, Woolley R, Dowling F, Patel R, Roberts H, Jowett S, Wheatley K, Kelly D, Sands G. Lee

Silverman Voice Treatment versus standard speech and language therapy versus control in Parkinson's disease: a pilot randomised controlled trial (PD COMM pilot) Pilot and Feasibility Studies. (submitted)

- Herd CP, Tomlinson CL, Deane KHO, Brady MC, Smith CH, Sackley C, Clarke CE. Speech and language therapy versus placebo or no intervention for speech problems in Parkinson's disease. *Cochrane Database of Systematic Reviews* 2011, Issue 2. Art. No.:CD002812. DOI: 10.1002/14651858.CD002812.
- Herd CP, Tomlinson CL, Deane KHO, Brady MC, Smith CH, Sackley C, Clarke CE. Comparison of speech and language therapy techniques for speech problems in Parkinson's disease. *Cochrane Database of Systematic Reviews* 2011, Issue 2. Art. No.:CD002814. DOI: 10.1002/14651858.CD002814.

Presentations:

- Sackley CM, Patel S, Woolley R, Ives N, Rick CE, Dowling F, Wheatley K, Smith C, Brady M, Clarke CE. A pilot randomised-controlled-trial of Lee Silverman Voice treatment (LSVT) versus NHS speech and language therapy (SLT) versus control in Parkinson's (PD COMM Pilot). 20th International Congress of the Parkinson and Movement Disorders Society 19th -23rd June 2016, Berlin, Germany.

Posters:

- Beaton G, St George B, Clarke CE, Dowling F, Patel S, Woolley R, Ives N, Rick C, Wheatley K, Smith C, Brady MC, Sackley CM. Challenging clinical decisions relating to the provision of LSVT for people with Parkinson's Disease: a single case study. Royal College of Speech and Language Therapists, 17-18th September, Leeds, UK.

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- Dowling F, Clarke CE, Patel S, Woolley R, Ives NJ, Rick CE, Wheatley K, Smith CH, Brady MC, Kelly D, Sackley C. PDCOMM Pilot: A pilot randomised controlled trial of Lee Silverman Voice Treatment versus Standard NHS Speech and Language Therapy versus control in Parkinson's disease. 18th International Congress of Parkinson's Disease and Movement Disorders, June 8-12, 2014, Stockholm, Sweden.
 - Rick C, Clarke CE, Patel S, Dowling F, Woolley R, Ives N, Jowett S, Wheatley K, Smith C, Brady MC, Sackley CM. A pilot randomised-controlled-trial of Lee Silverman Voice treatment (LSVT) versus NHS speech and language therapy (SLT) versus control in Parkinson's (PD COMM Pilot). Parkinson's UK Research Conference. 7-8th November 2016, Leeds, UK
 - Dowling F, Clarke CE, Rick C, Patel S, Woolley R, Ives N, Jowett S, Burton C, Smith C, Brady MC, Sackley CM. A Multi-Centre Randomised Controlled Trial to Compare the Clinical and Cost Effectiveness of Lee Silverman Voice Treatment Versus Standard NHS Speech and Language Therapy Versus Control in Parkinson's Disease (PD COMM) Parkinson's UK Research Conference. 7-8th November 2016, Leeds, UK
 - Sackley CM, Patel S, Woolley R, Ives NJ, Rick CE, Dowling F, Wheatley K, Smith C, Brady MC, Clarke CE. PD COMM Pilot: A pilot randomised controlled trial of Lee Silverman Voice Treatment (LSVT) versus NHS speech and language therapy (SLT) versus no intervention control in Parkinson's. Movement Disorder Society. 19th- 23rd June 2016, Berlin, Germany

Project Number:	LTCM03.10
Status:	In Progress
Project Title:	A multi-centre randomised controlled trial to compare the clinical and cost effectiveness of Lee Silverman Voice Treatment versus standard NHS speech and language therapy versus control in Parkinson's disease (PD COMM II)
Source of funding and total value of award:	NIHR HTA, £1,830,109.60
Value of funding to NMAHP RU:	£397,723
Principal investigator/co-applicants:	Sackley C (PI) (King's College London), Brady MC (Glasgow Caledonian University), Burton C (Bangor University), Clark CE, Ives N, Jowet S, Patel S, Rick C (University of Birmingham), Smith CH (University College London).
NMAHP RU investigators:	Brady MC, Nicol A, Dickson S.
Workstream:	Long Term Conditions Management
Start date:	December 2015
Duration:	5 Years +

Aim(s):

1. To evaluate the clinical and cost-effectiveness of speech and language therapy (SLT) for people with Parkinson's disease using three comparisons: Lee Silverman Voice Treatment (LSVT) versus control; standard NHS SLT versus control; and LSVT versus standard NHS SLT.
2. To contextualise and interpret the PD COMM trial results.

Research Questions:

1. Is speech and language therapy intervention for people with Parkinson's disease more effective and cost-effective than no intervention?
2. Is Lee Silverman Voice Treatment or standard NHS speech and language therapy inherently more effective and / or cost-effective?
3. How did people with Parkinson's disease experience the trial, their allocated trial arm, and any impact on their communication?

4. How did speech and language therapists experience trial implementation, the interventions, and any impact or lack of impact on participants?
5. What components of intervention, in what combination, were used (i.e. dosage)?

Summary:

Communication problems are a common and disabling feature of Parkinson's disease, yet high quality randomized controlled trial evidence for effectiveness of speech and language therapy interventions is lacking. This three-arm UK multi-site trial, developed following a successful pilot, is recruiting 546 people with Parkinson's disease who have self or carer-reported problems with their speech or voice and no dementia. It compares two routine NHS interventions with no SLT intervention for 12 months, and with each other. The interventions are Lee Silverman Voice Treatment (a standardized program delivered in 16 sessions over 4 weeks) and other standard NHS intervention (typically weekly sessions for 6-8 weeks tailored to individual needs,

incorporating impairment, compensatory, functional and alternative / augmentative communication components). All outcome measures of communication and quality of life are patient-reported (one carer-reported), including the primary outcome measure the Voice Handicap Index, with the majority completed at baseline, then 3, 6 and 12 months. Adverse events are vocal strain or abuse. A mixed method process evaluation includes interviews with a purposive sample of participants and therapists to understand implementation of the trial and experience of its interventions, and a quantitative exploration of therapy components and their combinations.

Outcomes/Impact:

The trial is in process.

Publications:

- Brady MC, Smith C Parkinson's Disease SLT Trial. RCSLT Bulletin April 2016; 4.
- Palmer R, Nicoll A. Contributing to the evidence base. RCSLT Bulletin July 2017; 24-25.
- Masterson-Algar P, Burton CR, Brady MC, Nicoll A, Clarke CE, Rick C, Hughes M, Au P, Smith CH, Sackley CM. The PD COMM trial: a protocol for the process evaluation of a randomised trial assessing the effectiveness of two types of SLT for people with Parkinson's disease. Trials (in press, TRLS-D-17-00327R1).

Presentations:

- Nicoll A. Taking on the big questions: PD COMM trial of speech and language therapy interventions for people with Parkinson's disease. Adult Acquired Communication Disorders Clinical Excellence Network Scotland, 28th April 2017, Edinburgh.
- Nicoll A. PD COMM trial: speech and language therapy interventions for people with Parkinson's disease. Scotland South East region meeting of UK Parkinson's

Excellence Network, 9th June 2017, Edinburgh.

- Nicoll A. PD COMM trial: speech and language therapy interventions for people with Parkinson's disease. Scotland North region meeting of UK Parkinson's Excellence Network, 26th June 2017, Aberdeen.
- Nicoll A. PD COMM trial: speech and language therapy interventions for people with Parkinson's disease. Scotland West region meeting of UK Parkinson's Excellence Network, 30th June 2017, Glasgow.

Posters:

- Nicoll A, Brady MC, Dickson S, Au P, Hughes M, Rick C, Sackley CM, Smith CH, Clarke CE, Masterson-Algar P, Burton CR. Recruiting speech and language therapy departments in Scotland to deliver two routine NHS interventions for people with Parkinson's disease as part of a randomised controlled trial (PD COMM). Royal College of Speech and Language Therapists, 27-28th September 2017, Glasgow, UK.

PELVIC HEALTH



PROLAPSE



The NMAHP RU provides unique knowledge and skills around the most appropriate methodologies to use in complex intervention studies, which are also transferrable to other contexts. The Unit has a recognised excellent reputation for delivering high quality and useful research



Project Number:	PVH01.1
Status:	Complete
Project Title:	Multicentre Randomised Controlled Trial of Pelvic Floor Muscle Training to Prevent Pelvic Organ Prolapse in Women (PREVPROL)
Source of funding and total value of award:	Wellbeing Of Women Research Grant, £148,000
Value of funding to NMAHP RU:	£148,000
Principal investigator/co-applicants:	Hagen S (PI) (Glasgow Caledonian University), McClurg D (Glasgow Caledonian University), Glazener C (HSRU), Bain C (NHS Grampian), Tooze-Hobson P (Birmingham Women's Hospital), Macarthur C (University of Birmingham), Wilson D (University of Otago), Herbison P (University of Otago), Hay-Smith J (University of Otago).
NMAHP RU investigators:	Hagen S, McClurg D.
Workstream:	Pelvic Health
Start date:	February 2010
Duration:	36 Months

Aim(s):

The aim of the PREVPROL trial was to identify the clinical and cost-effectiveness of pelvic floor muscle training in the secondary prevention of prolapse symptoms,9 worsening of prolapse severity, and uptake of prolapse treatment.

Summary:

Pelvic floor muscle training can reduce prolapse severity and symptoms in women seeking treatment. We aimed to assess whether this intervention could also be effective in secondary prevention of prolapse and the need for treatment in the future.

This was a multicentre, parallel-group, randomised controlled trial at three centres in New Zealand and the UK. Women from a longitudinal study of pelvic floor function after childbirth were potentially eligible for inclusion. Women of any age who had stage 1–3 prolapse, but had

not sought treatment, were randomly assigned (1:1), via remote computer allocation, to receive either one-to-one pelvic floor muscle training (five physiotherapy appointments over 16 weeks, and annual review) plus Pilates-based pelvic floor muscle training classes and a DVD for home use (intervention group), or a prolapse lifestyle advice leaflet (control group). Randomisation was minimised by centre, parity (three or less vs more than three deliveries), prolapse stage (above the hymen vs at or beyond the hymen), and delivery method (any vaginal vs all caesarean sections). Women and intervention physiotherapists could not be masked to group allocation, but allocation was masked from data entry researchers and from the trial statistician until after database lock. The primary outcome was self-reported prolapse symptoms (Pelvic Organ Prolapse Symptom Score [POP-SS]) at 2 years, higher scores indicating worse symptoms. Analysis was by intention to treat. (ClinicalTrials.gov, number NCT01171846)

Outcomes/Impact:

We randomised 414 women to the intervention (n=207) or the control group (n=207). One woman in each group was excluded post-randomisation, leaving 412 for analysis. At baseline, 399 (97%) women had prolapse above or at the level of the hymen. The mean POP-SS score at 2 years was 3.2 (SD 3.4) in the intervention group versus 4.2 (SD 4.4) in the control group (adjusted mean difference -1.01, 95% CI -1.70 to -0.33; p=0.004). The mean symptom score was similar across time points in the control group, but decreased in the intervention group.

We showed that pelvic floor muscle training leads to a small, reduction in prolapse symptoms. This is of importance for women and healthcare professionals considering preventive strategies.

Publications:

- Hagen S, Glazener C, McClurg D, Macarthur C, Elders A, Herbison P, Wilson D, Tooze-Hobson P, Hemming C, Hay-Smith J, Collins M. Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial. *The Lancet*. 2017 Feb 3;389(10067):393-402.
- Hagen S, Glazener C, McClurg D, Macarthur C, Herbison P, Wilson D, Tooze-Hobson P, Bain C, Hay-Smith J, Collins M, Elders A. A multicentre randomised controlled trial of a pelvic floor muscle training intervention for the prevention of pelvic organ prolapse (PREVPROL). In *Neurourology and Urodynamics* 2014 Aug 1 (Vol. 33, No. 6, pp. 852-853). 111 RIVER ST, HOBOKEN 07030-5774, NJ USA: WILEY-BLACKWELL.

Other dissertation activity:

- Wellbeing of Women charity event, Edinburgh 2011. SH gave a keynote presentation on the PREVPROL trial progress. Over 100 members of the public, charity organisers and charity's patron (Sarah Brown) attended to raise funds for the Wellbeing of Women charity.
- International Continence Society Conference Tokyo 2016. PREVPROL trial 3 year follow-up results presented by SH to around 200 delegates regarding 3 year follow up of women in a trial of pelvic floor muscle training for prevention of prolapse.

Project Number:	PVH01.2
Status:	Complete
Project Title:	Surgery and physiotherapy for prolapse to avoid recurrence: a feasibility study – SUPER
Source of funding and total value of award:	Physiotherapy Research Foundation, £65,518
Value of funding to NMAHP RU:	£65,518
Principal investigator/co-applicants:	McClurg D (PI) (Glasgow Caledonian University), Dolan L (NHS Lothian University Hospitals), Frawley H (University of Melbourne), Hagen S (Glasgow Caledonian University), Hilton P (Newcastle-upon-Tyne Hospitals NHS Trust), Monga A (Southampton University Hospitals NHS Trust).
NMAHP RU investigators:	McClurg D, Hagen S, Dickinson L, Jamieson K.
Workstream:	Pelvic Health
Start date:	March 2010
Duration:	24 Months

Aim(s):

1. To develop the methods and assess the feasibility of a multi-centre randomised controlled trial of peri-operative physiotherapy for patients who undergo surgical intervention for pelvic organ prolapse. Information on recruitment, retention and suitability of outcome measures specific to POP and associated symptoms will be obtained.
2. To collect pilot data to inform sample size calculations and optimal health economics methods in preparation for undertaking a multi-centre pragmatic randomised controlled trial.

Summary:

This was a two-group single blind feasibility study with 30 participants per group who were recruited at three centres. At each centre there was a local PI (Consultant urogynaecologist) was responsible for recruiting, and two physiotherapists, an Outcome Physiotherapist (OP) who

was blind to group allocation, and a Treatment Physiotherapist (TP). All data was anonymised before analysis, and stored as per the Data Protection Act 1986.

Following completion of the consent form eligible participants were randomised, using a remote computer system to:- Control Group; (n=29), who were posted a Lifestyle advice leaflet post-operatively.

Treatment Group; (n=28), who received peri-operative physiotherapy by a women's health physiotherapist with dedicated time (TP). This included:-

- A pre-operative appointment which was primarily used to teach correct pelvic floor muscle (PFM) contraction and to instigate a home programme of PFM exercises. A digital vaginal examination was undertaken to inform the individual exercise programme.
- One post-operative visit on the ward prior to discharge. Women were advised on bladder and bowel care, and given guidance on resumption of normal activities.

- Out-patient review 6 weeks post-operatively. Vaginal assessment was undertaken to determine the PFM exercise programme, symptoms were re-assessed and advice given.
- 5 further once weekly physiotherapy out-patient appointments within a period of 12 weeks. A detailed programme was developed following discussions with the participating physiotherapists which was aimed at maximum progression of PFM exercises

Primary Outcome Measures:

- Symptom severity as measured by the Pelvic Organ Prolapse Symptom Score (POP-SS).

Secondary Outcome Measures:

- Those undertaken by the Outcome Physiotherapist
 - Recurrence of prolapse as measured by the POP-Q
 - Digital assessment of the pelvic floor muscles
- Patient self-completed questionnaires
 - International Consultation on Incontinence Urinary Incontinence Short Form Questionnaire (ICIQ-UI SF).
 - International Consultation on Incontinence Bowel Symptom Questionnaire (ICIQ-BS)
 - The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire -12 (PISQ-12).
 - SF-12. A 12 item generic measure of perceived health

57 women were randomised, 28 to the intervention group and 29 to the control group. The mean age was 60(SD10) years, the average number of children was 2.19(SD.83), mean BMI was 27(SD3). Mean duration of prolapse symptoms was 17 months, and the most common prolapse stage was II with 50% being anterior edge prolapse. Both groups demonstrated similar demographics and symptom severity at base-line except that the Intervention group were slightly more troubled by bowel dysfunction when compared to the control. When comparing the POP-Q assessment at base-line those in the Intervention Group measured with more severe posterior prolapse which could account for the more severe bowel dysfunction. The primary outcome measure was the POP-SS and both groups reported similar improvement from base-line to 6 months. Similar improvements were reported in the ICIQ and SF 12 from baseline to 6 months. A difficulty in two centres where the physiotherapists did not have access to operating lists was keeping track of when

patients had their operation. Another was that sometimes participants were operated on earlier than anticipated, perhaps as a cancellation and thus did not have their pre-operative intervention visit. Those undertaking the intervention reported that most participants were very pleased to be in that group and felt it helped with their recovery. In some cases the number of visits appeared to be too many and the protocol would need to be more pragmatic depending on the patient.

Outcome/Impact:

Invaluable information on study processes for the definitive trial has been gathered. Additionally it would appear that there may be benefit in some form of peri-operative support for women undergoing surgery for prolapse which supports the findings of a small study by Jarvis et al 2005, although a more recent small study by Frawley et al 2010 did not demonstrate benefit.

The results of this study and those referenced provide the evidence of the need for a randomised controlled trial relating to the prevention of prolapse re-occurrence using PFM training and advice based on the physiological processes of healing and repair.

With the increasing pressures on physiotherapy time it is important that patients receive the optimum information and support at the optimum time. There was a lot of feedback relating to the lack and or the variability of information some patients received. It is important that further research is undertaken to optimise input and maximise patient benefit for those contemplating gynaecological surgery especially in the light of the MESH saga.

Publications:

- McClurg D, Hilton P, Dolan P, Monga A, Hagen S, Dickinson, Frawley H. Pelvic floor muscle training as an adjunct to prolapse surgery – a randomized feasibility study. *International Urogynecological Journal* 2014 25(7):883-91
- McClurg D, Hilton P, Dolan P, Monga A, Hagen S, Dickinson, Frawley H. Pelvic floor muscle training as an adjunct to prolapse surgery – a randomized feasibility study. *CSP Conference* 2013

Project Number:	PVH01.3
Status:	In Progress
Project Title:	VUE: Vault or Uterine prolapse surgery Evaluation: two parallel randomised controlled trials of surgical options for upper compartment (uterine or vault) pelvic organ prolapse
Source of funding and total value of award:	National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme - £1,436,693.00 + £89,751 extension
Value of funding to NMAHP RU:	£10,397
Principal investigator/co-applicants:	Glazener C (PI), Breeman S, McPherson G, McDonald A, Norrie J, (HSRU, University of Aberdeen), Montgomery IBG (University of Aberdeen), Elders A, Hagen S (Glasgow Caledonian University), Smith ARB (St. Mary's Hospital Manchester), Freeman RM (Plymouth Hospital NHS Trust), Bain C, Cooper K (NHS Grampian), Kilonzo M (HERU).
NMAHP RU investigators:	Elders A, Hagen S.
Workstream:	Pelvic Health
Start date:	November 2012
Duration:	7 years

Aim(s):

The primary objective is to determine the optimal surgical management for women with upper compartment (uterine or vault) pelvic organ prolapse, in terms of clinical effectiveness, cost-effectiveness and adverse events. The two parallel trials will compare: (a) in women having uterine prolapse surgery, the effects of removal of the uterus versus uterine preservation; (b) in women having vault prolapse surgery, the effects of a vaginal vault suspension versus an abdominal vault suspension.

Summary:

Gynaecologists have recognised for some time that both anatomical failure and recurrence of prolapse symptoms after surgery are common: one in three women who have a prolapse operation will go on to have another, though not necessarily in the same compartment. More recently, it

has also been recognised that surgery can be followed by a greater impairment of quality of life than from the original prolapse itself (for example the development of new-onset urinary incontinence after surgery, or prolapse at a different site). Whilst anterior and posterior prolapse surgery is most common (90% of operations), around 43% of women also have a uterine (34%) or vault (9%) procedure at the same time. Indeed, this demonstrates that women who have a hysterectomy have around a 27% chance of needing a subsequent vault prolapse repair. These data are derived from the first 700 women recruited in PROSPECT, a large HTA-funded UK RCT of anterior or posterior prolapse surgery with or without the use of mesh (HTA No. 07/60/18). In VUE, the opportunity has arisen to then switch from randomising between lower compartment surgery to trials involving different surgical options for upper compartment prolapse (uterine and vault).

Publications:

- Glazener, C., Constable, L., Hemming, C., Breeman, S., Elders, A., Cooper, K., Freeman, R., Smith, A. R., Hagen, S., McDonald, A., McPherson, G.,
- Montgomery, I., Kilonzo, M., Boyers, D., Goulao, B. and Norrie, J. (2016) 'Two parallel, pragmatic, UK multicentre, randomised controlled trials comparing surgical options for upper compartment (vault or uterine) pelvic organ prolapse (the VUE Study): study protocol for a randomised controlled trial' [Protocol], *Trials*, 17(1), 441.

Project Number:	PVH01.4
Status:	Long term follow-up ongoing
Project Title:	PROSPECT: Clinical and cost-effectiveness of surgical options for the management of anterior or posterior vaginal wall prolapse, pragmatic evaluation by multicentre randomised controlled trial - PROlapse Surgery, Pragmatic Evaluation and randomised Controlled Trial
Source of funding and total value of award:	National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme - £193,864 for long-term follow-up (£2,866,992 for original grant)
Value of funding to NMAHP RU:	£1,174
Principal investigator/co-applicants:	Glazener C (PI), Grant A, Norrie J, Maclennan G, McDonald A, McPherson G (HSRU, University of Aberdeen), Vale L (HERU/ HSRU), Smith ARB (St. Mary’s Hospital Manchester), Freeman RM (Plymouth Hospital NHS Trust), Bain C, Cooper K (NHS Grampian), Hagen S (Glasgow Caledonian University), Montgomery IBG (Aberdeen).
NMAHP RU investigators:	Hagen S.
Workstream:	Pelvic Health
Start date:	February 2015
Duration:	5 years 3 months (end date 30/4/20)

Aim(s):

To estimate the effectiveness and cost-effectiveness of different surgical options for the repair of vaginal prolapse

Summary:

The lifetime risk of undergoing surgery for prolapse is nearly 10%. There are several different traditional surgical techniques, none of which have been properly evaluated. The study embedded two large RCTs investigating different surgical techniques for two distinct patient populations of women with vaginal prolapse (primary and secondary) within a comprehensive cohort of all patient s. The economic evaluation investigated the costs and cost-effectiveness of the interventions from the perspective of the NHS and for the women and their families. Information on the cost of the intervention and the use of

primary and secondary NHS services by the women (including referral for specialist management) were collected, as were personal costs to the women (such as costs of travelling to appointments and work/social restrictions). Trial participants were asked to complete the EQ-5D at baseline and at 6, 12 and 24 months after randomisation, and -responses were used to compute QALYs. In a sensitivity analysis, QALYs were also estimated from the SF-12 completed at the same time points.

The difference in effectiveness was expressed in terms of the numbers of patients cured and improved. Incremental cost-utility ratios were computed comparing the intervention s. An economic model that considers a longer time horizon was developed to provide additional information for policy makers. In the model, the findings of the trial were extrapolated to the patient’s lifetime.

Outcomes/Impact:

The study concluded that there is no clear superiority of the synthetic mesh, biological graft or mesh kit over standard repair in the first two years after surgery. Unless there is a significant decrease in the reoperation rates for failure in the medium or long term in the mesh or graft arms, compared to standard repair, it is unlikely that any type of mesh or graft is going to be cost-effective, given the excess cost over standard repair and the excess cost of treatment for the adverse effect of mesh exposure or extrusion. Long-term follow-up is now on-going.

Publications:

- Glazener, C.M.A., Breeman, S., Elders, A., Hemming, C., Cooper, K. G., Freeman, R.M., Smith, A.RB., Reid, F., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., McDonald, A., McPherson, G., Maclennan, G. and Norrie, J. (2016) 'Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT)', *Lancet*, [Epub ahead of print].
- Glazener, C., Breeman, S., Elders, A., Hemming, C., Cooper, K., Freeman, R., Smith, A., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., McDonald, A., McPherson, G., Maclennan, G. and Norrie, J. (2017) 'Clinical effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study - results from the PROSPECT Study', *Health Technology Assessment*, 20(95).

Project Number:	PVH01.5
Status:	In Progress
Project Title:	Mind the Gap – making pessary use for prolapse woman-centred and evidence-based
Source of funding and total value of award:	GCU PhD studentship £44,500; UK Continence Society £5000; Pelvic Obstetric and Gynaecological Physiotherapy £2000; NMAHP RU £3000
Value of funding to NMAHP RU:	£51,500
Principal investigator/co-applicants:	Lough L, PhD Student (Glasgow Caledonian University), Supervisory team: Hagen S, McClurg D, Pollock A (Glasgow Caledonian University)
NMAHP RU investigators:	Hagen S, McClurg D, Pollock A.
Workstream:	Pelvic Health
Start date:	October 2015
Duration:	36 months

Aim(s):

The aim of the project study is to:

1. Identify the top ten priorities for future research relating to pessary use for pelvic organ prolapse for which there is no existing evidence.
2. To conduct a systematic scoping review of the published research and synthesise the results to identify the levels of evidence and evidence gaps
3. Use stages (i) and (ii) to inform a pilot study or feasibility trial protocol to answer one of the priorities identified in (i).

Summary:

Prolapse affects up to 50% of women. Treatments include surgery, which has a high reoperation rate, and conservative management which may involve the use of a vaginal device called a pessary. The current evidence-base for pessary use is limited with no available systematic reviews to inform practice.

This mixed methods research project seeks to identify, by consensus, the top ten priorities for future research about pessary use for prolapse. A systematic scoping review and the priority setting exercise involving clinicians and women with experience of prolapse will illustrate what the evidence is and where the gaps are.

The scoping review to date has identified considerable gaps in evidence and highlighted inconsistencies and the lack of quality research. The questions submitted to the priority setting exercise demonstrate the wide level of uncertainties from women and clinicians.

The final workshop of the JLA Pessary PSP on 8th September will identify the top ten which will be published and promoted to increase the opportunity for funding research about this topic. Previously published James Lind Alliance 'Top Tens' have been significant in influencing funded research.

The collaborative and broad scope of this project gives voice to those involved with pessary provision and use. It is anticipated that publications relating to the Scoping Review, and the JLA Pessary PSP process and results will be submitted to the relevant journals.

The final phase of this project will investigate ways of answering an identified Top Ten by way of research with a feasibility or pilot project anticipated.

Other dissemination activity:

- Poster UKCS March 2017
- Association for Continence Advice podium presentation
- Poster and Presentation Postgraduate Research Symposium May 2017
- GCU 3 Minute Thesis competition winner

Project Number:	PVH01.6
Status:	In Progress
Project Title:	NIHR HS&DR Project: 14/04/02 - Implementation of an evidence based pelvic floor muscle training intervention for women with pelvic organ prolapse (PROlapse and PFMT: implementing Evidence Locally - PROPEL)
Source of funding and total value of award:	NIHR HS&DR Researcher led, £583,217
Value of funding to NMAHP RU:	£558,825
Principal investigator/co-applicants:	Maxwell M (PI) (University of Stirling), Hagen S (Glasgow Caledonian University), Duncan E (University of Stirling), McClurg D (Glasgow Caledonian University), Abhyankar P (University of Stirling), Elders A (Glasgow Caledonian University), Calveley E (University of Stirling), Bowel and Bladder Foundation, Guerrero K (NHS Greater Glasgow and Clyde), Mason H (Glasgow Caledonian University), Tincello D (University Hospitals of Leicester NHS Trust), Wilkinson J (University of Stirling)
NMAHP RU investigators:	Maxwell M, Hagen S, Duncan E, McClurg D, Elders A, Calveley E
Workstream:	Pelvic Health
Start date:	April 2016

Aim(s):

To maximise the delivery of effective PFMT for women with prolapse through the study of its implementation in three diverse settings using an evidence-based PFMT protocol. This will involve developing different service delivery models, incorporating a variety of staff skill mixes and number of sessions to increase capacity, with the format of delivery being determined locally.

To assess the impact of PFMT on longer term treatment outcomes using linked healthcare data for the majority of the original POPPY trial participants (i.e. those based in Scotland).

Summary:

Pelvic Organ Prolapse (POP) is estimated to affect 41%-50% of women aged over 40. The Pelvic Organ Prolapse Physiotherapy (POPPY) trial was a multi-centre randomised controlled trial of the effectiveness and cost-effectiveness of individualised pelvic floor muscle training (PFMT) compared to a lifestyle advice leaflet in newly-diagnosed women with stages I-III prolapse. Individualised PFMT was effective in reducing symptoms of prolapse, improved quality of life and showed clear potential to be cost-effective. Despite this evidence, provision of PFMT for prolapse continues to vary across the UK, with limited numbers of physiotherapists specialising in women’s health. Implementation of this robust evidence will require attention to different models of delivery to fit with differing care environments. Research is needed to support the implementation of PFMT as a first line treatment.

The opportunity also exists to examine the longer term treatment outcomes of original trial participants. This project aims to study implementation and outcomes of different models of delivery to increase service provision of PFMT across contrasting NHS sites; and to use linked healthcare data for longer term follow up of treatment outcomes for original POPPY trial participants.

Design: Realist Evaluation based on multiple case studies of implementation and outcomes of PFMT delivery in 3 contrasting NHS settings. A Realist Evaluation (RE) with substantial local stakeholder engagement will permit a detailed exploration of how local sites make decisions on how to deliver PFMT (e.g. using different skills mixes and numbers of appointments) and how these lead to service change. The RE will track how implementation is working; understand what influences outcomes; and guided by the RE-AIM framework will collect robust outcomes data. This will require mixed methods data collection and analysis.

Setting: Specialist women's health services in three sites: Glasgow, Leicester and Caithness/Inverness.

Methods: Qualitative data will be collected at 4 time-points across each site to understand local contexts and decisions regarding options for delivery of PFMT and to monitor implementation, uptake, adherence and outcomes. **Outcomes:** Patient outcomes used in the POPPY trial will be collected at baseline, six months and one year follow-up for 120 women. Primary outcome will be the Pelvic Organ Prolapse Symptom Score (POP-SS). Secondary outcomes are: quality of life EQ-5D-5L; prolapse severity (POPQ); need for further treatment. An economic evaluation will assess the cost effectiveness and cost utility for each of the different models of delivery. Longer term follow-up of consenting original POPPY trial participants (those based in Scotland) will be undertaken using record linkage of hospital and outpatient datasets.

Outcomes/Impact:

Obtaining robust qualitative and quantitative data on the implementation and outcomes of different models of PFMT service provision will give NHS sites alternative options for PFMT delivery. This could lead to wider changes in practice (beyond this study) that will have a significant impact on a large number of patients across the UK. To achieve this we will deliver findings at 2 Dissemination and Implementation events (England and Scotland) to many urogynaecological services and stakeholders across the UK.

The study also addresses issues of quality in that it will seek to study whether different models of delivery do not compromise the quality of the services that women deserve, and especially the quality of outcomes that can be obtained from specialist delivery.

There is also a knowledge gap in whether PFMT leads to longer term benefits for women, namely prevention of future surgery. This study will seek to address this knowledge gap by making use of existing routine NHS datasets which can be uniquely linked for every patient in Scotland. Such knowledge can help inform NHS managers what long term benefits they might expect if they implement a PFMT service. Predicting longer term cost savings from treatment avoided can help NHS managers to justify more immediate service investments which may result in more targeting of resources to deliver PFMT.

This study has also, in partnership with the POGP, developed the full one day intensive training course required by non specialist physiotherapy staff groups. This legacy can be a resource for future service needs.

Publications:

- M Maxwell, K Semple, S Wane, D McClurg, S Hagen on behalf of the PROPEL research team. Pelvic floor muscle training in the real world of the National Health Service: PROPEL into implementation. *Journal of Pelvic, Obstetric and Gynaecological Physiotherapy*, Spring 2017, 120

Other dissemination activity:

- Presentation to Implementation science workshop Stirling December 18th 2015
- PROPEL International Knowledge Exchange: As part of a British Council sponsored event to Uruguay, a video was produced on the topic of Implementation Science to describe some of the models and frameworks that could be applied using PROPEL as an example of such application. See <https://youtu.be/MweVo3f0mOE>
- Dissemination in the Nursing, Midwifery and Allied Health Professions Research Unit Newsletter: NMAHP Research Unit ebulletin Sep/Oct 2015. <http://us2.campaign-archive1.com/?u=d934368f-8d964e07179fe81ab&id=110f32edbc>

BLADDER



At a time of huge changes and pressures on the NHS and the GP workforce in particular, we need good evidence for new models of care in terms of effectiveness and cost-effectiveness. The NMAHP Research Unit is ideally placed to do this, in collaboration with others.



Project Number:	PVH02.1
Status:	Complete
Project Title:	A prospective exploration of the experiences and factors affecting the continuity of use of intermittent self-catheterisation in people with MS - COSMOS
Source of funding and total value of award:	Multiple Sclerosis Society, £136,849
Value of funding to NMAHP RU:	£136,849
Principal investigator/co-applicants:	McClurg D (PI) (Glasgow Caledonian University), Buckley B (National University of Ireland), Bugge C (University of Stirling), Fader M (Southampton University), Hagen S (Glasgow Caledonian University), Lowe-Strong A (University of Ulster), Moore K (University of Alberta).
NMAHP RU investigators:	McClurg D, Hagen S, Irshad T.
Workstream:	Pelvic Health
Start date:	August 2010
Duration:	36 Months

Aim(s):

To determine the factors that affect continuation or discontinuation of the use of clean intermittent catheterisation.

Summary:

The use of clean intermittent catheterisation is often advocated in people with MS but there is evidence that around 25% stop within the first month.

A 3-part mixed method study (prospective longitudinal cohort (n=56), longitudinal qualitative interviews (n=20) and retrospective survey (n=456)) was undertaken which identified the factors that influenced CIC continuation/discontinuation. The potential explanatory variables investigated in each study were the individual's age, gender, social circumstances, number of urinary tract infections (UTIs), bladder symptoms, presence of co-morbidity, stage of MS and years since diagnosis, as well as clean intermittent catheterisation teaching method and intensity.

Outcomes/Impact:

For some people with multiple sclerosis the prospect of undertaking clean intermittent catheterisation is difficult and may take a period of time to accept before beginning the process of using clean intermittent catheterisation. Ongoing support from clinicians, support at home and a perceived improvement in symptoms such as nocturia were positive predictors of continuation. In many cases, the development of a urinary tract infection during the early stages of clean intermittent catheterisation use had a significant detrimental impact on continuation.

Procedures for reducing the incidence of urinary tract infection during the learning period (i.e. when being taught and becoming competent) should be considered, as well as the development of a tool to aid identification of a person's readiness to try clean intermittent catheterisation.

Other dissemination activity:

- McClurg, D et al 2015 Factors affecting the continuity of use of intermittent self-catheterisation in people with multiple sclerosis - the COSMOS study” ICS, Montreal October 2015 Podium presentation.
- McClurg D, Bugge C, Irshad T, Hagen S, Moore K, Buckley B. Comparison of data collection using a web portal and hard copy completion. Research in MS Conference 2015 Abstract No. 0025.
- McClurg D, Bugge C, Irshad T, Hagen S, Moore K, Buckley B. Comparison of data collection using a web portal and hard copy completion. Research in MS Conference Use of intermittent self-catheterisation in people with MS – results of a UK MS Register survey Abstract No 002.

Project Number:	PVH02.2
Status:	Complete
Project Title:	A pilot trial of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in older adults in residential care
Source of funding and total value of award:	Glasgow Caledonian University, £8,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Booth J (PI), Hagen S, McClurg D (Glasgow Caledonian University), Norton C (Bucks New University), C MacInnes C (NHS Greater Glasgow & Clyde), Collins B (St Marks Hospital), Donaldson C (Glasgow Caledonian University).
NMAHP RU investigators:	Hagen S, McClurg D.
Workstream:	Pelvic Health
Start date:	April 2011
Duration:	12 Months

Aim(s):

This pilot study aimed to assess the feasibility of a full-scale randomised trial of effectiveness of transcutaneous posterior tibial nerve stimulation (TPTNS) on bladder and bowel dysfunction in frail older adults in residential care.

Summary:

This project combined a systematic review of the literature and a feasibility study, both relating to the effectiveness and cost-effectiveness of transcutaneous peripheral tibial nerve stimulation (TPTNS) for the alleviation of bladder and bowel symptoms.

A pilot, individual-patient, parallel group randomised trial (n=30), with randomisation to either TPTNS or sham therapy was undertaken. The trial recruited male and female older people in care home settings with bladder or bowel problems. The older people recruited often had conditions such as stroke, Parkinson's Disease and dementia, therefore the feasibility of recruitment and data collection was of particular interest. The setting was two care homes

(1 residential and 1 nursing home), recruiting over a 6 month period. The TPTNS intervention was based on published protocols, and included 18-12 sessions of TPTNS of 30 minutes' duration, 1-2 times per week. The control group receive sham therapy of identical duration.

Bladder and bowel symptoms were self-reported prior to treatment and on completion of the 6 week treatment programme using the International Prostate Symptom Score (IPSS), International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-SF) and Bowel Short Form (early version of the ICIQ-Bowel). Treatment acceptability was assessed at each treatment session by directly questioning residents and care staff. Protocol fidelity was recorded. Changes in bladder and bowel symptoms (overall scores and individual symptoms) were compared between the groups. The healthcare costs associated with urinary and bowel problems for study participants (e.g. costs of continence pads and products, healthcare professional time) were quantified, as well as costs of the intervention.

Outcomes/Impact:

Total IPSS score reduced in the TPTNS group by a median of 7 (IQR -8 to -3) and increased by a median of 1 (IQR -1 to 4) in the sham group, representing a significant difference between the groups (Mann-Whitney U 16.5000, Z = -3.742, $p < 0.001$). Total ICIQ-SF scores improved by a median of 2 (IQR -6 to 0) in the TPTNS group and 0 points (IQR -3 to 3) in the sham group, representing a non-significant difference between the groups (Mann-Whitney U 65.000, Z = -1.508, $p = 0.132$). Change in residual urine volumes showed a difference in the mean reduction between the groups of 55.2ml (95% CI 0.5, 110) which was significant ($t = -2.215$, $df = 11.338$, $p = 0.048$) and indicated a greater decrease in residual urine in the TPTNS group (mean reduction 60ml, SD 80, 95%CI 6, 114) compared with the sham group (mean reduction 4.8ml, SD 23, 95% CI -9, 18).

There was a trend towards reported improvements in individual bladder and bowel symptoms in the TPTNS group; differences between groups were significant for incomplete bladder emptying ($X^2 = 8.086$, $df = 2$, $p = 0.018$) and weak urinary stream ($X^2 = 8.299$, $df = 2$, $p = 0.016$).

Reports of improved bowel urgency were more common in the TPTNS group compared to the sham group (27% vs 8%) however the difference was not statistically significant ($X^2 = 2.395$, $df = 2$, $p > 0.302$). Similarly 47% of the TPTNS group reported reduced faecal leakage compared with 23% of the sham group but the difference were not statistically significant ($X^2 = 4.480$, $df = 2$, $p > 0.106$).

The exception to this trend was constipation which got worse in the treatment group. TPTNS was reported to be an acceptable intervention by care home residents and care staff. No adverse effects were identified. Fidelity to the protocol was high: 28 of the 30 participants completed the full 12 session course. Two discontinued due to unrelated infection.

Publications:

- Booth J, Hagen S, McClurg D, Norton C, MacInnes C, Collins B, Donaldson C, Tolson D. A feasibility study of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in elderly adults in residential care. *Journal of the American Medical Directors Association*. 2013 Apr 30;14(4):270-4.

Other dissemination activity:

- Booth J, Hagen S, McClurg D, Norton C, MacInnes C, Collins B, Donaldson C, Tolson D. A feasibility study of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in elderly adults in residential care. 2012 ICS Abstract

Project Number:	PVH02.3
Status:	Phase 1 complete, Phase 2 suspended
Project Title:	Development and clinical trial of a mixed (multi/single-use) catheter management package for users of intermittent catheterisation – MULTICATH
Source of funding and total value of award:	NIHR RP-PG-0610-10078 £1,999,199
Value of funding to NMAHP RU:	£260,478
Principal investigator/co-applicants:	Fader M (PI) (Southampton University), McClurg D (Glasgow Caledonian University), Buckley B, Cottenden A (University College London), Cotterill N (Bristol Urological Institute), Malone-Lee J (Royal Free and University College Medical School), Gage H (University of Surrey), Moore M (Primary Care Research Network), Morris N (Bristol Urological Institute), Nicholls P (University of Southampton), Prieto J (University of Southampton), Shaw C (University of Glamorgan), Williams J (Southampton City PCT), Bowling A (University College London).
NMAHP RU investigators:	McClurg D, Coyle J, Matthews E.
Workstream:	Pelvic Health
Start date:	February 2012
Duration:	60 Months

Summary:

In the UK about 50,000 people have bladder-emptying problems managed by IC. A Cochrane review found insufficient evidence to recommend any particular catheter for IC, yet the UK supplies most patients with single-use ones (which are expensive, £60 million pa) but worldwide multi-use catheters are typical. Reuse of catheters could benefit patients, and allow substantial NHS savings.

Evaluating the safety and acceptability of reusing catheters for intermittent catheterisation (IC - passing a tube into the bladder to drain urine) is one of the top 10 continence research priorities. UK practice is only to use single-use catheters but new draft NICE guidance recommends multi-use catheters whilst acknowledging the limited evidence for doing so. We need evidence that multi-use of catheters is at least as good as using only single-use

catheters and a strong implementation plan, if we are to change practice, but currently we do not have a robust intervention or well-developed outcomes to measure infection, acceptability and preference in order to carry out a trial. This programme of work aims to prepare these and carry out a non-inferiority clinical trial comparing a multi/single-use 'mixed package' with use of only single-use catheters.

Research Plans:

Phase 1 (months 1-24) - preparation of intervention and outcomes, feasibility study

Cleaning module (months 1-24): With a user panel (N=20) we identified safe and practical techniques to clean and manage catheters for multi-use.

Interviews module (months 1-24): Using IC-user interview data (N=up to 40) we i) developed and validated a short questionnaire to measure acceptability of the mixed package (or single-use catheters only) ii) developed and validated published symptoms of UTI in IC users.

Implementation module (months 1-24): We mapped out the context of IC practice using telephone interviews (N=20) and internet survey (N=300) to inform a knowledge transfer and implementation plan using normalisation process theory.

Due to unavailability of suitable catheters with approval for re-use the Phase 2 study has been suspended until these have been approved. NIHR have agreed to this suspension. We will then undertake a feasibility study (months 21-24): We will test our recruitment plan for the Phase 2 RCT during a 4 month feasibility study involving primary and secondary care centres in the Southampton, Bristol and Glasgow areas.

Phase 2 (original months 25-60) - RCT

Carry out a non-inferiority randomized controlled trial comparing use of the mixed package with use of only single-use catheters, and a preference survey. This will be dependent on successful recruitment in the feasibility study done in 21-24.

This is a collaboration of leading continence research groups with expertise in catheter-related infection, psychometrics, continence product development, implementation theory, health economics, recruitment and clinical trials. Key collaborators are user and professional continence organisations and international catheter experts. The research environments have strong links to: local clinical continence services, primary care research networks, purpose-built laboratories for urological devices work and laboratories for urine infection and biofilm work. The NCTU has a strong record in the design and delivery of multi-centre trials, including those of complex interventions.

Outcomes/Impact:

Implementation of a mixed IC package is likely to offer important benefits to patients by providing the advantages of multi-use (e.g. fewer packs to carry) and single-use (e.g. no added lubricant). Were around half of patients to change to a mixed package there would be NHS savings of more than £10 million pa.

If it can be shown that a mixed IC package is safe and acceptable widespread adoption will require major practice change. A robust knowledge transfer plan and framework for change will be needed which will be developed in the 'implementation' module.

Publications:

- McClurg D, Coyle J, Long A, Moore K, Cottenden A, May C, Fader M. A two phased study on health care professionals' perceptions of single or multi-use intermittent catheters International Journal of Nursing Studies 2017 72 83-90.

Other dissemination activity:

- McClurg D et al 2015 ACAA study to determine clinician's views about intermittent catheterisation and the re-use of catheters (the MultiCath study). Podium presentation.
- McClurg D et al 2015 Clinician's views on intermittent-self catheterisation and the potential for re-use of catheters (part of the MultiCath study) ICS, Montreal October 2015 Accepted for podium presentation. Podium presentation.
- McClurg et al 2015 ICS A survey to determine the factors that influence catheter selection when intermittent catheterisation is being considered. ICS, Montreal October 2015 Podium presentation.

Project Number:	PVH02.4
Status:	Questionnaire follow-up in progress
Project Title:	OPAL – Optimal PFMT for Adherence Long Term: Multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence.
Source of funding and total value of award:	National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme - £2,074,737
Value of funding to NMAHP RU:	£1,201,670
Principal investigator/co-applicants:	Hagen S (PI), McClurg D, Elders A, Booth J (Glasgow Caledonian University), Glazener C, Norrie J, McDonald A, McPherson G, Kilonzo M, Abdel-Fattah M (University of Aberdeen), Agur W (NHS Ayrshire and Arran), Bugge C (University of Stirling), Dean S (University of Exeter), Hay-Smith J, (University of Otago, NZ), Guerrero KL (Clinical Expert), Wilson LE (PPI).
NMAHP RU investigators:	Hagen S, McClurg D, Elders A.
Workstream:	Pelvic Health
Start date:	September 2013
Duration:	63 Months

Aim(s):

To establish if a PFMT regimen intensified via the addition of a theory-based biofeedback protocol, compared to basic PFMT, is more effective and cost-effective in reducing severity of urinary incontinence (UI) at 24 months, and providing greater improvement in quality of life, reduced need for surgery and other UI treatment, improved pelvic floor muscle function and increased self-efficacy for, and adherence to, PFMT

Summary:

Based on past research, current UK guidelines recommend that women with stress incontinence are offered at least three months of pelvic floor muscle exercises. The exercises are taught by a specialist physiotherapist or nurse. There is evidence that these exercises can

strengthen the muscles and decrease leakage. It is not clear how “intensively” women have to exercise to get a good result that lasts, thus improving the woman’s quality of life and reducing the likelihood of surgery.

This multicentre trial aims to find out whether the use of biofeedback can help to improve the results of pelvic floor muscle exercises in the short- and longer-term. We also want to find out how much urine leakage women in both groups have, how much this impacts on their lives, what other bladder problems they have, what other treatments they have had, how much exercise they did, how confident they were about exercising and how much their muscles have strengthened. We will also measure the costs of the treatments and any costs to the woman and her family, and balance these against any benefits of the intensive treatment.

Other dissemination activity:

- Hagen, S. (2013) 'OPAL Trial', Scottish Pelvic Floor Network, 5th Annual Scientific Meeting, Glasgow, 5 June 2013.
- McClurg, D. (2013) 'Multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence (OPAL-Optimal PFMT for Adherence Long-term) [Poster], The Association of Chartered Physiotherapists in Women's Health, Bristol, 20-21 September 2013.
- Hay Smith, J., Dean, S., McClurg D., Hagen S. (2014) 'Incorporating health behaviour theory, qualitative evidence synthesis, behaviour change techniques, and current standards of clinical practice in intervention development: Example from the OPAL (optimising pelvic floor exercise to achieve long –term benefits) trial', Australasian Society for Behavioural Health and Medicine, Auckland, 12 - 14 February, 2014.
- Dean, S., Hay-Smith, J., McClurg, D., Hagen, s. and the OPAL Team (2014), 'Behaviour Change Checklists for contributing to the assessment of Intervention Fidelity: an example from the OPAL (Optimising Pelvic Floor Exercise to Achieve Long-term Benefits) Trial', British psychological society Process Evaluation, Cardiff, 9 June 2014.
- Dean, S., Hay-Smith, J., McClurg, D. 9 (2015), 'Exercise Adherence - integrating theory, evidence and behaviour change techniques', World Confederation of Physical therapy, Singapore, 1-4 May 2015.
- Dean, S. (2015) 'Changing patient attitudes towards exercise therapy' Primary Care and Public Health, Birmingham, 20-21 May 2015.
- Dean, S. (2015) 'Strategies to Increase Adherence-Understanding motivation', Annual Meeting of the International Continence Society, Montreal, 6-9 Oct 2015.
- Goodman, K., Hagen, S., McClurg, D., Sergenson, N., Stratton, S., Treweek, S. (2017), Can Behaviour change theory increase questionnaire response rates within trials? [Poster], 4th International Clinical Trials Methodology Conference, Liverpool, 7-10 May 2017.
- Bugge, C., Grant, A., Dean, S., Hay Smith, J. McClurg, D., Hagen, S. (2017), 'Qualitative Studies linked to Trials of Complex Interventions: what does case study methodology have to offer' [Poster], 4th International Clinical Trials Methodology Conference, Liverpool, 7-10 May 2017.

Project Number:	PVH02.5
Status:	Complete
Project Title:	A Feasibility And Acceptability Study For A Randomised Controlled Trial Of Urinary Catheter Washout Solutions To Prevent Blockage In Long-Term Catheter Users
Source of funding and total value of award:	Chief Scientist Office, £19,060
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Shepherd A (PI) (University of Stirling), Hagen S (Glasgow Caledonian University), Mackay WG (University of the West of Scotland), Fader M (University of Southampton).
NMAHP RU investigators:	Hagen S.
Workstream:	Pelvic Health
Start date:	January 2017

Aim(s):

This study aimed to assess the feasibility of a future trial relating to the use of catheter washout solutions. It aimed to identify issues likely to arise in recruiting to and running a trial from the perspectives of patients and healthcare staff; to describe current practice in relation to catheter washout use in Scotland; to identify patients' needs and preferences when they experience catheter blockage.

Summary:

Long-term urinary catheters, utilised in 25% of elderly people in residential care, are a leading cause of infection and are associated with significant mortality and morbidity. With the population in Scotland aged over 64 estimated to increase by 59% to 1.47m by 2037, the numbers living with long-term catheters will rise. Approximately 75% of catheter users have recurrent blockages causing pain, discomfort and often hospitalisation. Washout solutions are commonly used to treat blockages. Our Cochrane review demonstrated the urgent need for a trial to assess the effectiveness of these solutions. This study was developed to collect data needed to develop such a trial.

Seven Senior District Nurses were interviewed over the phone from the following NHS boards: Dumfries & Galloway, Greater Glasgow & Clyde, Forth Valley, Ayrshire & Arran, Fife, Highlands, and Lanarkshire. In addition, three

boards were selected for staff focus group discussion and patient interviews.

Outcomes/Impact:

The results suggested that blockages and bypassing were common issues in the community and can have a substantial impact on patient quality of life. The treatment of blockages and the use of maintenance solutions was variable across the seven NHS boards.

When asked about the acceptability and feasibility of a randomised controlled trial of urinary catheter washout solutions to prevent blockage, staff in the focus groups provided useful information about various issues relating to their current practice and how easy it would be to recruit to the proposed arm; what type and frequency of washout solution would be acceptable.

Most patients and their carers hypothetically agreed to take part in a future RCT. Reasons for participating included: perceived personal benefit; benefiting others, and a sense of indifference. Those who were unsure about participation cited preference for a certain treatment and were concerned about being randomised into either the control or treatment group. The length of time for participation was also an issue highlighted by both nurses and patients, with both having concerns about an intervention period greater than 12 weeks.

Project Number:	PVH02.6
Status:	In Progress
Project Title:	Development and validation of a clinical prediction rule to guide and improve the treatment of female stress urinary incontinence
Source of funding and total value of award:	Canadian Institutes for Health Research, £474,388
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Dumoulin C (PI) (University of Montreal), Hagen S (Glasgow Caledonian University), Desmeules F (Université de Montréal), Mayrand MH (Université de Montréal), Morin M (Université de Sherbrooke), Mâsse B (Université de Montréal), Svabik K (Charles University in Prague), Tang A (Université de Montréal), Campeau L (Jewish General Hospital (Montreal)), Girard I (Université de Sherbrooke), Lemieux MC (Hôpital Maisonneuve-Rosemont), Leroux N (CHU Ste-Justine), Reichetzer B (Centre hospitalier de l'Université de Montréal), Tu LM (Université de Sherbrooke), McGill EW.
NMAHP RU investigators:	Hagen S.
Workstream:	Pelvic Health
Start date:	September 2016
Duration:	48 Months

Aim(s):

To develop and test a clinical prediction rule to identify before treatment, those women likely to benefit from PFM training.

Summary:

Urinary incontinence (UI) affects 1 in 3 women 18 years and over. UI can lead to significant social problems, embarrassment, and negative self-perception; reduces social interactions and physical activities; and, among older women, increases nursing-home admissions. UI interferes with quality of life and healthy aging; left untreated, it can also lead to the need for surgery. The treatment of UI and related problems alone adds \$1.9 billion to Canada's healthcare costs. Pelvic floor muscle (PFM) training, taught to women by a specially-trained physiotherapist is effective, cost-effective and is recommended as the first-line treatment option. Research indicates training strengthens PFMs

and reduces/eliminate leakages in 76% of women, but there is currently no way to identify which women would benefit. Consequently, many women are steered towards more costly and potentially risky surgical options. Other women may be offered PFM training when ultimately surgery is required. Based on previous research, this study aims to develop and test a clinical prediction rule to help researchers and clinicians identify before treatment, those women likely to benefit from PFM training, increasing their chances of conservative treatment success. The rule will use information from demographic, clinical and biomechanical data to make the predictions. 465 women with stress UI will complete a pre-treatment UI assessment, then 12 weekly 1-hour group-based PFM training sessions. One-year after, the women's UI will be reassessed. Using the post-treatment results as an outcome, a clinical prediction rule will be developed to inform clinicians on the pre-treatment factors which best distinguish women who will or will not benefit from group-based PFM training.

Project Number:	PVH02.7
Status:	Final report due Oct 2017
Project Title:	(Phase I) Identifying messages for physiotherapists treating female urinary incontinence: a Cochrane overview of the evidence - CRUISE
Source of funding and total value of award:	Physiotherapy Research Foundation 37302, £51,304
Value of funding to NMAHP RU:	£51,304
Principal investigator/co-applicants:	McClurg D (PI), Campbell P, Elders A, Hagen S, Pollock A (Glasgow Caledonian University).
NMAHP RU investigators:	McClurg D, Campbell P, Elders A, Hagen S, Pollock A, Hazleton C, Hill D.
Workstream:	Pelvic Health
Start date:	February 2013
Duration:	12 Months

Aim(s):

To produce an accessible synthesis of evidence that will provide a succinct overview to guide and aid translation of evidence into practice for the physiotherapy management of female urinary incontinence (UI).

Summary:

A clinical guideline for the physiotherapy management of stress urinary incontinence in women was developed and endorsed by CSP in 2001, and updated in 2004. Physiotherapists have continued to rely on these guidelines but, due to the growing body of evidence, they are now deemed no longer fit for practice by the Pelvic Obstetric and Gynaecological Professional Network, and have been withdrawn. Cochrane Reviews are kept up to date and are the best form of evidence to guide management decisions but, overwhelmingly to some clinicians, there are at least 55 which address urinary incontinence, often exploring single interventions. This approach to evidence synthesis, similar to the narrow approach to intervention evaluation, lacks external validity, since in practice, the choice will be between a variety of interventions (or some combination) rather than an 'all or nothing' choice of using or not using one of the interventions.

Research Plans:

1. Undertake a Cochrane overview of relevant Cochrane reviews
2. Convene a stakeholder group of clinicians, patients and commissioners to develop the protocol for the review. Based on the evidence this group, using consensus methodologies, will produce an agreed key messages document

Such an overview will provide a rigorous assessment of the limitations of the systematic reviews whilst providing a comprehensive accessible overview of all evidence relating to UI.

A protocol detailing the methods which followed the methods in the Cochrane Handbook was developed and outlined.

The stakeholder group consisted of between 10-14 purposely-selected patients, clinicians and commissioners and met on two occasions to

1. Agree strategies for the Cochrane overview
2. Agree on the key clinical messages arising from the evidence.

Outcomes/Impact:

27 reviews and 8 protocols were included in the review. Data relating to the effects of conservative interventions were extracted from 23/27 reviews: 13 reviews focussed on conservative interventions, and 10 on non-conservative interventions (but included comparisons with conservative treatments). 4/27 reviews focussed on a specific aetiology or condition and results were described narratively. The 23 reviews included 460 relevant meta-analyses: 134 relating to SUI, 172 to UUI and 154 to Mixed UI. We judged the quality of evidence to be high in 33 of 460 comparisons, 215/460 moderate and 179/460 low and the remainder very low or inestimable. There is high GRADE evidence (using primary outcomes) that pelvic floor muscle training is more beneficial than control for all types of UI and the training is more effective when individualised, more intense and combined with behavioural interventions Only 39/460 comparisons synthesised data relating to our primary outcome of quality of life, and only 4 of these were judged to be high GRADE evidence.

There is a large and growing body of systematic review evidence relating to conservative management of UI, but the quality of the current evidence base is limited by lack of specificity of the intervention, variance in outcome measures, and methodological quality of research. Pelvic floor muscle training should remain the intervention of choice. Evidence is currently insufficient to give certainty over the relative effectiveness of other conservative interventions.

Publications:

- McClurg D, Pollock A, Campbell P, Hazelton C, Elders A, Hagen S, Hill DC. Conservative interventions for urinary incontinence in women: Overview of Cochrane systematic reviews. *Cochrane Database of Systematic Reviews* 2016, Issue 9. Art. No.: CD012337. DOI: 10.1002/14651858.CD012337.

Project Number:	PVH02.8
Status:	Final report submitted Aug 2017
Project Title:	Antibiotic Treatment for Intermittent Bladder Catheterisation: A Randomised Controlled Trial of Once Daily Prophylaxis (The AnTIC study)
Source of funding and total value of award:	NIHR HTA, £1,253,764
Value of funding to NMAHP RU:	£158,137
Principal investigator/co-applicants:	Pickard R, (Newcastle Foundation NHS Trust), McClurg D (Glasgow Caledonian University), Chadwick Dr (Newcastle CTU), Fader M (Southampton University), Hilton P (Newcastle-upon-Tyne Foundation Trust), Little P (Southampton University), McColl E (Newcastle CTU), Vale L (Newcastle CTU).
NMAHP RU investigators:	McClurg D, Gillespie N.
Workstream:	Pelvic Health
Start date:	September 2013
Duration:	40 Months

Aim(s):

To assess benefit, harms and cost-effectiveness of the use of antibiotic prophylaxis to prevent UTI in people who perform CISC.

Summary:

People who carry out clean intermittent self-catheterisation (CISC) to empty their urinary bladders often suffer recurrent urinary tract infection (UTI). Continuous once daily low-dosage of an antibiotic (antibiotic prophylaxis) is commonly advised but knowledge of effectiveness and harms is lacking.

This was a parallel group open-label patient-randomised trial with a 12-month duration of allocated intervention and follow-up (3-monthly). Outcome assessors were blind to allocation. The trial setting was UK NHS with recruitment of patients attending primary, community, and secondary care services at 51 sites. Four hundred and four adults performing CISC and predicted to continue for at least 12 months, who

had suffered at least two UTIs in the past year or had been hospitalised for UTI at least once in the past year were to be recruited. A central randomisation system allocated participants to the experimental (prophylaxis) arm (once daily oral antibiotic using either nitrofurantoin 50mg, trimethoprim 100mg or cefalexin 250mg) or the control arm of no prophylaxis, both for 12 months.

The primary clinical effectiveness outcome was relative frequency of symptomatic, antibiotic-treated UTI. Cost-effectiveness was assessed by cost per UTI avoided. Secondary measures were; frequency of microbiologically-proven UTI; change in pattern of pathogen sensitivity; health status; and participants' attitudes to antibiotic use.

Outcomes/Impact:

Frequency of symptomatic antibiotic-treated UTI was reduced by 48% using prophylaxis (incidence rate ratio [IRR; 95% CI] 0.52 [0.44 to 0.61]). Reduction in microbiologically-proven UTI was similar (IRR [95% CI] 0.49 [0.39 to

0.60]). Absolute reduction in UTI episodes over 12 months was from a median (interquartile range) of 2 (0-4) in the no prophylaxis group to 1 (0-2) in the prophylaxis group. Results were unchanged by adjustment for days at risk of UTI and presence of factors giving higher risk for UTI. Development of antimicrobial resistance was seen more frequently in strains of *Escherichia coli* isolated from urine and perianal swabs from patients receiving antibiotic prophylaxis. Use of prophylaxis incurred an extra cost of £99 to prevent one UTI not including potential costs related to increased bacterial resistance. The emotional and practical burden of CISC and UTI influenced well-being but health status measured over 12-months was similar between groups and did not deteriorate significantly at time of UTI. Participants were generally unconcerned about using antibiotics including possible development of antimicrobial resistance.

The results of this large randomised controlled trial, conducted according to best practice has demonstrated clear benefit for antibiotic prophylaxis in terms of reducing frequency of UTI for people carrying out CISC. This strategy appears safe for individuals over 12-months but the emergence of resistant bacteria may affect longer-term management and is a public health concern. Longer-term studies of effects on bacterial resistance in people taking antibiotic prophylaxis and studies of effectiveness and cost-effectiveness of non-antibiotic approaches are required.

Publications:

- McClurg D., Walker K, et al. Participant experiences of clean intermittent self-catheterisation, urinary tract infections and antibiotic use on the ANTIC trial – a qualitative study. “Inconvenient, but not a problem.” IJNS Submitted 2017
- Brennand C, von Wilamowitz-Moellendorf F, Dunn S, McClurg D, et al. Antibiotic treatment for intermittent bladder catheterisation with once daily prophylaxis (the AnTIC study): Study protocol for a randomised controlled trial *Trials* (2016) 17:276

Project Number:	PVH02.9
Status:	In Progress
Project Title:	ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes: ELECTRIC
Source of funding and total value of award:	NIHR HTA, £1,236,293
Value of funding to NMAHP RU:	£19,760
Principal investigator/co-applicants:	Booth J (PI), Hagen S, McClurg D, Lawrence M, Mason H, Skelton D (Glasgow Caledonian University), Norton C (King's College London), Surr C (Leeds Beckett University), Goodman C (University of Hertfordshire).
NMAHP RU investigators:	McClurg D, Hagen S.
Workstream:	Pelvic Health
Start date:	July 2017
Duration:	36 Months

Aim(s):

Urinary incontinence (UI) is highly prevalent in care home (CH) residents, associated with high personal, social, physical and economic burden all of which are predicted to increase in line with changing demography. Despite this UI treatment options are limited and predominantly rely on containment using expensive and undignified absorbent products. The proposed trial aims to evaluate a simple, non-invasive, low-cost option aimed at actively treating UI and reducing its impact on residents and care providers.

Summary:

ELECTRIC is a pragmatic, multicentre, placebo controlled randomised parallel group trial comparing the effectiveness of transcutaneous posterior tibial nerve stimulation (TPTNS) with sham stimulation in 500 CH residents with UI. The TPTNS programme comprises a total of twelve 30 minute sessions delivered twice weekly for 6 weeks. The trial will take place in 20 CHs (nursing or residential) for older adults in England and Scotland. Men and women resident in CHs

who experience UI at least weekly, including those with cognitive impairment, will be recruited. The primary outcome measure is volume of UI leaked over a 24 hour period as determined by a 24 hour pad weight test measured at 6 weeks.

An internal pilot for the proposed trial will confirm recruitment rates, fidelity to TPTNS and outcome completion in 50-60 residents of two CHs and stop-go criteria will determine continuation of recruitment into the main trial. A longitudinal nested process evaluation will investigate intervention fidelity and views on our intervention delivery support. Mediating factors that impact on the effectiveness of TPTNS from the perspective of CH residents and/or their family members and CH staff will be elicited through qualitative interviews and focus groups.

Project Number:	PVH02.10
Status:	Complete
Project Title:	Promoting continence following stroke – developing and evaluating the implementation of a stroke rehabilitation intervention for urinary incontinence
Source of funding and total value of award:	Chest, Heart and Stroke, Scotland, £29,789
Value of funding to NMAHP RU:	£29,789
Principal investigator/co-applicants:	Brady M (Glasgow Caledonian University), Hagen S (Glasgow Caledonian University), Langhome P (University of Glasgow), Capewell A (St Helens and Knowsley Hospitals NHS Trust), Bugge C (University of Stirling), McClurg D (Glasgow Caledonian University), Chalmers C (NHS Lanarkshire).
NMAHP RU investigators:	Brady M, Hagen S, McClurg D, Jamieson K
Workstream:	Pelvic Health
Start date:	2008
Duration:	24 months

Aim(s):

1. To establish the current practices and policies in use across Scottish stroke care settings (acute, rehabilitation and combined) to promote continence.
2. To develop and evaluate the implementation of a stroke-specific multi-dimensional urinary incontinence intervention (comprised of an evidence based assessment and management tool) in a stroke care setting.

Summary:

We distributed our survey to 69 stroke care settings across Scotland and had a **93% response rate** thus providing a comprehensive overview of continence care following stroke. Only half the sites described continence training in the previous year (n=35/64, 55%) which was provided by continence advisors in 23 sites (68%). Most training was delivered to clinical support workers (CSW; n=20) followed by nurses (n=10). All but two sites stated registered nurses

were responsible for assessing patients' urinary continence (97%). A fifth of the sites reported CSWs also conducted continence assessments (22% n=14). Micturition diaries were the most popular bladder assessment tool (n=31; 49%) with 18 sites using this tool alone (58%) and the remaining sites using them in combination with the Barthel Index (n=11), the IQOL (n=1) or a locally devised tool (n=1). Following a systematic review of the assessment tools and in consultation with our expert Advisory Group we found no suitable continence care screening and assessment tool for use in stroke care settings. We developed and piloted the implementation of a complex continence care intervention (targeting service, staff and patients) in a single stroke care site. We recruited 30 participants (16 females) to the study with a mean age of 68 years (SD 14; range 37-88) and for a mean length of hospital stay of 18 days (SD 17; range 2-64). Of the participants recruited to this study 20 were considered to have continence problems. Thirty-three members of the multidisciplinary stroke team received training across 13 sessions (including 14 nurses and 9 CSW).

Outcomes/Impact:

Participants were diagnosed with a variety of continence problems including stress, urge, mixed and functional continence considered moderate (n=8) or severe (n=10). Four participants were catheterised prior to admission to the ward (following transfers from other wards) though none had a catheter prior to their stroke.

We collected baseline admission data from all 30 participants of which, 20 continued to remain on the ward after one week, 12 remained after two weeks, with declining numbers over the subsequent weeks. We found the incidence of UI was marginally higher amongst those with significant communication impairment than those without (75% versus 70%) with a more pronounced difference between those with cognitive impairment and those without (82% versus 62%). The sample size was insufficient to identify any clear differences between those with communication or cognitive impairment and the severity of continence problems identified.

Publications:

- Brady MC, Jamieson K, Bugge C, Hagen S, McClurg D, Chalmers C and Langhorne P. Caring for continence in stroke care settings –a qualitative study of patients' and staff perspectives on the implementation of a new continence care intervention in a stroke ward setting. *Clinical Rehabilitation*. 2016 30(5) 481-494. DOI:10.1177/0269215515589331.
- Jamieson K, Peacock C, Brady M. Urinary dysfunction: assessment and management in stroke patients. *Nursing Standard* 2010;25(3);49-55.
- Jamieson K, Brady M, Hagen S, Langhorne P, Capewell A, Bugge C, McClurg D, Chalmers C. A survey of urinary continence care practices in Scottish Stroke Care Settings (Abstract). *Clinical Rehabilitation*, 2009; 23:762-763.

Presentations:

- Brady MC, Hagen S, McClurg D, Jamieson K et al. Incontinence Stroke Project Inspiring Rehabilitation Excellence (INSPIRE) -a mixed methods approach to piloting a complex intervention to improve continence care following stroke. UK Stroke Forum 2010, Glasgow, UK.
- McClurg D, Brady MC, Hagen S, Langhorne P, Capewell A, Bugge C, Chalmers C, Jamieson K. Rising to the challenge of continence care in stroke care settings – patients' and staff perspectives. UK Continence Society 18th Annual Scientific Meeting, Bristol, 6th-8th April 2011.
- Brady M. Methods Symposium. Stroke 2015, August 2015, Melbourne, Australia.
- Jamieson K, Brady MC, Hagen S, Langhorne P, Capewell A, Bugge C, McClurg D, Campbell Chalmers. INSPIRE - Incontinence stroke project inspiring rehabilitation excellence: A mixed methods approach to the implementation of a complex intervention for the screening, assessment and management of urinary incontinence in patients following stroke: Is it feasible? NHS Lanarkshire Clinical Research and Audit Conference, 2011. Scotland, UK.
- Jamieson, K, Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C. (2009) A survey of urinary continence care practices in Scottish stroke care settings. Royal College of Nursing International Nursing Research Conference, February 2nd 2009.

Awards:

- Dorothy Mandelstam Award 2011 awarded by the Association for Continence Advice – Kathy Jamieson [Research Assistant] for INSPIRE Promoting continence following stroke – developing and evaluating the implementation of a stroke rehabilitation intervention for urinary incontinence - Brady MC, Hagen S, Langhorne P, Capewell A, Bugge C, McClurg D, Chalmers C, Jamieson K. The award acknowledges the pioneering continence work of Dorothy Mandelstam, who was a founder member of the Association for Continence Advice and is awarded to a continence service development that improves the quality of patient care.

- Scottish Stroke Nursing Forum Prize at the UK Stroke Forum 2010 for the abstract. Brady MC, Hagen S, McClurg D, Capewell A, Bugge C, Jamieson K, Langhorne P. Incontinence Stroke Project Inspiring Rehabilitation Excellence (INSPIRE) -a mixed methods approach to piloting a complex intervention to improve continence care following stroke.

Posters:

- Brady, M, Jamieson, K, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C, (2009) Delivery of the teaching component of a complex intervention to Stroke Nursing and AHPs in the INSPIRE pilot. UK Stroke Forum, Glasgow, December 1-3.
- Jamieson, K, Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C. (2009) A survey of urinary continence care practices in Scottish stroke care settings. Society for Research in Rehabilitation. Derby, February 2nd 2009.
- Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C, Jamieson, K. Incontinence stroke project inspiring rehabilitation excellence (INSPIRE). Phase 1: Existing practices and policies in Scottish stroke care settings. Scottish Stroke Research Network Glasgow
- Jamieson, K, Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C. Incontinence stroke project inspiring rehabilitation excellence (INSPIRE) Phase 1: Existing practices and policies in Scottish stroke care settings. Glasgow Caledonian Celebration of Research June 2009.
- Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C, Jamieson, K. (2008) INSPIRE Promoting continence following stroke – developing and evaluating the implementation of a stroke rehabilitation intervention for urinary incontinence. Scottish Stroke Research Network Meeting. Glasgow.
- Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C, Jamieson, K INSPIRE

Promoting continence following stroke – developing and evaluating the implementation of a stroke rehabilitation intervention for urinary incontinence (2008) Celebrating Lanarkshire – ‘Celebrating Leadership’ Conference, November 7th 2008.

- Brady, M, Hagen, S, Langhorne, P, Capewell, A, Bugge, C, McClurg, D, Chalmers, C, Jamieson, K INSPIRE Promoting continence following stroke – developing and evaluating the implementation of a stroke rehabilitation intervention for urinary incontinence (2008) Scottish Stroke Nurses Forum, Stirling, October 3rd 2008.

Project Number:	PVH02.11
Status:	Complete
Project Title:	A feasibility study for a randomised controlled trial of transcutaneous posterior tibial nerve stimulation to alleviate stroke-related urinary incontinence
Source of funding and total value of award:	Stroke Association, £162,033
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Booth J/Hagen S (PI), McClurg D (Glasgow Caledonian University), Watkins C, Thomas L, Sutton C (University of Central Lancashire), Mason H (Glasgow Caledonian University), McKim C, McKim I, Chalmers C, Agnew R (NHS Greater Glasgow & Clyde).
NMAHP RU investigators:	Hagen S, McClurg D.
Workstream:	Pelvic Health
Start date:	May 2014
Duration:	27 Months

Aim(s):

To establish the feasibility of undertaking a phase III trial of transcutaneous posterior tibial nerve electrical stimulation (TPTNS) to alleviate stroke-related urinary incontinence (UI).

Summary:

The completed pilot trial has allowed us to determine the potential effectiveness and cost-effectiveness of the TPTNS programme for adults with stroke-related UI in terms of reducing the number of episodes of urinary incontinence, severity of urinary incontinence and symptoms of urinary urgency, frequency, nocturia and retention.

Outcomes/Impact:

The results indicate the possibility of potential effect in favour of the TPTNS over the three data collection time points in reducing the severity of UI; however no results were statistically significant and must thus be treated with caution.

The results suggest a possible trend in favour of the TPTNS for urgency and for frequency at weeks 12 and 26. There is no potential effect on nocturia.

The patient reported single Patient Perception of Bladder Condition question suggests that bladder condition was perceived to have improved in the TPTNS group at the 26 week time point however at the 6 and 12 week measurement points the sham group reported better perceived bladder condition than the TPTNS group. Therefore, in selecting a primary outcome for a full-scale trial, these results indicate the severity of UI at 12 weeks post randomisation to be the best candidate.

The objective data showed good fidelity with 45% participants receiving the full 6 hour programme, 68% receiving 5 hours or more and 83% receiving at least 4 of the 6 hours. Only 7 participants received half or less of the stimulation programme.

A total of four adverse events were reported during the pilot trial, one of which was expected. All were minor and transient.

The cost of delivering a full 6 week programme of TPTNS, including providing education and support for self-administration is £45 (where the electrical stimulator is on loan). To purchase a stimulator costs £56.50, therefore the entire cost if individuals were provided with their own stimulator would be £101.50. This is the total charge for the TPTNS treatment and includes the ongoing self-management costs by the participant, where necessary. We conclude that TPTNS is a safe and acceptable intervention with evidence provided of the potential for clinical and cost effectiveness in treating urinary incontinence in stroke survivors. The data support the feasibility of a substantive trial of TPTNS as first line intervention for UI in this population.

Other dissemination activity:

- Treat-UI feasibility trial report – in preparation for submission to Pilot and Feasibility Studies, a BMC Open Access journal
- Qualitative interview report – ‘Ongoing issues with urinary dysfunction following stroke: impact on quality of life and experience of using Transcutaneous Posterior Tibial Nerve Stimulation (TPTNS) to self-manage bladder symptoms’. In preparation for submission to the Journal of Advanced Nursing.
- We have worked with the aphasia charity Speakeasy members to develop an aphasia-friendly report of the results. This has been sent to the Treat-UI participants. The involvement process and study findings were presented at the Speakeasy annual conference in October 2016.

BOWEL



The Scottish based NMAHP-RU has spearheaded an international collaboration of the highest quality... The work being done here is not being done anywhere else, and is a resource to researchers around the world. I cannot emphasise enough how important this work is, nor the respect with which this project is held nationally and internationally.



Project Number:	PVH03.1
Status:	Complete
Project Title:	(Phase 1) Feasibility of abdominal massage for the alleviation of symptoms in people with Parkinson's Disease – SCAMP
Source of funding and total value of award:	Parkinson's UK K0908, £33,357
Value of funding to NMAHP RU:	£33,357
Principal investigator/co-applicants:	McClurg D (PI), Hagen S (Glasgow Caledonian University), Cunnington AL (NHS Greater Glasgow & Clyde), Paul L (University of Glasgow).
NMAHP RU investigators:	McClurg D, Hagen S, Dickinson L, Jamieson K.
Workstream:	Pelvic Health
Start date:	January 2010
Duration:	12 months

Aim(s):

The primary objective was to test the recruitment, retention, and the appropriateness of the intervention methods and outcome measures.

Summary:

Constipation is one of the most common non- motor features of Parkinson's affecting up to 90% of patients. In severe cases it can lead to hospitalisation, and is usually managed with laxatives which in themselves can lead to side effects. Abdominal massage has been used as adjunct in the management of constipation in various populations, but not in those with Parkinson's.

32 patients with Parkinson's were recruited from three movement disorder clinics and were randomised to receive either six weeks of daily abdominal massage plus lifestyle advice on managing constipation (Intervention Group n=16) or lifestyle advice (Control Group n=16). Data were collected prior to group allocation (Baseline), at week 6 (following intervention) and four weeks later (week 10).

Outcome tools included the Gastro-intestinal Rating Scale and a bowel diary.

Outcomes/Impact:

Constipation has a negative impact on quality of life. The study recruited to target, retention was high and adherence to the study processes was good. The massage was undertaken as recommended during the 6 weeks of intervention with 50% continuing with the massage at 10 weeks. Participants in both groups demonstrated an improvement in symptoms although this was not significantly different between the groups.

Abdominal massage, as an adjunct to management of constipation offers an acceptable and potentially beneficial intervention to patients with Parkinson's. UTI influenced well-being but health status measured over 12-months was similar between groups and did not deteriorate significantly at time of UTI. Participants were generally unconcerned about using antibiotics including possible development of antimicrobial resistance.

PVH03.1 (Phase 1) Feasibility of abdominal massage for the alleviation of symptoms in people with Parkinson's Disease – SCAMP

Publications:

- McClurg D, Walker K, Aitchison P, Jamieson K, Dickinson L, Paul, Hagen S, Cunnington AL. Abdominal massage for the Relief of Constipation in People with Parkinson's: A Qualitative study. *Parkinson's Disease*. Volume 2016, Article ID 4842090, 10 page <http://dx.doi.org/10.1155/2016/4842090>
- McClurg D, Hagen S, Jamieson K, Dickinson L, Paul L, Cunnington A Abdominal massage for the alleviation of symptoms of constipation in people with Parkinson's: a randomised controlled pilot study. *Age Ageing* (2016) 45(2): 299-303

Other dissemination activity:

- McClurg D, Dickinson L, Hagen S, Campbell P. Abdominal massage for the treatment of chronic constipation: ICS Tokyo 2016 Results from a Cochrane Review.

Project Number:	PVH03.2
Status:	Final report submitted
Project Title:	Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis - AMBER
Source of funding and total value of award:	NIHR HTA, £904,675
Value of funding to NMAHP RU:	£741,762
Principal investigator/co-applicants:	McClurg D (PI), Hagen S, Mason H (Glasgow Caledonian University), Harris F, (University of Stirling), Norrie J, Treweek S, (University of Aberdeen), Norton C, Coggrave M, (Kings College London) Donnan P, (University of Dundee) Emmanuel A, (University College London).
NMAHP RU investigators:	McClurg D, Hagen S, Harris F, Doran S, Goodman K.
Workstream:	Pelvic Health
Start date:	September 2013
Duration:	36 Months

Aim(s):

To determine the effectiveness and cost effectiveness of advice on optimised bowel care plus abdominal massage on PwMS compared to advice on optimised bowel care only. A process evaluation investigated the mediating factors that impacted upon effectiveness and possible implementation.

Summary:

Fifty to 80% of people with multiple sclerosis (PwMS) report constipation which impacts on their quality of life and can lead to hospitalisation if impaction occurs.

A randomised controlled trial with process evaluation and health economic component was undertaken in 12 secondary care hospitals in the UK recruiting 189 PwMS who had 'bothersome' constipation. Following individualised training abdominal massage was undertaken daily by the participant or a carer for 6 weeks. Advice on good bowel management as per the MS Society Care and Advice Booklet was provided to both groups. All participants received weekly telephone calls from the research clinician to support the intervention.

Results:

189 participants were randomised and intention to treat analysis performed. Participants had a mean age of 52 years (SD 10.83), 81% (n=154) were female, 11% (n=21) were wheel chair dependent. 15 from the Intervention Group and 5 from the Control Group withdrew or were lost to follow up.

The NBD Score at Week 24 demonstrated no significant difference between Groups (mean difference -1.64 95% CI -3.32 to 0.04, p=0.0558); secondary outcomes recorded in the bowel diary demonstrated a significant mean difference in change between the groups of 0.62 (95% CI 0.03 to 1.21, p=0.039) in the frequency of stool evacuation and on the number of times participants felt they emptied their bowels completely (mean difference 1.08 95% CI 0.41 to 1.76, p=0.002) with the Intervention Group showing greater effect. Laxative use at Week 24 was twice as likely to be lower in the Intervention Group than the Control Group (OR = 2.37, 95% CI 0.87, 6.46), p = 0.092).

25 health care providers and 6 stakeholders were interviewed (providing a total of 88 interviews). 15/20 participant interviewees reported benefits e.g. less difficulty passing stool and feeling they had emptied their bowel completed, feeling less bloated and improved appetite, with 17/20 continuing with the massage. A cost utility analysis was conducted from an NHS and patient cost perspective. The mean incremental cost for the Intervention Group compared to the Control Group was £132.96. The incremental gain in Quality Adjusted Life Years (QALYs) was 0.0024. The incremental cost per QALY gained was £55,400.

Conclusion:

Abdominal massage is a non-invasive, non-pharmacological intervention that may be clinically effective in some PwMS.

Publications:

- McClurg D, Goodman K, Hagen S, Harris F, Treweek S, Emmanuel A, Norton C, Coggrave C, Doran S, Norrie J, Donnan P, Mason H, Manoukian S. Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis (AMBER - Abdominal Massage for Bowel Dysfunction Effectiveness Research)- study protocol for a randomised controlled trial. 2017: *Trials*. 18, 150

Other dissemination activity:

- McClurg D., Goodman K. and the AMBER study Group (2015) "Abdominal Massage for Neurogenic Bowel Dysfunction in People with Multiple Sclerosis: The AMBER study" [Poster], MS Trust Annual Conference, Windsor, 8th-10th November 2015.
- McClurg D., Doran S. (2016) "Continence issues for people with Multiple Sclerosis" Scottish Parliament Cross-Party Group Meeting on Multiple Sclerosis, 1st March 2016.
- Doran S., McClurg D., Hagen S., Harris F and the AMBER study Group (2016) "It's exceeded my expectations": The Role of Hope in Trial Recruitment and Retention, British Sociological Association emotions workshop, Edinburgh 14th October 2016

- Goodman, K., Hagen, S., McClurg, D., Sergenson, N., Stratton, S., Treweek, S. (2017), Can Behaviour change theory increase questionnaire response rates within trials? [Poster], 4th International Clinical Trials Methodology Conference, Liverpool, 7-10 May 2017
- Doran S., Harris F., McClurg D., Goodman K. and the AMBER Study Group (2016) "The Role of Risk and Uncertainty in Trial Recruitment", BSA Medical Sociology Scottish Study Group conference; University of Glasgow 16th June 2017
- Doran S., Harris F., McClurg D., Goodman K. and the AMBER Study Group (2017) "Abdominal Massage for the Relief of Constipation Symptoms in People with Multiple Sclerosis: Results of a Qualitative Study" [Poster], MS Frontiers Conference, Edinburgh, 29th-30th June 2017
- McClurg D., Harris F., Goodman K. and the AMBER Study Group (2017) "Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis - preliminary results of a randomised controlled trial", MS Frontiers Conference, Edinburgh, 29th-30th June 2017

Further abstracts accepted for the International Continence Society Sept 2017, and ECTRIMS November 2017.

Dissemination will also include training days supported by the project and a proposed video through an on line publisher.

STROKE



STROKE01

COMMUNICATION



The research undertaken as part of the re-engagement fellowships is highly relevant to practice. NMAHP RU has vital role in encouraging NMAHPs who have been research active in the past to rekindle their passion knowledge and skills to consolidate and further develop their research skills with the support and guidance from experienced research staff within the unit.



STROKE01.1 Cochrane review of speech and language therapy for aphasia following stroke

Project Number:	STROKE01.1
Status:	Complete
Project Title:	Cochrane review of speech and language therapy for aphasia following stroke
Source of funding and total value of award:	£0
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Brady MC(PI) (Glasgow Caledonian University), Kelly H (University of Cork), Enderby P (University of Sheffield), Godwin J, Campbell P (Glasgow Caledonian University).
NMAHP RU investigators:	Brady MC, Campbell P.
Workstream:	Stroke
Start date:	2011 (update 2012) and 2015 (update 2016)
Duration:	6 Years

Aim(s):

To review the evidence of the effect of speech and language therapy (SLT) on language problems experienced by people after a stroke (known as aphasia).

Summary:

About a third of people who suffer a stroke develop aphasia which may affect one or more areas of communication: speaking, oral comprehension, reading, and writing. Speech and language therapists assess, diagnose, and treat aphasia at all stages of recovery after stroke. They work closely with the person with aphasia, families, and other healthcare professionals. We wanted to see whether SLT for aphasia was effective and whether it was better or worse than non-specialist social support. We also wanted to see which approaches to therapy offered the best recovery. In our most recent search of the literature (September 2015) we found and included 57 studies involving 3002 people with aphasia in our review. We reviewed all SLT types, regimens, and methods of delivery. Based on 27 studies (and 1620 people with aphasia), speech and language therapy benefits functional use of language, language comprehension (for example listening or reading), and

language production (speaking or writing), when compared with no access to therapy, but it was unclear how long these benefits may last.

There was little information available to compare SLT with social support. Information from nine trials (447 people with aphasia) suggests there may be little difference in measures of language ability. However, more people stopped taking part in social support compared with those that attended SLT.

Thirty-eight studies compared two different types of SLT (involving 1242 people with aphasia). Studies compared SLT that differed in therapy regimen (intensity, dosage and duration), delivery models (group, one-to-one, volunteer, computer-facilitated), and approach. We need more information on these comparisons. Many hours of therapy over a short period of time (high intensity) appeared to help participants' language use in daily life and reduced the severity of their aphasia problems. However, more people stopped attending these highly intensive treatments (up to 15 hours a week) than those that had a less intensive therapy schedule.

Outcomes/Impact:

- 2013 Highest accessed Cochrane Stroke Review
- 2015 Top 3 most accessed Cochrane Stroke Review
- 2015 Top 50 most accessed Cochrane Reviews (50th) in the world

Has informed the development of the national stroke clinical guidelines in Norway and the UK (RCP 2016, 2012; and NICE 2013) and the national speech and language therapy clinical guidelines in the Netherlands.

Publications:

- Brady MC and Evans J. [invited] Language and Cognitive Rehabilitation. Book Chapter in Stroke Treatment and Prevention (in press).
- Brady MC, Kelly H, Godwin J, Enderby P, Campbell P. Speech and language therapy for aphasia following stroke. Cochrane Database of Systematic Reviews 2016, Issue 6. Art. No.: CD000425. DOI: 10.1002/14651858.CD000425.pub4.
- Brady MC, Godwin J, Enderby P, Kelly H, Campbell P. [invited] Speech and language therapy for aphasia after stroke; an updated systematic review and meta-analyses. Stroke (in press)
- Kelly H, Brady MC, Enderby P. Speech and language therapy for aphasia following stroke. Cochrane Database of Systematic Reviews 2010, Issue 5. Art. No.: CD000425. DOI: 10.1002/14651858.CD000425.pub2

Presentations:

- Brady MC, Kelly H, Godwin J, Enderby P, Campbell P. What's new? Cochrane Systematic Review of speech and language therapy (SLT) for aphasia after stroke: International Aphasia Rehabilitation Conference, 14-16th December 2016. London, UK.
- Brady MC, Kelly H, Godwin J, Enderby P, Campbell P. Speech and language therapy (SLT) for aphasia after stroke: Cochrane Systematic Review evidence of therapy regimens, delivery models and theoretical approaches. European Stroke Organisation Conference, Barcelona, Spain. [High Scoring Abstract]
- Brady MC, Campbell P, Kelly H, Godwin J, Enderby P. [invited] Aphasia rehabilitation – a Cochrane Systematic Review of the evidence for speech and language therapy compared with no speech and language

therapy, UK Stroke Forum 2011, Glasgow, UK.

- Brady M. [Keynote] Trials and Tribulations, Collaboration and Coordination. International Aphasia Rehabilitation Conference, 18-20th June 2014. The Hague, the Netherlands.
- Brady MC, Kelly H, Godwin J, Enderby P. Aphasia rehabilitation – a Cochrane Systematic Review of the evidence for Speech and Language Therapy (SLT) compared with no SLT. 20th European Stroke Conference 2011, Hamburg, Germany.
- Campbell P, Kelly H, Enderby P, Godwin Brady MC. [invited] Cochrane Systematic Review of the evidence for Speech and Language Therapy. May 2017, South West NHS Stroke Conference (Joining Forces), UK.
- Brady M. [invited] Cochrane Aphasia Review UK Stroke Forum Nov 2016, Liverpool, UK
- Brady M. [invited] Update on the Cochrane Systematic Review of Speech and Language Therapy for Aphasia after Stroke. Dutch Society of Speech and Language Therapists. March, 2016 Rotterdam, the Netherlands.
- Brady M. [invited] Aphasia Symposium Stroke 2015 August 2015, Melbourne, Australia.

Awards:

- The Tavistock Trust for Aphasia - Robin Tavistock Award. Marian Brady
- UK Stroke Forum 2011 - Highest Scoring Abstract across disciplines for Brady MC, Kelly H, Enderby P. Aphasia rehabilitation – a Cochrane Systematic Review of the evidence for Speech and Language Therapy (SLT) compared with no SLT.

Other Presentations to Third Sector Groups from across the UK:

- Brady MC. [invited] Speech and language therapy for aphasia following stroke. Aphasia Alliance. Edinburgh, November 2013.

Other dissemination activity:

SLTs Professional Journal:

- Brady M, Mackenzie C, Enderby P, Whitworth AB, Kelly H, Sellars C. SIGN 118 overlooks- new evidence on aphasia. RCSLT Bulletin 2011;705:11.

Project Number:	STROKE01.2
Status:	Complete
Project Title:	Collaboration of Aphasia Trialists (Phase 1)
Source of funding and total value of award:	EU Cooperation in Science and Technology Association (COST) £464,848.00
Value of funding to NMAHP RU:	£464,848.00
Principal investigator/co-applicants:	Brady MC (PI) Glasgow Caledonian University), Ali M, (Glasgow Caledonian University) Bowen A (University of Manchester), Denes F, (University Ca' Foscari Venice, Italy) Godecke E (Edith Cowan University, Australia), Kukkonen T (University of Tampere, Finland), Laska AC (Karolinska Institutet, Sweden), Pulvermuller F (Freie Universität Berlin) , Smania N (University of Verona), Visch-Brink E (Erasmus MC, the Netherlands).
NMAHP RU investigators:	Brady MC , Ali M.
Workstream:	Stroke
Start date:	May 2013
Duration:	4 Years

Aim(s):

Our network aimed to establish a network of leading European multidisciplinary aphasia investigators in stroke rehabilitation, social science, linguistics, medicine, neuropsychology and language research.

(on the individual, on families), assessment, diagnosis, prognosis, rehabilitation, recovery and reintegration (functional, rehabilitation, occupational, societal and economic) of people with aphasia.

Objectives:

1. Develop a formal international network of investigators and clinicians from a range of settings and specialist domains with an interest in aphasia rehabilitation research.
2. Develop a sustainable web-based application to support the network functions.
3. Facilitate members' access to data, resources, consensus statements, expertise and promote knowledge transfer between researchers and settings.
4. Foster the development of an international network of coordinated and collaborative research activities which will improve our understanding of the impact of aphasia

Summary:

Each year 1.1 million people in Europe, Iceland, Norway and Switzerland experience their first stroke and an estimated 360,000 Europeans per annum experience a loss or impairment of language, known as aphasia. Aphasia research has faced methodological and infrastructural challenges. Typically it remains language, region and discipline specific limiting the efficiency, strength and broader relevance of any research. Our network sought to address these challenges.

Box 1: CATs participating countries

Belgium	Denmark	Russia	Sweden	Netherlands
Finland	Greece	Australia	Serbia	Ireland
Hungary	Italy	South Africa	Israel	Turkey
Lithuania	Norway	New Zealand	Spain	Germany
Portugal	France	Croatia	Malta	Cyprus
United Kingdom				

Outcomes/Impact:

The Collaboration of Aphasia Trialists (Action IS1208 2013-2017) succeeded in supporting the development of an international network of 179 researchers that worked to bridge different disciplinary, linguistic, geographic and research paradigm perspectives to discover a shared ambition to enhance the rehabilitation and recovery of people with aphasia after stroke. While our COST network included 26 countries (Box 1) several of our projects extended that network further, collaborating with researchers from a further 10 countries (including Brazil, Canada, Chile, People’s Republic of China, Egypt, Iran, Japan, Poland, South Korea, Switzerland and USA) (Map 1).

MAP 1: International collaborative network



We co-ordinated our research activities across 27 on-going collaborative research proposals (12 additional projects under review with funders or in preparation) reflecting our four research orientated Working Groups' focus on (1) Assessments and outcomes, (2) Predictors and prognosis, (3) Effective interventions and (4) Societal impact and reintegration. During the COST funding period network members secured an additional €1.1M in competitive external research funding to support their collaborative research activities.

We also demonstrated the synergistic development of multiple parallel projects - adapting an aphasia assessment tool into 14 languages¹, developing consensus on an ICF based definition of aphasia, sought multidisciplinary consistency in the use of the term 'aphasia', supported the development of a core outcome set, created an international database of secondary individual patient data from aphasia researchers which will inform highlight predictors of recovery and inform our prognoses, evaluated the quality of aphasia intervention reports in the literature, reviewed the evidence of the effectiveness of interventions, evaluated the effectiveness of new interventions and explored ways in which we can support people's reintegration back into society with aphasia. We established the top ten aphasia research priorities as identified by people with aphasia, family members and therapists.

Our network communications, functions and members needs were well supported by our [website](#). Our outputs have been published in 11 papers to date (with an additional six manuscripts in preparation). We delivered seven workshop events about our research and contributed to one consensus meeting. We presented our activities in 34 conference papers and additional posters. We hosted two conferences and three training schools. Our dissemination efforts sought to share our findings with people with aphasia and their families, health and social care professionals and third sector groups supporting people with aphasia. Through these efforts we successfully met the objectives of our network.

¹ Basque, Catalan, Croatian, Finnish, French, Greek, Hungarian, Lithuanian, Norwegian, Portuguese, Serbian, Spanish, Swedish, Turkish

Our work within the Collaboration of Aphasia Trialists has been supported for an additional three years by the Tavistock Trust for Aphasia (STROKE01.3). As a result of this investment we aim to further develop and enhance our current portfolio of research activities.

Publications:

- Brady MC, Ali M, Fyndanis C, Kambanaros, M, Kleanthes K, Hernández-Sacristán C, Laska A-C, Varloksta S on behalf of the Collaboration of Aphasia Trialists. Time for a step change? Improving the efficiency, relevance, reliability, validity and transparency of aphasia rehabilitation research through core outcome measures, a common data set and improved reporting criteria. *Aphasiology*. 2014;28(11):1385-1392. doi:10.1080/02687038.2014.930261.
- Worrall L, Brady MC, Simmons-Mackie N, Wallace S, Rose T, Murray LL, Hallowell B. Let's call it "aphasia": Rationales for eliminating the term "dysphasia". *International Journal of Stroke*. *International Journal of Stroke* 2016; 11(8) 848-851. DOI: 10.1177/1747493016654487.
- Aguiar V, Bastiaanse R, Capasso R, Gandolfi M, Smania N, Rossi G, Miceli G. (2015). Can tDCS enhance item-specific effects and generalization after linguistically motivated aphasia therapy for verbs? *Frontiers in Behavioral Neuroscience*, 9, 190.

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Project Number:	STROKE01.3
Status:	In Progress
Project Title:	Collaboration of Aphasia Trialists [Phase 2]
Source of funding and total value of award:	Tavistock Trust for Aphasia
Value of funding to NMAHP RU:	£confidential
Principal investigator/co-applicants:	Brady MC (PI), Ali M (Glasgow Caledonian University)
NMAHP RU investigators:	Brady MC, Ali M.
Workstream:	Stroke
Start date:	May 2017
Duration:	3 Years

Objectives:

Supporting the development, conduct, reporting and dissemination of randomised controlled trials of aphasia interventions to optimise the rehabilitation and recovery of people with aphasia.

Summary:

Continued growth of multidisciplinary, international network:

- Seeking broader collaboration beyond EU COST countries. Inviting collaborators with considerable expertise in aphasia from across Commonwealth countries and the USA to participate in the network.

Development of trials

- Arising from our 2016-2017 activities (and building upon priority setting work 2016-17) will be a new shared aphasia research agenda mapping the important research topics that need to be addressed, people leading these activities and proposed methodologies. Collaborative support for strategically coordinated, multi-centered aspiration research activities would also be provided to increase mainstream funding secured to support aphasia research (for example National Institute for Health Research (UK), National Institute for Health (USA)).

Conduct of trials

- Supporting and facilitating international access to secondary data-analysis via our anticipated individual patient data archive (estimated 3000 individual patient data) in CATs would inform the development, feasibility and planning of new trials. This will evolve from the RELEASE database (STROKE01.4). New trials in aphasia are still emerging (15 identified in the recent Cochrane Systematic Review STROKE01.1) and so continued recruitment particularly of randomised controlled trial individual patient data would continue to strengthen the quality of the dataset. Access to such a dataset infrastructurally supported by CATs would 'fast-track' the refinement of new research questions before costly feasibility testing 'in the field'.

Capacity Building

- Funded PhD training fellowships are very limited for junior researchers with a specific interest in aphasia. Sponsorship of a modest PhD studentship (stipend plus fees) will support the development of the next generation of aphasia trialists. Studentship opportunities would be advertised internationally and be awarded following competitive application rounds to the best candidate in a high quality aphasia research training environment. CATs would further support capacity building in trial development and management through specific training schools, support participation in trial management training and mentorship of new trialists by experienced colleagues. This programme of capacity building internationally would enhance the quality of the trials conducted and the opportunities for international multi-centred trials.
- Reporting and Dissemination: Improvements in reporting of trials would be supported through writing workshops and mentorship and a journal special issue. The network have applied to COST to support some additional costs for a special issue within the International Journal of Stroke. New publications would be shared amongst the group and feed into the next strategy development group meeting.

Project Number:	STROKE01.4
Status:	In Progress
Project Title:	REhabilitation and recovery of peopLE with Aphasia after Stroke (RELEASE): Utilizing secondary data to enhance speech and language therapy interventions for people with aphasia after stroke
Source of funding and total value of award:	NIHR HS&DR, £446,158
Value of funding to NMAHP RU:	£446,158
Principal investigator/co-applicants:	Brady M (PI), Ali M, Elders A (Glasgow Caledonian University), Bowen A (University of Manchester), Godecke E (Edith Cowan University), Godwin J (Glasgow Caledonian University), Hilari K (The City University), Hinkley J (University of South Florida), Horton S (University of East Anglia), Howard D (University of Newcastle-upon-Tyne), Laska AC (Karolinska Institutet), Kukkonen T (University of Tampere), MacWhinney B (Carnegie Mellon University), Palmer R (University of Sheffield), Price C (University College London), Thomas S (University of Nottingham), Visch-Brink (Erasmus University Rotterdam), Worrall L (University of Queensland).
NMAHP RU investigators:	Brady MC, Ali M, Elders A, Williams L, VandenBerg K
Workstream:	Stroke
Start date:	January 2016
Duration:	2 Years

Aim(s):

To explore the contribution that individual characteristics (including stroke and aphasia profiles) and intervention components make to the natural history of recovery and rehabilitation of people with aphasia following stroke and to inform future research design by utilising pre-existing IPD aphasia data to explore:

Research questions:

- What is the natural history of language recovery following stroke related aphasia?
- What are the predictors of language recovery outcomes?

- What are the components of effective aphasia rehabilitation interventions?
- Are some interventions (or intervention components) more beneficial for some patient subgroups (individual, stroke or aphasia characteristics) than others?

Summary:

Patients that receive speech and language therapy (SLT) recover better than those that receive no SLT. However, most continue to experience significant communication impairment and much uncertainty remains around the delivery of SLT interventions in relation to, for example, the optimum timing after stroke onset, intensity, frequency, duration, therapy tasks (or mechanisms) and theoretical approach.

In addition, conflicting evidence relating to the impact of patients' age, sex, handedness and educational background and other variables on language recovery outcomes creates uncertainty about which patients will spontaneously recover, not recover well and those that are most likely to benefit from therapy. Interaction between the language impairment (modalities affected, severity), individual patient characteristics (age, sex, educational background, languages used), stroke (severity, lesion location and time since onset) and therapeutic options is poorly understood. Clinically effective and affordable approaches, based on an informed prognosis of recovery profile for people with aphasia after stroke are urgently required.

However, rather than moving forward with multiple, large, costly, logistically challenging, prospective randomised controlled trials we believe that much understanding can be gained from coordinated analyses of the rich aphasia datasets already in existence prior to progression towards definitive trails evaluating defined interventions amongst patient groups most likely to demonstrate benefit. Thorough exploration of pooled individual patient data (from pre-existing aphasia research datasets would quickly, and cost effectively, address some of the uncertainties highlighted above.

Fig 1: RELEASE Collaborators



Outcomes/Impact:

We are collaborating with more than 60 multidisciplinary aphasia researchers (representing 75 primary research datasets) from 24 countries (Fig 1) and have created a database of >5500 individual patients' data for our planned analyses.

Publications:

- Brady MC Why there is fresh hope for stroke patients who are struggling to communicate. The Conversation [<http://theconversation.com/why-theres-fresh-hope-for-stroke-patients-who-are-struggling-to-communicate-51172>] [4335 views].

Presentations:

- The RELEASE Collaboration - LR Williams, K Vandenberg, M Ali, A Elders, J Godwin, S Abel, M Abo, F Becker, A Bowen, C Brandenburg, C Breitenstein, D Copland, T Cranfill, ES Duncan, M di Pietro-Bachmann, J Fillingham, M Gandolfi, B Glize, E Godecke, K Hilari, J Hinckley, S Horton, D Howard, P Jaecks, B Jefferies, LMT Jesus, M Jungblut, M Kambanaros, E Khedr, T Kukkonen, E Kyoung Kang, MA Lambon Ralph, M Laganaro, A-C Laska, B Leeman, A Leff, RR Lima, A Lorenz, B MacWhinney, IP Martins, F Mattioli, İ Maviş, M Meinzer, E Noé Sebastián, R Nilipour, N-J Paik, R Palmer, B Patricio, C Price, T Prizl Jakovic, E Rochon, M Rose, C Rosso, I Rubi-Fesson, M Ruiter, R Shisler Marshall, C Snell, JP Szaflarski, S Thomas, I van de Meulen, M van de Sandt-Koenderman, E Visch-Brink, L Worrall, H Wright Harris, MC Brady. Establishing an international shared aphasia individual patient dataset for the REhabilitation and recovery of peopLE with Aphasia after StrokE (RELEASE). International Aphasia Rehabilitation Conference (IARC), December 2016. London, UK.

- The RELEASE Collaboration - The RELEASE Collaboration - LR Williams, K VandenBerg , M Ali, A Elders , J Godwin, S Abel, M Abo, F Becker, A Bowen , C Brandenburg , C Breitenstein, D Copland, T Cranfill, ES Duncan, M di Pietro-Bachmann, J Fillingham, M Gandolfi, B Glize, E Godecke, K Hilari, J Hinckley, S Horton, D Howard, P Jaecks, B Jefferies, LMT Jesus , M Jungblut, M Kambanaros, E Khedr, T Kukkonen, E Kyoung Kang , MA Lambon Ralph, M Laganaro, A-C Laska, B Leeman, A Leff, RR Lima, A Lorenz, B MacWhinney, IP Martins, F Mattioli, İ Maviş , M Meinzer, E Noé Sebastián, R Nilipour, N-J Paik, R Palmer, B Patricio, C Price, T Prizl Jakovic, E Rochon , M Rose, C Rosso, I Rubi-Fesson, M Ruitter, R Shisler Marshall, C Snell, JP Szaflarski , S Thomas, I van de Meulen, M van de Sandt-Koenderman, E Visch-Brink, L Worrall, H Wright Harris, MC Brady. REhabilitation and recovery of peopLE with Aphasia after Stroke (RELEASE): The creation of a multidisciplinary, international aphasia database of individual patient data. Collaboration of Aphasia Trialists Conference, February 2017, Rotterdam, The Netherlands.
- Brady M. [invited] Stroke rehabilitation research initiatives. Neurology and Central & Eastern European Stroke Conference (ESOEast) March, 2016. Warsaw, Poland.
- Brady M. [invited] Update on the Cochrane Systematic Review of Speech and Language Therapy for Aphasia after Stroke. Dutch Society of Speech and Language Therapists. March, 2016 Rotterdam, the Netherlands.
- Brady M. [invited] Aphasia Research. Edinburgh Aphasia Interest Group, January 28th 2016, Edinburgh, UK.
- Brady M. [invited] Are we nearly there yet? Aphasia Symposium Stroke 2015 August 2015, Melbourne, Australia.
- The RELEASE Collaboration - LR Williams, K VandenBerg , M Ali, A Elders , J Godwin, S Abel, M Abo, F Becker, A Bowen , C Brandenburg , C Breitenstein, D Copland, T Cranfill, ES Duncan, M di Pietro-Bachmann, J Fillingham, Galli F, Gandolfi, B Glize, E Godecke, K Hilari, J Hinckley, S Horton, D Howard, P Jaecks, B Jefferies, LMT Jesus , M Jungblut, M Kambanaros, E Khedr, T Kukkonen, MA Lambon Ralph, M Laganaro, A-C Laska, Law SP, B Leeman, A Leff, RR Lima, A Lorenz, B MacWhinney, F Mattioli, İ Maviş , M Meinzer, E Noé Sebastián, R Nilipour, N-J Paik, R Palmer, B , Papathanasiou I, B Patricio, Shisler Marshall R, Pavão Martins I, Prizl Jakovac T , Price C , E Rochon , M Rose, C Rosso, I Rubi-Fesson, M Ruitter, C Snell, JP Szaflarski , S Thomas, I van de Meulen, M van de Sandt-Koenderman, E Visch-Brink, L Worrall, H Wright Harris, MC Brady. REhabilitation and recovery of peopLE with Aphasia after Stroke (RELEASE) project. UK Stroke Forum, Liverpool, UK, December 2016.
- The RELEASE Collaboration - A Elders, M Ali, K VandenBerg, LR Williams , J Godwin, S Abel, M Abo, F Becker, A Bowen , C Brandenburg , C Breitenstein, D Copland, T Cranfill, ES Duncan, M di Pietro-Bachmann, J Fillingham, Galli F, Gandolfi, B Glize, E Godecke, K Hilari, J Hinckley, S Horton, D Howard, P Jaecks, B Jefferies, LMT Jesus , M Jungblut, Kyoung Kang E, M Kambanaros, E Khedr, T Kukkonen, MA Lambon Ralph, M Laganaro, A-C Laska, Law SP, B Leeman, A Leff, RR Lima, A Lorenz, B MacWhinney, F Mattioli, İ Maviş , M Meinzer, E Noé Sebastián, R Nilipour, N-J Paik, R Palmer, B , Papathanasiou I , B Patricio, Shisler Marshall R, Pavão Martins I, Prizl Jakovac T , Price C , E Rochon, M Rose, C Rosso, I Rubi-Fesson, M Ruitter, C Snell, JP Szaflarski , S Thomas, I van de Meulen, M van de Sandt-Koenderman, E Visch-Brink, L Worrall, H Wright Harris, MC Brady. Building on the past: Systematic identification, data extraction and synthesis of pre-existing individual stroke patient datasets to inform the development and design of future clinical trials. International Clinical Trials Methodology Conference, Liverpool, UK April 2017. <http://www.ictmc2017.com/programme/>

Posters:

- The RELEASE Collaboration - Ali M, Becker F, Brady MC, Bowen A, Elders A, Godecke E, Godwin J, Hilari K, Hinckley J, Horton S, Howard D, Jesus LMT, Kagan A, Kukkonen T, Laska AC, MacWhinney B, van der Meulen I , Palmer R, Price C, Thomas S, Visch-Brink EG, VandenBerg K , Williams LR, Worrall L. RELEASE: Rehabilitation and recovery of people with aphasia after stroke. National Congress of the Italian Society of Neu-

STROKE01.4 REhabilitation and recovery of peopLE with Aphasia after Stroke (RELEASE): Utilizing secondary data to enhance speech and language therapy interventions for people with aphasia after stroke

Other dissemination activity:

National Interview - Portugal

- Luis Jesus [PT] recently (20th May 2017) was invited to participate in a live RTP (National Portuguese) radio programme called 'The art of the possible' [A arte do possível com Filipe Teles] about aphasia and the RELEASE project. A podcast of this interview is available, Title: Projeto RELEASE analisa bases de dados de doentes com afasia; potencialidades da aquacultura multitrófica integrada - <http://www.rtp.pt/play/p384/e293523/click>

Project Number:	STROKE01.5
Status:	In Progress
Project Title:	Clinical and cost effectiveness of aphasia computer therapy compared with usual stimulation or attention control long term post stroke (Big CACTUS)
Source of funding and total value of award:	NIHR HTA, £1,445,589.00
Value of funding to NMAHP RU:	£22,438
Principal investigator/co-applicants:	Palmer R (PI), Enderby P, Brady MC (Glasgow Caledonian University), Bowen A (University of Manchester), Cooper C, Latimer N, Julious S (University of Sheffield).
NMAHP RU investigators:	Brady MC.
Workstream:	Stroke
Start date:	January 2014
Duration:	54 months

Aim(s):

To provide definitive evidence of the clinical and cost effectiveness of self managed computerised therapy for post stroke aphasia through a randomised controlled trial (RCT).

Research questions:

- To establish whether self-managed computerised speech and language therapy for word finding increases the ability of people with aphasia to use vocabulary of personal importance (impairment).
- To establish whether self-managed computerised speech and language therapy for word finding improves functional communication ability in conversation (activity)

- To investigate whether patients receiving self-managed computerised speech and language therapy perceive greater changes in social participation in daily activities and quality of life (participation).
- To establish whether self-managed computerised speech and language therapy is cost effective for persistent aphasia post stroke.
- To identify whether any effects of the intervention are evident 12 months after therapy has begun.

Summary:

Speech and language therapy is frequently available only for the first few months after stroke. During this time many people are medically unwell, tired and concentrating on competing demands of recovering physical skills. Many do not meet their potential for recovery over this time period. Persisting aphasia impact on the ability to participate in everyday activities, communicate with family/friends or work, often leading to depression.

Evidence suggests that aphasia can improve if therapy is provided intensively in the longer term. Opportunities for therapy in the later stages after stroke would enable people to access therapy when their health has improved, and as communication needs change over time. Providing intensive face to face therapy in the long term is costly and difficult to achieve with competing demands on limited therapy resources. The Big CACTUS trial will evaluate the clinical and cost effectiveness of self managed computerised therapy exercise practice for persistent aphasia, tailored by speech and language therapists and supported by volunteers. The Big CACTUS trial is informed by our pilot study (n=34) which randomised people with persistent aphasia to using available computer software designed for treating aphasia, or usual long term care (most frequently this was social support). On average people with aphasia practiced their speech exercises on the computer independently for 25 hours over 5 months (20 minutes, 3 times a week). The findings indicated that self managed computer therapy supported by volunteers could help people with aphasia to continue to practise, improving their vocabulary and their confidence talking. Patients and carers found it an acceptable alternative to face to face therapy. Self managed computer therapy could improve the quality of life of people with persistent aphasia, reducing costs to the NHS and society.

Big CACTUS is a large randomised controlled trial to compare the clinical and cost effectiveness of aphasia computer therapy with usual care in the long term post stroke. Working with 20 speech and language therapy departments across the UK we have identified potential participants from speech and language therapy records and from voluntary support groups.

Publications:

- Palmer R, Cooper C, Enderby P, Brady M, Julious S, Bowen A, Latimer N. Clinical and cost effectiveness of computer treatment for aphasia post stroke (Big CACTUS): study protocol for a randomised controlled trial. *Trials* 2015;16:18. doi: 10.1186/s13063-014-0527-7.
- Palmer R, Cross, E, Harrison M, Enderby P. (2016) Negotiating Excess Treatment Costs in a clinical research trial: The good the bad and the innovative. *Trials* DOI: 10.1186/s13063-016-1208-5
- Palmer R, Hughes H, Chater T (2017) What do people with aphasia want to be able to say? A content analysis of words identified as personally relevant by people with aphasia. *PLOS ONE* <https://doi.org/10.1371/journal.pone.0174065>

Posters/newsletters:

- Palmer R, Hughes H, Chater T. What do people with aphasia want to be able to say? UK Stroke Forum. December 2016, Liverpool, UK.
- Big CACTUS ongoing trial poster. UK Stroke Forum in December 2015, Liverpool, UK.
- Big CACTUS ongoing trial. Society for Rehabilitation Research in July 2016, Coventry, UK.
- Consensus of what the StepbyStep approach is and how adherence to the key components should be measured have been accepted for the UKSF December 2016.

Presentations:

- Palmer R, Hughes H. 'What do people with aphasia want to be able to say?' Society for Rehabilitation Research in July 2016, Coventry, UK.
- MA Harrison, RL Palmer and C Cooper. Defining and measuring the components of a complex neuro-rehabilitation intervention for aphasia. Society for Rehabilitation Research in July 2016, Coventry, UK.
- Palmer R, [Invited] Big CACTUS clinical and cost effectiveness of aphasia computer treatment. June 2016, UCL Institute of Neurology, London, UK.
- Palmer R, [Invited] Big CACTUS and pragmatic trial design. Kent Association of Chartered Physiotherapists in Neurology stroke conference, October 2016. UK.
- Palmer R, [Invited] Innovative methods for managing aphasia. 14th Welsh Stroke Conference. 24th September 2015, Cardiff, UK.

Awards:

- Rebecca Palmer awarded the Vera Wright prize for best oral presentation by a new member. By the Society for Rehabilitation Research in July 2016
- Big CACTUS – runner up Patient, Carer and Public Involvement Prize presented at the UK Stroke Forum, 2016.

Project Number:	STROKE01.6
Status:	In Progress
Project Title:	Aphasia telerehabilitation early post stroke
Source of funding and total value of award:	Regional Health Trust South East Norway, €307,495
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Prag Øra H (PI) Supervisors: Kirmess M (Sunnaas Rehabilitation Hospital and University of Oslo, Norway), Brady MC (Glasgow Caledonian University), Winsnes I (Sunnaas Rehabilitation Hospital Norway, Becker F (Sunnaas Rehabilitation Hospital and University of Oslo, Norway).
NMAHP RU investigators:	Brady MC.
Workstream:	Stroke
Start date:	2015
Duration:	3 years

Aim(s):

To investigate the feasibility and acceptability of telerehabilitation for people with aphasia after stroke.

Research questions:

As a pilot study it is not powered to establish whether language function improves as a consequence of this telerehabilitation intervention. We will however seek to examine

- What are participants' and therapists' experience of participating in therapy in this delivery mode?
- Are the procedures for delivery of SLT via telerehabilitation feasible?
- What is the impact on patients' quality of life?
- We also aim to gather additional details on recruitment rate, outcome measures used, training, procedures and processes to inform the development of a definitive trial.

Summary:

The Norwegian guidelines for treatment and rehabilitation of aphasia following stroke recommend intensive speech and language therapy. Ensuring individually tailored aphasia rehabilitation of sufficient intensity and duration is however a challenging task. Language training by telemedicine could

improve this situation by widening the access to speech and language therapists despite geographical barriers or insufficient capacity. The research within this field of aphasia rehabilitation is in its infancy, there are few studies on the effectiveness of telerehabilitation to date. At Sunnaas Rehabilitation Hospital (Nesoddtangen, Norway) we completed feasibility study using telemedicine in the treatment of aphasia. This pilot randomised controlled clinical trial will further explore the feasibility and acceptability of the provision of speech and language therapy by telerehabilitation.

Other dissemination activity:

Hege Prag Øra participated in a Short Term Scientific Mission to visit the NMAHP Research Unit in 2016 funded by the Collaboration of Aphasia Trialists.

Poster:

- Hege Prag Øra Melanie Kirmess, Marian Brady, Ingvild Winsnes, Frank Becker. Aphasia telerehabilitation post stroke - protocol of a randomized controlled trial. Collaboration of aphasia trialists, Rotterdam, the

STROKE01.7 A family-centred approach to the management of lifestyle risk factors for recurrent stroke

Project Number:	STROKE01.7
Status:	Complete
Project Title:	A family-centred approach to the management of lifestyle risk factors for recurrent stroke
Source of funding and total value of award:	Stroke Association Senior Research Training Fellowship, £139,989
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Lawrence M (PI), Dennis M (University of Edinburgh), Cheater F, Brady MC (Glasgow Caledonian University).
NMAHP RU investigators:	Brady MC.
Workstream:	Stroke
Start date:	January 2012
Duration:	3 years

Aim(s):

To develop and test the feasibility and acceptability of an evidence-based, theoretically informed, family-centred intervention designed to reduce the risk of recurrent stroke. The self-management intervention was multimodal for use by stroke multi-disciplinary team members in a variety of settings.

Objectives:

- To develop a web-based family-centred secondary prevention intervention
- To test aspects of accessibility and utility of the intervention, specifically in relation to lifestyle risk factor behaviour

Summary:

After having a stroke, there is a high risk of having another stroke and many stroke survivors live in fear of one. This fear may reduce over time. For many stroke survivors and their families this fear persists. Adherence to prescribed medicines can be poor however, especially if they have

unpleasant side effects. Lifestyle choices such as smoking, physical inactivity, excessive use of alcohol and a poor diet also contributes to health problems (including stroke). Stroke survivors have reported a lack of information about lifestyle choices and support to make changes that would reduce their risk of stroke.

In this fellowship Dr Maggie Lawrence conducted systematic reviews of the effectiveness of interventions to support stroke survivors and their families in management of lifestyle risk factors for recurrent stroke and reduce feelings of stress, anxiety and depression. Working with stroke survivors and their families, the research team used the systematic review findings to inform the development of the [Keeping Well](#) webpage within the [Selfhelp4Stroke](#) site (2015 Chest, Heart and Stroke Scotland). The self-management website provides access to information and advice to help stroke survivors and families make healthy changes that may help them avoid another stroke.

A survey of 42 stroke survivors (users of the Keeping Well website) found that most respondents reported they had enough information about stroke and what to do to try to prevent another one. They also knew that high blood pressure is a major risk factor for stroke.

STROKE01.7 A family-centred approach to the management of lifestyle risk factors for recurrent stroke

Most respondents knew about the importance of adherence to prescribed medication. About a third of respondents answered questions about healthy eating and physical activity and of these most knew about healthy eating. Only two respondents reported considering making positive changes in their lifestyle choices as a result of the website. All survey respondents said they would recommend it those who had recently experienced a stroke.

We also invited stroke survivors (n=7) to participate in qualitative interviews to explore in more depth how people used the website. We wanted to know if using the website had given people the information they needed about stroke and stroke prevention. We also wanted to explore whether using the website had helped people to make, or think about making, changes in their lifestyles.

Outcomes/Impact:

The [Keeping Well](#) website is a valuable evidence-based, theory-informed, self-management resource for people living with stroke in the long-term and for their families. It has the potential to empower people to reduce the risk of recurrent stroke and improve their quality of life. The resource is free-to-access and its interactive, modular design means that it can be tailored to meet the needs and preferences of individuals and their families. Keeping Well is also flexible enough to be used as part of a patient-centred, tailored programme of rehabilitation.

International Network: INSPiRE

An international network of 14 multidisciplinary, stroke secondary prevention researchers has been established (GCU London, 2015) to develop a Consensus Statement on Outcomes and Outcomes Measures for use in Stroke Secondary Prevention (behavioural) research. Led by Dr Maggie Lawrence, the consensus statement will identify core outcomes and outcome measurement tools a key methodological and reporting weakness identified in the systematic reviews undertaken as part of this fellowship.

The findings of this fellowship has also informed the development of a successful application to the Chief Scientist Office (Mindfulness Based Stress Reduction to support self-management of anxiety and depression following stroke: development and feasibility study (HEADS: UP project: STROKE01.8).

Awards:

Self-Help-4-Stroke was highly commended in the British Medical Association (BMA) Patient Information Awards 2016.

Publications:

- Lawrence M, Pringle J, Kerr S, Booth J. (2016) Stroke survivors' and family members' perspectives of multi-modal lifestyle interventions for secondary prevention of stroke and transient ischaemic attack: a qualitative review and meta-aggregation. *Disability & Rehabilitation*, 38(1):11-21 doi: 10.3109/09638288.2015.1031831.
- Lawrence M, Pringle J, Kerr S, Booth J, Govan L, Roberts NJ. (2015) Multimodal Secondary Prevention Behavioral Interventions for TIA & Stroke: Systematic Review & Meta-Analysis. *PLoS ONE* 10(3):e0120902 DOI:10.1371/journal.pone.0120902
- Lawrence M, Booth J, Mercer S, Crawford E. (2013) A systematic review of the benefits of Mindfulness-Based Interventions following transient ischaemic attack and stroke. *International Journal of Stroke*, 8:465-474 DOI: 10.1111/ijs.12135

STROKE01.7 A family-centred approach to the management of lifestyle risk factors for recurrent stroke

Presentations:

- Lawrence M, Pringle J, Kerr S, Booth J. Effectiveness of multimodal lifestyle secondary prevention interventions following stroke and transient ischemic attack: results of a systematic review and meta-analysis. 2014, European Stroke Conference, Nice, France and published in *Cerebrovascular Disorders* 2014;37(suppl 1): Abstract eBook 1–2, DOI: 10.1159/000362854
- Lawrence M, Kerr S, Booth J. Meta-aggregation: its utility as a method for developing evidence syntheses to support an evidence-based approach to healthcare, using stroke as a clinical example. 2015 International Institute of Qualitative Methods 14th Annual Qualitative Methods Conference, Toronto, Canada.
- Lawrence M, Kerr S, Booth J. What works in non-pharmacological stroke secondary prevention: patient & family perspectives. 2015. Scottish Stroke Allied Health Professionals' Forum (SSAHPF) Annual Conference, Stirling, UK.
- Lawrence, M, Kerr S, Booth J. Keeping Well evaluation. 2017 INSSPIRE Seminar (URL: goo.gl/tZtwPd), June, Glasgow Caledonian University.
- Lawrence M, Booth J, Mercer S. An introduction to Mindfulness and its benefits following transient ischemic attack and stroke. *Clinical Rehabilitation*, 2014; 28: 403-15
- Lawrence M, Kerr S, Dennis M, Cheater F, Brady M, Gillespie D, Booth J, 2012. Using the Medical Research Council's framework to develop a complex family-centred behavioural intervention designed to address lifestyle risk factors for recurrent stroke. The Society for Rehabilitation Research, January 2012, Ely, UK.

Posters:

- Lawrence M, Kerr S, Booth J. Are multimodal stroke secondary prevention interventions effective and how are they 'received' by patients and their families? UKSF Conference 2015, Harrogate and published in the *International Journal of Stroke*, 10(suppl. 5): 27
- Lawrence M, Pringle J, Kerr S, Booth J. Stroke survivors' and family members' perspectives of participation in multimodal stroke secondary prevention interventions: results of a qualitative review and meta-aggregation. 2014 European Stroke Conference, Nice, France and published in *Cerebrovascular Disorders* 2014;37(suppl 1): Abstract e-Book 1–2, DOI:10.1159/000362854

STROKE01.8 Mindfulness based stress reduction to support self management of anxiety and depression following stroke: a development study.

Project Number:	STROKE01.8
Status:	In Progress
Project Title:	Mindfulness based stress reduction to support self management of anxiety and depression following stroke: a development study.
Source of funding and total value of award:	Chief Scientist Office, £85,339
Value of funding to NMAHP RU:	£300
Principal investigator/co-applicants:	Lawrence M (PI), Booth J, Mason H (Glasgow Caledonian University), Maxwell M (University of Stirling), Dougall N (Edinburgh Napier University), Grealley M (University of Strathclyde), Mercer M, Jani B (University of Glasgow), Dickson S (Glasgow Caledonian University), Shearer X (PPI co-applicants).
NMAHP RU investigators:	Maxwell M.
Workstream:	Stroke
Start date:	August 2017
Duration:	10 Months

Aim(s):

We aim to co-create an adapted mindfulness based stress reduction course that accounts for common consequences of stroke e.g. communication impairments, fatigue, physical disabilities.

Objectives:

To examine whether we can we co-create an adapted mindfulness based stress reduction course to promote stroke survivors' adherence to the taught course?

To explore whether we can co-create an adapted mindfulness based stress reduction course to promote stroke survivors' adherence to home practice?

Summary:

Anxiety and depression are common after stroke, but people do not always have the skills they need to cope with symptoms. Mindfulness Based Stress Reduction is a standardised, eight-week course that teaches people with

long-term conditions skills, including meditation and mindfulness breathing, to help them to self-manage symptoms of anxiety and depression. Skills taught during the course are practiced at home. Although some people find mindfulness based stress reduction helpful, many people do not complete the whole course or find it difficult to practice at home. Using 'taster sessions' and focus groups, we will work with stroke survivors and other experts to make changes to the standard course. Together we will look at what is taught and how it is taught. We will try to identify changes that will help stroke survivors follow the whole course and practice their new skills, and use them to self-manage symptoms of anxiety and depression. When we have made the changes, we will apply for funding for a research project that will help us to find out if stroke survivors follow the adapted course, including the home practice and whether MBSR is effective in reducing anxiety and depression.

STROKE01.8 Mindfulness based stress reduction to support self management of anxiety and depression following stroke: a development study.

Outcomes/Impact:

Roll out of mindfulness based stress reduction for self-management of anxiety and depression following stroke has potential for significant impact to improve long-term health outcomes for large numbers of stroke survivors and family members. However, to date trials of mindfulness based stress reduction interventions in stroke have been poor quality with equivocal results. High quality randomised controlled trials are required to provide robust evidence. Once we have completed this developmental work i.e. adapted the standardised mindfulness based stress reduction course, we will develop a proposal for a feasibility study for an efficacy trial to submit to the Stroke Association.

Project Number:	STROKE01.9
Status:	In Progress
Project Title:	Peer support for people with aphasia following stroke
Source of funding and total value of award:	The Tavistock Trust for Aphasia, £Confidential
Value of funding to NMAHP RU:	£Confidential
Principal investigator/co-applicants:	Brady M (PI), VandenBerg K (Glasgow Caledonian University) Supervisors: Ali M (Glasgow Caledonian University), Cruice M (City University, London),
NMAHP RU investigators:	VandenBerg K (awarded PhD Fellowship), Ali M, Brady M.
Workstream:	Stroke
Start date:	May 2015
Duration:	4 years

Aim(s):

We aim to co-create an adapted mindfulness based stress reduction course that accounts for common consequences of stroke e.g. communication impairments, fatigue, physical disabilities.

Research questions:

1. What are the prevalence, distribution and principal characteristics of peer support groups for people with aphasia in the UK?
2. Ethnographic investigation of peer support for people with aphasia and mixed methods analysis of online social media feed content
3. What are the factors influencing peer support effectiveness and accessibility, as experienced by facilitators and people with aphasia?

Summary:

An estimated 350,000 people living in the UK have aphasia, an acquired language disorder. One in three stroke survivors are affected to differing degrees of severity. Aphasia affects speaking, understanding speech,

reading and writing and has a significant impact on quality of life, physical and psychological well-being. Improving the evidence base for aphasia support and rehabilitation was highlighted twice within the Top 10 research priorities for life after stroke as identified by stroke survivors, carers and healthcare professionals.

Clinical guidelines recommend community based communication and support groups for “conversation and social enrichment with people who have the training, knowledge, skills and behaviours to support communication”². Peer support groups can offer frequent, accessible and flexible support from individuals who understand the challenges of living with aphasia. Peer support activities have flourished in other healthcare settings including cancer, diabetes and mental health. Earlier discharge to community settings, the integration of health and social care and increasing fiscal constraints on formal therapeutic interaction have spurred interest in peer support activities.

² National Clinical Guideline Centre, 2013 Recommendation 66

Evidence suggests that much can be achieved in supporting the reintegration of people with aphasia back into their communities, networks and participation in activities. However, based on pooled data analyses from five trials (n=413), there are significantly more people dropping out of social support interventions compared to formal SLT interventions ($p = 0.005$, OR 0.51 95% CI 0.32 to 0.82). Social support interventions therefore may not be beneficial, acceptable or feasible for all people with aphasia.

A cross-sectional, UK wide survey will gather primary-source descriptive data from facilitators of community-based communication and support groups for people with aphasia. Respondents to this survey will be invited to participate in an ethnographic investigation of peer support for people with aphasia. Through these interviews and observations we will consider the factors influencing the effectiveness and accessibility of peer support as experienced by facilitators and people with aphasia.

Publications:

- VandenBerg K, Campbell P, Cail A, Brady M (2015) Peer-support for people with aphasia following stroke: A systematic review. *Int J Stroke*, 10: 17–18. DOI:10.1111/ijss.12634_3.

STROKE01.10 Long term consequences and recovery from stroke: what is important to stroke survivors and health professionals?

Project Number:	STROKE01.10
Status:	Complete
Project Title:	Long term consequences and recovery from stroke: what is important to stroke survivors and health professionals?
Source of funding and total value of award:	Chief Scientist Office, PhD Fellowship, £115,047
Value of funding to NMAHP RU:	£115,047
Principal investigator/co-applicants:	Davis B (PI) (Glasgow Caledonian) Supervisors: Pollock A (Glasgow Caledonian University), Williams B (University of Stirling) , Quinn T (University of Glasgow)
NMAHP RU investigators:	Davis B, Pollock A, Williams B.
Workstream:	Stroke
Start date:	August 2012
Duration:	48 Months

Aim(s):

To explore the long-term consequences from stroke and establish what is important to stroke survivors in terms of measurement of long term outcome. Meaningful stroke survivor involvement was central to this proposed programme of work.

Summary:

Phase 1 - Qualitative focus groups and interviews with stroke survivors and health professionals were used to identify long-term consequences of stroke. Nine focus groups of between two and seven stroke survivor participants and nine individual interviews were held over six NHS regions of Scotland (Glasgow, Ayr, Lanarkshire, Lothian, Grampian and Dumfries & Galloway). Participants were long-term stroke survivors with a range of stroke-related impairments including communication, arm function, visual and motor impairment. Ten focus groups of between two and six health professional participants were also held. These health professionals had experience of caring for long term stroke survivors within the same six NHS health

boards across Scotland as the participating stroke survivors. The thematic analysis of focus groups and interviews revealed eight main themes relating to the long-term consequences of stroke; 1) independence, 2) loss of previous self, 3) stroke is a struggle, 4) interaction with others, 5) recovery and the future, 6) close relationships, 7) embracing the challenge of stroke, and 8) other life events. This analysis revealed 34 statements representing those long-term consequences of stroke perceived as important by stroke survivors and health professionals. Phase 2 - Q-methodology was used to prioritise those long-term consequences and analyse using by-person factor analysis. Forty-eight participants (21 stroke survivors and 27 health professionals) across the same 6 Scottish NHS regions as Phase 1 participated within focus groups and interviews. The 34 statements collated from Phase 1 constituted the Q-sets that were sorted by each participant (n=48). By-person factor analysis of the Q sorts yielded three factors, one factor being bipolar which demonstrated directly opposing viewpoints between stroke survivors and health professionals.

STROKE01.10 Long term consequences and recovery from stroke: what is important to stroke survivors and health professionals?

Phase 3 – A review of stroke trials was undertaken to identify whether current outcome measures reflected those consequences identified as important to stroke survivors. This review was focussed on Patient-Reported Outcome Measures (PROMs). The review identified 51 PROMS used within stroke studies involving long-term stroke survivors. Of the 51 identified PROMs three (5.8%) were stroke-specific, namely the Stroke Impact Scale (SIS), Stroke Specific Quality Of Life scale (SS-QOL), and the Stroke-Adapted Sickness Impact Profile (SA-SIP30). The identified PROMs were mapped to the study statements taken directly from the eight main themes within this study. Mapping results demonstrated that the identified PROMs mapped to only a few of the important consequences of stroke. Further research is therefore indicated to provide PROMs that best reflect the stroke survivor perspective for use within future stroke research.

STROKE01.11 Improving stroke clinical trial design and conduct through investigations using a clinical trials resource

Project Number:	STROKE01.11
Status:	Complete
Project Title:	Improving stroke clinical trial design and conduct through investigations using a clinical trials resource
Source of funding and total value of award:	Chief Scientist Office, £173,551
Value of funding to NMAHP RU:	£173,551
Principal investigator/co-applicants:	Ali M (PI) (Glasgow Caledonian University), Brady M (Glasgow Caledonian University), Ford I, Lees KR (University of Glasgow)
NMAHP RU investigators:	Ali M, Brady M.
Workstream:	Stroke
Start date:	August 2010
Duration:	36 Months

Aim(s):

To examine issues surrounding quality of life (QoL), particularly in those who may be underrepresented in stroke research i.e. those with communication impairment or visual impairment.

Objectives:

We conducted secondary analyses of pooled, anonymised stroke clinical trial data within the Virtual International Stroke Trials Archive (VISTA) (STROKE02.7) to examine:

- Inclusion and attrition of patients in whom trial follow-up may be challenging.
- Stroke-induced impairments, outcome measures and patient quality of life (QoL).

Summary:

Anonymised individual Participants' Data (IPD) from a clinical trials archive (VISTA) were utilised. Analysis of data from the general stroke population revealed that 28% experienced aphasia at baseline. In acute stroke clinical

trials, 30% experienced severe/global aphasia and 70% experienced dysarthria at baseline. In the general stroke population, 28% also presented with visual impairment at baseline. In acute stroke clinical trials, this figure was 61%. By 3 months, 18% of those with aphasia at baseline had recovered; aphasia persisted in almost a quarter of patients at 3 months. By 3 months, 40% of those with dysarthria at baseline had recovered but more than a quarter had persistent dysarthria. Recovery from visual impairment occurred in 45% by 3 months, but persisted in 21%. Aphasia at baseline and persistent aphasia at 3 months were associated with poorer functional outcome at 3 months. Eye movement disorders and complete homonymous hemianopia at baseline were associated with poorer functional outcome at 3 months following stroke. The presence of inattention/neglect at baseline in addition to motor stroke was associated with poorer QoL in stroke survivors when compared to those with pure motor stroke at baseline. Presence of other non-motor impairments in addition to motor stroke at baseline showed no significant association with poorer QoL.

Dependence on carers for bathing, toilet use, transfer from bed to chair and mobility were each significantly associated with increased carer strain at the 6 month assessment. Bowel and bladder incontinence were not significantly associated with increased carer strain.

Patient-assessed QoL had a stronger association with the modified Rankin Scale (mRS) than with either of the other common stroke outcome measures (Barthel Index or National Institutes of Health Stroke Scale).

Publications:

- Ali M, Hazelton C, Lyden P, Pollock A, Brady M, on behalf of the VISTA Collaboration, Recovery from Post-Stroke Visual Impairment: Evidence from a Clinical Trials Resource, JNNR 2013 Feb;27(2):133-141
- Ali M, Bath PM, Lyden P, and Brady M, On behalf of the VISTA Collaboration. Representation of People with Aphasia in Randomised Controlled Trials of Acute Stroke Interventions. International Journal of Stroke, 2013 DOI: 10.1111/ijis.12043.
- Ali M, Lyden P, Brady M, on Behalf of the VISTA Collaboration. Aphasia and Dysarthria in Acute Stroke: Recovery and Functional Outcome. International Journal of Stroke 2013 DOI: 10.1111/ijis.12067.
- Ali M, Fulton R, Quinn T, Brady M, on behalf of the VISTA Collaboration, How well do Standard Stroke Outcome Measures Reflect Quality of Life? A Retrospective Analysis of Clinical Trial Data. Stroke 2013; doi: 10.1161/STROKEAHA.113.001126.

Presentations

- Ali M, Hazelton C, Brady M, Lyden P, Pollock A, On Behalf of the VISTA Collaboration. Recovery from Post-Stroke Visual Impairment: Evidence from a Clinical Trials Resource. UK Stroke Forum, 2011.
- Ali M, Hazelton C, Brady M, Lyden P, Pollock A, On Behalf of the VISTA Collaboration. Recovery from Post-Stroke Visual Impairment: Evidence from a Clinical Trials Resource. International Stroke Conference 2012, New Orleans, USA.
- Ali M, Hazelton C, Lyden P, Pollock, Brady M on behalf of the VISTA Collaboration. Recovery from Post-Stroke Visual Impairment: Evidence from the Virtual International Stroke Trials Archive (VISTA), European Stroke Conference 2012, Lisbon, Portugal.

- Ali M, Lyden P, Brady M, on behalf of the VISTA Collaboration. Evolution of Post-Stroke Aphasia and Dysarthria in Acute Stroke: Analysis of Data from the Virtual International Stroke Trials Archive (VISTA), European Stroke Conference 2012, Lisbon, Portugal.
- Ali M, Lyden P, and Brady M, On Behalf of the VISTA Collaboration. Evolution of Aphasia in Acute Stroke, European Federation of Neurological Societies 2012, Stockholm, Sweden.
- Ali M, Fulton R, Bath PM, and Brady M, on behalf of the VISTA Collaboration. Impairment-Based determinants of Quality of Life after Stroke. UK Stroke Forum 2013, Harrogate, UK
- Ali M, Hazelton C, Lyden P, Pollock A, Luby M, Warach S, Weimar C, Brady M, On Behalf of the VISTA-Plus Collaboration, Prevalence of Visual Impairments after Stroke. Society for Research in Rehabilitation 2013, Nottingham, UK.

Posters:

- Ali M, Bath P, Lyden P, Brady M on behalf of the VISTA Collaboration, Inclusion and Attrition of Patients with Aphasia in Acute Stroke Clinical Trials, European Stroke Conference 2012, Lisbon, Portugal.
- Ali M, Bath PM, Lyden P, and Brady M, On Behalf of the VISTA Collaboration. Inclusion and Retention of Patients with Aphasia in Acute Stroke Clinical Trials. European Federation of Neurological Societies 2012, Stockholm, Sweden.
- Ali M, Bath PM, Lyden P, and Brady M, On Behalf of the VISTA Collaboration. Inclusion of Patients with Aphasia in Acute Stroke Clinical Trials: Geographical and Longitudinal Variations. UK Stroke Forum 2012. Harrogate, UK.
- Ali M, Fulton R, Quinn T, Brady M, on behalf of the VISTA Collaboration. How well do Trial Outcome Measures Reflect Patients' Quality of Life (QoL)? A Retrospective Analysis of Clinical Trial Data. European Stroke Conference 2013, London UK.
- Ali M, Fulton R, Lincoln N, Brady M on behalf of the VISTA-Rehab Collaboration. Carer Strain and Dependence for Activities of Daily Living. A Retrospective Analysis of Clinical Trial Data. European Stroke Conference 2013, London UK.
- Ali M, Fulton R, Bath PMW, and Brady M, On Behalf of the VISTA Collaboration Impairment Based Determinants of Quality of Life after Stroke, European Stroke Conference 2014, Nice, France.

Project Number:	STROKE01.12
Status:	Complete
Project Title:	Hearing after stroke
Source of funding and total value of award:	Forth Valley Sensory Centre, £22,823
Value of funding to NMAHP RU:	£22,823
Principal investigator/co-applicants:	Pollock A (PI), Brady M, Campbell P (Glasgow Caledonian University), Dick M (Forth Valley Sensory Centre)
NMAHP RU investigators:	Pollock A, Brady M, Campbell P.
Workstream:	Stroke
Start date:	August 2013
Duration:	6 months

Aim(s):

1. To comprehensively review the evidence relating to hearing problems after stroke
2. To determine gaps in evidence relating to hearing problems after stroke
3. To explore feasibility of assessing hearing problems after stroke within an acute stroke in-patient setting
4. To develop a research proposal and funding application to support key research to meet the key gaps in evidence

Summary:

A systematic review of all evidence relating to hearing problems after stroke was completed. The key gaps in evidence were systematically identified from the synthesised research evidence. Clear recommendations for future research were written. Discussions took place with the clinical staff involved with Forth Valley One Stop Transformation project and those involved in the new vision 'clinic' which is operating within Forth Valley Hospital. These discussions explored the feasibility of introducing a standardised assessment of hearing. Contact and, where appropriate, visits to known experts in the field of hearing after stroke took place. This was used to systematically gather information pertaining to perceived good practice in different areas of Scotland.

Presentations:

- Campbell P. [invited] "Hearing after stroke". College of

Occupational Therapy (COT) SSNP Conference 2016. Campbell P, Visch-Brink E, Pollock A, Brady M. Post-stroke aphasia and peripheral hearing loss: A systematic review of prevalence, audiological assessment and hearing aid use. Royal College of Speech and Language Therapy 'Mind the Gap' Conference 2014, Leeds, UK.

- Campbell P, Visch-Brink E, Pollock A, Brady M. Aphasia after stroke and peripheral hearing loss: A systematic review of prevalence, audiological assessment and hearing aid use Society for Research and Rehabilitation, June 2014, Glasgow, UK.

Published Abstracts:

- Campbell P, Visch-Brink E, Pollock A, Brady M. Aphasia after stroke and peripheral hearing loss: A systematic review of prevalence, audiological assessment and hearing aid use Clin Rehabilitation February 17, 2015. doi: 10.1177/0269215515570099
- Campbell P, Pollock A, Brady M. Should hearing be screening in the first 30 days after an acute stroke: a systematic review (2014), Communication. International Journal of Stroke, 9: 38–39. doi: 10.1111/ij.s.12374_15.

Posters:

- Campbell P, Pollock A, Brady M. Should hearing be screened in the first 30 days after an acute stroke: a systematic review. UK Stroke Forum, Harrogate, UK. December 2-4th 2014.

Project Number:	STROKE01.13
Status:	Complete
Project Title:	Fluoxetine Or Control Unlocks Stroke (FOCUS)
Source of funding and total value of award:	NIHR SRN Portfolio Development Application, £2,500
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Mead, G (PI) Dennis, M (University of Edinburgh), Brady MC (Glasgow Caledonian University), Forbes, J, Hackett M (University of Sydney), House A (University of Leeds), Lewis S, MacLeod M, Perry D, Sandercock P (University of Edinburgh), Sullivan F, van Wijck F (Glasgow Caledonian University, Watkins C (University of Central Lancashire).
NMAHP RU investigators:	Brady MC.
Workstream:	Stroke
Start date:	July 2011
Duration:	6 months

Aim(s):

- To support the development of an application for a pilot RCT of Fluoxetine versus a placebo.
- To discuss the provision of information, the consent and recruitment of people with aphasia to the FOCUS trial.

Summary:

Fluoxetine is a selective serotonin re-uptake inhibitor. Frequently used to treat post-stroke depression and emotionalism it may also have beneficial effects on brain recovery after injury including neurogenesis, neuroprotection and modulation of adrenergic activity. Small trials have demonstrated that fluoxetine improves motor function after stroke while the largest (n=118) showed dependency at 3 months was also reduced. This writing group sought to inform the development of an application for a multicentre start-up phase of a randomised, double-blind placebo controlled trial of fluoxetine 20mg daily. For people with persisting neurological deficits after stroke they would start between 5 and 15 days after their stroke continue for

6 months. The primary outcome chosen was the modified Rankin score. The pilot trial sought to establish: a trial management team; an IT system to manage web-based randomisation, drug allocation, stock control, follow-up, data collection and verification; and to determine important aspects of feasibility including recruitment, medication adherence, questionnaire response and follow-up rates.

Outcomes/Impact:

Global cognitive impairment is a common consequence of stroke, and some stroke patients will have had dementia prior to their stroke. Thus, many people with acute stroke are often considered unable to consent to participation in research and proxy consent is standard. Aphasia is a common neurological consequence of stroke, affecting several aspects of language including speaking, writing, reading and understanding but not necessarily impacting on self determination. Ethically, patients with capacity to consent should be enabled to engage in the information provision and consent process rather than making an assumption of incapacity.

An 'easy access' aphasia accessible version of the information sheet and consent form for this trial was co-produced in an iterative process with the members of Speakability in Dundee. An application for the FOCUS randomised controlled trial pilot study was developed, submitted and funded by the Chief Scientist Office. The adapted information sheets and consent forms were approved by the relevant NHS ethics committee. The FOCUS research team also successfully applied to the NHIR HTA for funding to support the definitive trial which sought to recruit more than 3000 participants and proposed a planned meta-analysis with the AFFINITY and EFFECTS trials. The trial has recently closed recruitment with 3127 people participating in the study. To our knowledge this is the first drug trial that developed accessible versions of their information sheet and consent form with the participation of people with aphasia.

Posters:

- Mead G, Dennis M, Brady MC. Developing easy access patient information booklets and consent forms for use in multicentre stroke trials. 2nd International Clinical Trials Methodology Conference, Edinburgh, UK.

Published Abstract:

- Mead G, Dennis M, Brady MC. Developing easy access patient information booklets and consent forms for use in multicentre stroke trials. 2nd International Clinical Trials Methodology Conference, Edinburgh, UK. Trials201314(Suppl 1):P58

STROKE01.14 Living with dysarthria: evaluation of the feasibility of the implementation of a group intervention programme for stroke patients and carers, addressing the impact of dysarthria

Project Number:	STROKE01.14
Status:	Complete
Project Title:	Living with dysarthria: evaluation of the feasibility of the implementation of a group intervention programme for stroke patients and carers, addressing the impact of dysarthria
Source of funding and total value of award:	Stroke Association, £54,293
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Mackenzie C (PI) (University of Strathclyde), Brady M (Glasgow Caledonian University), Paton G (Greater Glasgow and Clyde NHS).
NMAHP RU investigators:	Brady M.
Workstream:	Stroke
Start date:	July 2010
Duration:	18 months

Aim(s):

To examine the feasibility and acceptability of an eight-session weekly group intervention programme, Living with Dysarthria, designed for people with chronic dysarthria following stroke and their main communication partners.

Research questions:

- How feasible is the Living with Dysarthria programme?
- How do participants perform prior to and at the conclusion of the programme on measures of speech intelligibility, communication effectiveness, general well-being, quality of communication life, and knowledge of stroke and dysarthria?
- What personal goals do participants have for the programme and how do they rate their achievement of these?

Summary:

Dysarthria is a motor disorder which results from abnormalities in speed, strength, steadiness, range, tone, or accuracy of movements required for the control of speech. Dysarthria is a frequent and persisting sequel to stroke and arises from varied lesion locations. Speech impairments of dysarthria relate to articulation, phonation, respiration, nasality and prosody, and affect intelligibility, audibility, naturalness, and efficiency of spoken communication. The broad life implications of acquired dysarthria are recognized, but they have received little attention in stroke rehabilitation. Although the presence of dysarthria is well documented, for stroke there are scant data on presentation and the effectiveness of intervention outcomes.

Two groups of people with dysarthria and available family members or carers were identified from the speech and language therapy case records for the previous six years in two Scottish hospitals. Group 1: seven people with dysarthria and four family members; Group 2: five people with dysarthria and three family members.

Speech intelligibility, communication effectiveness, general well-being, quality of communication life, and knowledge of stroke and dysarthria were assessed pre- and post-programme. Recruitment to the programme was lower than anticipated and below target. The 12 people with dysarthria were recruited from 62 potential participants identified following screening of the patient records using the study eligibility criteria. The programme was viable with only minor content alterations, in community accommodation, and with good participant engagement. Group median score changes were in a positive direction for all measures and effect sizes ranged from 0.17 (quality of communication life) to 0.46 (intelligibility). The participant engagement and performance results from the piloting of the programme indicate that the Living with Dysarthria programme is feasible and has potential for effecting positive change.

Outcomes/Impact:

This research built upon the findings of a previous CSO funded study (reported in some of the publications and presentations listed below). Similarly, this research project has in turn informed the development of further pre-clinical dysarthria work contributing to a large multi-disciplinary writing group funded by the NIHR Stroke Clinical Research Network and awarded to the University of Manchester. There was much interest in this intervention but the group ultimately concluded that additional pre-clinical work was required before taking this forward to a full clinical trial. This additional work has included a survey of the current SLT approaches for dysarthria after stroke in the UK which has been led by colleagues from the University of Newcastle and City, University of London.

Publications:

- Brady MC, Clarke A, Dickson S, Paton G, Barbour R. Impact of dysarthria following stroke on social participation. *Disability and Rehabilitation*. 2011; 33(3):178-186. doi:10.3109/09638288.2010.517897.
- Brady MC, Clarke A, Dickson S, Paton G, Bar-

bour R. Dysarthria following stroke – the patient's perspective on management and rehabilitation. *Clinical Rehabilitation*. 2011;25:935-952. doi:10.1177/0269215511405079.

- Mackenzie, C., Kelly, S., Paton, G., Brady, M. and Muir, M. (2013), The Living with Dysarthria group for post-stroke dysarthria: the participant voice. *International Journal of Language & Communication Disorders*, 2013 Jul-Aug;48(4):402-20. doi: 10.1111/1460-6984.12017. Epub 2013 Apr 17.
- Mackenzie C, Paton G, Kelly S, Brady M, Muir M. The Living with Dysarthria group: implementation and feasibility of a group intervention for people with dysarthria following stroke and family members. *International Journal of Language and Communication Disorders*. 2012; 47(6):709-724.

Other dissemination activity:

- Brady MC, Dickson, Clarke, Paton, Barbour. Patients' perceptions of rehabilitation and management strategies adopted during life with dysarthria. UK Stroke Forum 2010, Glasgow Nov-Dec.
- Brady MC, Clark A, Barbour RS, Dickson S, Paton G. Understanding the impact on social participation of an acquired speech impairment. *International Institute for Qualitative Methodology Qualitative Health Research Conference 2010*. Canada.
- Mackenzie C, Brady MC, Paton G, MacLeod S, Muir M. The Living with Dysarthria programme for post-stroke dysarthria. *Comité Permanent de Liaison des Orthophonistes (CPLOL) Congress, 25-26th May 2012, The Hague, The Netherlands*.

STROKE01.15 Can an arts based creative engagement intervention following stroke improve psychosocial outcomes? A feasibility trial of a creative engagement intervention for in-patient rehabilitation

Project Number:	STROKE01.15
Status:	Complete
Project Title:	Can an arts based creative engagement intervention following stroke improve psychosocial outcomes? A feasibility trial of a creative engagement intervention for in-patient rehabilitation.
Source of funding and total value of award:	Chief Scientist Office, £214,647
Value of funding to NMAHP RU:	£0, no costs applicable for Prof Brian Williams
Principal investigator/co-applicants:	Morris J and Kelly C (PI), Joice S (University of Dundee), Williams B (University of Stirling), Donnan P (University of Dundee), Mead G (University of Edinburgh), Kroll T (University of Dundee).
NMAHP RU investigators:	Williams B.
Workstream:	Stroke
Start date:	March 2013
Duration:	24 Months

Aim(s):

Art participation within stroke rehabilitation may confer psychosocial benefits however intervention and outcome definition for effectiveness evaluation is challenging. This study modelled a Tayside Creative Engagement Intervention to define an intervention protocol and identify potential outcome measures. A feasibility randomised controlled trial provided estimation of recruitment, retention, potential effects and effect of preference.

Summary:

Phase one involved interviews and qualitative analysis with artists and previous participants of an existing arts programme. The Creative Engagement Intervention appeared to enhance mood, physical recovery, communication and self-esteem possibly mediated by self-efficacy, control of recovery and hope. Our explanatory model illustrated intervention components and mechanisms of action and informed intervention protocol development and measure-

ment selection for the Phase 2 feasibility trial.

In the feasibility trial, 41 stroke survivors were randomised to the Creative Engagement Intervention and 40 to usual care (n=40). The Intervention group received up to eight art sessions in groups and one-to-one with artists. A total of 29% (95% CI 0.28 to 0.39) of the admitted population was recruited. Retention at end of intervention (T2) was 71 (88%) and 62 (77%) at 3-month follow-up (T3). Preference for art and test burden appeared to influence intervention drop-out rate, given that the eight dropouts in the intervention group had low preference for art.

Between-group comparison favoured the creative engagement intervention for social participation, positive affect and self-efficacy for art but other differences favoured –those receiving usual care for performance on measures of self-esteem (p<0.05). Change scores were however higher for intervention group in six primary outcome domains and eight secondary outcome domains compared to those receiving usual care. Preference for art participation appeared important to both retention and intervention responses.

Outcomes/Impact:

Patients and staff valued the creative engagement intervention and conducting a randomised controlled trial was feasible. The intervention may benefit positive affect and social participation underpinned by self-efficacy for art. However other predicted benefits were not realised. Preference for art appears important to retention and outcome. Drop-out and stroke recovery itself may have influenced findings. Intervention and outcomes will be further refined before undertaking a full-scale cluster or stepped-wedge trial.

Publications:

- Morris JH, Kelly C, Toma M, Kroll T, Joice S, Mead G, Donnan P, Williams B. Art participation for psychosocial wellbeing during stroke rehabilitation: a feasibility randomised controlled trial 2017, *Disability and Rehabilitation* (in Press).
- Kelly C, Morris J. Practice makes research, makes better practice. Participatory visual arts Participatory visual arts as a therapeutic inpatient rehabilitation intervention for stroke. 2017. *engage 39:Visual Arts and Wellbeing*, 2017,
- Morris JH, Kelly C, Toma M, Kroll T, Joice S, Mead G, Donnan P, Williams B. Feasibility study of the effects of art as a creative engagement intervention during stroke rehabilitation on improvement of psychosocial outcomes: study protocol for a single blind randomized controlled trial: the ACES study. *Trials*. 2014 Sep 28;15:380. doi: 10.1186/1745-6215-15-380.
- Morris JH, Toma M, Kelly C, Joice S, Kroll T, Mead G, Williams B. Social context, art making processes and creative output: A qualitative study exploring mechanisms by which participation in an art programme may lead to perceived psychosocial benefits during stroke rehabilitation. *Disability and Rehabilitation* 2015. <http://dx.doi.org/10.3109/09638288.2015.1055383>

Presentations:

- Kelly C, A Creative Engagement Intervention (CEI) Protocol. The Third International Teaching Artist Conference – Best, next and radical practice in participatory arts, August 2016, Edinburgh, UK.
- Kelly C, Art participation in stroke rehabilitation. Arts & Health Network Scotland, Falkirk, March 2016.
- Morris J, Kelly C, Kroll T, Joice S, Mead G, Donnan P, Williams B, Is evaluation of psychosocial effects of an arts based creative engagement intervention during in-patient stroke rehabilitation possible? A feasibility randomised controlled trial (RCT). UK Stroke Forum December 2015, Liverpool, UK.
- Morris J, Kelly C. [Invited] Art participation in stroke rehabilitation. Welsh Stroke Forum, September 2015,
- Toma M, Morris JH, Kelly C, Kroll T, Joice S, Mead G, Williams B. Engages the parts that other therapies cannot reach: experiences of stroke survivors, artists and healthcare staff of an arts based creative engagement intervention in in-patient rehabilitation. UK Stroke Forum, 4th December 2013, Glasgow, UK.

Posters:

- Morris J, Kelly C. An art based creative engagement intervention for in-patient stroke rehabilitation: how does participant preference influence retention and outcomes in a randomised controlled feasibility trial? World Congress of Neurorehabilitation, May 2016 Philadelphia, USA.

Project Number:	STROKE01.16
Status:	Complete
Project Title:	Factors associated with fatigue in non-depressed stroke patients
Source of funding and total value of award:	NIHR (Stroke Research Network - Portfolio Development), £2,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Drummond A (PI) (University of Nottingham), Pollock A (Glasgow Caledonian University), Cooper A (Swansea University), Kelly M (Patient Representative), Knapp P (University of Hull), Lincoln N (University of Nottingham), Mead G (University of Edinburgh/NHS Lothian), Mistri A (University of Leicester), Morgan C (Patient Representative), Sprigg N (University of Nottingham), Tyrell P (Salford Royal Hospital's Foundation Trust), Ward N (National Hospital for Neurology and Neurosurgery)
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	December 2011
Duration:	12 months

Aim(s):

To develop a funding application to support research relating to factors associated with fatigue in non-depressed stroke patients.

Summary:

This funding led to the collaborative development of a funding application to The Stroke Association for the NotFAST study (STROKE01.17).

Outcomes/Impact:

The NotFAST study was funded by the Stroke Association.

Project Number:	STROKE01.17
Status:	Complete
Project Title:	Nottingham Fatigue After Stroke (NotFAST study): Understanding the nature of the clinical problem and determining factors associated with fatigue in stroke patients without depression
Source of funding and total value of award:	The Stroke Association, £170,082
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Drummond A (PI) (University of Nottingham), Pollock A (Glasgow Caledonian University), Cooper A (Swansea University), Kelly M (Patient Representative), Knapp P (University of Hull), Lincoln N (University of Nottingham), Mead G (University of Edinburgh/NHS Lothian), Mistri A (University of Leicester), Morgan C (Patient Representative), Sprigg N (University of Nottingham), Tyrell P (Salford Royal Hospital's Foundation Trust), Ward N (National Hospital for Neurology and Neurosurgery)
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	January 2013
Duration:	36 months

Aim(s):

To determine the frequency of fatigue in the absence of depression and to identify associated factors as a means to determine potential management strategies.

Summary:

Methods: Participants were recruited from four stroke units and assessed within six weeks of first stroke. Fatigue was measured using the Fatigue Severity Scale. The assessment included the Rivermead Mobility Index, Nottingham Extended Activities of Daily Living scale, Beck Anxiety Index, Brief Assessment Schedule Depression Cards, Sleep Hygiene Index, 6m walk test and measures of cognitive ability.

Results: Of the 317 participants recruited, 268 were assessed and 115 (43%) had post-stroke fatigue, with 71 (62%) of these reporting this to be a new symptom. Multivariate analysis using Fatigue Severity Scale as the outcome variable found pre-stroke Fatigue Severity Scale, having a spouse/partner, Rivermead Mobility Index, Brief Assessment Schedule Depression Cards and Beck Anxiety Index scores accounted for approximately 47% of the variance in Fatigue Severity Scale.

Outcomes/Impact:

Fatigue is a common problem in stroke survivors without depressive symptoms. Pre-stroke fatigue, low mood and impaired mobility were predictive of post-stroke fatigue.

Publications:

- Wu, S., Kutlubae, M., Chun, H., Cowey, E., Pollock, A., Macleod, M., Dennis, M., Keane, E., Sharpe, M. and Mead, G. (2016) Interventions for post-stroke fatigue. Cochrane Database of Systematic Reviews, (7, Art. No.: CD007030. DOI: 10.1002/14651858.CD007030.pub3.).
- McGeough, E., Pollock, A., Smith, L.N., Dennis, M., Sharpe, M., Lewis, S., Mead, G.E. (2010) Interventions for Fatigue After Stroke. Stroke, 41, pp. e564-e565.

Presentations:

- S Wu, M A Kutlubae, HY Chun, E Cowey, A Pollock, MR Macleod, M Dennis, EC Keane, M Sharpe, GE Mead. Interventions for post-stroke fatigue: A systematic review and meta-analysis. International Journal of Stroke. 2015; 10 (Suppl. 2): 111

Project Number:	STROKE01.17
Status:	Complete
Project Title:	Exploring the barriers and facilitators to maintaining engagement in physical activities after the end of post-stroke rehabilitation: a qualitative study of stroke survivors, caregivers and stroke physiotherapists.
Source of funding and total value of award:	Chief Scientist Office, £128,429
Value of funding to NMAHP RU:	£1,579.50
Principal investigator/co-applicants:	Morris J (PI) (University of Dundee), Williams B (University of Stirling), Kroll T (University of Dundee), Joice S (University of Dundee), Oliver T (University of Dundee).
NMAHP RU investigators:	Williams B.
Workstream:	Stroke
Start date:	January 2011
Duration:	18 Months

Aim(s):

1. To explore views and experiences of stroke survivors, and roles played by caregivers and physiotherapists to identify issues influencing PA participation after rehabilitation.
2. To identify strategies to support survivors to engage in long-term participation in PA.

Summary:

Regular participation in physical activity after stroke is important for function, fitness, physical and mental and health. However levels PA participation after stroke are low. Detailed understanding of the beliefs, barriers and facilitators underpinning physical activity behaviour after stroke will enable development of effective interventions to support PA participation in this population.

In-depth interviews (n=38) were conducted with stroke survivors from Tayside and Fife to examine their beliefs and attitudes to PA after stroke. Carers (n=12) and physiotherapists (n=15) participated in separate focus groups to

examine their perceived roles in supporting stroke survivors to be active after rehabilitation.

Survivor attitudes towards physical activity were constructed from beliefs about stroke and the role of physical activity in recovery. Experiences of physical activity and perceived social drivers for recovery also influenced attitudes and therefore the types and levels of physical activity that survivors engaged in. Motivational and volitional barriers were identified which were appraised by survivors in terms of motivation and capability to overcome them. Physiotherapists' role in supporting physical activity was facilitatory but limited by perceptions about specialism, role boundaries, role restrictions and safety, leading to inconsistencies in physical activity support strategies. Carers adopted enabling partnerships for recovery, using common-sense motivational measures to maintain and improve their partners' recovery. Strategies to support participation should be enjoyable, provide social support and match perceived capability. Survivors were particularly enthusiastic about being active outdoors.

Outcomes/Impact:

Our findings suggested the need for development of effective complex interventions, to support physical activity after stroke. Intervention should be based on sound understanding of psychosocial influences on physical activity participation and include components at individual, family, professional and organisational levels.

Publications:

- Morris JH, Oliver T, Kroll T, Joice S, Williams B. Physical activity participation in community dwelling stroke survivors: synergy and dissonance between motivation and capability. A qualitative study. *Physiotherapy* 103 (2017) 311–321 <http://dx.doi.org/10.1016/j.physio.2016.05.001>
- Morris J. Body, Person and Environment: why promoting PA with stroke survivors requires holistic thinking. *Brain Impairment* 2016, <http://dx.doi.org/10.1017/Brlmp.2016.4>
- Morris J, Oliver T, Kroll T, Joice S, Williams B (2014). From physical and functional to continuity with pre-stroke self: A qualitative exploration of stroke survivors', carers' and physiotherapists' perceptions of physical activity after stroke. *Disability and Rehabilitation*. DOI: 10.3109/09638288.2014.907828 ISSN: 0963-8288
- Morris J, Oliver T, Kroll T, MacGillivray S (2012). The importance of psychological and social factors in influencing the uptake and maintenance of physical activity after stroke: a structured review of the empirical literature. *Stroke Research and Treatment*; Article ID 195249, doi:10.1155/2012/195249 ISSN1747-4949

Published Abstract

- Morris JH, Oliver T, Williams B, Joice S, Kroll T (2013). From physical and functional towards identity enhancing and life-fulfilling: exploring stroke survivors, carers and physiotherapists experiences of physical activity after stroke. *International Journal of Stroke*; 8

(Suppl. 3); December 2013; 1–75 ISSN: 1747-4949.

- Oliver T, Morris J, Kroll T, Williams B, Joice S (2012). Motivation and capability: the dynamic interplay of attitudes, beliefs and experiences that influence decisions to engage in physical activity after stroke. *International Journal of Stroke*; 7 (Suppl. 2); 1–79. ISSN: 1747-4949.

Presentation:

- Oliver T, Morris J, Kroll T, Williams B, Joice S (2012). Motivation and capability: the dynamic interplay of attitudes, beliefs and experiences that influence decisions to engage in physical activity after stroke. UK Stroke Forum, December, Harrogate, UK.
- Morris J, McFarlane S, MacGillivray S (2012).
- Interventions to promote long-term participation in physical activity after stroke: an evidence synthesis. UK Stroke Forum, Harrogate, 4th December.

Poster:

- Morris J, Kroll T, Oliver T, Macgillivray S (2010) Barriers and facilitators to long-term engagement in physical activity following stroke and interventions to support engagement: A literature review. American Public Health Association Seattle, October 12th.

STROKE01.19 Too much sitting in extended bouts in stroke survivors: a qualitative study to inform novel interventions

Project Number:	STROKE01.19
Status:	In Progress
Project Title:	Too much sitting in extended bouts in stroke survivors: a qualitative study to inform novel interventions
Source of funding and total value of award:	Chief Scientist Office, £182,062
Value of funding to NMAHP RU:	£798
Principal investigator/co-applicants:	Fitzsimons C/Niven A (PI), Morris J), Chastin S(Glasgow Caledonian University, Mead G. (University of Edinburgh)
NMAHP RU investigators:	Morris J.
Workstream:	Stroke
Start date:	July 2015
Duration:	34 Months

Aim(s):

Informed by the COM-B system for behaviour change (Michie, van Stralen, & West, 2011), the aims of this study are to investigate the perceived psychological and physical capacity and motivation of stroke survivors to reduce or alter the pattern of accumulation of their sedentary time, to identify opportunities (both physical opportunity afforded by the environment and social opportunity) for behaviour change and to develop an intervention strategy. The study aimed to interview 30 stroke survivors three months after their stroke.

Summary:

Interviews have been conducted with thirty-one stroke survivors at 3 months posts stroke (15 females; 16 males). An initial framework has been developed and will be applied to the remaining transcripts by one researcher, with double coding by a second researcher to maintain reliability of coding. Initial findings from the analysis of the qualitative interviews suggest that the concepts of the COM-B model are proving relevant to stroke survivors' sedentary behaviours. Once further analysis has been undertaken we

shall use the Behaviour Change Wheel (Michie et al., 2011) to identify intervention functions to ultimately develop a comprehensive theoretical and evidence based intervention strategy..

Poster:

- "Sitting it's an old age thing- stroke survivors" perceptions of sedentary behaviour" Scottish Physical Activity Research Connections (SPARC); Edinburgh, UK. 26th October 2016
- "Too much sitting in extended bouts in stroke survivors: a qualitative study to inform novel interventions" UK Stroke Forum, Liverpool, UK. 28-30th November 2016

Presentations:

- "Too much sitting in extended bouts in stroke survivors: a qualitative study to inform novel interventions" Stroke and sedentary behaviour seminar at Physical Activity for Health research Centre, University of Edinburgh. 23rd November 2016

Project Number:	STROKE01.20
Status:	Complete
Project Title:	Life after stroke - nurse research priorities
Source of funding and total value of award:	Chest Heart & Stroke Scotland, £11,461
Value of funding to NMAHP RU:	£1,788
Principal investigator/co-applicants:	Rowat A (PI) (Edinburgh Napier University), Pollock A (Glasgow Caledonian University), Booth J (Glasgow Caledonian University), Lawrence M (Glasgow Caledonian University)
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	August 2014
Duration:	12 Months

Aim(s):

We aimed to reach consensus on the Top Ten stroke nursing research priorities.

Summary:

We built on a previously completed James Lind Alliance research prioritisation project, and used James Lind Alliance methodologies.

Participants: nurses (qualified or unqualified) working in stroke care in Scotland.

Interim priority setting: participants selected their personal top 10 from 226 unique unanswered research questions relating to life after stroke which were determined from stroke survivors, carers and health professionals during the James Lind Alliance project. We distributed the list of 226 in person at the Scottish Stroke Nurses Forum annual conference, providing dedicated time for completion; and by email/post to all members. The top shared priorities were objectively identified using a scoring system.

Consensus meeting: A purposively selected group of nurses, representing a range of stroke care settings, role/grades and geographical locations debated and reached

consensus on the Top Ten priorities for stroke nursing research. 97 nurses participated in the interim priority setting process. Analysis of these data identified the shared Top 28 research priorities. A total of 27 nurses attended the final consensus meeting and agreed the Top 10 research priorities relating stroke nursing.

Outcomes/Impact:

The research agenda for stroke nursing has now been clearly defined and nurses and nursing-oriented research organisations should establish collaborative activities to address these research priorities.

Top Ten nursing research priorities relating to life after stroke:

- What are the best ways to manage and/or prevent fatigue?
- What are the best ways to improve cognition after stroke?
- What are the best ways to manage urinary and faecal incontinence?
- What are the best ways to manage altered mood and emotion after stroke?

- What are the best ways to promote self-management and self-help after stroke?
- What are the best ways of helping stroke survivors and their families come to terms with uncertainty of prognosis and the long-term consequences of stroke?
- Can a goal setting approach help recovery after stroke?
- What is the impact of thrombolysis on emotion, cognition and communication?
- Is a 'young stroke environment' better than other stroke rehabilitation environments at improving recovery of young people after stroke?
- What is the optimal amount and intensity of therapy provided by nurses for patients with stroke?

Publications:

- Rowat, A., Pollock, A., St George, B., Cowey, E., Booth, J., Lawrence, M. and Scottish Stroke Nurses Forum (SSNF). (2016) Top 10 research priorities relating to stroke nursing: a rigorous approach to establish a national nurse-led research agenda. *Journal of Advanced Nursing*, 72 (11), pp. 2831-2843.

Published Letter:

- Pollock, A., St George, B., Rowat, A. and the Scottish Stroke Nurses Forum (SSNF). (2015) Top 10 research priorities relating to stroke nursing. *International Journal of Stroke*, 10, pp. 164.

STROKE02

ARM FUNCTION



The programmes proposed are fundamental to NMAHPs' contribution to underpin safe, effective and person-centred care, and will enable the Unit to continue to provide the evidence to inform strategy in a way that supports change and improvements in practice.



STROKE02.1 Quality of Life and Health Utilities at 3 Months after Acute Ischaemic Stroke

Project Number:	STROKE02.1
Status:	Complete
Project Title:	Quality of Life and Health Utilities at 3 Months after Acute Ischaemic Stroke
Source of funding and total value of award:	Genentech £20,000
Value of funding to NMAHP RU:	£6,000
Principal investigator/co-applicants:	Ali M (PI) (Glasgow Caledonian University), Fulton R, Quinn T (University of Glasgow), Veenstra D (University of Washington), Chen E (Genentech) Bath P (University of Nottingham), Brady MC (Glasgow Caledonian University), Lees KR (University of Glasgow), on behalf of the VISTA Collaboration
NMAHP RU investigators:	Ali M, Brady MC.
Workstream:	Stroke
Start date:	April 2014
Duration:	12 months

Aim(s):

Health utilities assign preference weights to specific health states and are required for cost effectiveness analyses. Existing health utilities for stroke inadequately reflect the spectrum of post-stroke disability. Using international stroke trial data, we sought to calculate health utilities stratified by disability to improve precision in future cost-effectiveness analyses.

Summary:

We used European Quality of Life Score (EQ-5D-3L) data from the Virtual International Stroke Trials Archive (VISTA) to calculate health utilities, stratified by modified Rankin Scale scores (mRS) at 3 months. We applied published value sets to generate health utilities, and validated these using ordinary least squares regression, adjusting for age and baseline National Institutes of Health Stroke Scale (NIHSS) scores.

We included 3858 patients with acute ischemic stroke in our analysis (mean age: 67.5+-12.5, baseline NIHSS: 12+-5). We derived health utilities using value sets from 13 countries and observed significant international variation in health utilities distributions (Wilcoxon signed-rank test $p < 0.0001$, compared with UK values). For mRS=0, mean health utilities ranged from 0.88 to 0.95; for mRS=5, mean health utilities ranged from -0.48 to 0.22. Ordinary Least Squares (OLS) regression generated comparable health utilities (for mRS=0, health utilities ranged from 0.9 to 0.95; for mRS=5, health utilities ranged from -0.33 to 0.15).

Patients' mRS scores at 3 months accounted for 65–71% of variation in the generated health utilities.

Outcomes/Impact:

We generated health utilities stratified by dependency level, using a common trial endpoint, and describing expected variability when applying diverse value sets to an international population. Our findings will improve future cost-effectiveness analyses. However, care should be taken to select appropriate value sets.

Publications:

- Ali M, Maclsaac R, Quinn TJ, Bath PM, Veenstra DL, Xu Y, Brady MC, Patel A, Lees KR, on behalf of the VISTA Collaborators. Dependency and health utilities in stroke: Data to inform cost-effectiveness analyses. *European Journal of Stroke*. (2017), 2 (1). pp. 70-76. ISSN 2396-9873.

Other dissemination activity::

- Ali M, Fulton RL, Quinn TJ, Bath PM, Veenstra DL, Xu Y, Brady MC on behalf of the VISTA Collaboration. Quality of Life after Acute Ischemic Stroke: Analysis of Utility Data from the Virtual International Stroke Trials Archive (VISTA). European Stroke Organisation Conference, 17-19th April 2015, Glasgow, UK.

STROKE02.2 A Cochrane overview of interventions to improve upper limb function after stroke (OSCAR)

Project Number:	STROKE02.2
Status:	Complete
Project Title:	A Cochrane overview of interventions to improve upper limb function after stroke (OSCAR)
Source of funding and total value of award:	Chief Scientist Office £84,534
Value of funding to NMAHP RU:	£76,561
Principal investigator/co-applicants:	Pollock A (PI) (Glasgow Caledonian University), Mead G (University of Edinburgh), Van Wijck F (Glasgow Caledonian University), Mehrholz J (Klinik Bavaria Kreischa Germany), Langhorne P (University of Glasgow), Brady M (Glasgow Caledonian University)
NMAHP RU investigators:	Pollock A, Brady M.
Workstream:	Stroke
Start date:	October 2012
Duration:	12 months

Aim(s):

To carry out a Cochrane Overview, synthesising systematic reviews of interventions to improve upper limb function after stroke.

Summary:

- We searched for Cochrane and non-Cochrane reviews of the effectiveness of treatments to improve arm function after stroke.
- We included 40 systematic reviews (19 Cochrane reviews and 21 non-Cochrane reviews). This evidence was current to June 2013.
- We assessed the quality of all the included reviews, using a quality assessment tool ('AMSTAR').
- We extracted details of 127 comparisons which had been explored within the reviews and graded the level of evidence of each of as 'high', 'moderate', 'low' or 'very low', based on 'GRADE' criteria.

We also documented challenges associated with carrying out a Cochrane Overview, so we could make recommendations for the conduct of future Overviews of stroke reviews.

Key Results:

- There is currently no high quality evidence for any treatments that are currently used as part of routine practice. There is insufficient evidence to judge which treatments are the most effective at improving arm function.
- There is moderate quality evidence that the following interventions may be effective: Constraint-Induced Movement Therapy (CIMT), mental practice, mirror therapy, virtual reality and a relatively high dose of repetitive task practice.
- Specific recommendations for future research are derived from the current evidence, and advice related to future Cochrane Overviews proposed.

Outcomes/Impact:

- Cochrane Overviews are useful tools for signposting key stakeholders to high quality synthesised evidence, potentially having a substantial impact on efficiency of evidence-based practice.
- Clinicians should be familiar with the evidence within the systematic reviews of treatments which provide moderate quality evidence of beneficial effect, and should use this evidence to support the delivery of effective arm function rehabilitation.

Publications:

- Pollock A, Campbell P, Brunton G, Hunt H and Estcourt L. (2017) Selecting and implementing overview methods: implications from five exemplar overviews. *Systematic Reviews* (e-Pub Ahead of Print) Doi: 10.1186/s13643-017-0534-3, *Systematic Reviews*.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J and van Wijck F. (2016) An algorithm was developed to assign GRADE levels of evidence to comparisons within systematic reviews. *Journal of Clinical Epidemiology*, 70, pp. 106-110.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, Wiffen P and van Wijck F. (2016) The purpose of rating quality of evidence differs in an overview, as compared to guidelines or recommendations. *Journal of Clinical Epidemiology* [Epub Ahead of Print] Doi:10.1016/j.jclinepi.2016.01.001.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J and van Wijck F. (2015) Cochrane Overview: Interventions for Improving Upper Limb Function After Stroke. *Stroke*, 46, pp. e57-e58.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J and van Wijck F. (2014) Interventions for improving upper limb function after stroke *Cochrane Database of Systematic Reviews*, Issue 11. Art. no.: CD010820, Doi:10.1002/14651858.CD010820.pub2.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J and van Wijck F. (2013) Interventions for improving upper limb function after stroke (Protocol). *Cochrane Database of Systematic Reviews*, Issue 11. Art. no.: CD010820. DOI: 10.1002/14651858.CD010820.

Other dissemination activity:

- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F. Quality of evidence relating to interventions to improve upper limb function: results of a Cochrane Overview (2014), *Rehabilitation 2. International Journal of Stroke*, 9: 29–31. doi: 10.1111/ijis.12374_11.
- Mehrholz J, Pollock A. Evidenzlage: Obere Extremität. *Neuroreh* 2011; 4: 174-176.

Presentation:

- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F. [invited] Which interventions are most effective at improving upper limb function after stroke? A Cochrane overview of reviews Keele University. 18th November 2014.

- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F. OSCAR – Overview of Stroke rehabilitation Arm Reviews. Scottish Stroke AHP Forum, Perth, 12th June 2014.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F. Completing the first Cochrane overview of stroke reviews: experiences of the Cochrane Stroke Group. 23rd Cochrane Colloquium, Vienna, Austria, 4-10 October 2015.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F, P Wiffen. An algorithm to assign GRADE levels of evidence to comparisons within systematic reviews. 23rd Cochrane Colloquium, Vienna, Austria, 4-10 October 2015.
- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F. Interventions to improve upper limb function after stroke: a Cochrane Overview. Society for Research in Rehabilitation, Glasgow, 10th June 2014.

Posters:

- Pollock A, Farmer S, Brady M, Langhorne P, Mead G, Mehrholz J, van Wijck F. Quality of evidence relating to interventions to improve upper limb function: results of a Cochrane Overview (poster). UK Stroke Forum, Harrogate, UK. December 2-4th 2014.
- A Pollock, S Farmer, M Brady, P Langhorne, G Mead, J Mehrholz, F van Wijck. Which interventions are most effective at improving upper limb function after stroke? A Cochrane Overview of reviews (eposter). European Stroke Conference. Nice, France. 6-9th May 2014.
- Pollock A, Farmer SE, Brady M, Langhorne P, Mead G, Mehrholz J, Van Wijck F. A Cochrane Overview of reviews of interventions for improving upper limb function after stroke: Protocol for the first stroke Cochrane Overview. UK Stroke Forum, Harrogate, UK. December 3-5th 2013.

Local NHS based training days:

- NHS Greater Glasgow & Clyde (5th March 2014) – Training session “Latest evidence in stroke rehabilitation research” to a multidisciplinary audience (approx 40 people).
- NHS Lothian (19th March 2014) – Training session (as above) – audience of physiotherapists and occupational therapists (approx 30 people).
- NHS Grampian (19th June 2014) – Training session “(as above) – audience of physiotherapists and occupational therapists (approx 30 people).

STROKE02.3 Physical rehabilitation treatment approaches following stroke: Cochrane systematic review of the evidence (SPRUCE)

Project Number:	STROKE02.3
Status:	Complete
Project Title:	Physical rehabilitation treatment approaches following stroke: Cochrane systematic review of the evidence (SPRUCE)
Source of funding and total value of award:	Chief Scientist Office, £53,391
Value of funding to NMAHP RU:	£47,858
Principal investigator/co-applicants:	Pollock A (PI) (Glasgow Caledonian University), Morris J (University of Dundee), Forster A (University of Leeds)
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	March 2012
Duration:	15 months

Aim(s):

Physical treatment is an important part of rehabilitation for people who have had a stroke. There is considerable debate among physiotherapists about the relative benefits of different physical treatment approaches, which means that it is important to bring together the research evidence and highlight what best practice ought to be in selecting these different approaches. Our aim was to update of a Cochrane systematic review of trials of physiotherapy treatment approaches. We aimed to enhance the clinical relevance of this systematic review by involving a 'Stakeholder Group', which contributed to key decisions around the review methods and presentation of findings.

Summary:

Our stakeholder group comprised purposively selected stroke survivors and carers (n=4) and physiotherapists (n=9). The group met three times during the review update. Formal methods were used to reach consensus decisions around review aims and methods, focusing on clinical relevance. We updated and amended the Cochrane review following a protocol and using standard Cochrane methodology. We searched for trials published before December 2012.

We also arranged for translation of all foreign language studies so that this evidence could be included for the first time.

Key Results:

We found 96 studies (including 10,401 stroke survivors) which investigated physical treatment approaches. We found that:

- There is moderate quality evidence to show that physiotherapy improves functional outcomes after stroke (when compared to no treatment), and that the benefits may persist long term.
- There is moderate to high quality evidence that physiotherapy improves function and mobility (when compared to usual care), and that faster walking speeds may persist long-term.
- There is low to moderate quality evidence that no single physiotherapy approach is any better (or worse) than any other approach.

Outcomes/Impact:

This updated Cochrane review provides the most up-to-date comprehensive synthesis of evidence relating to physical treatment interventions.

The stakeholder involvement in this review provided a new approach for involving people in systematic reviews.

Publications:

- Pollock, A., Baer, G., Campbell, P., Choo, P., Forster, A., Morris, J., Pomeroy, V. and Langhorne, P. (2014) Physical rehabilitation approaches for the recovery of function and mobility following stroke. Cochrane Database of Systematic Reviews, Issue 4, Art. no.: CD001920 DOI: 10.1002/14651858.CD001920.pub3.
- Pollock, A., Baer, G., Campbell, P., Choo, P., Forster, A., Morris, J., Pomeroy, V. and Langhorne, P. (2014) Physical rehabilitation approaches for the recovery of function and mobility following stroke. Major update. *Stroke*, 45 (10), pp. e202.
- Pollock, A., Baer, G., Campbell, P., Choo, P., Langhorne, P., Morris, J., Pomeroy, V. and Forster, A. (2014) Challenges in integrating international evidence relating to stroke rehabilitation: experiences from a Cochrane systematic review. *International Journal of Stroke*, 9 (8), pp. 965-967.
- Pollock, A., Campbell, P., Baer, G., Choo, P., Morris, J. and Forster, A. (2015) User-involvement in a Cochrane systematic review: using structured methods to enhance the clinical relevance, usefulness and usability of a systematic review update. *Systematic Reviews*, 4, pp. 55.
- Baer G, (2013). A new taxonomy of current physiotherapy treatment approaches, developed with a stakeholder group, enables clinically relevant synthesis within a Cochrane systematic review. *International Journal of Stroke*, 8 (Supplement 3), pp. 6.
- Campbell P, (2013). Using the nominal group technique to engage stakeholders with experience of stroke in a Cochrane systematic review of physiotherapy treatment approaches. *International Journal of Stroke*, 8 (Supplement 3), pp. 16.

Poster:

- Pollock, A., Baer, G., Campbell, P., Choo, P., Langhorne, P., Morris, J., Pomeroy, V. and Forster, A. (2014). Physical treatment is effective in the promotion of functional recovery after stroke: results of a Cochrane systematic review. European Stroke Conference 2014.

Published Abstracts:

- Pollock A, Campbell P; Choo PL; Langhorne P; Morris J; Pomeroy VM; Forster A; Baer G. (2014). Achieving clinically relevant evidence synthesis: involvement of patients, carers and clinicians in a Cochrane systematic review leads to development and use of a new taxonomy of physiotherapy treatment approaches for stroke. *Clinical Rehabilitation*, 28 (11), pp. 1147-1155. Published Proceedings from the Society of Research in Rehabilitation.
- Pollock A, Baer G; Campbell P; Choo PL; Langhorne P; Morris J; Pomeroy VM; Forster A. (2014). A Cochrane systematic review of physiotherapy treatment approaches to promote functional recovery after stroke. *Clinical Rehabilitation*, 28 (11), pp. 1147-1155. Published Proceedings from the Society of Research in Rehabilitation.

STROKE02.4 Development of the Standardisation of Measurements in Arm Rehabilitation Trials (SMART) toolbox

Project Number:	STROKE02.4
Status:	In Progress
Project Title:	Development of the Standardisation of Measurements in Arm Rehabilitation Trials (SMART) toolbox
Source of funding and total value of award:	Chest, Heart and Stroke Scotland (£3,954) for Phase II, Glasgow Caledonian University funded studentship, £58,000
Value of funding to NMAHP RU:	£61,954
Principal investigator/co-applicants:	Duncan Millar J, Ali M, Pollock A.
NMAHP RU investigators:	Ali M, Brady MC.
Workstream:	Stroke
Start date:	October 2014
Duration:	36 Months

Aim(s):

We sought to inform development of the SMART toolbox for arm function rehabilitation trials after stroke.

Summary:

We identified the outcome measures most frequently used in current stroke upper limb rehabilitation trials. We used nominal group technique to determine the most important outcomes related to living with an upper limb impairment following stroke. We presented this information to a group comprising of stroke survivors, carers, healthcare professionals, trialists and researchers to generate recommendations on which measures should be collected in future stroke upper limb rehabilitation trials.

Posters:

- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2017) Development of the Standardising Measures in Arm Rehabilitation Trials for stroke (SMART) Toolbox. (work in progress poster) International Clinical Trials Methodology Conference, May 2017, Liverpool, UK.

- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2016) The Mexican wave always stops with me: which upper limb outcomes matter most after stroke, and to whom? UK Stroke Forum Conference, November, 2016, Liverpool, UK.
- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2016) Upper limb function after stroke: what outcomes matter most? (work in progress poster) Scottish Stroke AHP Forum Conference June 2016, Perth, UK.
- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2016) Outcome measurement in stroke upper limb rehabilitation trials: what tools are used and how often? European Stroke Organisation's Conference, May 2016 Barcelona, Spain.

Published Abstracts:

- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2017) Development of the Standardising Measures in Arm Rehabilitation Trials for stroke (SMART) Toolbox (Work in progress). *Trials* 18(Suppl 1), 200, p.108.

STROKE02.4 Development of the Standardisation of Measurements in Arm Rehabilitation Trials (SMART) toolbox

- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2016) The Mexican wave always stops with me: which upper limb outcomes matter most after stroke, and to whom? *International Journal of Stroke*, 11 (4S), p. 56.
- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali (2016) Outcome measurement in stroke upper limb rehabilitation trials: what tools are used and how often? *European Stroke Journal* Vol 1, 1 Suppl; AS10-015 pp 533.
- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali Outcome measurement in stroke upper limb rehabilitation trials: do we measure what matters? *European Stroke Journal* 2(IS), pp 33.
- J Duncan Millar “Important outcomes in stroke UL rehabilitation research” [invited] Perth and Kinross Physiotherapy Department Neurological and Elderly Network Meeting January 2017 Perth, UK.

Presentations:

- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali [invited speaker] “The Mexican wave always stops with me” What matters most about the arm – and do outcome measures capture this? Scottish Stroke AHP Forum Conference June 2017, Perth, UK.
- J. Duncan Millar, A. Pollock , F. van Wijck and M. Ali (2017) Improving the relevance of stroke upper limb rehabilitation research outcomes to stroke survivors, carers and health professionals. European Federation of Research in Rehabilitation May 2017, Glasgow, UK.
- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali Outcome measurement in stroke upper limb rehabilitation trials: do we measure what matters? European Stroke Organisation Conference, Prague, the Czech Republic, May 2017 (platform presentation)
- J. Duncan Millar, A. Pollock, F. van Wijck and M. Ali [invited] (2017) “The Mexican wave always stops with me”: Gaining perspectives from stroke survivors, carers and health professionals to inform upper limb rehabilitation research. International Association of Chartered Physiotherapists in Neurology Conference March 2017, London, UK.

STROKE02.5 Adherence diaries: How can they be optimised for use in home-based rehabilitation?

Project Number:	STROKE02.5
Status:	Complete
Project Title:	Adherence diaries: How can they be optimised for use in home-based rehabilitation?
Source of funding and total value of award:	Glasgow Caledonian University studentship, £58,000
Value of funding to NMAHP RU:	£58,000
Principal investigator/co-applicants:	Brady MC (PI) (Glasgow Caledonian University), Frost R (Glasgow Caledonian University), Williams B (University of Stirling), McClurg D (Glasgow Caledonian University)
NMAHP RU investigators:	Frost R, Williams B, Brady MC, McClurg D.
Workstream:	Stroke
Start date:	October 2012
Duration:	36 Months

Aim(s):

To identify, optimise and evaluate an adherence measure for use in rehabilitation interventions.

Objectives:

- Outline an operationalisable definition of adherence to home-based allied health professional rehabilitation therapies
- Summarise and evaluate currently used measures in order to select a measure for further development
- Explore the mechanisms through which this measure could be optimised
- Evaluate the effect of optimising the measure on its validity, reliability and acceptability

Summary:

Rehabilitation plays a significant role in modern healthcare, with allied health professionals (AHPs) providing essential support to reduce disability and improve functional outcomes. Recent policies encourage placing greater focus on home-based therapies and self-management to reduce the burden on services, however this requires

greater patient engagement with prescribed therapies. A large component of this is adherence to these home-based treatments, which needs to be maximised where possible for optimum outcomes. Furthermore, adherence is crucial within rehabilitation clinical trials in order to assess whether an intervention's effectiveness is dependent upon the intervention dosage and to assess whether patients will engage with a prescribed therapy.

Whilst many studies have assessed predictors of, and ways to, increase adherence, these are hindered by problems with adherence measurement. These include poor construct definition, a multitude of limited measures that lack clear evidence of measurement properties and the increased burden or motivational effects of recording behaviour. Few attempts have been made to address these problems, with most authors simply developing and using new adherence measures.

Outcomes/Impact:

An operationalisable definition of adherence was developed which divided 'adherence' into its component parts: frequency, intensity, duration and accuracy. This definition underpinned the comparison of measures, exploration of diaries and the evaluation of diaries.

We found no differences in validity, reliability and acceptability between a diary whose design has been optimised for simplicity and greater salience and a non-optimised one. Interestingly, we found there was high inter- and intra-individual variation in diary validity across all outcomes though this balances out at the sample level. Moderate inter- and intra-individual variation in week-to-week reliability in adherence diaries was also observed but again this was no longer observed at the sample level. Consequently, diary data is more likely to be valid and reliable when considered at a sample rather than an individual level. Where the activity is unambiguously defined and carried out less frequently, diaries can support the collection of valid and complete data. Diaries are more likely to be completed when there is greater participant engagement with the overall trial. Diaries are generally acceptable, but individuals vary greatly in their preferences regarding design. Preferring one diary over another appears to have only a slight effect on diary validity, but not completion. Validity and reliability vary with the dimension of adherence assessed – duration and percentage adherence have greater validity and reliability than frequency adherence.

Publications:

- Frost R, Levati S, McClurg D, Brady MC, Williams B. What adherence measures should be used in trials of home-based rehabilitation interventions? A systematic review of the validity, reliability and acceptability of current measures. *Archives of Physical Medicine and Rehabilitation*. 2017, 98 (6) 1241-1256.e45
- Frost R, McClurg D, Brady MC, Williams B. Optimising the validity and completion of adherence diaries; a multiple case study and randomised crossover trial. *Trials*. 2016, 17:489 doi.:10.1186/s13063-016-1615-7

Published Abstract:

- Frost R, Williams B, Brady MC, McClurg D. A systematic review of adherence measurement methods currently used in randomised controlled trials of home-based rehabilitation interventions. *Clinical Rehabilitation*, 2014 29(4) 396-397.

Presentations:

- McClurg D, Frost R, Brady MC, Williams B. Diaries - are they valid? 23rd UK Continence Society Scientific Meeting 2016, Belfast, UK.
- Frost R, Williams B, Brady MC, McClurg D. A systematic review of adherence measurement methods currently used in randomised controlled trials of home-based rehabilitation interventions. Society for Research in Rehabilitation Annual Summer Meeting, Glasgow, UK 2014.
- Frost R, Williams B, Brady MC, McClurg D. Optimising the use of adherence diaries in randomised controlled trials (RCTs) of home-based allied health professional (AHP) rehabilitation interventions: A multiple case study of seven trials. 10th UK Society for Behavioural Medicine Annual Scientific Meeting, 3rd-4th December 2014, Nottingham, UK.

Posters:

- Frost, R., Williams, B., Brady, MC, McClurg, D. A systematic review of adherence measurement methods currently used in randomised controlled trials of home-based rehabilitation interventions. Royal College of Nursing Conference, 2014, Glasgow, UK.
- Frost R, Williams B, Brady MC, McClurg, D. A systematic review of adherence measurement methods used in randomised controlled trials of allied health professions (AHP) home-based rehabilitation intervention. UK Society for Behavioural Medicine Annual Scientific Meeting, 2014, Nottingham, UK.

Awards:

- UK Society for Behavioural Medicine (2014) High Scoring Abstract Award. Frost R, Brady M, McClurg D, Williams B. Optimising the use of adherence diaries in randomised controlled trials (RCTs) of home-based allied health professional (AHP) rehabilitation interventions: A multiple case study of seven trials.
- Royal College of Nursing Conference - Poster Prize. Frost, R., Williams, B., Brady, MC, McClurg, D. A systematic review of adherence measurement methods currently used in randomised controlled trials of home-based rehabilitation interventions. Royal College of Nursing Conference, Glasgow, 2014.
- UK Society for Behavioural Medicine Annual Scientific Meeting – Poster Prize. Frost R, Williams B, Brady MC, McClurg, D. A systematic review of adherence measurement methods used in randomised controlled trials of allied health professions (AHP) home-based rehabilitation intervention. Nottingham, UK 2014.

Project Number:	STROKE02.6
Status:	Complete
Project Title:	Practical methods for meta-analysis of continuous outcomes in stroke rehabilitation trials (MASK)
Source of funding and total value of award:	The Stroke Association and the Rosetrees Trust, £94,411
Value of funding to NMAHP RU:	£3,600
Principal investigator/co-applicants:	Weir C (PI) (University of Edinburgh), Brady M (Glasgow Caledonian University), Lewis S (University of Edinburgh), Murray G (University of Edinburgh), Langhorne P (University of Glasgow).
NMAHP RU investigators:	Brady MC.
Workstream:	Stroke
Start date:	January 2013
Duration:	24 months

Aim(s):

To identify and develop improved methods for handling continuous outcomes within meta-analysis, enabling best use to be made of the clinical trial evidence available for stroke treatments.

Research questions:

1. What is the best approach to impute the mean and SD within a meta-analysis when key summary statistics are missing from a trial publication?
2. How often have trials been omitted from newly published or recently updated Cochrane stroke meta-analyses due to missing mean or SD data? How have missing mean or SD data from such trials been addressed in these meta-analyses?
3. How feasible are the methods identified in RQ1 (above) for use within a stroke rehabilitation meta-analysis?
4. What is the optimum approach for dealing with missing SD or mean data according to (i) the nature of the true underlying distribution and (ii) which summary statistics are available?
5. Where the underlying outcome distribution is skewed or has some other non-normal distribution the mean and SD are likely to be inappropriate statistics on which to base meta-analysis?
 - a. What alternative approaches might be possible (such as

utilising information on the empirical distribution of outcomes contained in individual patient data)?

- b. How feasible are these methods when used in an exemplar review of early supported discharge following acute stroke?
6. What is the optimum approach which avoids using mean or SD values from non-normally distributed outcomes on their original scales within stroke rehabilitation meta-analyses?

Summary:

Systematic reviews and meta-analyses seek to summarise large quantities of findings from different stroke trials, while taking account of varying trial quality. A summary of the available information on a particular stroke topic forms a valuable resource for patients, researchers, healthcare professionals, guideline developers and policymakers. With the continuing rapid expansion in the availability of new stroke trial evidence, it is essential that systematic reviews summarise the available research findings in as unbiased and precise a manner as possible to inform stroke patients and healthcare professionals and to guide future stroke research.

The validity of a systematic review depends critically on avoiding bias in the identification of trials, in the selection of trials for meta-analysis and in the extraction of data. It is essential to include as much of the available data as possible, not only to preserve the clinical context but also to minimise one potential source of bias and to maximise the precision of the meta-analysis conclusions.

Although much of the implementation of meta-analysis has been in the context of binary outcomes, continuous outcomes are often of crucial relevance to stroke survivors and carers (for example, quality of life measures) or are pivotal in economic evaluations (for example, hospital length of stay).

Over one third of stroke reviews in the Cochrane Database of Systematic Reviews include a continuous primary outcome while almost three-quarters contain a continuous secondary outcome.

Although some continuous outcomes are normally distributed, many are not: examples include hospital length of stay (frequently recorded as a secondary outcome following acute stroke) and measures of physical function and depression post-stroke. For skewed outcomes such as these, analysis strategies and reporting vary and the clinical trial publication often summarises outcome using the median and either the maximum and minimum or the upper and lower quartiles. In contrast, the standard method of meta-analysis in the absence of individual patient data requires information on the mean and standard deviation. As gaining access to the original individual patient data or additional summary statistics is often difficult, the systematic reviewer is left with a choice. One option, unattractive due to the resulting potential bias and reduced precision, is to exclude the trial from the meta-analysis. The alternatives were explored in this research project.

Publications:

- Weir CJ, Butcher I, Lewis SC, Murray GD, Langhorne P, Brady MC. Meta-analysis of continuous outcomes: systematic review identifies new methods for dealing with missing standard deviation and mean values. *BMC* (submitted)

Presentations:

- Weir, C.J. Handling missing data summaries in meta-analysis: systematic review of methods. Physical Activity for Health Research Centre (PAHRC), University of Edinburgh, 31 May 2017.

Posters:

- Meta-analysis of continuous outcomes: systematic review of methods available for dealing with missing mean and standard deviation values. Butcher, I., Brady, M.C., Lewis, S.C., Murray, G.D., Langhorne, P., Weir, C.J. International Society for Clinical Biostatistics, Vienna, Austria, August 2014.
- Meta-analysis of continuous outcomes: systematic review of methods available for dealing with missing mean and standard deviation values. Butcher, I., Brady, M.C., Lewis, S.C., Murray, G.D., Langhorne, P., Weir, C.J. Cochrane Colloquium, Hyderabad, India, September 2014.
- Na LH, Lewis SC, Murray GD, Langhorne P, Brady MC, Weir CJ. Online Survey to Identify Methods Used in Meta-Analysis to Handle Missing Continuous Outcome Summaries in Stroke Rehabilitation Systematic Reviews. Cochrane Colloquium, 23-27 October 2016, Seoul, South Korea.
- Assi V, Langhorne P, Lewis SC, Brady MC, Murray GD, Weir CJ. Evaluation of practical methods for estimating means for meta-analysis of continuous, non-normally-distributed outcomes. 38th Annual Conference. International Society for Clinical Biostatistics 9th-13th July 2017, Vigo, Spain.

Project Number:	STROKE02.7
Status:	Ongoing
Project Title:	VISTA-Rehab
Source of funding and total value of award:	Various, £6,520
Value of funding to NMAHP RU:	£6,520
Principal investigator/co-applicants:	Brady M (PI), Ali, M, Pollock, A, (Glasgow Caledonian University)
NMAHP RU investigators:	Brady M, Ali, M, Pollock, A,
Workstream:	Stroke
Start date:	October 2008
Duration:	Ongoing

Aim(s):

We sought to collate and grant the scientific community with access to anonymised clinical trial data on stroke rehabilitation trials for the purpose novel exploratory analyses.

Summary:

This ongoing initiative has collated data on more than 11,000 patients to date, from across 48 different randomised controlled trials. These data have facilitated novel exploratory analyses to optimise stroke rehabilitation, leading to 7 peer-reviewed publications and commentary articles, and 22 abstract presentations at national and international conferences.

Publications:

- Ali M, Ashburn A, Bowen A, Brodie E, Corr S, Drummond A, Edmans J, Gladman J, Kalra L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Patchick E, Pollock A, Pomeroy V, Sackley C, Sunnerhagen KS, van Vliet P, Walker M, Brady M, On behalf of the VISTA-Rehab Investigators, VISTA-Rehab: A Resource for Stroke Rehabilitation Trials, *International Journal of Stroke*, 2010;5: 447–452.
- Brady M, Reduce, Reuse, Recycle. *International Journal of Stroke*, 2010;5:421-2
- Ali M, Hazelton C, Lyden P, Pollock A, Brady M, on behalf of the VISTA Collaboration, Recovery from Post-Stroke Visual Impairment: Evidence from a Clinical Trials Resource, *JNNR* 2013;27: 133-141
- Ali M, English C, Bernhardt J, Sunnerhagen KS and Brady M on behalf of the VISTA-Rehab Collaboration. More Outcomes than Trials: A Call for Consistent Data Collection across Stroke Rehabilitation Trials. *International Journal of Stroke*, 2013; 8:18-24.
- Ali M, More Outcomes than Trials: A Call for Consistent Data Collection across Stroke Rehabilitation Trials. *International Journal of Stroke Podcast* 2013, <https://itunes.apple.com/ua/podcast/rehabilitation-edition-international/id610378155>
- Maclsaac RL, Ali M, Petes M, English C, Rodgers H, Jenkinson C, Lees KR, Quinn TJ on behalf of the VISTA Collaboration. Derivation and Validation of a Modified Short Form of the Stroke Impact Scale, (*J Am Heart Assoc*. 2016;5:e003108 doi: 10.1161/JAHA.115.003108)
- Maclsaac RL, Ali M, Taylor-Rowan, M, Rodgers H, Lees KR, Quinn TJ, on behalf of the VISTA Collaborators. Utility of a three item short form version of the Barthel Index for use in Stroke: systematic review and external validation, *Stroke* 2017; 48(3):618-623. doi: 10.1161/STROKEAHA.116.014789

Posters:

- Ali M, Corr S, Drummond A, Edmans J, Gladman J, Jongbloed L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Pollock A, Pomeroy V, Sackley C, Walker M and Brady M. Rehabilitation trials within the Virtual International Stroke Trials Archive (VISTA-Rehab). Society for Research in Rehabilitation Conference 3rd Feb 2009, Derby, UK.
- Ali M, Corr S, Langhorne P, Lees KR, Pollock A, Walker M and Brady M. Rehabilitation trials within the Virtual International Stroke Trials Archive (VISTA-Rehab). UK Stroke Forum, 2nd -4th Dec 2008, Harrogate, UK.
- Ali M, Corr S, Langhorne P, Lees KR, Pollock A, Walker M and Brady M. Rehabilitation trials within the Virtual International Stroke Trials Archive (VISTA-Rehab). Scottish Stroke Research Network, 28th Oct 2008, Glasgow, UK.
- Ali M, Ashburn A, Bowen A, Brodie E, Corr S, Drummond A, Edmans J, Gladman J, Jongbloed L, Kalra L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Patchick E, Pollock A, Pomeroy V, Sackley C, van Vliet P, Walker M, Brady M, On behalf of the VISTA-Rehab Investigators, Rehabilitation Trials within the Virtual International Stroke Trials Archive - VISTA-Rehab. European Stroke Conference, 26th-29th May, 2009, Stockholm, Sweden.
- Ali M, Ashburn A, Bowen A, Brodie E, Corr S, Drummond A, Edmans J, Gladman J, Jongbloed L, Kalra L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Patchick E, Pollock A, Pomeroy V, Sackley C, Sunnerhagen KS, van Vliet P, Walker M, Brady M, On behalf of the VISTA-Rehab Investigators, Rehabilitation Trials within the Virtual International Stroke Trials Archive - VISTA-Rehab. Research into Practice Conference November, 2009, Stirling, Scotland.
- Ali M, Ashburn A, Bowen A, Brodie E, Corr S, Drummond A, Edmans J, Gladman J, Jongbloed L, Kalra L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Patchick E, Pollock A, Pomeroy V, Sackley C, Sunnerhagen KS, van Vliet P, Walker M, Brady M, On behalf of the VISTA-Rehab Investigators, VISTA-Rehab: Expansion of the VISTA clinical trial resource UK Stroke Forum, 2009, Glasgow, Scotland.
- Ali M, Ashburn A, Bowen A, Brodie E, Corr S, Drummond A, Edmans J, Gladman J, Jongbloed L, Kalra L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Patchick E, Pollock A, Pomeroy V, Sackley C, van Vliet P, Walker M, Brady M, On behalf of the VISTA-Rehab Investigators, VISTA-Rehab: A Resource for Stroke Rehabilitation Trials, International Stroke Conference, 2010, San Antonio, Tx.
- Ali M, Ashburn A, Bowen A, Brodie E, Corr S, Drummond A, Edmans J, Gladman J, Jongbloed L, Kalra L, Langhorne P, Lees KR, Lincoln N, Logan P, Mead G, Patchick E, Pollock A, Pomeroy V, Sackley C, van Vliet P, Walker M, Brady M, On behalf of the VISTA-Rehab Investigators, VISTA-Rehab: A Resource for Stroke Rehabilitation Trials, Indian Stroke Association 2011, Delhi, India.
- The VISTA-Rehab Steering Committee members, Rehabilitation trials within the Virtual International stroke Trials Archive: VISTA-Rehab, European Stroke Conference 2010, Barcelona, Spain.
- Ali M, Bath P, Lyden P, Brady M on behalf of the VISTA Collaboration, Inclusion and Attrition of Patients with Aphasia in Acute Stroke Clinical Trials, European Stroke Conference 2012, Lisbon, Portugal.

Presentations:

- Ali M, Hazelton C, Brady M, Lyden P, Pollock A, On Behalf of the VISTA Collaboration. Recovery from Post-Stroke Visual Impairment: Evidence from a Clinical Trials Resource. UK Stroke Forum, 2011.
- Ali M, Hazelton C, Brady M, Lyden P, Pollock A, On Behalf of the VISTA Collaboration. Recovery from Post-Stroke Visual Impairment: Evidence from a Clinical Trials Resource. Presented at International Stroke Conference 2012, New Orleans, USA.
- Ali M, Hazelton C, Lyden P, Pollock, Brady M on behalf of the VISTA Collaboration. Recovery from Post-Stroke Visual Impairment: Evidence from the Virtual International Stroke Trials Archive (VISTA), Platform Presentation at European Stroke Conference 2012, Lisbon, Portugal.
- Ali M, Lyden P, Brady M, on behalf of the VISTA Collaboration. Evolution of Post-Stroke Aphasia and Dysarthria in Acute Stroke: Analysis of Data from the Virtual International Stroke Trials Archive (VISTA), Platform Presentation at European Stroke Conference 2012, Lisbon, Portugal.

Project Number:	STROKE02.8
Status:	In Progress
Project Title:	Recruitment to stroke rehabilitation trials
Source of funding and total value of award:	Glasgow Caledonian University Studentship, £58,000
Value of funding to NMAHP RU:	£58,000
Principal investigator/co-applicants:	McGill K (PI), Godwin J, Sackley C and Brady MC (Glasgow Caledonian University).
NMAHP RU investigators:	McGill K, Brady MC.
Workstream:	Stroke
Start date:	October 2015
Duration:	3 years

Aim(s):

- To systematically gather, extract and synthesise recruitment data from stroke rehabilitation trials over a 10 year period and to examine their recruitment efficiency and reporting standards.
- To explore the challenges encountered by stroke rehabilitation researchers when planning recruitment and implementing recruitment methods in randomised controlled trials (RCTs).
- To explore the adequacy of participant sample sizes for (RCTs) of stroke rehabilitation interventions in relation to statistical accuracy and effect size interpretation

Research questions:

1. What is the **efficiency** of recruitment to stroke rehabilitation trials when described in terms of:
 - a. **Rate** (numbers randomised as a percentage of those initially screened for eligibility).
 - b. **Speed** (numbers of people randomised per month per site).
 - c. **Dropout** (number of people that dropout during the trial).
2. Does rate, speed and rate of dropouts impact on the recruitment efficiency?

3. Are recruitment data from stroke rehabilitation RCTs reported to the standards recommended in the CONSORT (Consolidated Standards of Reporting Trials) statement?
4. How and when do stroke rehabilitation trialists identify recruitment issues
 - a. What strategies do trialists employ to improve recruitment during trial implementation?
 - b. What are trialists approaches to optimise recruitment for future stroke rehabilitation RCTs.

How many stroke survivors should be included in stroke rehabilitation RCTs to be confident in the accuracy of significance levels and of producing results that accurately estimate the effect sizes of the interventions?

Summary:

Half of clinical trials experience difficulty reaching their recruitment targets, resulting in underpowered studies with less reliable findings. Only 31% of stroke rehabilitation trials (funded by two UK funders) achieved their original recruitment targets, half were awarded monetary or time extensions, and recruitment problems were identified in 63%.

While extensions to trial recruitment periods are possible there are considerable costs associated with such a step. There appeared to be a complex link between piloting trials and recruitment successes. Recruitment improved when changes were made to written materials, exclusion criteria, recruitment targets, recruitment strategy, and numbers of sites.

Working with a comprehensive list of stroke trials (published 2005 to 2015) we applied the following inclusion criteria: evaluation of a stroke rehabilitation intervention, patient participants only, non-pharmacological experimental intervention. We employed no language limitations. Information on recruitment efficiency was extracted; (i) Rate: the percentage of people screened for eligibility that was randomised, (ii) Speed: monthly recruitment numbers by site (iii) and Dropout rates. Information was also extracted on; number of recruitment sites, number of recruiters, the setting, profession of the recruiter, funding support, ethical approval, type of intervention, targeted impairment, control condition, and country of recruitment. Two independent reviewers screened titles, abstracts, full texts, and data extracted from included RCTs. Discrepancies were resolved by a third reviewer.

Results:

To date we have reviewed 12,939 titles, 1,270 abstracts, 788 full texts. A total of 515 trials were included in our review. We found recruitment inefficiencies in stroke rehabilitation RCTs with 39% of stroke survivors screened being randomised. Subgroup analysis revealed that recruitment efficiency was significantly affected by the type of intervention, stage of stroke survivor rehabilitation, targeted impairment, control condition, and recruitment setting. The second and third phases of our study are currently underway and results are pending.

Outcomes/Impact:

Shortlisted - Society for Clinical Trials Thomas C. Chalmers Student Award 4th International Clinical Trials Methodology Conference and the 38th Annual Meeting of the Society for Clinical Trials, 7th-10th May 2017, Liverpool, UK (below).

Oral Presentation:

- McGill K, Godwin J, Sackley C, Brady MC. Efficiency of Recruitment to Stroke Rehabilitation Randomised Controlled Trials: Secondary Analysis of Recruitment Data. International Clinical Trials Methodology Conference and the 38th Annual Meeting of the Society for Clinical Trials, 7th-10th May 2017, Liverpool, UK.

Poster Presentation:

- McGill K, Godwin J, Sackley C, Brady MC. Efficiency of Recruitment to Stroke Rehabilitation Randomised Controlled Trials: Secondary Analysis of Recruitment Data. 14th Congress of the European forum for Research and Rehabilitation. May 2017, Glasgow, Scotland.

Project Number:	STROKE02.9
Status:	Complete
Project Title:	Goal setting in community based stroke rehabilitation: A feasibility and acceptability study of implementing a goal setting and action planning practice framework
Source of funding and total value of award:	The Stroke Association, £106,543
Value of funding to NMAHP RU:	£107,832
Principal investigator/co-applicants:	Scobbie L (PI) (University of Stirling) Supervisors: Wyke S (Glasgow University), Duncan E (University of Stirling), Brady M (Glasgow Caledonian University),
NMAHP RU investigators:	Scobbie L, Duncan E, Brady M,
Workstream:	Stroke
Start date:	August 2011
Duration:	36 Months

Aim(s):

To investigate current goal setting practice in community rehabilitation teams (CRTs) providing services to people recovering from stroke across the UK. To investigate the implementation of the Goal setting and Action Planning (G-AP) framework with people recovering from stroke, in three different CRTs.

Summary:

Goal setting creates an ideal opportunity for person-centred care in stroke rehabilitation. Lesley had developed and tested a goal setting and action planning (G-AP) framework for use in community rehabilitation teams (CRTs) with promising results. This fellowship examined the acceptability and feasibility of implementing G-AP in other CRT's, and gathered information to inform the design of a future effectiveness study.

A mixed methods study in two phases was conducted.

Phase 1: A national survey of CRTs was conducted to investigate (i) the structure and organisation of CRTs providing stroke rehabilitation services in the UK, and (ii) current goal setting practice used within them. **Phase 2:** G-AP was implemented in three CRTs to identify patient, carer and therapists' views about its acceptability, feasibility and impact (if any) in practice. Case note analysis was conducted to investigate the fidelity with which G-AP has been implemented.

Findings Phase 1: Responses were analysed from 437 services from across the UK. The size, composition and input provided by CRTs was highly variable. Services were not typically stroke specific with 71% providing input to a mixed diagnostic group of patients. Ninety one percent of services reported setting goals with "all" or "most" stroke survivors. Seventeen percent reported that no methods were used to guide goal setting practice and 47% reported use of informal methods only. Reported goal setting practice was highly variable.

Findings Phase 2: G-AP was implemented in three CRTs with varying degrees of success. Facilitators and barriers to implementation were identified. On-going monitoring, and tailoring, of G-AP delivery within each service was viewed as an important way to optimise implementation. Stroke survivors reported landmarks in recovery which included improvements in goal sub-skills (e.g. walking ability; arm movement) and achieving personal goals (e.g. holding grandchild; return to work; attending church). Understanding, accepting and adjusting to limitations was a salient theme in stroke survivors' accounts of their recovery. Staff and stroke survivors reported ways in which G-AP had contributed to recovery (e.g. improving patient centred practice; increasing stroke survivors' focus, motivation and practise of goal related activities).

Conclusions: Goal setting is embedded within CRTs; however, practice is highly variable and potentially sub-optimal. G-AP can be implemented in CRTs and help stroke survivors meet important landmarks in recovery. The interaction between G-AP and the context in which it is delivered is critical to its success or failure.

Outcomes/Impact:

The survey findings represent the most detailed description of CRTs and goal setting practice used within them to date. The implementation study highlighted how services' organisational structure, and staff perceptions of value, impact on G-AP delivery in practice. It also suggests that G-AP can help stroke survivors meet important landmarks in their recovery. G-AP is designed for use within health and social care settings; it is well positioned for use in current and emerging CRTs across the UK.

Publications:

- Scobbie L, Duncan E A, Brady MC, Wyke S. Goal setting practice in services delivering community-based stroke rehabilitation: A United Kingdom (UK) wide survey. *Disability and Rehabilitation*, 37:14, 1291-1298, DOI:10.3109/09638288.2014.961652.

Oral Presentations:

- Scobbie L, Duncan E, Brady MC, Dixon D, Wyke S. [invited] Goal setting in stroke rehabilitation: Have we got a bit ahead of ourselves? Royal College of Physicians and Surgeons Stroke Symposium, Sept 2013, Glasgow, UK.

- Scobbie L, Brady MC, Duncan E, Wyke S. [invited] A UK wide survey of goal setting practice in community stroke rehabilitation settings. Community Therapist Network annual conference, Oct 2013, Birmingham, UK.
- Scobbie L, Duncan E, Brady MC, Dixon D, Wyke S. [invited] A Goal setting and Action Planning (G-AP) Framework. Goal Setting Consensus Group Meeting, April 2015, London, UK.
- Scobbie L, Duncan E, Brady MC, Dixon D, Wyke S. [invited] A Goal setting and Action Planning (G-AP) framework for use in community based stroke rehabilitation settings. 3rd European Federation of NeuroRehabilitation Societies (EFNR), Dec 2015, Vienna, Austria.
- Scobbie L, Duncan E, Brady MC, Dixon D, Wyke S [invited]. A Theory-based Approach to Goal Setting Practice. 9th World Congress of the International Society of Physical and Rehabilitation Medicine, July 2015, Berlin, Germany.
- Scobbie L, Duncan E, Brady MC, Dixon D, Wyke S. Goal setting in community based stroke rehabilitation: Is where we are at where we want to be? UK Stroke Forum, Nov 2016, Liverpool, UK.
- Scobbie L, Brady MC, Duncan E, Wyke S [invited]. A Goal Setting and Action Planning (G-AP) Framework for use in community rehabilitation settings. NHS Forth Valley Stroke Advanced Competencies Study day, May 2017, Larbert, UK.
- Scobbie L, Brady MC, Duncan E, Wyke S [invited]. Optimising stroke survivor recovery through effective goal setting in community rehabilitation teams... A research journey. NHS Forth Valley Allied Health Professional Show Case event. May 2017, Larbert, UK.
- Scobbie L, Duncan E, Brady MC, Dixon D, Wyke S [invited]. Key components of the goal setting process: What are they and why are they important? Scottish Stroke Improvement Group, May 2017, Edinburgh, UK.

Poster Presentations:

- L Scobbie, M Brady, E Duncan & S Wyke. Goal setting practice in services delivering community based stroke rehabilitation: A United Kingdom wide survey. UK Stroke Assembly, June 2014, Nottingham, UK.
- L Scobbie, M Brady, E Duncan & S Wyke. Goal setting practice in services delivering community based stroke rehabilitation: A United Kingdom wide survey. UK Stroke Forum, Nov 2016, Harrogate, UK.

STROKE02.10 Optimising stroke survivor recovery through effective goal setting practice in community based rehabilitation settings: implementing research to enhance practice and improve outcomes

Project Number:	STROKE02.10
Status:	In Progress
Project Title:	Optimising stroke survivor recovery through effective goal setting practice in community based rehabilitation settings: implementing research to enhance practice and improve outcomes
Source of funding and total value of award:	Stroke Association Clinical Lectureship Award, £173,530
Value of funding to NMAHP RU:	£173,531
Principal investigator/co-applicants:	Scobbie L (PI), Brady M (Glasgow Caledonian University).
NMAHP RU investigators:	Scobbie L, Brady M.
Workstream:	Stroke
Start date:	September 2016
Duration:	60 Months

Aim(s):

The aims of this clinical lectureship research programme are to: 1. Optimise a developed Goal setting and action planning (G-AP) framework in line with the findings of a recent evaluation (this will involve: understanding of the regulatory function of goal non-attainment; improving the functionality of G-AP online training, developing an app version of the G-AP record and an accessible version for stroke survivors with communication difficulties) 2. Develop a flexible G-AP implementation protocol and 3. Evaluate the clinical and cost effectiveness of G-AP.

Summary:

Community rehabilitation should be effective and responsive to stroke survivors' personal goals. Goal setting practice is highly variable and carried out in the absence of high quality evidence to demonstrate its effectiveness. An evidence based Goal setting and Action Planning (G-AP) framework (pilot training programme and stroke survivor held record) was developed to enhance patient-centred goal setting practice and stroke survivor recovery.

This Stroke Association clinical lectureship research programme aims to build on this work to meet the above noted aims.

Methods: A series of inter-related studies will be conducted involving development work, qualitative and quantitative methodologies and a research visit to four Australian centres of excellence in stroke rehabilitation research.

Outcomes/Impact:

This research programme will (i) produce freely available G-AP training resources and G-AP stroke survivor held record options (ii) inform the effective management of goal adjustment in stroke rehabilitation contexts and (iii) develop evidence of effectiveness of G-AP in practice to optimise stroke survivor recovery and wellbeing.

These outcomes will impact on stroke rehabilitation practice in community settings (for example, by producing training materials and resources to optimise goal setting practice; reducing the evidence-practice gap in goal setting practice) and stroke survivor recovery and wellbeing (for example, by supporting stroke survivors through the experience of goal adjustment; producing accessible resources to support their engagement in the goal setting process). This project is also expected to make a methodological contribution to the evaluation and implementation of complex interventions.

Project Number:	STROKE02.11
Status:	Complete
Project Title:	Executive function in people with stroke
Source of funding and total value of award:	£0
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Chung C (PI), Supervisors: Pollock A (Glasgow Caledonian University), Campbell T (NHS Fife), Durward B (Glasgow Caledonian University).
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	2008
Duration:	72 months

Aim(s):

To explore rehabilitation options for addressing executive dysfunction following stroke

Summary:

This work comprised three key studies:

1. Review of executive function research and development of the executive function task application model: an exploration of components within established definitions of executive function suggested that executive function can be explained by five core components: concept formation, planning, initiation, inhibition and flexibility. However, within existing executive function models the task process was limited to one stage, while, in contrast, occupational performance models conceptualise tasks as multifactorial. This suggested the need for a new model which integrated models of executive function and occupational performance. Hence the executive function task application model was constructed with the key aim of providing a model to demonstrate how executive function is applied at the various stages of task performance.
2. Cochrane systematic review of cognitive rehabilitation found insufficient evidence to support the effectiveness of cognitive rehabilitation for improving executive function after stroke and acquired brain injury. The review also identified limitation relating to assessment of executive function leading to the hypothesis that instructing patient to verbalise their thoughts may be a method of determining how patients apply executive function during tasks. Thus, a qualitative study to explore how participants expressed executive function through their actions and talking was indicated.
3. Ethnomethodological study to explore how individual express executive function through talking and actions: 20 participants with stroke, upper limb injury and a healthy individual were video-recorded during a semi-structured interview including an upper body dressing task. Data analysis, using a narrative analysis framework, and based around the executive function core components and the task application model, explored how executive function was expressed during application to the task. The participants demonstrated several patterns of executive function expression and dressing ability from their combined actions and talking.

Outcomes/Impact:

A new model integrating EF and task performance theories has been generated with the potential to provide a useful tool for profiling EF during task performance. Innovative methods were used to explore storytelling during task performance, providing new insights in relation to how EF is applied to the different stages of a task.

Publications:

- Gillespie, D., Bowen, A., Chung, C., Cockburn, J., Knapp, P. and Pollock, A. (2015) Rehabilitation for post-stroke cognitive impairment: An overview of recommendations arising from systematic reviews of current evidence. *Clinical Rehabilitation*, 29 (2), pp. 120-128
- Chung, C., Pollock, A., Campbell, T., Durward, B. and Hagen, S. (2013) Cognitive rehabilitation for executive dysfunction in adults with stroke or other adult non-progressive acquired brain damage: a Cochrane systematic review. *Stroke*, 44 (7), pp. 377-378.
- Chung, C., Pollock, A., Campbell, T., Durward, B. and Hagen, S. (2013) Cognitive rehabilitation for executive dysfunction in patients with stroke or other adult non-progressive acquired brain damage (Review). *Cochrane Database of Systematic Reviews*, Issue 4, Art. no.:CD008391. DOI: 10.1002/14651858.CD008391.pub2
- Chung, C., Pollock, A., Campbell-Breen, T., Durward, B. (2010) Cognitive rehabilitation for executive dysfunction in patients with stroke or other adult non-progressive acquired brain damage [Protocol]. *Cochrane Database of Systematic Reviews*, (3).
- Smith, L.N., James, R., Barber, M., Ramsay, S., Gillespie, D. and Chung, C. (2010) Rehabilitation of patients with stroke: summary of SIGN guidance. *BMJ (Clinical Research Ed)*, 340, pp. c2845

Thesis:

- Chung, C. Executive function during dressing: expression through talking and actions by people with and without stroke. 2015. PhD Thesis, Glasgow Caledonian University.

Presentations:

- Chung, C., Pollock, A., Campbell, T., Durward, B. Perception and Executive Function: Considerations for Assessment and Treatment of Stroke Patients 18 March 2015, Stroke Association Professional Training Event, Bromsgrove, United Kingdom.
- Chung, C., Pollock, A., Campbell, T., Durward, B. Perception and executive function December 2014, UK Stroke Forum Conference, Harrogate, UK.
- Chung, C., Pollock, A., Campbell, T., Durward, B. Executive Function Task Application Model Scottish Stroke Allied Health Professions Forum Conference, June 2014, Perth, UK.
- Chung, C., Pollock, A., Campbell, T., Durward, B. Comparing the effect of music therapy and music listening on the mood of acute stroke patients: a pilot randomised controlled trial. *Music Therapy Advances in Neuro-Disability: innovations in research and practice*, June 2013, London, UK.
- Chung, C., Pollock, A., Campbell, T., Durward, B. Attention and executive function: clinical assessment and intervention, September 2010, 2010 College of Occupational Therapists Specialist Section Neurological Practice Conference, Manchester, UK.
- Chung, C., Pollock, A., Campbell, T., Durward, B. Visual Problems Scottish Intercollegiate Guidelines Network Guideline 118 Management of patients with stroke: rehabilitation, prevention, and management of complications, and discharge planning June 2010, Glasgow, UK.
- Chung, C., Pollock, A., Campbell, T., Durward, B. Using narrative and observation to assess the application of executive function to upper body dressing after stroke World Federation of Occupational Therapists (WFOT) XV Congress, June 2010, Santiago, Chile.

Project Number:	STROKE02.12
Status:	Complete
Project Title:	Commercial gaming devices for stroke upper limb rehabilitation
Source of funding and total value of award:	£0
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Thomson K (PI), Pollock A (Glasgow Caledonian University), Bugge C (University of Stirling), Brady MC (Glasgow Caledonian University)
NMAHP RU investigators:	Pollock A, Brady MC.
Workstream:	Stroke
Start date:	2010
Duration:	72 months

Aim(s):

In order to address the identified gaps in the evidence base concerning effectiveness and implementation of commercial gaming devices (such as the Wii, Playstation or XBox), as well as the stroke survivor experience, this study aimed to answer four research questions:

1. What is the evidence for the effectiveness of commercial gaming devices for stroke upper limb rehabilitation?
2. How are therapists currently using commercial gaming devices for stroke upper limb rehabilitation?
3. What are stroke survivors' experiences of using gaming devices within their stroke upper limb rehabilitation?
4. Are commercial gaming devices an acceptable intervention for stroke upper limb rehabilitation?

Summary:

An integrative, systematic review of 29 studies (n=448), a survey of therapists (n=112; 88% response rate) and a qualitative study (n=13 stroke survivors) were completed. Findings were integrated via a triangulation protocol. Gaming was found to be a safe, feasible and meaningful rehabilitation activity, which had a positive

impact on treatment adherence and used by a fifth of Scottish therapists. Meta-analyses demonstrated no evidence of effect for arm function, movement or activities of daily living. Studies were small scale with methodological limitations and thus effectiveness remained unclear. Stroke survivors varied in their enthusiasm for commercial gaming devices. Enthusiastic players completed unsupervised practice of arm movements at a similar treatment intensity as seen within research contexts (greater than therapy-led sessions). Unsupervised practice using gaming devices may offer a resource and cost effective adjunct to standard upper limb rehabilitation.

Publications:

- Thomson, K., Pollock, A., Bugge, C. and Brady, M. (2015) Commercial gaming devices for stroke upper limb rehabilitation: a survey of current practice. *Disability & Rehabilitation: Assistive Technology*, 11 (6), pp. 454-461
- Thomson, K., Pollock, A., Bugge, C. and Brady, M. (2014) Commercial gaming devices for stroke upper limb rehabilitation: a systematic review. *International Journal of Stroke*, 9 (4), pp. 479-488.

Thesis:

- Thomson, K. The use of commercially available gaming as an intervention for stroke upper limb rehabilitation. 2015. PhD Thesis, Glasgow Caledonian University.

Published Abstract

- Thomson K, Pollock A, Bugge C, Brady M. The use of commercial gaming devices for stroke upper limb rehabilitation: a survey of current practice (2014), Rehabilitation 4. International Journal of Stroke, 9: 49–50. doi: 10.1111/ijss.12374_22
- Thomson K, Pollock A, Bugge C. The use of commercial gaming devices in stroke upper limb rehabilitation: A systematic review Published online before print February 17, 2015, doi: 10.1177/0269215515570099 Clin Rehabil February 17, 2015.

Presentations:

- Thomson K, Pollock A, Brady M, Bugge C. The use of commercial gaming in stroke upper limb rehabilitation: a systematic review. UK Stroke Forum, Glasgow UK. December 2-4th 2011.

Posters:

Thomson K, Pollock A, Bugge C, Brady M. The use of commercial gaming devices for stroke upper limb rehabilitation: a survey of current practice. UK Stroke Forum, Harrogate, UK. December 2-4th 2014.

STROKE02.13 LYCRA. Lycra orthosis for therapy in upper limb Rehabilitation after Stroke: The LOTUS Study

Project Number:	STROKE02.13
Status:	In Progress
Project Title:	LYCRA. Lycra orthosis for therapy in upper limb Rehabilitation after Stroke: The LOTUS Study
Source of funding and total value of award:	Chief Scientist Office, £246,182
Value of funding to NMAHP RU:	£141,554
Principal investigator/co-applicants:	Morris J (PI) (Glasgow Caledonian University), Kroll T, Donnan P (University of Dundee), Crighton G, Wedderburn L, R Mendes (NHS Tayside).
NMAHP RU investigators:	Morris J.
Workstream:	Stroke
Start date:	August 2015
Duration:	31 Months

Aim(s):

This two part study aims to explore feasibility, acceptability and potential effectiveness of dynamic lycra orthoses as an adjunct to upper limb rehabilitation after stroke to inform the design of a definitive randomised control trial. Phase one is a qualitative evaluation of stroke survivors', staff and carers experiences of using the dynamic lycra orthoses as an adjunct to usual practice. Phase two is a feasibility randomised controlled trial to explore feasibility and to provide estimated effect sizes to inform a definitive trial.

Summary:

Phase one is complete and phase two is ongoing. For Phase 1, Stroke survivors (n=17), with persistent upper limb activity limitation, 2-4 weeks after stroke, were purposively sampled by severity of activity limitation to wear tailor made dynamic lycra orthoses gauntlets, involving thumb, wrist and elbow, for eight hours per day for eight weeks.

Individual semi-structured interviews after lycra orthoses wear explored experiences of wear and perceived benefits. Analysis using the framework approach showed most participants could put on the lycra orthoses with ease and

adapted patterns of wear to their needs and perceptions of usefulness. Control of movement, task performance, jerkiness and muscle tightness were perceived benefits, as was greater sensory awareness of the limb. However, six more severely affected participants discontinued wear due to onset of upper limb swelling. Findings informed the development of the intervention and selection of outcome measures for the feasibility trial. To date, 33 stroke survivors have been recruited to the feasibility trial, of a target of 51. Completion date is the 31st March 2018.

Outcomes/Impact:

Phase 1 analysis to date shows that most participants could put on the lycra orthoses with ease and adapted patterns of wear to their needs and perceptions of usefulness. Control of movement, task performance, jerkiness and muscle tightness were perceived benefits, as was greater sensory awareness of the limb. However, six more severely affected participants discontinued wear due to onset of UL oedema.

Posters:

- John A, Morris J, Wedderburn L. Perspectives of staff within rehabilitation units on implementing Dynamic Lycra Orthoses as an adjunct to usual upper limb rehabilitation: A qualitative study. Scottish Stroke AHP Forum, June 2017, Perth, UK.
- Morris J, Wedderburn L, Mendes R Dynamic Lycra Orthosis as an Adjunct to Upper Limb Rehabilitation after Stroke: A Feasibility Study and Trial, Scottish Stroke AHP Forum June 2015, Perth, UK.

Presentations:

- Morris J, John A, Wedderburn L. Dynamic Lycra Orthoses as an adjunct to upper limb rehabilitation after stroke. European Forum on Rehabilitation Research May 2017, Glasgow, UK.

STROKE02.14 Early VERSus Later Augmented Physiotherapy (EVERLAP) compared with usual upper limb physiotherapy: an exploratory RCT of arm function after stroke

Project Number:	STROKE02.14
Status:	In Progress
Project Title:	Early VERSus Later Augmented Physiotherapy (EVERLAP) compared with usual upper limb physiotherapy: an exploratory RCT of arm function after stroke
Source of funding and total value of award:	Chartered Society of Physiotherapy, £198,750
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Van Wijck F (PI), Pollock A (Glasgow Caledonian University), Alexander G (NHS Greater Glasgow & Clyde), Baillie L (Glasgow Caledonian University), Bain B (Glasgow Caledonian University), Barber M (NHS Lanarkshire), Dall P, Donaldson C (Glasgow Caledonian University), Fleming A (Different Strokes), Granat M (Glasgow Caledonian University), Kerr A (Strathclyde University), McConnachie A (University of Glasgow), Langhorne P (University of Glasgow), Molloy K (Different Stroke), Rowe P (University of Strathclyde)
NMAHP RU investigators:	Pollock, A.
Workstream:	Stroke
Start date:	April 2015
Duration:	36 Months

Aim(s):

To test the feasibility of conducting a definitive three-arm randomised controlled trial and determine its methodology, size and cost. All three groups will receive usual upper limb physiotherapy; two of the three groups will receive additional, augmented upper limb physiotherapy delivered at different time points after stroke.

The three groups comprise:

(1) early augmented upper limb therapy within 3 weeks after stroke + usual physiotherapy; (2) later augmented upper limb therapy at 3 months after stroke + usual physiotherapy; and (3) usual upper limb therapy only.

Summary:

Recruitment to this trial commenced in November 2015.

Poster:

van Wijck F, Alexander G, Baillie L, Bain B, Barber M, Collins M, Dall P, Donaldson C, Fleming, Granat M, Kerr A, Langhorne P, McConnachie A, Micallef N, Molloy K, Pollock A, Rowe P, Uzor 3, Young HJ. EVERLAP: Early VERSus Later Augmented Physiotherapy compared with usual upper limb physiotherapy, protocol for an exploratory RCT of arm function after stroke. Society for Rehabilitation Research, Winter 2016

STROKE02.15 Physical activity for non-ambulatory stroke survivors living at home: developing a feasible and acceptable intervention

Project Number:	STROKE02.15
Status:	Complete
Project Title:	Physical activity for non-ambulatory stroke survivors living at home: developing a feasible and acceptable intervention
Source of funding and total value of award:	Chief Scientist office, £104,460
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	F van Wijck (PI), D Skelton (Glasgow Caledonian University), B Williams (University of Stirling), G Mead (University of Edinburgh and Edinburgh Royal Infirmary).
NMAHP RU investigators:	Williams B.
Workstream:	Stroke
Start date:	October 2012
Duration:	32 Months

Aim(s):

To design and evaluate the feasibility, experiences and potential effectiveness of an evidence-based, person-centred intervention to increase physical activity for non-ambulatory stroke survivors living at home.

Summary:

The project is ongoing and in receipt of a no cost extension after slow recruitment.

Stage 1: systematic literature review on effects and experiences of physical activity for non-ambulatory stroke survivors.

Stage 2: focus groups to explore views of non-ambulatory stroke survivors, carers and health care professionals on needs, barriers and motivators for physical activity interventions, personal physical activity goals and attitudes towards technology (i.e. Microsoft Kinect) designed to support a home-based PA intervention.

Stage 3: an iterative process of intervention development and evaluation, embedding an ongoing assessment of feasibility to ensure that the final intervention, based on stages 1 and 2, maximises stroke survivor engagement.

STROKE03

VISION



The proposed programmes of work will build on and consolidate the evidence base to demonstrate the impact of NMAHPs contribution to the delivery of health and social care services which will enable workforce planners and managers to design service delivery supported by an evidence base.



STROKE03.1 Visual scanning training after stroke: dissemination to facilitate translation of evidence into practice

Project Number:	STROKE03.1
Status:	Complete
Project Title:	Visual scanning training after stroke: dissemination to facilitate translation of evidence into practice
Source of funding and total value of award:	Stroke Improvement Fund, £6,594
Value of funding to NMAHP RU:	£6,594
Principal investigator/co-applicants:	Pollock P (PI), Brady M (Glasgow Caledonian University)
NMAHP RU investigators:	Pollock A, Brady M, Hazelton C.
Workstream:	Stroke
Start date:	April 2015
Duration:	12 Months

Aim(s):

We aimed to support translation of our research findings relating to visual scanning training for visual field loss into clinical practice across Scotland. Specifically, we aimed to provide access to health and social care professionals to the full range of available scanning training interventions, and the potential advantages and disadvantages of each of these tools when applied to individual patients with visual field loss.

Our key objectives were to :

1. Host training and dissemination events for health professionals involved in the delivery of visual rehabilitation for patients with stroke in Scotland.
2. Disseminate summaries of evidence, aimed at informing treatment choices of health professions.
3. Develop a training video, summarising the key points from the training events and summaries of evidence.

Summary:

We hosted five half day training events throughout Scotland. At each of these events we:

- Described the parameters of the different scanning training interventions available in Scotland

- Presented the results of our research findings, emphasising issues relating to practical challenges and individual patient preferences.
- Demonstrated a range of these interventions
- Provided “hands-on” opportunities for clinicians to try out these interventions.
- Facilitated discussion amongst participants in relation to the delivery of scanning training interventions within their local area.

We produced brief summaries of evidence, which described the different scanning training interventions and key parameters which health and social care professionals may use to inform patient-centred treatment decisions. We are developing a training video which summarises the key points from the training events and summaries of evidence.

Outcomes/Impact:

Over 100 clinicians from both vision care and stroke care backgrounds attended. Chest Heart and Stroke Scotland carried out an independent survey of the opinions of those attending the Lothian training event. Fifteen attendees replied, including OTs (5), physios (4), community support workers (2), rehabilitation officers (1). All reported the workshop was good (53.3%) or very good (46.7%) and relevance/usefulness to their clinical practice was graded as good by 60% and very good by 40%.

STROKE03.1 Visual scanning training after stroke: dissemination to facilitate translation of evidence into practice

Other dissemination activity:

Five half day training events were held in five geographically diverse locations across Scotland (Table1).

Table 1: Details of training events held:

Date	Location	Partner organisations	Attendees
14/5/15	Forth Valley Sensory Centre, Camelon	Falkirk Council	18
22/5/15	Summerfield House, Aberdeen	NHS Grampian	20
5/6/15	Visibility, Queens Crescent, Glasgow	Visibility & NHS Lanarkshire	25
10/6/15	Wishaw Hospital	Visibility	27
16/6/15	Edinburgh Royal Infirmary	NHS Lothian & Chest Heart and Stroke Scotland	21

STROKE03.2 Visual scanning training interventions for people with visual field loss after stroke

Project Number:	STROKE03.2
Status:	Complete
Project Title:	Visual scanning training interventions for people with visual field loss after stroke
Source of funding and total value of award:	The Stroke Association Research Training Fellowship, £105,000
Value of funding to NMAHP RU:	£105,000
Principal investigator/co-applicants:	Hazelton C (PI), Supervisors:, Pollock A,, Walsh G, Brady M (Glasgow Caledonian University)
NMAHP RU investigators:	Pollock A, Hazelton C, Walsh G, Brady M.
Workstream:	Stroke
Start date:	March 2011
Duration:	36 Months

Aim(s):

Visual field loss after stroke persists in around one fifth of survivors. Typically it makes the person blind to one side of space; however the impact on daily life is not clearly described. Scanning training aims to compensate for visual field loss by improving the eye movements made into the affected field. This project sought to explore the impact of visual field loss on daily life and investigate scanning training effect, feasibility and mechanisms of action.

Summary:

Scanning training was defined as a complex intervention and a pragmatic, mixed methods approach used. Scanning training effects, feasibility and theories of action were systematically identified and synthesised in a rigorous review of the literature. An email survey used snowball sampling to identify currently used interventions, and their components were described using methods that included consensus-based expert panel assessment. Stroke survivors were interviewed and qualitative analyses explored their perceptions of the impact of visual field loss. The effect and feasibility of four interventions were explored using an n-of-1 study with both qualitative interviews and quantitative measures.

Stroke survivors (n=12, median age 55.5) reported that visual field loss impacted on three areas of daily life: practical abilities, social interactions and emotions (notably fear and self-confidence). Scanning interventions had limited published quantitative evidence of effect, reports of feasibility or qualitative data (studies=33; 30 low quality). Whilst there were a number of hypothesized mechanisms of action, understanding of these was hampered by ambiguous descriptions. Ten different home-based scanning interventions used in Scotland were identified, across four different delivery modalities. Interventions were feasible for use by stroke survivors, but the effect of therapy was less clear. Participants (n=11, median age 56) reported experiencing effects on their emotions, visual skills, cognitive skills and practical abilities. Interventions and participant factors associated with feasibility and effect were identified. The inter-relation between these factors was mapped and a resulting model of intervention effect was proposed.

Outcomes/Impact:

The use of a mixed methodology approach provided unique insight into the impact of visual field loss, mechanisms of action and feasibility and effect of scanning training. Visual field loss has a broad impact on the daily lives of stroke survivors. Scanning training interventions are feasible and are perceived by stroke survivors to have a beneficial effect on their emotions and abilities in everyday tasks and activities. This project resulted in a PhD awarded to Christine Hazelton. Christine has now secured a post as a research fellow within the NMAHP Research Unit funded by Glasgow Caledonian University, enabling the continuation of this body of work relating to vision after stroke.

Publications:

- Hazelton CR. Visual field loss after stroke: a mixed methods exploration of scanning training interventions. PhD Thesis. Glasgow Caledonian University. 2016.

Other dissemination activity:

- See dissemination project entitled "Visual scanning training after stroke: dissemination to facilitate translation of evidence into practice" [Stroke03.1].
- Knowledge exchange event 11th May 2017 at Glasgow Caledonian University on "Vision and Stroke".

Published abstracts:

- Hazelton C, Pollock A, Walsh G, Brady 2012. Scanning training for visual field loss: a mixed methods literature review and exploration of available interventions. *International Journal of Stroke*, 7(Suppl 2), p.41.
- Hazelton C, Pollock A, Walsh G, Brady M. 2013. Rehabilitation for visual field loss: exploring scanning training interventions. *Cerebrovascular Diseases*, 35(Suppl 3), p.585.

- Hazelton C, Pollock A, Walsh G, Brady M. 2013. The "what, who and how" of scanning training for visual field loss after stroke: a comprehensive mixed methods systematic literature review. *Cerebrovascular Diseases*, 35(Suppl 3), p.826.
- Hazelton C, Pollock A, Walsh G, Brady M. 2014. Rehabilitation for visual field loss after stroke: exploring scanning training interventions in Scotland. *Ophthalmic and Physiological Optics*, 34, p.106.
- Hazelton C, Pollock A, Walsh G, Brady M. 2015. Scanning training for visual field loss after stroke: an exploration and comparison of current interventions. *Clinical Rehabilitation*, 29(4), p.408.
- Hazelton C, Pollock A, Walsh G, Brady M. Visual field loss after stroke: exploring the impact on daily life. *Clinical Rehabilitation*, 29(10), p.1016

STROKE03.3

A pilot RCT to compare the clinical and cost effectiveness of prism glasses, visual search training and standard care in patients with hemianopia following stroke (VISION trial)

Project Number:	STROKE03.3
Status:	Complete
Project Title:	A pilot RCT to compare the clinical and cost effectiveness of prism glasses, visual search training and standard care in patients with hemianopia following stroke (VISION trial)
Source of funding and total value of award:	The Stroke Association, £209,926
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Rowe F (PI) (University of Liverpool), Conroy EJ, Bedson E (University of Liverpool), Cwiklinski E (Oxford University Hospitals NHS Trust), Drummond A (University of Nottingham), García-Fiñana M (University of Liverpool), Howard C Salford Royal NHS Foundation Trust, Shipman T (Sheffield Teaching Hospitals NHS Foundation Trust), Dodridge C, MacIntosh C (Oxford University Hospitals NHS Trust), Pollock A (Glasgow Caledonian University), Johnson S (RNIB), Noonan C Aintree University Hospital NHS Foundation Trust, Barton G (Warrington and Halton Hospitals NHS Foundation Trust), Sackley C (University of East Anglia).
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	July 2010
Duration:	36 months

Aim(s):

This pilot trial compared visual rehabilitation interventions with NHS standard care, in patients with hemianopia following stroke. This pilot trial gathered important recruitment and feasibility data in preparation of a definitive trial to explore whether visual rehabilitation was more effective than standard care (advice only) at improving functional outcome in patients with hemianopia following stroke and whether prism therapy or visual search therapy was more effective at improving functional outcome in patients with hemianopia following stroke.

Summary:

Methods

Prospective, multicentre, parallel, single-blind, three-arm RCT across fifteen UK acute stroke units.

Participants:

Stroke survivors with homonymous hemianopia.

Interventions:

1. Fresnel prisms for minimum 2 hours, 5 days per week over 6 weeks versus 2. visual search training for minimum 30 minutes, 5 days per week over 6 weeks Versus 3. Standard care comprised of information provision. Inclusion criteria: Adult stroke survivors (>18 years), stable hemianopia, visual acuity better than 0.5 logMAR, refractive error within ± 5 dioptres, ability to read/understand English and provide consent.

Inclusion criteria:

Adult stroke survivors (>18 years), stable hemianopia, visual acuity better than 0.5 logMAR, refractive error within ± 5 dioptres, ability to read/understand English and provide consent.

Outcome measures:

Primary outcomes were change in visual field area from baseline to 26 weeks and calculation of sample size for a definitive trial. Secondary measures included Rivermead Mobility Index, Visual Function Questionnaire 25/10, Nottingham Extended Activities of Daily Living, Euro Qual, Short Form-12 questionnaires and Radner reading ability. Measures were post-randomization at baseline and 6, 12 and 26 weeks.

Randomisation:

Block lists stratified by site and partial/complete hemianopia.

Blinding:

Allocations disclosed to patients. Primary outcome assessor blind to treatment allocation.

Were compared to baseline. Sample size calculation for a definitive trial determined as 269 participants per arm for a 200 degree² visual field area change at 90% power. Non-significant relative change in area of visual field was 5%, 8% and 3.5%, respectively, for the three groups. Visual Function Questionnaire responses improved significantly from baseline to 26 weeks with visual search training (60 [SD 19] to 68.4 [SD 20]) compared to Fresnel prisms (68.5 [SD 16.4] to 68.2 [18.4]: 7% difference) and standard care (63.7 [SD 19.4] to 59.8 [SD 22.7]: 10% difference), $P=.05$. Related adverse events were common with Fresnel prisms (69.2%; typically headaches).

Outcomes/Impact:

Visual search training may provide significant improvement in vision-related quality of life. Prism therapy produced

adverse events in 69%. Visual search training results warrant further investigation. The pilot data provided important information to inform the development of a full-scale multi-centre RCT of visual search training.

Publications:

- Rowe FJ, Barton PG, Bedson E, Breen R, Conroy EJ, Cwiklinski E, C Dodridge, A Drummond, M Garcia-Finana, C Howard, S Johnson, C MacIntosh, C P Noonan, A Pollock, J Rockliffe, C Sackley, T Shipman. A randomised controlled trial to compare the clinical and cost-effectiveness of prism glasses, visual search training and standard care in patients with hemianopia following stroke: a protocol. *BMJ Open* [Internet]. 2014;4(7):e005885.
- Rowe FJ, Conroy EJ, Barton PG, Bedson E, Dodridge C, Drummond A, M Garcia-Finana, C Howard, S Johnson, C MacIntosh, C P Noonan A Pollock, J Rockliffe, C Sackley, T Shipman. A Randomised Controlled Trial of Treatment for Post-Stroke Homonymous Hemianopia : Screening and Recruitment. *Neuro-Ophthalmology*; (40) 2016;8107(February):1–7.
- Rowe FJ, Conroy EJ, Bedson E, Cwiklinski E, Drummond A, M Garcia-Finana, C Howard, A Pollock, T Shipman, C Dodridge, C MacIntosh, S Johnson, C P Noonan, PG Barton, C Sackley, A pilot randomized controlled trial comparing effectiveness of prism glasses, visual search training and standard care in hemianopia. *Acta Neurol Scand*. 2016; (November):1–12.

STROKE03.4

Writing group to develop proposals aimed at evaluating the effectiveness of visual scanning training on activity and participation in patients with visual problems after stroke

Project Number:	STROKE03.4
Status:	In Progress
Project Title:	Writing group to develop proposals aimed at evaluating the effectiveness of visual scanning training on activity and participation in patients with visual problems after stroke
Source of funding and total value of award:	BASP / NIHR, £1882.48
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Clatworthy P (PI) (University of Bristol), Leff A (, Lane A, Gilchrist I, Atan D, Angilley J, Turton A (University of Bristol), Howard C (Salford Royal NHS Foundation Trust), Rowe F (University of Liverpool), Forster A (University of Leeds), Bowen A (University of Manchester), Hazelton C (Glasgow Caledonian University), Ben-Shlomo Y (University of Bristol), Burton C (university of Bangor), Jenkinson D (Dorset County Hospital NHS Trust), Bateman A (Oliver Zangwell Centre).
NMAHP RU investigators:	Hazelton C.
Workstream:	Stroke
Start date:	August 2016
Duration:	24 Months

Aim(s):

To develop grant proposals to examine whether a complex intervention comprising specific vision assessment, defined therapist treatment including accompanying education, and computerised vision training is effective at reducing disability following stroke causing visual field loss?

Summary:

This proposal relates to assessment and treatment of visual loss following stroke. The most common pattern of visual field loss is loss of visual field to one side (hemianopia). There have been numerous small clinical studies of interventions for hemianopia, indicating probable effectiveness at reducing disability following stroke, but there has been no large clinical trial. Interventions include therapist-led interventions, computerised/paper based interventions and scrolling text for reading difficulties.

To date no clinical trial has evaluated an integrated intervention for assessment and treatment of hemianopia, nor a combination of interventions for different impairments and causes of disability and loss of social function in hemianopia, for example activity-based occupational therapy with computerised visual search and reading therapy software.

This writing group combines expertise from multiple disciplines, including patients, carers and the public, to devise a clinical trial or series of trials with the maximum chance of success, both in terms of attracting funding and likelihood of demonstrating clinical effectiveness.

STROKE03.4 Writing group to develop proposals aimed at evaluating the effectiveness of visual scanning training on activity and participation in patients with visual problems after stroke

We will seek a practical consensus regarding the design of a programme of clinical studies culminating in a definitive clinical trial of a complex intervention for hemianopia. The likely outcome will be an application for a pilot clinical trial through Research for Patient Benefit followed by a Health Technology Assessment, or an NIHR Programme Development Grant. The resulting study/studies will therefore be eligible for CRN support. Other NIHR partner organisations, such as The Stroke Association, will also be considered as sources of funding.

Outcomes/Impact:

- The group is in the process of developing a number of grant applications relating to scanning training interventions, including an application to NIHR.
- Through facilitating face-to-face group meetings, this project has allowed new networks to be created, of potential value for future scanning training development

STROKE04

ORAL HEALTH CARE



NMAHP-RU should continue to work collaboratively to strengthen and influence clinical academic research collaborations with a focus on policy, national priorities and impact. Moving forward, continue to strengthen the Unit's influence on: using innovative approaches to inform and assess the effectiveness of health and social care interventions; capacity building of NMAHP researchers; and encourage more NMAHPS to use evidence to inform their practice.



STROKE04.1 Cochrane review of staff-led interventions for improving oral hygiene in patients following stroke

Project Number:	STROKE04.1
Status:	In Progress
Project Title:	Cochrane review of staff-led interventions for improving oral hygiene in patients following stroke
Source of funding and total value of award:	£0
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Brady MC (PI), Furlanetto D (Glasgow Caledonian University and Unieuro Centro Universitário, Brazil), Hunter R (University of Dundee), Lewis SC (University of Edinburgh), Milne, V, Bain, B (Glasgow Caledonian University).
NMAHP RU investigators:	Brady MC, Furlanetto D, Milne, V, Bain B.
Workstream:	Stroke
Start date:	May 2010 and January 2017
Duration:	Ongoing

Aim(s):

To compare the effectiveness of staff-led oral care interventions with standard care for ensuring oral hygiene for individuals after a stroke.

Summary:

Keeping the mouth clean (removing dental plaque and traces of food) is a crucial factor in maintaining the health of the mouth, teeth and gums. A clean and healthy mouth also prevents pain or discomfort and allows people to eat a range of nutritious foods. Maintaining good oral hygiene may be difficult after a stroke and healthcare staff may have to assist in providing such care.

We reviewed the available evidence from investigative trials that addressed staff-led oral care interventions for inclusion on the basis of study design, interventions and outcome measures used. All randomised controlled trials that examined oral care interventions for elderly groups (which had the potential to have included individuals post stroke) were eligible for inclusion.

Two review authors independently evaluated relevant trials (based on the full texts). They confirmed the inclusion of the study within the review. In some cases we asked the trial authors to provide additional information before we could make a final decision. We resolved conflicting decisions through discussion.

We included three studies involving 470 participants. These trials were of limited comparability evaluating an OHC education training programme, a decontamination gel and a ventilator-associated pneumonia bundle of care augmented with an OHC component by comparing them to a deferred intervention, a placebo gel or standard care respectively. The OHC educational intervention demonstrated a significant reduction in denture plaque scores up to six months ($P < 0.00001$) after the intervention but not dental plaque. Staff knowledge ($P = 0.0008$) and attitudes ($P = 0.0001$) towards oral care also improved. The decontamination gel reduced the incidence of pneumonia amongst the intervention group ($P = 0.03$).

The 2011 review of three studies found little evidence of how this care is best delivered. Information on a small number of nursing home residents who had a stroke (67 participants from a larger trial) showed that training nursing staff improved their knowledge of oral care and resulted in improved oral hygiene in their patients. Another trial demonstrated the beneficial impact of a decontamination gel on the incidence of pneumonia amongst patients in a stroke ward. However, there was no other information on how best to provide oral hygiene and more studies are urgently needed.

Outcomes/Impact:

The findings of this Cochrane review have been cited in a range of national (Royal College of Physicians 2010) and international stroke clinical guidelines (Australia, Canada, New Zealand). As a result of this Cochrane review we developed and secured funding for a small pilot trial of oral health care in stroke care settings (Stroke04.2). Following the completion of that pilot trial (and the emergence of additional evidence from several trials of the effectiveness of OHC interventions after stroke) we are updating this Cochrane review again. We expect a publication date of 2018.

We were also invited to participate in a British Association of Stroke Physicians funded writing group on the topic of oral healthcare after stroke in Manchester in 2016. A multidisciplinary consensus paper on the current evidence base for OHC for people after stroke and recommendations for future research in this topic area is currently under review.

Publications:

- Brady MC, Furlanetto D, Hunter RV, Lewis S, Milne V. Oral Health Care for Patients after Stroke. *Stroke*. 2011;42:e636–e637 (originally published online October 13, 2011) doi: 10.1161/STROKEAHA.111.628198.
- Brady MC, Furlanetto D, Hunter RV, Lewis S, Milne V. Staff-led interventions for improving oral hygiene in patients following stroke. Issue 4, 2011 Cochrane Database of Systematic Reviews Art. No.: CD003864. DOI: 10.1002/14651858.CD003864.pub2.

Other dissemination activity:

- Walton C, Brady MC. Oral health for stroke patients (invited) *The Dentist* (2014-15).

Presentations:

- Brady M. [invited] Oral healthcare after stroke; A deceptively simple or complex intervention? UK Swallowing Research Group, 4th and Friday 5th February 2016, London, UK.
- Brady MC. [invited] Interventions for improving oral hygiene following a stroke. *Advancing Stroke Practice*. National Stroke Nursing Forum, October 2011, Royal Preston Hospital, Preston, UK.

STROKE04.2

A multi-centred, stepped wedge, cluster randomised controlled trial to compare the clinical and cost effectiveness of a complex oral health care intervention and standard oral health care in stroke care settings: a Phase II pilot trial (SOCLE II)

Project Number:	STROKE04.2
Status:	Complete
Project Title:	A multi-centred, stepped wedge, cluster randomised controlled trial to compare the clinical and cost effectiveness of a complex oral health care intervention and standard oral health care in stroke care settings: a Phase II pilot trial (SOCLE II)
Source of funding and total value of award:	The Stroke Association Clinical Trial Project Grant £163,008 and Scottish Stroke Action Plan and Implementation fund £6650
Value of funding to NMAHP RU:	£169,658
Principal investigator/co-applicants:	Brady MC (PI) (Glasgow Caledonian University), Stott D (University of Glasgow), Chalmers C (NHS Lanarkshire), Weir C (University of Edinburgh), Sweeney P (Glasgow Dental School), Donaldson C, Pollock A (Glasgow Caledonian University), Barr M, Barr J (Stroke Survivor and Carer representatives), Langhorne P (University of Glasgow).
NMAHP RU investigators:	Brady MC, Pollock A (researchers) McGowan S, Bowers N, McQueen J, Bain B, Gray H.
Workstream:	Stroke
Start date:	January 2015
Duration:	36 months

Aim(s):

To conduct a Phase II pragmatic multi-centred stepped wedge cluster RCT pilot of a complex OHC intervention.

Research questions:

1. Are our SOCLE intervention and data collection process viable across multiple sites?
2. Can we refine our sample size calculations and estimates of recruitment and retention?
3. Can we determine pneumonia event rates across several sites and distribution over time post stroke onset? Can we establish the association between dental and denture plaque and SAP?
4. Can we meet our predetermined criteria for progression to Phase III definitive multi-centred stepped wedge cluster RCT with economic evaluation?

Summary:

Stroke associated pneumonia affects a fifth of stroke survivors annually, tripling the risk of death at 30 days and contributing to poorer rehabilitation outcomes, prolonged hospital stays and dependency at discharge. Systematic review evidence indicates that enhanced oral health care (OHC) has a preventative effect on the incidence of pneumonia amongst nursing home populations (absolute risk reductions 6.6% to 11.7%; numbers needed to treat 8.6 to 15.3 individuals).

Similar benefits might be observed in stroke care settings but current empirical evidence is weak (Stroke04.1). Following an extensive pre-clinical programme of work, we undertook a pilot stepped-wedge cluster RCT of a well-developed and defined complex OHC intervention versus usual OHC. This project represents one stage in the development, evaluation and delivery of enhanced oral healthcare after stroke. SOCLEII represents the culmination of pre-existing Cochrane systematic review, survey of practice and feasibility testing. We recruited 324 patients from across four Scottish hospital sites. Our analyses across usual care, intervention and enhanced care phases were informed by n=135, n=56 and n=147 patients respectively. While the number of patient recruits were lower than anticipated, a key insight arising from our pilot was the development of realistic recruitment targets and participant representation across the trial phases. We also recruited 112 staff. Most were registered nurses (n=62; 55%) or clinical support workers (n=44; 39%) with a small number of student nurses (n=5; 5%). We are currently preparing manuscripts reporting the findings from this pilot study.

Outcomes/Impact:

- The SOCLE II data will contribute to the evidence update of the relevant Cochrane review (Stroke04.1).
- In addition, we are working on updating our understanding of current OHC practice in an updated parallel survey of UK and Australian stroke nurse practice (with Prof Sandy Middleton (Australian Catholic University) and Dr Dominique Cadilhac (Florey Neurosciences Institute, University of Melbourne) Australia and Prof Dame Caroline Watkins, University of Central Lancashire).
- Our online training tool (supported by the Scottish Stroke Action Plan and Implementation fund) was developed with the support of Stewart Cromer, University of Edinburgh's Learning Technology section with the view towards its inclusion (post-trial) in the online Stroke Training and Awareness Resources (STARS).
- We participated in a recent research writing group meeting led by Prof Craig Smith, University of Manchester. Jointly funded by the British Association of Stroke Physicians and the National Institute for Health Research Clinical Research Network (Stroke Portfolio Development Opportunity) the first writing group meeting took place in February 2016 (London) with a second group hosted later in the year (Manchester).

Together the multidisciplinary group have contributed to drafting a manuscript describing the challenges of conducting OHC research and has researched consensus on key recommendations for future research which is currently under review.

Publications:

- Brady MC, Stott DJ, Chalmers C, Sweeney MP, Weir C, Donaldson C, Bowers N, McGowan S, Langhorne P. Clinical and cost effectiveness of enhanced oral health care in stroke care settings (SOCLE II): A pilot, stepped wedge, cluster randomised, controlled trial protocol. *International Journal of Stroke*.2015 (10), 979-984. DOI: 10.1111/ijis.12530
- Brady MC, Stott DJ, Norrie J, Chalmers C, St George B, Sweeney MP, Langhorne P. Developing and evaluating the implementation of a complex intervention: using mixed methods to inform the design of a randomised controlled trial of an oral healthcare intervention after stroke. *Trials*. 2011;12:168. doi:10.1186/1745-6215-12-168

Other dissemination activity:

- Walton C, Brady MC. Oral health for stroke patients (invited) *The Dentist* (2014-15).

Presentations:

- Brady M. [invited] Oral healthcare after stroke – a deceptively simple or complex intervention UK Swallowing Research Group, 4th and Friday 5th February 2016, London, UK
- Brady M. [Keynote] Oral healthcare after stroke – a deceptively simple or complex intervention. *Stroke 2015* August 2015, Melbourne, Australia.
- Brady M, Stott D, Sweeney MP, Chalmers C, Weir C, Barr J, Barr M, Donaldson C, Langhorne, P. Stroke Oral health Care pLan Evaluation (SOCLE). UK Stroke Forum, 3-5th December 2013, Harrogate, UK
- Brady MC. [invited] Interventions for improving oral hygiene following a stroke. *Advancing Stroke Practice*. National Stroke Nursing Forum, October 2011, Royal Preston Hospital, Preston, UK.
- Brady MC, Stott D, Langhorne P, Norrie J, Sweeney MP, Chalmers C, St George B. Oral health care: development of a structured approach, [invited] Welsh Stroke Conference, 25th June 2010, Glasgow, UK.

Project Number:	STROKE04.3
Status:	Complete
Project Title:	DORIS Guidelines Project
Source of funding and total value of award:	Stroke Action Plan Implementation Fund, £22,390
Value of funding to NMAHP RU:	£21,257
Principal investigator/co-applicants:	Langhorne P (PI) (University of Glasgow), Pollock A (Glasgow Caledonian University)
NMAHP RU investigators:	Pollock A.
Workstream:	Stroke
Start date:	September 2013
Duration:	6 months

Aim(s):

To update the guidelines section of DORIS to incorporate two recent major British clinical practice guidelines (RCP Stroke Guideline 2012, NICE Stroke Rehab Guidelines 2013).

Summary:

This project focused on improving education and training in stroke services by enabling easy access to up-to-date national clinical practice guidelines, within an established web-based resource (DORIS: Database Of Research In Stroke. www.askDORIS.org).

DORIS provides easy access to: current best evidence, including guidelines, systematic reviews and RCTs; ongoing research and priorities for future research. In 2013, this web-based database contained 19860 references to 8202 trials and 1024 systematic reviews. It facilitates education and training relating to best evidence for stroke care, and can enable a collaborative approach to research activity and implementation, enhancing efficient resource utilisation.

One of the key resources to facilitate education and training, and enhance evidence-based practice, is the provision of easy access to – and ability to browse – recommendations from national guidelines. Currently DORIS contains the

individual recommendations relating specifically to rehabilitation from the SIGN guidelines (SIGN 118) and from the RCP guidelines (2008 version). These guideline recommendations were entered into the DORIS database during the development phase. However – since the inception of DORIS – two major national guidelines have been published (RCP Stroke Guideline 2012, NICE Stroke Rehab Guidelines 2013). Adding new guidelines to DORIS is labour intensive and requires substantial dedicated time input.

Outcomes/Impact:

DORIS was updated to contain the planned UK guidelines, as well as a number of international guidelines.

Publications:

- Pollock, A., St George, B., Fenton, M., Crowe, S. and Firkins, L. (2014) Development of a new model to engage patients and clinicians in setting research priorities *Journal of Health Services Research and Policy*, 19 (12), pp. 18.
- Pollock, A., St George, B., Fenton, M., Crowe, S. & Firkins, L. (2013) Top Ten Research Priorities relating to Life after Stroke – consensus from stroke survivors, caregivers, and health professionals. *International Journal of Stroke*, 9 (3), pp. 313-320.

Published Letter:

- Pollock, A., St George, B., Fenton, M., Firkins, L. (2012)
Top ten research priorities relating to life after stroke
Lancet Neurology, 11 (3), pp. 209.

Professional Journal:

- Pollock, A. (2010) The involvement of stroke survivors
and carers in stroke research. Stroke Matters, 7, pp. 15.

Published Abstracts:

- A Pollock, B St George on behalf of the 'Life after
stroke' Priority Setting Partnership. Research priorities
relating to life after stroke: differences in the priorities of
health professionals and stroke survivors. Cerebrovasc
Dis 2013;35 (suppl 3): 774.
- St George B, Pollock A on behalf of the 'Life after
stroke' priority setting partnership. Communication after
stroke: a top research priority for stroke survivors. Int J
Stroke 2012;7(suppl 2): 4.
- St George B, Pollock A, Fenton M, Crowe S, Firkins L.
Facilitating representative and equitable engagement
of stroke survivors and health professionals in setting
research priorities. Int J Stroke 2012; 7(suppl 2): 17.
- St George B, Pollock A, Firkins L. Research priorities
relating to life after stroke: results of a James Lind
Alliance priority setting project. Int J Stroke 2011;
6(suppl 2); 51.

HEALTH AND BEHAVIOUR CHANGE



PRIMARY PREVENTION OF ILL HEALTH THROUGH BEHAVIOUR CHANGE

“

The infectious enthusiasm of the researchers and their stoicism when things were difficult have been singular.

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Project Number:	HBC01.1
Status:	In Progress
Project Title:	Feasibility study of how best to engage obese men in narrative Short Message System (SMS) and incentive interventions for weight loss, to inform future effectiveness and cost-effectiveness trial
Source of funding and total value of award:	NIHR/PHR, £490,970
Value of funding to NMAHP RU:	£241,968
Principal investigator/co-applicants:	Hoddinott P (Co-PI) (University of Stirling), Elders A (Glasgow Caledonian University), Grindle M (University of Stirling), Dombrowski S (Co-PI) (University of Stirling), Avenell A (University of Aberdeen), Gray C (University of Glasgow), Jones C (University of Dundee), Kee F (Queens University Belfast, Men's Health Forum Charity), McKinley M (Queens University Belfast), van der Pol M (University of Aberdeen).
NMAHP RU investigators:	Hoddinott P, Elders A, Grindle M, (moved to University of Highlands and Islands 01/01/17) McDonald M, Harris F, Skinner R (PhD student).
Workstream:	Health Behaviour Change
Start date:	June 2016
Duration:	27 Months

Aim(s):

To co-produce with PPI, an acceptable and feasible RCT design with broad reach to test a narrative theory-based SMS intervention with embedded BCTs, with and without an endowment incentive, compared to waiting list control, to inform a future full trial.

Objectives:

Phase 1: intervention adaptation

1. To collaborate with a charity for men and obese men to minimise inequalities and maximise intervention appeal and reach.
2. To refine the theoretical basis of the intervention by integrating systematic review findings and NICE evidence for reducing diets, PA, BCTs and theory to refine a logic model.
3. To operationalise acceptable and effective BCTs to embed in a novel narrative SMS delivery form, which builds on existing NIHR-funded narrative SMS alcohol interventions.
4. To identify acceptable ways to provide a menu of information resources on e.g. diet, PA, visual feedback of self-report weight and waist circumference, pedometer readings using our own or other available open source websites.
5. To optimise an endowment incentive in order to motivate behaviour change. This will be achieved through applying insights from behavioural economics and a survey/DCE with obese men to define the frequency, constant or varying values and contingency of incentives on targets met for i) initial weight loss ii) weight loss maintenance.
6. To select acceptable and valid outcome and cost-effectiveness measures with potential for future long-term data linkage.
7. To produce: a library of SMS content, recruitment materials and a Phase 2 protocol.

Phase 2: feasibility trial to refine approach, recruitment, randomisation, intervention delivery, engagement, retention and follow-up processes

8. To assess the acceptability and willingness to be randomised to i) SMS ii) SMS and endowment incentive or iii) waiting list for SMS.
9. To assess the acceptability and feasibility of recruiting from GP practice obesity registers and community venues, identified in Phase 1.
10. To determine the acceptability of intervention content, delivery and attendance levels for objective weight measures at baseline, 3, 6, and 12 months and any unintended consequences.
11. To assess the likely impact on % weight loss at 12 months and health inequalities via assessment of differential uptake and potential effectiveness by socio-economic group

Summary:

In the UK 25% of people are obese, with higher prevalence in men and those from deprived backgrounds. Obesity conveys an increased risk of serious health conditions and is a major public health priority. This novel narrative SMS and endowment incentive feasibility study fits the NICE research recommendations to investigate new technologies and specific behaviour change techniques. It builds on Unit work by Pat Hoddinott on the NIHR funded ROMEO systematic reviews on obesity in men [HBC01.6] and on incentive interventions for health related behaviour change [HBC02.1]. It also builds on the PhD undertaken by Mark Grindle, who has a background in film, television and computer games script writing and production (graduated 2014, University of Stirling) entitled: The power of digital storytelling to influence human behaviour. Mark's PhD was supervised by the Unit's Brian Williams. The study also builds on learning gained by Brian Williams and the Dundee collaborators on delivering SMS interventions to men with alcohol problems [HBC01.3 HBC01.7, HBC01.8] The Game of Stones study is collaborating with the Men's Health Forum, who also provided Patient and Public Involvement (PPI) in the ROMEO study [HBC01.6]

Additional PPI and qualitative research has been undertaken with men in the target population via community groups like Men's Sheds to refine the design of the intervention and trial processes. A survey and a Discrete Choice Experiment (DCE) informs the design of a feasibility RCT which has three arms: narrative SMS, narrative SMS with financial incentives linked to target weight loss, a waiting list for the SMS intervention (control). Men are followed up at 3, 6 and 12 months. A University of Stirling PhD student, Rebecca Skinner, supervised by Pat Hoddinott will follow up men for a further year after the study has finished to investigate their experiences with weight management.

Outcomes/Impact: The survey and DCE was completed by a representative UK sample of 1044 obese men. The feasibility RCT is in progress and met the pre-specified recruitment target of recruiting 105 obese men within 4 months at 2 sites using two strategies; obese men registered at GP practices and through community venues. The sample includes more men from disadvantaged backgrounds than most other obesity intervention studies.

Publications:

- Hoddinott, P., Dombrowski, S., van der Pol, M., Kee, F., Grindle, M., Gray, C., Avenell, A. and McKinley, M. on behalf of the research team. (2017) Opportunities and pitfalls encountered when using the template for intervention description and replication (TIDIER) to develop a complex intervention to reduce obesity in men. *Trials*, 18 (suppl 1), pp. 249.

Other dissemination activity:

- Hoddinott, P., Dombrowski, S., van der Pol, M., Kee, F., Grindle, M., Gray, C., Avenell, A. and McKinley, M. on behalf of the research team. (2017) Opportunities and pitfalls encountered when using the template for intervention description and replication (TIDIER) to develop a complex intervention to reduce obesity in men. Poster presentation. Society for Clinical Trials/ International Clinical Trials Methodology Conference, Liverpool, May 2017.

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- Van der Pol M, Collacott H, Hoddinott P, Dombrowski SU, Kee F on behalf of the Game of Stones research team. Optimising the design of a financial incentive scheme for weight loss using behavioural economics and a survey of individuals' preferences. Health Economics Study Group, University of Birmingham, January 2017.
 - Hoddinott P and Skinner R. The Game of Stones Study: Texting men to help them lose weight. University of Stirling event to celebrate International Men's Day. 16 November 2016.
 - Foster K. Now NHS will pay you £400 to lose weight. The Scottish Mail on Sunday, cited 22 May 2016) <https://www.pressreader.com/uk/the-scottish-mail-on-sunday/20160522/281479275650039>
 - Howarth M. The Million Pound Blob. The Scottish Sun. (cited 28 August 2016)

Project Number:	HBC01.2
Status:	Complete
Project Title:	Feasibility study for a weight loss intervention for women treated for breast cancer (PhD studentship)
Source of funding and total value of award:	CRANES and the University of Aberdeen Development Trust, £78,000.00
Value of funding to NMAHP RU:	£0.
Principal investigator/co-applicants:	Heys S (PI), Clark J, McNeill G (University of Aberdeen)
NMAHP RU investigators:	Hoddinott P.
Workstream:	Health Behaviour Change
Start date:	January 2010
Duration:	36 Months

Aim(s):

To assess the feasibility of a commercial weight watchers groups with additional dietitian-led group sessions tailored for breast cancer patients and measuring weight and quality of life outcomes compared to its regular programme or a wait-list control to inform the design of a future trial in women treated for breast cancer.

Objectives:

1. To assess the feasibility of randomising women treated for breast cancer to a Weight Watchers programme with additional dietitian-led group sessions, a regular Weight Watchers programme or a wait-list control group
2. To assess the feasibility and acceptability of recruiting and retaining women treated for breast cancer until the trial exit
3. To explore women's experiences of the intervention
4. To assess the opportunities and barriers of delivering the intervention

To assess the feasibility of collecting outcome data on the effects on body weight and quality of life in women

randomised to either a Weight Watchers programme with additional dietitian-led group sessions, a regular Weight Watchers programme or a wait-list control group to inform sample size calculations for a larger trial.

Summary:

Weight gain is common among women treated for breast cancer. Many women report gaining weight as a result of their breast cancer diagnosis and due to the effects of certain treatment regimens such as chemotherapy. Obesity is associated with an increased risk of developing breast cancer and with increased all-cause mortality following diagnosis. Overweight or obesity at the time of breast cancer diagnosis and/or after diagnosis is associated with a poorer quality of life score, higher rates of anxiety, depression, various co-morbidities (e.g. cardiovascular disease (CVD) and diabetes) and also disease recurrence or decreased survival. Lack of support and guidance from health professionals following cancer diagnosis also has been reported as a barrier to maintaining a healthy weight.

This pilot study assessed the effect of 12 weeks' free Weight Watchers vouchers, with or without dietitian-led support groups, on weight and quality of life in women treated for breast cancer. 45 overweight or obese women previously treated for breast cancer were randomly allocated to three groups: Weight Watchers vouchers for 12 weeks plus 5 dietitian-led support groups; Weight Watchers vouchers or waiting-list control (Weight Watchers vouchers after 3 months). Participants were followed up at 0, 3 and 12 months and qualitative interviews were undertaken to understand their experiences.

Outcomes/Impact:

1. Rumana Newlands gained her PhD at the University of Aberdeen in October 2016. She undertook the PhD part time following maternity leave.
2. A systematic review of studies reporting weight management interventions for breast cancer was completed and submitted for publication.
3. A paper reporting the main outcomes of the feasibility trial is almost ready for submission to Pilot and Feasibility Studies Journal.

Publications:

1. Newlands R, Clark J, Craig LCA, McNeill G, Hoddinott P, Heys S. Focus group discussions to inform the design of a weight loss programme suitable for overweight and obese women treated for breast cancer. Nutrition Society, Aberdeen. March 2012. (Winner of the poster presentation prize). Proceedings of the Nutrition Society 71 (OCE1), E3. http://journals.cambridge.org/download.php?file=%2F-PNS%2FPNS71_OCE1%2FS0029665112000316a.pdf&code=e98dd4dad485bbc1799cf8f415584175
2. Newlands R, Clark J, Craig LCA, McNeill G, Hoddinott P, Heys S. A survey to inform the design of a weight loss programme suitable for overweight and obese women treated for breast cancer. Nutrition Society, Aberdeen. March 2012. Proceedings

of the Nutrition Society: 2013; 71 (OCE1), E4. http://journals.cambridge.org/download.php?file=%2F-PNS%2FPNS71_OCE1%2FS0029665112000316a.pdf&code=25a9102a1c62c66c559d97c60a9e146d

3. Newlands, R., Haseen, F., Craig, L., Hoddinott, P., Heys, S. & McNeill, G. (2013). Interventions to promote weight loss in women treated for breast cancer: a systematic review. Obesity Facts, vol 6, no. Suppl. 1, T1:P.149, pp. 85. [Online] DOI: 10.1159/000170983 <https://www.karger.com/Article/Pdf/170983>

Other dissemination activity:

- Newlands R, Craig LCA, Clark J, McNeill G, Hoddinott P, Heys S. 'A randomised feasibility trial with women treated for breast cancer comparing a commercial weight loss programme alone; with additional breast cancer focused dietitian-led groups and waiting-list control: The Breast Cancer Healthy Weight (BRIGHT) Trial'. Proceedings of the American Institute of the Cancer Research Annual Research Conference on Food, Nutrition, Physical Activity and Cancer: October, 2014, Washington DC, USA.

Project Number:	HBC01.3
Status:	Complete
Project Title:	Reducing alcohol-related harm in disadvantaged men: development and feasibility assessment of a brief intervention delivered by mobile phone
Source of funding and total value of award:	NIHR, £220,000
Value of funding to NMAHP RU:	£0.
Principal investigator/co-applicants:	Crombie I (PI) (University of Dundee), Irvine L, Slane P, Norrie J (University of Aberdeen).
NMAHP RU investigators:	Williams B.
Workstream:	Health Behaviour Change
Start date:	March 2010
Duration:	21 months

Aim(s):

Disadvantaged men suffer substantial harm from heavy drinking. This feasibility study developed and evaluated the methods for a trial of a brief intervention delivered by text messages to disadvantaged men. It aimed to test the methods for recruitment and retention, to monitor engagement with the intervention and assess the overall acceptability of study methods.

Summary:

Disadvantaged men aged 25–44 years who had ≥ 2 episodes of binge drinking (≥ 8 units in one session) in the preceding month were recruited. Two recruitment strategies were assessed: recruitment from general practice registers and by a community outreach strategy. Theoretically and empirically based text messages were tailored to the target group.

Results: The study recruited 67 disadvantaged men at high risk of alcohol-related harm, exceeding the target of 60. Evaluation showed that 95% of text messages were delivered, and the men engaged enthusiastically with the intervention. Retention at follow up was 96%.

Outcomes were successfully measured on all men followed up. This provided data for the sample size calculation for the full trial. Post-study evaluation showed high levels of satisfaction with the study.

Discussion and Conclusions: This study has shown that disadvantaged men can be recruited and follow-up data obtained in an alcohol intervention study. The study methods were acceptable to the participants. The men recruited were at high risk of alcohol-related harms. It also clarified ways in which the recruitment strategy, the baseline questionnaire and the intervention could be improved. The full trial is currently underway. [Crombie IK, Irvine L, Falconer DW, Williams B, Ricketts IW, Jones C, Humphris G, Norrie J, Slane P, Rice P. Alcohol and disadvantaged men: A feasibility trial of an intervention delivered by mobile phone.

Outcomes/Impact:

This led on to the award of a further grant from NIHR for the full trial – TRAM.

Publications:

1. Iain K Crombie, Linda Irvine, Brian Williams, Falko F Sniehotta, Dennis Petrie, Josie MM Evans, Carol Emslie, Claire Jones, Ian W Ricketts, Gerry Humphris, John Norrie, Peter Rice, Peter W Slane. (2015) A mobile phone intervention to reduce binge drinking among disadvantaged men: study protocol for a randomised controlled cost-effectiveness trial. *Trials*. 15:494. <http://www.trialsjournal.com/content/15/1/494>.
2. Crombie I, Irvine M, Falconer D, Williams B, Ricketts I, Jones C, Humpries G, Norrie J, Slane P, Rice P. (2017) Alcohol and disadvantaged men: A feasibility trial of an intervention delivered by mobile phone: Text message alcohol intervention. *Drug & Alcohol Review*. 2017 Mar 13. doi: 10.1111/dar.12455.
3. Real time monitoring of engagement with a text message intervention to reduce binge drinking among men living in socially disadvantaged areas of Scotland. (2017) *International Journal of Behavioural Medicine*. 17:43. DOI: 10.1186/s12877-017-0541-1.

Other dissemination activity:

<http://www.bbc.co.uk/news/uk-scotland-tayside-central-25407779>

Project Number:	HBC01.4
Status:	Complete
Project Title:	(Phase I) Community-based health improvement for disadvantaged women: Could a physical activity / healthy eating intervention be delivered in Bingo clubs in Scotland
Source of funding and total value of award:	Chief Scientist Office, £116,842
Value of funding to NMAHP RU:	£249
Principal investigator/co-applicants:	Evans E (PI), Jepson R, Gray C, Shepherd A, Mackison D, McMurdo M, Williams B (University of Stirling).
NMAHP RU investigators:	Williams B.
Workstream:	Health Behaviour Change
Start date:	March 2013
Duration:	13 Months

Aim(s):

1. To investigate the feasibility and acceptability of using Bingo clubs for delivery of an evidence-based physical activity and healthy eating intervention to socially disadvantaged women
2. To use participative methods to develop a context-sensitised, targeted physical activity and healthy eating intervention for delivery to socially disadvantaged women at their local Bingo club.

Summary:

This study used elements of a community-based participatory approach and was carried out in partnership with Stirling Carlton Bingo. Focus groups were carried out among 27 Bingo club members and a needs assessment questionnaire administered to 162. A literature review was conducted to identify components of effective interventions in other settings. Accelerometers were given to 29 women. A day-long participative workshop was held with over 20 Bingo players and intervention design was finalised during two round table research team meetings.

The final intervention consisted of a specific physical activity

intervention for women >55 years that is ready to undergo feasibility testing in Stirling. The intervention uses enjoyment and social opportunities as a way of encouraging increased physical activity, and moves away from the belief that promoting physical activity as inherently good for people will encourage them to be more active. The intervention consists of five core components, which can be adapted to suit the requirements of individual clubs. These include structured exercise sessions, intervention messages, a social component, Bingo-related attendance strategies and specific training of instructors. This development work has also generated a wider set of key principles to be applied to the design of other interventions as part of the Well!Bingo project.

The project shows that it is possible to engage with women living in areas of social disadvantage through a Bingo club setting for; i. discussions around health, and ii. to develop a health intervention.

A physical activity intervention targeted at women >55 years is the most realistic for recruitment, and for the needs of the potential recipients in the Stirling Carlton Bingo club.

Delivery of a physical activity intervention in the club appears to be feasible and acceptable to club members and staff.

The intervention has been designed with considerable input from Bingo club members and staff. Whether this results in high recruitment and retention rates now needs to be evaluated formally; as does feasibility of delivery.

Outcomes/Impact:

This grant led to a subsequent CSO grant to feasibility-test the Well!Bingo physical activity intervention in the Stirling Carlton Bingo club. It was evaluated highly by participants.

Exercise classes attended by Bingo players have continued in the Stirling Carlton Bingo club since then as a result of this project.

Funding has been obtained to deliver the Well!Bingo intervention in Aberdeen Carlton Bingo club in 2018.

Publications:

- Evans JMM, Connelly J, Jepson R, Gray C, Shepherd A, Mackison D. A physical activity intervention in a Bingo club: Significance of the setting. *Health Education Journal*; Submitted for publication
- Ryde G, Gorely T, Jepson R, Gray C, Shepherd A, Mackison D, Ireland A, Williams B, McMurdo MET, Evans JMM. How active are women who play bingo: A cross-sectional study from the Well!Bingo project. *BMC Women's Health* 2017; In press
- Evans JMM, Ryde G, Jepson R, Gray C, Shepherd A, Mackison D, Ireland AV, McMurdo MET, Williams B. Accessing and engaging women from socio-economically disadvantaged areas: A participatory approach to the design of a public health intervention for delivery in a Bingo club. *BMC Public Health* 2016; 16:345.

Project Number:	HBC01.5
Status:	Complete
Project Title:	Ways to intervene and support engagement of older adults weight loss study (WISE OWLS)
Source of funding and total value of award:	Chief Scientist Office, £49,202.00
Value of funding to NMAHP RU:	£1,490.00
Principal investigator/co-applicants:	Kiezebrink K (PI) (University of Aberdeen), Avenell A (University of Aberdeen), Clark A (University of Aberdeen), Witham M (University of Dundee).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Health Behaviour Change
Start date:	October 2012
Duration:	12 Months

Aim(s):

The primary aim of this study was to determine what components of a healthy lifestyle intervention for weight loss would be most acceptable, feasible and likely to succeed with obese older adults. In addition, the study aimed to investigate intervention processes including recruitment, place, access, delivery and outcome measurement. It was intended that the results of this study would inform an exploratory pilot study and then a definitive randomised controlled trial of weight management for older adults.

Summary:

Obesity is becoming more common in older people. This age group has been neglected by obesity research to date. Weight loss interventions specific to the needs of older people need to be developed and evaluated before entering clinical practice. The design followed MRC guidance for the development of a complex intervention. A multi-method qualitative approach to data collection was used to capture a holistic and contextual portrayal of the older adults' views of weight management and to identify the components of an acceptable and feasible intervention. Older adults preferred group weight loss interventions which include five main topics: 'How to change diet', 'How to change physical activity', 'Managing emotions', 'Managing

pain' and 'Monitoring progress'. Participants were asked to rank key components for a weight loss programme as essential, desirable or undesirable. The study concluded that a pilot trial could now be conducted.

Outcomes/Impact:

A final report was submitted to the CSO and was graded satisfactory.

Publications:

- Kiezebrink, K., Coyle, J., Hoddinott, P., Witham, M., Clarke, A. and Avenell, A. (2013) Ways to intervene and support engagement of older adults weight loss study (WISE OWLS) a mixed methods project developing an intervention. *Annals of Nutrition and Metabolism*, 63, pp. 721-722.

Other dissemination activity::

- Kiezebrink, K., Coyle, J., Hoddinott, P., Witham, M., Clarke, A., Avenell, A. Ways to Intervene, Support and Engage Older adults in a Weight Loss study (WISE OWLS). 20th International Congress of Nutrition. Granada, Spain. Sept. 2013.

Project Number:	HBC01.6
Status:	Complete
Project Title:	Systematic reviews and integrated report on the quantitative and qualitative evidence base for the management of obesity in adult men ROMEO
Source of funding and total value of award:	NIHR HTA, £252,839
Value of funding to NMAHP RU:	£4,770.00
Principal investigator/co-applicants:	Avenell A (PI) (University of Aberdeen), Douglas F (University of Aberdeen), van Teijlingen E (University of Bournemouth)
NMAHP RU investigators:	Hoddinott P.
Workstream:	Health Behaviour Change
Start date:	October 2012
Duration:	18 Months

Aim(s):

The aim of this study was to systematically review evidence-based management strategies for treating obesity in men, and how to engage men in these obesity services. The overarching objective was to integrate the quantitative, qualitative and health economic evidence base for the management and engagement of men with obesity in weight-loss services, researching concurrently to systematically review:

- The effectiveness and cost-effectiveness of interventions for obesity in men, and men in contrast to women.
- The effectiveness and cost-effectiveness of interventions to engage men in their weight reduction.
- Qualitative research with men about obesity management, and providers of such services for men.

Summary:

Obesity increases the risk of many serious illnesses, such as coronary heart disease, type 2 diabetes and osteoarthritis. More men than women are overweight or obese in the UK. Men are more likely than women to misperceive their weight, less likely to consider their body weight a risk for health, and less likely to consider trying to manage their weight. Perceptions of dieting and weight-loss programmes as a feminised realm have been cited as

possible explanations for men's under-representation in weight-loss services. That men are under-represented suggests that methods to engage men in services, and the services themselves, are currently not optimal. The research team worked closely with Men's Health Forum Charity throughout to ensure consumer views were integrated into the evidence syntheses.

Outcomes/Impact:

Six systematic reviews were completed:

1. Systematic review of long-term randomised controlled trials (RCTs) of interventions with men-only.
2. Systematic review of long-term RCTs of interventions where results were presented separately for men and women.
3. Systematic review of interventions for men, or for men and women compared, in the UK, any setting, any study design, any duration.
4. Systematic review of interventions to increase engagement of men with services for obesity management, any study design.
5. Systematic review of economic evaluations of obesity interventions, where data were presented either for men-only, or men compared with women.
6. Systematic review of qualitative research with men, or men in contrast to women with obesity, and providers of services.

Based on all the literature reviewed, the study concluded that weight reduction for men is best achieved and maintained with the combination of a reducing diet, physical activity advice or a physical activity programme and behaviour change techniques. Men were seldom involved in designing interventions. Tailoring interventions and settings for men may enhance effectiveness and further research was recommended to better understand the influence of context and content. The ROMEO report resulted in a Commissioned Call by NIHR in 2015 based on the research recommendations. Pat Hoddinott who led the ROMEO qualitative evidence synthesis led a successful bid for this call with the Game of Stones feasibility trial (See Project summary HBC01.1) which is currently in progress. The collaboration with Men's Health Forum and Prof Alison Avenell (HSRU, University of Aberdeen) who led ROMEO is continuing in the Game of Stones study.

Publications

- Robertson, C., Archibald, D., Avenell, A., Douglas, F., Hoddinott, P., Van Teijlingen, E., Boyers, D., Stewart, F., Boachie, C., Fioratou, E., Wilkins, D., Street, T. and Carroll, P. (2014) 'Systematic reviews of and integrated report on the quantitative, qualitative and economic evidence base for the management of obesity in men', *Health Technology Assessment*, 18(35).
- Stewart, F., Fraser, C., Robertson, C., Avenell, A., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2014) 'Are men difficult to find? Identifying male-specific studies in MEDLINE and Embase', *Systematic Reviews*, 3(1), 78.
- Boyers, D., Avenell, A., Stewart, F., Robertson, C., Archibald, D., Douglas, F., Hoddinott, P. and van Teijlingen, E. (2015) 'A systematic review of the cost effectiveness of non-surgical obesity interventions in men', *Obesity Research & Clinical Practice*, [Epub ahead of print].
- Robertson, C., Avenell, A., Boachie, C., Stewart, F., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2015) 'Should weight loss and maintenance programmes be designed differently for men? A systematic review of long-term randomised controlled trials presenting data for men and women: the ROMEO project', *Obesity Research & Clinical Practice*, 10(1), 70- 84.
- Robertson, C., Avenell, A., Stewart, F., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2015) 'Clinical effectiveness of weight loss and weight maintenance interventions for men: a systematic review of men only randomized controlled trials (The ROMEO Project)', *American Journal of Men's Health*, [Epub ahead of print].
- Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E., Stewart, F., Robertson, C., Boyers, D. and Avenell, A. (2015) 'A qualitative evidence synthesis on the management of male obesity', *BMJ Open*, 5(10), e008372.
- Avenell, A., Robertson, C., Stewart, F., Boyers, D., Douglas, F., Archibald, D., van Teijlingen, E., Hoddinott, P. and Boachie, C. (2016) 'Sex can affect participation, engagement, and adherence in trials' (letter), *BMJ*, 355, i6754.
- Men's Health Forum and Public Health England (2014). *How to make weight-loss services work for men*. [Booklet] ISBN: 978-1-906121-16-7. Haynes Publishing, UK.

Other dissemination activity:

- Robertson, C.F., Archibald, D., Avenell, A., Douglas, F., Hoddinott, P., Van Teijlingen, E., Boyers, D., Stewart, F., Boachie, C. and Fioratou, E. (2013) 'Using a combined realist and socio-ecological approach to integrating quantitative and qualitative systematic review evidence in a health technology assessment setting', 21st Cochrane Colloquium, Quebec, Canada, 19-23 September 2013.
- Archibald, D., Douglas, F., Hoddinott, P., Van Teijlingen, E., Robertson, C.F., Stewart, F., Boyers, D. and Avenell, A. (2013) 'A mixed-method evidence synthesis on the management of male obesity: the ROMEO (Review Of MEn and Obesity) Project', *Scottish Faculty of Public Health Conference*, Dunblane, 7-8 November 2013.
- Boyers, D., Avenell, A., Stewart, F., Robertson, C., Archibald, D., Douglas, F., Hoddinott, P. and van Teijlingen, E. (2014) 'Evaluating the cost-effectiveness of interventions for the management and treatment of obesity in men - results from the ROMEO study' [poster], *Men's Health and Well-being: Critical Insights Conference*, Leeds, England, 7-8 July 2014.

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- Robertson, C., Avenell, A., Stewart, F., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2014) 'Should weight loss programmes be designed differently for men? A systematic review of long-term weight loss randomised controlled trials: the Romeo project' [poster], Men's Health and Wellbeing: Critical Insights Conference, Leeds, England, 7-8 July 2014.
 - Hoddinott, P., Archibald, D., Robertson, C., Stewart, F., Boyers, D., Douglas, F., van Teijlingen, E. and Avenell, A. (2014) 'Obesity in men: evidence synthesis findings and their implications for primary care. The ROMEO (Review of Men and Obesity) Project', Society for Academic Primary Care, Edinburgh, 9- 12 July 2014.
 - Boyers, D., Avenell, A., Stewart, F., Robertson, C., Archibald, D., Douglas, F., Hoddinott, P. and van Teijlingen, E. (2014) 'A systematic review of the cost effectiveness of non-surgical obesity interventions in men' [poster], Association for the Study of Obesity , UK Congress on Obesity, Birmingham, England, 16-17 September 2014.
 - Robertson, C., Avenell, A., Boachie, C., Stewart, F., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2014) 'Should weight loss programmes be designed differently for men and women? The ROMEO (Review of Men and Obesity) project', Association for the Study of Obesity, UK Congress on Obesity, Birmingham, England, 16-17 September 2014.
 - Robertson, C., Avenell, A., Stewart, F., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2014) 'A systematic review of long-term weight management randomised controlled trials for obese men: the ROMEO project [poster]', Association for the Study of Obesity, UK Congress on Obesity, Birmingham, England, 16-17 September 2014.
 - Robertson, C., Avenell, A., Stewart, F., Archibald, D., Douglas, F., Hoddinott, P., van Teijlingen, E. and Boyers, D. (2014) 'A systematic review of weight loss interventions for obese men in the UK: the ROMEO project' [poster], Association for the Study of Obesity, UK Congress on Obesity, Birmingham, England, 16-17 September 2014.

Project Number:	HBC01.7
Status:	Complete
Project Title:	Reducing alcohol consumption in obese men: development and feasibility testing of a complex community-based intervention (MACRO)
Source of funding and total value of award:	NIHR, £220,846
Value of funding to NMAHP RU:	£5,262
Principal investigator/co-applicants:	Crombie I (PI) (University of Dundee), Emslie C (Glasgow Caledonian University), Evans J (University of Stirling), Irvine M, Norrie J (University of Aberdeen), Rice P (NHS Tayside), Sniehotta F (Newcastle University).
NMAHP RU investigators:	Williams B.
Workstream:	Health Behaviour Change
Start date:	May 2014
Duration:	21 Months

Aim(s):

The main aim of this feasibility study is to develop a recruitment strategy and a gender specific intervention tailored to reduce alcohol consumption among obese men. If successful, the intervention will subsequently be tested in a full scale randomised controlled trial.

Publications:

<https://www.journalslibrary.nihr.ac.uk/programmes/hta/1213912/#/>

Summary:

This feasibility study developed a novel intervention and evaluated all of the stages of a RCT that would test the effectiveness of the intervention. The main stages of a trial were completed successfully: recruitment, randomisation, intervention delivery, follow-up and measurement of study outcomes. Most of the men recruited drank very heavily and were also obese. This places them at a very high risk of liver disease, making them a priority for intervention.

Outcomes/Impact:

Plans to submit for full trial imminently.

Project Number:	HBC01.8
Status:	Complete
Project Title:	Reducing binge drinking among disadvantaged men through a brief intervention delivered by mobile phone: a multi-centre randomised controlled trial
Source of funding and total value of award:	NIHR, £873,649.72
Value of funding to NMAHP RU:	£2,817
Principal investigator/co-applicants:	Crombie IK (PI) (University of Dundee), Irvine L (University of Dundee), Sniehotta FF (Newcastle University), Petrie D (University of Dundee), Jones C (University of Dundee), Norrie J (University of Aberdeen), Evans JMM (University of Stirling), Emslie C (Glasgow Caledonian University), Rice PM (NHS Tayside), Slane PW, Humphris G (University of St. Andrews), Ricketts IW (University of Dundee), Melson A, Donnan PT, McKenzie A, Huang L, Achison M.
NMAHP RU investigators:	Williams B.
Workstream:	Health Behaviour Change
Start date:	July 2013
Duration:	39 Months

Aim(s):

The main objective is to determine whether a brief intervention delivered by mobile phone is an effective and cost-effective method of reducing the frequency of binge drinking by disadvantaged men. The impact of the intervention on other measures of drinking, such as total consumption, will also be assessed. The study will explore which components of the behaviour change strategy influence drinking behaviour. These components will be measured using the process measures which were developed in the feasibility study.

Summary:

The study is a four centre parallel group randomised controlled trial. The components of the study were developed and tested in a feasibility study. Target population: Men aged 25-44 years living in areas of high deprivation who have had two or more episodes of binge drinking (>8 units in a single

session) in the preceding month. To ensure good coverage of disadvantaged men two recruitment strategies will be used: through primary care and by community outreach. Intervention: The intervention is a series of Short Message Service (SMS) delivered by mobile phone. The intervention is based on effective empirical studies on alcohol and text message interventions. It employs theoretical models of behaviour change particularly the Health Action Process Approach and incorporates techniques from Motivational Interviewing and Communication Theory. The messages were constructed to take advantage of the conventional pattern of heavy weekend drinking: before weekend drinking, after a heavy drinking episode and midweek sobriety. Messages are tailored to the drinking culture of disadvantaged young men and use popular texting terms and abbreviations. Techniques to increase message effectiveness include: use of gain-framed texts; pairing of messages; and inclusion of questions to promote interactivity. The text messages will be sent over a 12 week period and will deliver the behaviour change strategy in four stages.

Stage 1 welcomes the men to the study, establishes empathy and increases the salience of the short term harms of binge drinking. Stage 2 creates the intention to reduce binge drinking by highlighting the discrepancy between an individual's drinking habits (becoming drunk) and the intended aims of drinking (having fun and socialising). It will promote engagement with the benefits of moderated drinking and increase self-efficacy for refusing drinks. Stage 3 transforms intention into action by encouraging goal setting and the formation of action plans and coping plans. Stage 4 supports the maintenance of long term behaviour change.

Outcome measures and duration of outcome: Outcomes will be assessed at 3 months and 12 months from the end of the intervention. The primary outcome measure is the frequency of binge drinking (consumption of >8 units in a single session) at 12 months. This outcome is particularly suitable for disadvantaged men: the feasibility study showed that most of the participants had regular episodes of binge drinking with periods of complete abstinence in between. The frequency of binge drinking at 3 months will assess the short term impact of the intervention. The Fast Alcohol Screening Test (FAST) will be used to determine the frequency of hazardous drinking. Total consumption of alcohol will be measured to ensure comparability with previous brief intervention trials.

Sample size: The sample size is 798 men. The feasibility study showed that 57% of men had 3 or more binge drinking sessions in the previous 30 days. We aim to detect a reduction in the proportion of men drinking in this way from 57% to 46%, a net reduction of 11% (as significance at $p=0.05$ with a power of 80%). A recent systematic review of conventional brief interventions found an 11% difference in frequency of binge drinking between intervention and control. The sample size allows for a 20% loss to follow-up. We expect that the loss to follow-up will be less than this, as the loss in our three month feasibility study was only 4%. However, as most alcohol brief intervention trials have a loss to follow-up at 12 months of over 20%, it is prudent to make suitable allowance.

Planned analyses: The effect size of the primary outcome will be presented as proportions, odds ratios and 95% confidence intervals. The secondary outcomes will be assessed in a similar way. Further analyses will use logistic regression to explore which of the cognitive antecedents of behaviour change predict change in the primary outcome. The analysis will also explore whether the recruitment method (through primary care or community outreach) influences treatment effect.

Project timetable: Months 1-2: Trial manager induction. Obtain for ethical permission. Establish the steering committee and register the trial. Months 3-8: Conduct fieldwork for recruitment. Update the text messages, the computer programme for intervention delivery and the questionnaires. Prepare for the economic evaluation. Train research staff. Months 9-18: Screen disadvantaged men to recruit 798 in total. Conduct baseline interviews. Randomise. Deliver the intervention. Months 15-24: Conduct three month post-intervention delivery follow-up interviews. Months 24-33: Conduct twelve month post-intervention follow-up interviews. Months 34-39: Analysis, report preparation and dissemination. Prepare papers for publication.

Project Number:	HBC01.9
Status:	Complete
Project Title:	Adapting and piloting an informal school-based peer-led intervention for smoking prevention in Scotland (ASSIST-Scotland): an exploratory trial.
Source of funding and total value of award:	Chief Scientist Office, £279,084
Value of funding to NMAHP RU:	£15,190
Principal investigator/co-applicants:	Bauld L (PI), Dobbie F, Dougall N (University of Stirling), Amos A (University of Edinburgh), Campbell R (University of Bristol), Moore L (University of Glasgow), White J (Cardiff University)
NMAHP RU investigators:	Dougall N.
Workstream:	Health Behaviour Change
Start date:	August 2014
Duration:	30 Months

Aim(s):

The overall aim of the study was to evaluate the process of implementing ASSIST in Scotland.

Summary:

ASSIST is a licensed peer-led, school-based smoking prevention programme that encourages the dissemination of non-smoking norms by training S1 (aged 12 to 13 years) and S2 (aged 13 to 14 years) students to work as peer supporters. In 2013 the Scottish Government made a commitment to undertake a pilot of ASSIST in its national Tobacco Control Strategy.² One of the key differences between the delivery of ASSIST in Scotland compared with England and Wales is the age difference in school years. The agreed approach in Scotland was to pilot in both S1 and S2 but to target S1 in the third term or second half of the school year.

In light of existing evidence demonstrating the effectiveness of ASSIST, this study focused on the acceptability and implementation of ASSIST to inform any potential future adoption in other areas of Scotland. The research design involved mixed methods, consisting of three elements: 1) evaluating the implementation planning process; 2) evaluating delivery in schools; and 3) assessment of costs.

A range of stakeholders (school staff, trainers and students, n=101) were consulted via in-depth interviews, paired interviews, mini focus groups and observation along with a before and after survey to gather data from students (n=2130, at follow-up). To maximise available resources a two-tier design was used. Tier one included consultation with school leads and a pre and post student survey in 20 schools. Tier two involved six case study schools (two in each area, selected from the 20 tier one schools) where qualitative methods were used to observe peer supporter training and follow-up sessions and consult with peer supporters and other students.

Outcomes/Impact:

Overall, this process evaluation has demonstrated that it is feasible and acceptable to deliver the ASSIST programme in Scottish schools. Findings show less certainty regarding the extent of message diffusion and any impact this may have had on adolescent smoking. Student survey results showed no significant change in self-reported smoking prevalence between baseline and follow-up and conversation recall with a peer supporter was low at 9%. Now may be the time to consider whether, 13 years on from the original RCT, an implementation trial of ASSIST is warranted to determine if it is still effective and cost effective.

Publications:

- Dobbie F, Purves R, McKell J, Dougall N, White J, Campbell R, Amos A, Moore L and Bauld L (2017). A process evaluation of the implementation of ASSIST in Scotland: Research findings. Report. Scottish Government: Health and Social Care Research <http://www.gov.scot/Resource/0051/00515631.pdf>
- Dobbie F, Purves R, McKell J, Dougall N, White J, Campbell R, Amos A, Moore L and Bauld L (2017). A process evaluation of the implementation of ASSIST in Scotland: Final Report. Scottish Government: Health and Social Care Research <http://www.gov.scot/Resource/0051/00515634.pdf>
- Dobbie, F (2015) Evaluation of ASSIST in Scotland. DECIPHer- ASSIST 2015 Annual Conference, London, UK, 23rd April 2015.
- Dobbie, F (2014) ASSIST (A Stop Smoking in Schools Trial). NHS Tayside, Perth & Kinross, Dundee City and Angus Education Department, Dundee, Scotland, 1st October 2014.
- Blog for the Faculty of Health Sciences and Sport (2017): <https://stirlinghealthsciences.wordpress.com/2017/03/24/assist/>

Other dissemination activity:

- Scottish Government Ministerial Working Group on Tobacco Control: F Dobbie invited to give verbal up-date on study (2016)
- Dobbie, F (2017) A mixed method process evaluation of assist a peer-led smoking prevention programme in secondary schools. Society for Research on Nicotine and Tobacco (SRNT), Florence, Italy 11th March 2017.
- Dobbie, F (2017) Key findings from the National evaluation of ASSIST in Scotland. Scottish Tobacco Alliance, Glasgow, UK 16th March 2017.
- Dobbie, F (2016) Key findings from the interim process evaluation of the ASSIST pilot in Scotland. NHS Lothian Tobacco Prevention seminar, Edinburgh, UK 23rd November 2016.
- Dobbie, F (2016) An exploration of the ASSIST smoking prevention programme in social networks beyond the school setting. Public Health PhD Symposium 'Methodologies in Public Health Research', Liverpool, UK 7th July 2016.
- Dobbie, F (2016) Key Findings from the Interim Evaluation of ASSIST. DECIPHer-ASSIST 2016 Annual Conference, Edinburgh, UK, 26th May 2016.
- Dobbie, F (2015) ASSIST Scotland process evaluation. Tobacco Prevention in Schools, ASH Scotland, Stirling, UK, 3rd September 2015.
- Dobbie, F (2015) Why do young people smoke? Trends, influence and policy response. DECIPHer- ASSIST 2015 Annual Conference, London, UK, 23rd April 2015.

Project Number:	HBC01.10
Status:	In Progress
Project Title:	Improving physical activity levels of older people living in care homes
Source of funding and total value of award:	Chief Scientist Office, £143,096
Value of funding to NMAHP RU:	£0. Grant held in Dundee, directly allocated costs not available for PhD studentships. JHM is a supervisor.
Principal investigator/co-applicants:	Wylie G (PI) (NHS Tayside), Morris J (Glasgow Caledonian University), Witham M (University of Dundee), Kroll T (University of Dundee).
NMAHP RU investigators:	Morris M.
Workstream:	Health Behaviour Change
Start date:	July 2015
Duration:	48 months

Aim(s):

Physical activity (PA) is beneficial to older people's health, function and quality of life. There is evidence that older people in care homes do not engage in PA. This is problematic, since this group are most at risk of functional and health decline.

This proposal aims to:

1. Explore from the perspective of residents and care home staff the barriers and facilitators to care home residents' levels of PA
2. Examine how care home systems, practices and
3. processes influence residents' physical activity.
4. Identify feasible opportunities for care home residents to engage in PA.
5. Develop feasible intervention(s) for care home staff and residents to increase PA levels.
6. This will be a multi-phase study, undertaken in four work packages (WP).

WP1: Systematic review and meta-analysis of effectiveness of PA interventions and meta-synthesis of the qualitative literature relating to attitudes and beliefs, barriers and facilitators to PA in care homes.

WP2: Exploration of attitudes and beliefs to physical activity amongst carers and residents and ethnographic analysis of daily life in a variety of care homes.

WP3: Development of potential interventions. WP1 and WP2 will inform selection of candidate theories and development of components of potential interventions to increase levels of care home PA.

WP4: These potential interventions will be fed back to users in focus groups in the form of vignettes. This will allow the intervention to be refined to one that is feasible to implement.

At the end we will have produced an intervention package ready for feasibility testing

Progress:

As this is a part-time PhD, Gavin successfully completed his upgrade review in June 2017

Work package 1, review work, nearing completion, papers in preparation

Work package 2, ethnographic study started – care homes recruited, preliminary observations undertaken. Review work informing topic guide development for final ethnographic work

Other dissemination activity:

Training undertaken:

- York CRD Systematic Review Course
- Wellcome Trust Qualitative Synthesis Course
- Social Research Association Qualitative Data Analysis Course
- Complex Intervention Development Course: University of Cardiff

Project Number:	HBC01.11
Status:	In Progress
Project Title:	Knowledge, attitudes and current practice of health professionals regarding the use of e-cigarettes and other smoking cessation interventions by cancer survivors
Source of funding and total value of award:	Tobacco Advisory Group, Cancer Research UK, £44,582
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Brett Jo (PI) (Oxford Brookes University), Wells M, (University of Stirling), Watson E, Foxcroft D, Davies E (all Oxford Brookes University), Aveyard P and Nicholson B (University of Oxford), Sinclair L (University of Glasgow).
NMAHP RU investigators:	Wells M.
Workstream:	Health Behaviour Change
Start date:	April 2017
Duration:	12 Months

Aim(s):

To explore health professionals' knowledge, attitudes and current practices towards the promotion of e-cigarette use and other smoking cessation interventions with cancer patients, and to identify behaviours to increase the implementation of e-cigarettes and other smoking cessation interventions in cancer survivors.

Summary:

This online survey will investigate knowledge, attitudes, current practice and behaviours of cancer surgeons (n=100), oncologists (n=100), cancer nurse specialists (n=100), GPs (n=100) and practice nurses (n=100) regarding the place of e-cigarettes as a smoking cessation intervention in cancer patients. Participants will be recruited through Doctors.Net online research body Medeconnect, and further promoted in online nursing forums and nurse journals. A conceptual map of behaviours by health professionals around e-cigarettes and other smoking cessation interventions will be mapped using the behaviour

change wheel model (COM-B) to identify the capability, opportunity and motivation behaviours of health professionals to engage in behaviours that will increase the implementation of e-cigarettes and other smoking cessation interventions in cancer survivors.

Outcomes/Impact:

The study will both help inform policy development around e-cigarettes for health professionals working with cancer patients, and inform the future trial design for e-cigarettes and other smoking cessation interventions in cancer patients.

Project Number:	HBC01.12
Status:	Complete
Project Title:	A systematic literature review of population level interventions to improve health, happiness and wellbeing in the transition from adolescence to adulthood
Source of funding and total value of award:	Royal Society of Edinburgh, £89,979
Value of funding to NMAHP RU:	£26,968
Principal investigator/co-applicants:	Pollock A, Campbell P (Glasgow Caledonian University), Maxwell M (University of Stirling), Biggs H, Ferriera N (University of Edinburgh), McIntyre A (University of Strathclyde), Williams A (University of Edinburgh), Woodhouse A (Children in Scotland).
NMAHP RU investigators:	Pollock A, Maxwell M, Campbell P.
Workstream:	Health Behaviour Change
Start date:	January 2016
Duration:	10 Months

Aim(s):

The main aim of this systematic overview was to systematically review and synthesise the research evidence on the impact of population interventions that were intended to improve health, happiness and wellbeing and/or reduce inequalities for young people undergoing transition to adulthood. The project team took a holistic approach to the scope of the overview, covering key aspects of physical health and mental wellbeing. This systematic overview is intended to make a contribution towards decision making about priorities for investment in, and the design of, future innovative and evidence informed universal interventions. The overview set out to answer the question: What works in population interventions designed to improve health, happiness and wellbeing or reduce inequalities for young people undergoing the transition to adulthood?

Summary:

Adolescent transitions to adulthood have been identified as an important phase of life for short-term and long-term health, happiness and wellbeing. Adolescence is a phase of development when risk behaviours such as substance use and sexual behaviour come into focus, and it can also be associated with the onset of long-term psychological difficulties. Evidence indicates that health promoting behaviours in adolescence may have a long-term impact into adulthood. Therefore, prevention approaches during adolescence, might lead to lasting improvements in adult health, happiness and wellbeing.

A step-wise methodology was used. The stepwise approach is an efficient and effective methodology for reviewing large bodies of evidence systematically, by identifying the highest quality evidence in a hierarchical and systematic way. This approach avoids duplication of effort and is particularly useful for reviews being undertaken within tight timescales.

A systematic search of electronic databases was performed. The search was limited to systematic reviews published between 1 January 2005 and 7 March 2016 and only included systematic reviews published in English. Pre-specified eligibility criteria were used to focus on the most relevant research evidence which was studies focusing mainly on population groups defined as 'adolescent' and/or of people aged 10-24 and of interventions aimed at the whole or 'average' population (i.e. irrespective of level of risk) with the intended outcome of improving health, happiness and wellbeing, or supporting successful transition from adolescence to adulthood, or reducing inequalities and building resilience. Studies were excluded if they focused on interventions which targeted clinical populations, the impact of interventions on disease end points, and those of interventions targeted at young people in higher risk groups. The literature searching identified 35310 possible records (4196 duplications). After elimination of 29161 obviously irrelevant records, two independent reviewers screened 1953 abstracts and considered 566 full papers. A total of 150 papers were selected for inclusion in the overview, all of which were judged either as low risk of bias or unclear risk of bias. Eleven overviews were also identified through the search and although not included were used to inform the synthesis. A summary of the evidence for the following intervention area was provided: mental health and wellbeing; tobacco free living; preventing drug abuse and excessive drinking; sexual and reproductive health; violence and abuse free living; active living; healthy eating; obesity; and general health.

Outcomes/Impact:

This review is being used by RSE to determine further areas of investigation and targeting of research funding.

Publications:

- RSE Final Report. 2017. J McLean, P Campbell, A Macintyre, J Williams, Claire Torrens, M Maxwell, H Biggs, A Pollock, A Woodhouse. Health, Happiness and Wellbeing in the Transition from Adolescence to Adulthood: A Systematic Overview of Population Level Interventions.
- The full report of the review is also published and advertised on the MHF and RSE main websites.

- J McLean. How effective are universal interventions for young Scots? Journal of the Foundation for Science and Technology. March 2017, Volume 21(10) 31-33 http://www.foundation.org.uk/Journal/pdf/fst_21_10.pdf

Other dissemination activity:

- J McLean, P Campbell, A Macintyre, J Williams, Claire Torrens, M Maxwell, H Biggs, A Pollock, A Woodhouse. Summary of the Systematic Review on Health, Happiness and Wellbeing in the Transition from Adolescence to Adulthood. Presentation to the Royal Society of Edinburgh, March 2017 http://www.foundation.org.uk/Events/AudioPdf.aspx?s=1461&f=20161026_McLean.pdf
- Do we know if interventions to improve health and wellbeing impact on everyone the same? Applying an "equity lens" to systematic review evidence. Preliminary Results. Centre for Innovation in Mental Health, City University of New York. 24th July 2017
- Health, happiness, wellbeing and inequalities in the transition from adolescence to adulthood. Applying an "equity lens" to an overview of systematic reviews of population level interventions. Department of Health Sciences, York University, 12th April 2017
- Which mental health interventions work well for young people in Scotland and what evidence supports how funding should be allocated, particularly for vulnerable groups? A national debate held at The Royal Society of Edinburgh on 26th October, 2016. http://www.foundation.org.uk/Events/pdf/20161026_Summary.pdf
- Population interventions for health, happiness and wellbeing in the transition from adolescence. CRISP Recovery, Rights and Experts by Experience Seminar. Lapinlahti Hospital Auditorium, Helsinki, 10th October 2016
- Population health and wellbeing among adolescents: Emerging findings from a Systematic Review. Silver School of Social Work, New York University, 12th September 2016
- J McLean, P Campbell, A Macintyre, J Williams, Claire Torrens, M Maxwell, H Biggs, A Pollock, A Woodhouse. Health, Happiness and Wellbeing in the Transition from Adolescence to Adulthood: A Systematic Overview of Population Level Interventions. Faculty of Public Health Annual Conference in June 2016.

Project Number:	HBC01.13
Status:	In Progress
Project Title:	Promoting smoking cessation during pregnancy: a combined feasibility and pilot trial of a theory-based intervention using narrative, images and embedded behaviour change techniques, delivered via text-messaging (SKIP-IT)
Source of funding and total value of award:	Chief Scientist Office, £279,019
Value of funding to NMAHP RU:	£269,624
Principal investigator/co-applicants:	Cheyne H (PI) (University of Stirling), Elders A (Glasgow Caledonian University), Williams B (Edinburgh Napier University), O'Carroll R, Abhyankar P, Bauld L (University of Stirling), Jones C (University of Dundee), Steele M (University of Southampton), Gardiner C (NHS Health Scotland), Winton M (NHS Tayside).
NMAHP RU investigators:	Cheyne H, King E, Elders A.
Workstream:	Health Behaviour Change
Start date:	February 2017
Duration:	30 Months

Aim(s):

The SKIP-IT project plans to investigate the feasibility and likelihood of success of a narrative and image-based intervention for smoking cessation in pregnant women. Recruitment methods, feasibility of delivering the intervention, retention and follow-up processes will be assessed for potential continuation to a full-scale (Phase III) multi centre randomised controlled trial.

Summary:

Smoking during pregnancy carries serious risks to mother and infant health. Smoking is strongly related to health inequality, more people in the lower socioeconomic groups smoke. Around half of smokers quit during pregnancy but relapse rates are high and many continue to smoke in particular in areas of high deprivation. In Scotland 17% of women were recorded as smokers at the first antena-

tal appointment; with rates as high as 38% in pregnant women under 20 years of age. Better smoking cessation interventions are urgently required to reduce the number of preventable stillbirths and neonatal deaths and improve the health of mothers and infants.

We have developed, and carried out initial testing of a theoretically and empirically informed intervention aimed at supporting smoking cessation in pregnant women. Findings informed the development of a novel, narrative, story-telling intervention delivered via automated text-messages. It aims to alter women's perceptions of risk, social norms, outcomes and self-efficacy using three key elements: 1) a narrative story of a fictional young pregnant woman 'Megan' trying to stop smoking by overcoming a series of commonplace barriers, 2) images showing the size of their fetus and its stage of development 3) a 'help' function to receive smoking cessation advice.

To achieve sustained smoking cessation through and after pregnancy women will need to engage with the intervention over an extended period of around nine months, this will require a high degree of appeal. We are therefore conducting a study in two phases to extend the intervention, develop recruitment strategies and to assess the likelihood of the intervention being effective

Outcomes/Impact:

This pilot trial focuses on feasibility issues and therefore has no single primary outcomes. Feasibility outcomes include recruitment and retention rates, and acceptability of the intervention. Smoking outcomes will be assessed through self-reported and validated smoking abstinence, both before and after delivery.

Project Number:	HBC01.14
Status:	In Progress
Project Title:	We Can Quit2: a randomised pilot trial of a community-based smoking cessation intervention for women in disadvantages areas of Ireland
Source of funding and total value of award:	Health Research Board of Ireland, £487,787
Value of funding to NMAHP RU:	£4,730
Principal investigator/co-applicants:	Hayes C (PI) (Trinity College Dublin), Darker C, Bauld L (University of Stirling), Dougal N (Edinburgh Napier University), Vance J.
NMAHP RU investigators:	Loudon K.
Workstream:	Health Behaviour Change
Start date:	May 2017
Duration:	34 Months

Aim(s):

To conduct a cluster randomised pilot trial comparing a new community-based smoking cessation intervention (We Can Quit 2; WCQ2) with HSE standard smoking cessation services, for women who smoke, and are living in disadvantaged areas of Ireland.

Background:

Tobacco use is the leading preventable cause of morbidity, mortality and health inequalities in Ireland. The 'We Can Quit2' (WCQ2) programme is a new smoking cessation intervention for women living in disadvantaged areas, previously developed and examined in promising feasibility research conducted by members of our team with the Irish Cancer Society.

Aims:

To conduct a cluster randomised pilot study which will determine the feasibility and acceptability of trial processes in evaluating a community based smoking cessation intervention (WCQ2), including randomisation of districts, recruitment and data collection in both the intervention and usual care arms, for women who smoke,

and are living in disadvantaged areas of Ireland, to inform the sample size estimates and design of a future definitive trial.

Design:

Pilot two-arm cluster randomised controlled study comparing the WCQ2 smoking cessation programme with usual care (HSE standard smoking cessation services). This is a pragmatic pilot study of a complex intervention and is a small-scale version of the future definitive trial. Four work packages (WPs) are planned. WP1 is the design, set up and analysis of the pilot trial involving 194 women (97 per arm) in four districts. The primary outcome is biochemically-validated abstinence of smoking at the end of programme (12 weeks) with secondary outcomes including continuous validated abstinence at 6 months. WP2 focuses on trial implementation and a process evaluation. WP3 is a cost activity analysis that involves a micro costing of the intervention and a preliminary analysis of the cost-effectiveness of the intervention to inform a decision of whether to undertake a full RCT. WP4 will develop strategies to optimise recruitment and dissemination of findings to trial stakeholders to inform knowledge exchange and future research.

Research Team:

The proposal is submitted by an experienced team of researchers from Ireland and the UK led by Professor Catherine Hayes at Trinity College Dublin and including experts in: trial design, statistics, process evaluation, behaviour change, smoking cessation, cost-effectiveness analysis and cancer prevention. Collaborators are drawn from a range of relevant agencies and include members of the public.

Outcomes/Impact:

This pilot trial focuses on feasibility issues and therefore has no single primary outcomes. Feasibility outcomes include recruitment and retention rates, and acceptability of the intervention. Smoking outcomes will be assessed through self-reported and validated smoking abstinence, both before and after delivery.

Publications:

Systematic review, publication of study results in a medical journal

INCENTIVE INTERVENTIONS TO CHANGE HEALTH RELATED BEHAVIOURS

“

...I have taken part in quite a number of things of this nature over the past 20 years and this is the first time that I have really felt that it has been successful and that I have been listened to...

(carer of stroke survivor)

”

Project Number:	HBC02.1
Status:	Complete
Project Title:	Benefits of incentives for breastfeeding and smoking cessation. A platform study for a trial. (BIBS)
Source of funding and total value of award:	NIHR HTA, £316,807.00
Value of funding to NMAHP RU:	£9,900.00
Principal investigator/co-applicants:	Hoddinott P (PI) (University of Stirling), Campbell M (HSRU, University of Aberdeen), Ludbrook A (HERU), Bauld L (University of Stirling), Sniehotta F (Newcastle University), Dykes F (University of Central Lancashire), Tappin D (University of Glasgow), Mastrick Café Creche, Aberdeen (PPI), Blackpool Children's Centre (PPI).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Health Behaviour Change
Start date:	February 2012
Duration:	26 Months

Aim(s):

The aim of this research was to try to find out which incentives (financial or non-financial), if any, were most likely to help women to stop smoking in pregnancy (and not restart) and to breastfeed their babies until 6 months old, as recommended by the World Health Organization to benefit the health of both mothers and babies.

Objectives:

1. To determine the evidence for the effectiveness of incentive interventions delivered within or outside the NHS, to (a) individuals, families or (b) organisations that aim to increase and sustain smoking cessation and breastfeeding during pregnancy.
2. To determine the acceptability and feasibility of a shortlist of promising incentive strategies and potential harms or adverse consequences.
3. To develop an incentive taxonomy.
4. To design a feasible trial.

Summary:

There were three key stages to the research which was undertaken with involvement of two co-applicant mother and baby groups in disadvantaged areas:

Stage 1. Evidence synthesis to meet the knowledge gap on the use of incentives in this underdeveloped field and to integrate evidence on two behaviours; smoking in pregnancy_ and breastfeeding. The evidence syntheses aimed to assess incentives at an individual recipient level as well as at provider and organisational levels. A meta-analysis was possible for financial incentives for smoking cessation in pregnancy. Mixed methods narrative synthesis was undertaken for smoking cessation studies not suitable for inclusion in the meta-analysis and for incentives aiming to improve breastfeeding outcomes.

Stage 2. Primary qualitative research and surveys with the UK public and with Early Years Health Professionals and relevant stakeholders were undertaken to assess the acceptability and feasibility of a shortlist of candidate incentives.

Stage 3. A discrete choice experiment (DCE) to inform the design of trials to test the effect of different levels of incentive and other intervention components for smoking cessation in pregnancy: expert support by phone or by text and a quitting pal (who does not receive an incentive).

Outcomes/Impact:

The research identified a shortlist of seven potential interventions for future trial. The acceptability and feasibility of each was assessed.

- Shopping vouchers for verified smoking cessation in pregnancy showed the most promise.
- The acceptability of financial incentives to the UK public and to health professionals is mixed.
- The DCE found that additional text messages and social network support in addition to the incentive were perceived to be effective for smoking cessation.
- A free breast pump was found to be the most acceptable of the seven incentive strategies to the UK public, childbearing women and early years health professionals. However, BIBS found that there are considerable inequalities of access to breast pumps for women on low incomes.
- Impact is being generated through grant applications, funded projects and publications relating to each of these bullet points.
- CPIT III trial. Pat Hoddinott is now leading the process evaluation for the Cessation in Pregnancy Trial III, together with Fiona Harris [HBC02.2]. Funding from the Chief Scientist Office and Cancer Research UK has been awarded for this multi-centre effectiveness and cost-effectiveness trial, due to start recruiting in September 2017.
- The public acceptability of financial incentives for smoking cessation in pregnancy have been compared between France and the UK following a request from Prof Ivan Berlin, Professor of Medicine, Pitié-Salpêtrière Hospital Medical School, Paris, France. The BIBS team have shared the survey questions and the database with the French team and a paper has been published in *The European Journal of Health Economics* (below). Following a presentation of the findings by Dr Noemi Berlin at the 2017 SRNT International Conference, Pat was approached by Associate Professor Megan Passey and colleagues at The Universities of Sydney and Tasmania to collaborate on extending the dataset to include acceptability data using the BIBS survey for Australia and the US (Prof Steve Higgins, University of Vermont)
- Helen Cheyne is leading an acceptability and feasibility CSO funded study of text messages to help women stop smoking in pregnancy [HCB01.13].
- Pat Hoddinott chaired the Advisory Group for a CRUK/BUPA Sandpit award to Fiona Dobbie, Institute for Social Marketing,

University of Stirling in 2014-2015 to commence development of a social networking intervention for smoking cessation in pregnancy. Pat and Fiona co-led an unsuccessful grant applications to CSO in 2015 and CRUK in 2016. A revised bid will be submitted to CRUK.

As a result, Glasgow Children's Charity and Scottish Government are funding the BABI suite of research studies [HBC02.3, HBC02.4] to assess the feasibility of a breast pump incentive (BABI 1 [HBC02.3]) and of a breast pump hire service (BABI 2 [HBC02.4]).

Publications:

- Hoddinott, P., Morgan, H., Maclennan, G., Sewel, K., Thomson, G., Bauld, L., Yi, D., Ludbrook, A. and Campbell, M.K. (2014) 'Public acceptability of financial incentives for smoking cessation in pregnancy and breast feeding: a survey of the British public', *BMJ Open*, 4(7), e005524.
- Thomson G, Morgan H, Crossland N, Bauld L, Dykes F, Hoddinott P. Unintended Consequences of Incentive Provision for Behaviour Change and Maintenance around Childbirth. *PLoS ONE*. 2014;9(10): e111322. doi:10.1371/journal.pone.0111322
- Morgan, H., Hoddinott, P., Thomson, G., Crossland, N., Farrar, S., Yi, D., Hislop, J., Moran, V.H., Maclennan, G., Dombrowski, S.U., Rothnie, K., Stewart, F., Bauld, I., Ludbrook, A., Dykes, F., Sniehotta, F.F., Tappin, D. and Campbell, M. (2015) 'Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design', *Health Technology Assessment*, 19(30).

- Moran, V. H.; Morgan, H; Rothnie, K; MacLennan, G; Stewart, F; Thomson, G; Crossland, N; Tappin, D; Campbell, M; Hoddinott, P. Incentives to Promote Breastfeeding: A Systematic Review. *Paediatrics*. 2015;135,(3). DOI: 10.1542/peds.2014-2221. www.pediatrics.org/cgi/doi/10.1542/peds.2014-2221
- Crossland N, Thomson G, Morgan H, Dombrowski SU, Hoddinott P on behalf of the 'BIBS' study team. Incentives for breastfeeding and for smoking cessation in pregnancy: An exploration of types and meanings. *Social Science and Medicine*. 2015;128(3):10-17.
- Hoddinott P, Thomson G, Morgan H, Crossland N, MacLennan G, Dykes F, Stewart F, Bauld L, Campbell MK. Perspectives on financial incentives to health service providers for increasing breastfeeding and smoking quit rates during pregnancy: a mixed methods study. *BMJ Open*, 2015;5:e008492.doi:10.1136/bmjopen-2015-008492
- Crossland N, Thomson G, Morgan H, Dykes F, MacLennan G, Campbell MC, Hoddinott P. Breast pumps as an incentive for breastfeeding: a mixed methods study of acceptability. *Maternal and Child Nutrition*. 2016; 12(4):726-739. DOI: 10.1111/mcn.12346.
- Morgan H, Thomson G, Crossland N, Dykes F, Hoddinott P. Combining PPI with qualitative research to engage 'harder-to-reach' populations: service user groups as co-applicants on a platform study for a trial. *Research Involvement and Engagement*; 2016, 2:7 DOI: 10.1186/s40900-016-0023-1.
- Farrar, S., Yi, D., Morgan, H., Ludbrook, A. and Hoddinott, P. (2016) 'Financial incentives to support smoking cessation in pregnant women - size matters', HERU Policy Brief, University of Aberdeen, May 2016.
- Berlin N, Goldzahl L, Bauld L, Hoddinott P, Berlin I. Public acceptability of financial incentives to reward pregnant smokers who stop smoking: a United Kingdom - France comparison. *European Journal of Health economics*. 2017. Available on-line: DOI 10.1007/s10198-017-0914-6.

Other dissemination activity:

- Morgan, H., Hislop, J., Rothnie, K., Stewart, F., Hoddinott, P. and Farrar, S. (2012) 'Incentives for smoking in pregnancy: are they the way forward?' Health Challenge Wales, Cardiff, Wales, June 2012.
- Hoddinott, P., Hislop, J., Morgan, H., Stewart, F., Rothnie, K., Bauld, L., Thomson, G. and Farrar, S. (2012) 'BIBS: Benefits of Incentives for Breastfeeding and smoking cessation: a platform study for a trial', Public Health Agency, Belfast, Ireland, November 2012.
- Hoddinott, P., Hislop, J., Morgan, H., Stewart, F., Farrar, S., Rothnie, K., Bauld, L. and Thomson, G. (2012) 'Incentive interventions for smoking cessation in pregnancy: A mixed methods evidence synthesis of incentive interventions for smoking cessation in pregnancy', Faculty of Public Health Scotland, Crieff, November 2012.
- Morgan, H., Hoddinott, P., Hislop, J., Stewart, F., Rothnie, K., Bauld, L., Thomson, G. and Farrar, S. (2012) 'More questions than answers: the role of incentives around childbirth', Faculty of Public Health Scotland, Crieff, November 2012.
- Hoddinott, P., Hislop, J., Morgan, H., Stewart, F., Farrar, S., Rothnie, K., Bauld, L. and Thomson, G. (2012) 'A mixed methods evidence synthesis [poster]', Royal Society of Medicine. Public Health Science: a National Conference Dedicated to New Research in Public Health. London, England, November 2012.
- Hoddinott P (Keynote) Breastfeeding, behaviour change and incentives. *Maternal and Infant Nutrition and Nurture Conference*, University of Central Lancashire. June 2013. *Maternal and Child Nutrition 2013, Supplement 3: 1-41*.
- Crossland N, Thomson G, Morgan H, Dykes F, Hoddinott P on behalf of the BIBS Research Team. Incentives to stop smoking and start and continue breastfeeding. *Maternal and Infant Nutrition and Nurture Conference*. Grange-over-Sands, Cumbria. June 2013. Abstract published in *Maternal and Child Nutrition 2013, Supplement 3: 1-41*.
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- Hoddinott, P., Morgan, H., Thomson, G., Crossland, N., Craig, L., Britten, J., Farrar, S., Newlands, R., Kiezebrink, K. and Coyle, J. (2013), 'Intervention vignettes as a qualitative tool to refine complex intervention design', 2nd Clinical Trials Methodology Conference, EICC, Edinburgh, 18-19 November 2013.
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- Hoddinott, P., Morgan, H., Maclennan, G., Sewel, K., Thomson, G., Bauld, L., Yi, D., Ludbrook, A. and Campbell, M.K. (2014) 'Public acceptability of financial incentives for smoking cessation in pregnancy and breastfeeding', Scottish School of Primary Care (SSPC), Cumbernauld, 29-30 April 2014.
- Hoddinott P, Morgan H, Thomson G, Crossland N, MacLennan G, Sewel K, Bauld L, Campbell M. Financial incentives to providers to improve smoking cessation in pregnancy and breastfeeding outcomes: acceptability and perceived consequences. Society for Academic Primary Care, Edinburgh, July 2014.
- Hoddinott P, Morgan H, Thomson G, Crossland N, Dombrowski SU. A ladder logic model to inform the design of incentive trials for women around childbirth. International Congress of Behavioural Medicine. Groningen, Netherlands. August 2014.
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- Bauld L, Marteau, Hoddinott P. Incentives for Smoking Cessation in Pregnancy Symposium. Public acceptability of financial incentives for smoking cessation in pregnancy. Society for Research into Nicotine and Tobacco (SRNT) Europe - 15th Annual Meeting. Santiago de Compostela, Spain. September 2014.
- Bauld L, Marteau T, Hoddinott P with Berlin I as discussant. Symposium on Incentives for Smoking Cessation in Pregnancy. Paper: Hoddinott, P., Morgan, H., Maclennan, G., Sewel, K., Thomson, G., Bauld, L., Yi, D., Ludbrook, A. and Campbell, M. (2014) 'Public acceptability of financial incentives for smoking cessation in pregnancy and breastfeeding', SRNT Europe Annual Meeting, Santiago de Compostela, Spain, 18-20 September 2014.
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- Hoddinott, P., Morgan, H., Thomson, G., Crossland, N., Farrar, S., Yi, D., Hislop, J., Hall Moran, V., Maclennan, G., Dombrowski, S.U., Rothnie, K., Stewart, F., Bauld, L., Ludbrook, A., Dykes, F., Sniehotta, F.F., Tappin, D. and Campbell, M. (2014) 'The 'push me-pull you' of financial incentives and health inequalities: a mixed methods study investigating smoking cessation in pregnancy and breastfeeding [Poster]', Public Health Science: a National Conference Dedicated to New Research in UK Public Health, Glasgow, 19-22 November 2014.
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- Hoddinott P, Morgan H, Thomson G, Crossland N, Dombrowski SU. A ladder logic model to inform the design of incentive interventions for breastfeeding. 6th International Conference on Maternal and Infant Nutrition and Nurture. Grange-over-Sands, Cumbria. June 2015. Maternal and Child Nutrition 2015; Supplement 2:63.

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- Hoddinott P, Thomson G (presenter), Morgan H, Crossland N, MacLennan G, Dykes F, Stewart F, Bauld L, Campbell MK. Perspectives on financial incentives to health service providers for increasing breastfeeding and smoking quit rates during pregnancy: a mixed methods study. 6th International Conference on Maternal and Infant Nutrition and Nurture. Grange-over-Sands, Cumbria. June 2015. *Maternal and Child Nutrition 2015; Supplement 2:113.*
 - Crossland N, Thomson G, Morgan H, Dykes F, Hoddinott P. Breast pumps as an incentive for breastfeeding: a mixed methods investigation. 6th International Conference on Maternal and Infant Nutrition and Nurture. Grange-over-Sands, Cumbria. June 2015. *Maternal and Child Nutrition 2015; Supplement 2:36.*
 - Bauld L, Hoddinott P, Radley A, Sinclair L, Boyd K. Symposium on financial incentives for smoking cessation in pregnancy. ASH International conference: Towards a generation free from tobacco: turning the vision into reality. John McIntyre Conference Centre, Edinburgh. 18-19 June 2015.
 - Hoddinott P (Keynote) Designing Incentive Trials for Behaviour Change in Women around Childbirth. Research day on Payment for Health Behaviours, FUSE, The Centre for Translational Health through Research, University of Newcastle, Sunderland. 22nd July 2015.
<http://fuseopenscienceblog.blogspot.co.uk/2015/07/would-you-accept-money-to-be-healthier.html>.
 - Hoddinott, P. on behalf of the BIBS Study Team (2015) 'Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design', Researching Complex Interventions in Health: the State of the Art, Rougemont Hotel, Exeter, England, 14-15 October 2015.
 - Hoddinott P (keynote) Nutrition Society Annual Conference, Financial incentives to increase and sustain healthy lifestyle behaviours. Dublin 11-13 July 2016.
 - Berlin N, Goldzahl L, Hoddinott P, Bauld L, Berlin I. Willingness to accept financial incentives for smoking cessation in pregnancy: a comparison France-United Kingdom. SRNT 23rd International Meeting. March 8-11 2017, Florence Italy. Abstract available at: http://c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2017_annual_meeting/SRNT_2017_Abstract_Book_Web.pdf.

Project Number:	HBC02.2
Status:	In Progress
Project Title:	CPIT III trial. Cessation of smoking in pregnancy incentives trial
Source of funding and total value of award:	Partnership funding CRUK £824,587.00; Chief Scientist Office £294,974.00
Value of funding to NMAHP RU:	£20,209.00
Principal investigator/co-applicants:	Tappin D (Co-PI) (University of Glasgow), Bauld L (Co-PI) (University of Stirling), Adamson J (University of York), Coleman T (University of Nottingham), Cooper S (University of Nottingham), Kee F (University of Belfast), Sinclair L (University of Stirling), Torgerson D (University of York), Usher M (London).
NMAHP RU investigators:	Hoddinott P, Harris F.
Workstream:	Health Behaviour Change
Start date:	September 2017
Duration:	36 Months

Aim(s):

To examine the effectiveness and cost-effectiveness of offering financial incentives to pregnant smokers to quit.

Research questions:

1. How effective is the addition of up to £400 of financial incentives to usual NHS smoking cessation services in terms of cotinine-validated abstinence in late pregnancy and six months after birth?
2. Is this strategy cost-effective both in terms of cost per extra quitter, and potential lifetime cost per Quality Adjusted Life Year (QALY) gained?
3. What effect does demographic diversity and differences in smoking cessation service configuration have on observed outcomes?
4. What are the barriers and facilitators to trial recruitment, retention and implementation in different areas with different population groups?

Summary:

Annually, in the UK, smoking causes 5000 early miscarriages, 100 stillbirths and 200 infant deaths. Smoking increases prematurity, low birth weight, asthma, attention deficit disorder and learning difficulties, adding substantial costs to health care. One in four UK women smoke for part and one in eight throughout pregnancy. Smoking cessation services offer counselling plus free Nicotine Replacement Therapy (NRT), however only 10% of pregnant smokers use these services and as few as 3% stop. Systematic reviews including those undertaken as part of the NIHR HTA funded BIBS study led by Pat Hoddinott [HBC02.1] show promise for financial incentives and NICE have put forward a research recommendation for a definitive trial of financial incentives. BIBS surveyed the public and relevant health professionals, conducted a discrete choice experiment on women with a smoking history and interviewed a range of stakeholders on types, acceptability and levels of incentive.

More than 85% of the general public found vouchers valued up to £40 per month acceptable. Vouchers above £20 per month were required, and higher values would increase the likelihood of quitting.

CPIT III is a multi-centre randomised controlled trial at 4 centres, with a parallel process evaluation led by the Unit's Pat Hoddinott and Fiona Harris, who have internationally recognised methodological expertise in qualitative methods applied to trials. It follows an efficacy trial (CPIT II) undertaken in Glasgow. It incorporates the findings from the BIBS platform study for incentive trials. The four trial sites have different smoking cessation service and maternity care configurations. The mixed methods process evaluation will investigate how CPIT III integrates at the four sites. In particular, qualitative interviews and observations will help to understand any differences in recruitment rates or engagement in the trial and the fit with local context.

Outcomes/Impact:

Ethics committee application has been submitted.

Project Number:	HBC02.3
Status:	In Progress
Project Title:	Use of breast pumps to improve breastfeeding outcomes: development and feasibility testing of novel incentive intervention. Short name: BABI 1: Breastfeeding And Breast-pumps Intervention
Source of funding and total value of award:	Glasgow Children's Hospital Charity, £39,629
Value of funding to NMAHP RU:	£36,501.90
Principal investigator/co-applicants:	McInnes R (PI) (Edinburgh Napier University), Currie S (University of Stirling).
NMAHP RU investigators:	Hoddinott P, Elders A, Gillespie N.
Workstream:	Health Behaviour Change
Start date:	March 2016
Duration:	17 Months

Aim(s):

To develop an acceptable and feasible breast pump incentive intervention for future testing in a trial. To describe NHS and voluntary sector breast pump provision, support and hire services in Scotland.

Summary:

Breast pumps are popular because they allow others to feed the baby and overcome anxiety about breastfeeding in public. Women have to buy or hire pumps and some women cannot afford to do this. A breast pump incentive worth £40 was the most popular incentive for breastfeeding in our recent UK BIBS study survey [HBC02.1]. Previous research led by Pat Hoddinott which was commissioned by NHS Health Scotland (<http://www.healthscotland.com/documents/4720.aspx>), and published in BMJ Open (<http://bmjopen.bmj.com/content/2/2/e000504.full>) and an on-line survey with mothers (HBC02.5] found that information on breast pumps is confusing and parents were dissatisfied with support.

We are:

- finding out about breast pump services and staff training across Scotland (NHS and charities) through analysis of Health Board documents, a survey and interviews with staff

- meeting with mother and baby groups and staff to design a new breast pump service which will help low-income women asking for feedback about our plans through NetMums.

Outcomes/Impact:

In progress. The main outcome will be an acceptable breast pump incentive intervention; assessment of usual care; and identification of a suitable comparator for a future pilot trial. BABI 1 is a suite of studies arising from the BIBS study [HBC02.1 and HBC02.5]

Publications:

Gillespie N, McInnes R, Hoddinott P. Breast-milk expression policies and practices in Scotland: a document analysis. Nutrition and Nurture in Infancy and Childhood: Biocultural Perspectives. International Conference held at Grange over Sands, 12-14th June 2017. Conference Abstract Maternal and Child Nutrition (in press).

Other dissemination activity:

An engagement workshop to start developing an intervention took place with mothers, babies, health professionals and the voluntary sector on 29th March 2017 at the Teachers Building, St Enoch, Glasgow.

Project Number:	HBC02.4
Status:	Complete
Project Title:	Breastfeeding And Breast-pumps Intervention (BABI 0). Opinions on breast pumps: an on-line survey
Source of funding and total value of award:	NHS Health Scotland, £12,261.00
Value of funding to NMAHP RU:	£7,851.00
Principal investigator/co-applicants:	McInnes R (PI) (Edinburgh Napier), Moran VH (UCLAN), Crossland N (UCLAN).
NMAHP RU investigators:	Hoddinott P, Elders A, Gillespie N.
Workstream:	Health Behaviour Change
Start date:	February 2017
Duration:	3 Months

Aim(s):

To gather information about expressing, use of pumps and opinions of the provision of a breast pump service as an incentive to breastfeed.

Summary:

Breast pumps are popular because they allow others to feed the baby and overcome anxiety about breastfeeding in public. Women have to buy or hire pumps and some women cannot afford to do this. A breast pump incentive worth £40 was the most popular incentive for breastfeeding in our recent UK BIBS study survey led by Pat Hoddinott [HBC02.1]. Earlier research led by Pat Hoddinott was commissioned by NHS Health Scotland in 2010 (<http://www.healthscotland.com/documents/4720.aspx>), and published in BMJ Open in 2012 (<http://bmjopen.bmj.com/content/2/2/e000504.full>) found that parents were dissatisfied with information and support about expressing breast milk and the use of breast pumps. Midwife Alex Arbuckle identified and analysed websites providing breast pump information to mothers as an MRes project in 2015 (unfunded work) supervised by Pat and Rhona (see outputs below). This online survey which included structured and free text

questions to mothers who had given birth within 5 years was undertaken by Rhona McInnes (previously University of Stirling) and Pat Hoddinott in 2015 (unfunded work). In addition, the purpose of the survey and the website analysis was to inform the BABI 1 funding application to Glasgow Children's Hospital Charity (HBC02.3) to develop a breast pump incentive intervention. This started as a small on-line survey disseminated through a local Mother and Baby Group who contribute Public and Patient Involvement to our research and to community mother and baby groups through the Scottish Infant Feeding Advisory Network, which Pat and Rhona are members of. The survey asked mothers about breast pump use, availability and support through the NHS, through 3rd sector organisations and about attitudes to hiring a breast pump or receiving a breast pump voucher worth £40. This survey proceeded to go viral via NetMums and Facebook. NHS Health Scotland have provided funding to assist with data management and analysis, in order to inform a proposed Scottish Government Breast Pump Hire Policy. This aims to address the health inequalities of breast pump access highlighted by the BIBS study (HBC02.1) and a Masters of Research student and inform the BABI suite of projects [HBC02.3].

Outcomes/Impact:

The survey had 666 respondents. Opinions on a free breast pump or hire service were favourable; however qualitative analysis of free text comments indicated a range of concerns and suggestions which could help inform a potential intervention. Scottish Government is planning to introduce a free breast pump hire service polity across Scotland, informed by the findings of this study. The team are currently negotiating funding for this work.

Publications:

- McInnes R, Arbuckle A, Hoddinott P. How UK internet websites portray breast milk expression and breast pumps: a qualitative study of content. *BMC Pregnancy and Childbirth*. 2015; 15:81. doi:10.1186/s12884-015-0509-0. <http://www.biomedcentral.com/content/pdf/s12884-015-0509-0.pdf>

A publication of the survey results is in preparation.

Other dissemination activity:

- McInnes R, Hall Moran V, Crossland N, Gillespie N, Hoddinott P. Breast pumps as an incentive: a survey of mothers' experiences and opinions. *Nutrition and Nurture in Infancy and Childhood: Biocultural Perspectives*. International Conference held at Grange over Sands, 12-14th June 2017. Conference Abstract Maternal and Child Nutrition (in press).
- McInnes R, Arbuckle A, Hoddinott P. How UK internet websites portray breast milk expression and breast pumps: a qualitative study of content. 6th International Conference on Maternal and Infant Nutrition and Nurture. Grange-over-Sands, Cumbria. June 2015. *Maternal and Child Nutrition 2015, Supplement 2:88*. <http://onlinelibrary.wiley.com/doi/10.1111/mcn.12238/epdf>.

MATERNAL AND CHILD HEALTH

MATERNAL AND INFANT MENTAL HEALTH AND WELLBEING

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To have been listened to as clinicians, um, with our aspiration of trying to deliver high quality evidenced-based practice, where there are real challenges doing that, but to really be listened to in that respect and then to translate is pretty unique.

(physiotherapist)

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Project Number:	MCH01.1
Status:	In Progress
Project Title:	The development and initial validation of a screening scale for antenatal anxiety
Source of funding and total value of award:	Chief Scientist Office, £119,922
Value of funding to NMAHP RU:	£119,922
Principal investigator/co-applicants:	Cheyne H (PI), Sinesi A, Maxwell M (University of Stirling)
NMAHP RU investigators:	Sinesi A, Cheyne H, Maxwell M.
Workstream:	Maternal and Child Health
Start date:	October 2015
Duration:	36 Months

Aim(s):

The primary aim of this study is to develop and validate a screening tool specifically devised to detect significant anxiety during pregnancy.

Objectives:

During pregnancy, a substantial minority of women develop significant clinical anxiety that can have a negative effect on long-term health and wellbeing of mothers and babies. However, recent reviews have highlighted the lack of anxiety measures with strong psychometric properties for screening use with pregnant women. This study aims to fill this gap by developing a questionnaire to screen for significant antenatal anxiety. In the initial phase of research, a systematic review of the literature on existing anxiety measures and qualitative interviews with women with experience of antenatal anxiety were conducted to inform the generation of a large item pool for potential inclusion in the screening tool. In order to refine this initial item pool, experts in perinatal mental health were consulted in order to reach consensus on questions to be considered as important indicators of problematic anxiety in pregnancy. Subsequently, a preliminary version of the questionnaire will be administered to 50 pregnant women in a pilot study, in order to further reduce the number of questions and identify any items that may be unclear to respondents.

In the final phase of the research, a larger sample of 200 women will be asked to complete the new scale and the questionnaire currently used by midwives to identify pregnant women experiencing anxiety. 60 of these women will also be assessed by a mental health specialist and the screening accuracy of the new scale will be compared to expert assessment. This will enable us to determine whether the new scale is an effective screening tool for anxiety in pregnancy.

Outcomes/Impact:

This study is currently in progress. The expected outcome is a short and reliable questionnaire that can be used to identify women experiencing problematic antenatal anxiety. Such a tool would be highly valuable, assisting midwives and other health professionals, to recognise when women would benefit from further support and appropriately targeting mental health interventions.

Other dissemination activity:

- Sinesi A (2016) 4th Scottish Mental Health Nursing Research Conference, oral presentation, Abertay University Dundee.
- Sinesi A, Cheyne H, Maxwell M, O'Carroll R (2016) Stirling Centre for Child Wellbeing & Protection Conference – poster.

Project Number:	MCH01.2
Status:	Complete
Project Title:	Aberlour Perinatal Befriending Support Service: An evaluation of the pilot delivery
Source of funding and total value of award:	Aberlour - Scotland's Children's Charity, £10,000
Value of funding to NMAHP RU:	£10,000
Principal investigator/co-applicants:	Cheyne H (PI), Maxwell M, Daniel B, Calveley E (University of Stirling)
NMAHP RU investigators:	Cheyne H, Maxwell M, Calveley E.
Workstream:	Maternal and Child Health
Start date:	July 2015
Duration:	12 Months

Aim(s):

To evaluate the impact of the pilot Aberlour Perinatal Befriending Support service on key outcomes relating to mothers' health and wellbeing, and to explore its fit with the Scottish policy and service context.

Summary:

The study used a realist evaluation approach to assess the impact of a pilot volunteer befriending support service for vulnerable women in the Forth Valley area with mild to moderate depression during the period from conception to their baby's first birthday. The evaluation assessed the appropriateness of quantitative outcome measures for anxiety/depression, maternal attachment, social support, self-esteem and self-efficacy. To explore aims, expectations and the experience of participants, focus groups were held with key stakeholders and volunteers, along with individual interviews with service users at the outset of the service and after befriending had been in place for between 4 and 12 months. A co-production approach was taken to the thematic analysis of the qualitative data. The service was found to have achieved its aims by reducing anxiety and depression, increasing self-esteem and maternal attachment, as well as increasing mother's self-efficacy in parenting and undertaking normal day-to-day activities. It fitted well with national and local policy objectives and service delivery.

Mechanisms for success were found to be: the structured, but flexible approach taken to delivering the service, with a strong training programme and a person-centred approach to the actual service provided; a high level of compassion for the service users; and the empowering nature of the service. Overall, it was considered to be an effective and acceptable approach to supporting vulnerable mothers during the perinatal stage.

Outcomes/Impact:

Pilot service evaluation. Has informed continuation and extension of service delivery. May inform full-scale evaluation and ongoing monitoring of the service's effectiveness. May inform policy.

Publications:

Calveley, E., Cheyne, H., Daniel, B. and Maxwell, M. (2016). Aberlour Perinatal Befriending Service: An evaluation of the pilot delivery. Aberlour Scotland's Children's Charity, Stirling. <http://www.aberlour.org.uk/publication/perinatal-befriending-support-service-evaluation/>

Other dissemination activity:

Parliamentary presentation (February 2017) to key MSPs, stakeholders, people affected by perinatal mental health issues and potential funders.

MATERNITY SERVICES POLICY AND QUALITY OF CARE DELIVERY

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a very useful project to be involved in as I feel that the results gained will be widely accessible and relevant.

(physiotherapist)

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Project Number:	MCH02.1
Status:	Implementation
Project Title:	Developing and implementing a decision support tool for redesign of postnatal care: PRAM
Source of funding and total value of award:	Royal College of Midwives, Scottish Government Chief Scientist Office and Knowledge Transfer Partnerships, £170,000
Value of funding to NMAHP RU:	£112,494
Principal investigator/co-applicants:	Cheyne H (PI) (University of Stirling), Bick D (King's College London), Bowers J, Harris F, Mould G (University of Stirling).
NMAHP RU investigators:	Cheyne H, Page M, Harris F.
Workstream:	Maternal and Child Health
Start date:	January 2011
Duration:	36 Months

Aim(s):

To develop and test a decision support tool for redesign of postnatal care.

Summary:

Maternity services across the UK currently face the twin issues of improving both quality and efficiency of care due to increased financial pressures and increases in complex pregnancies. This has stimulated much debate about service redesign and in particular the possible reallocation of resources, both along care pathways and between groups with different needs. A Postnatal care Resource Allocation Model (PRAM) was developed to support a more systematic appreciation of the consequences of redesign options. Many health care resource allocation decisions have to consider a wide range of criteria and diverse sources of evidence. It has been suggested that a combination of multicriteria decision analysis with programme budgeting and marginal analysis might offer a suitable basis for these decisions. This approach was adapted in the development of a resource allocation model to support the redesign of postnatal care in the National Health Service. The model analyses the consequences of varying design parameters, notably staff contacts and time, on the various quality domains and costs for different categories of mothers. Initial applications suggest that more targeted allocation of resources and a greater emphasis on community rather than hospital-based care can offer both cost savings and improved care quality.

The experiences in using the model indicate that the main benefits of the model include its structure for assembling the key data, sharing evidence amongst multi-professional teams and encouraging constructive, systemic debate.

Outcomes/Impact:

The PRAM tool has been successfully implemented in one NHS Trust and is currently being implemented in an NHS Board.

Publications:

- Bowers J, Cheyne H, Mould G, Miller M, Page M, Harris F, Bick D. A multi-criteria resource allocation model for the redesign of services following birth. *Value in Health* (under review).
- Bowers J, Cheyne H. (2016) Implications for cost and quality of care of reducing the length of postnatal hospital stay: an exploration using pre-existing data sets. *BMC Health Services Research*. 16(1):16. doi: 10.1186/s12913-015-1214-4.
- Bowers, J, Cheyne, H, Mould G, Page, M. (2014). Continuity of care in community midwifery. *Health Care Management Science (e-Pub Ahead of Print)* Doi:10.1007/s10729-014-9285-z.

Other dissemination activity:

- RCM Webinar. Using the PRAM Tool for Planning Resources for Postnatal Care.
<http://betterbirths.rcm.org.uk/resources/using-the-pram-tool-for-planning-resources-for-postnatal-care/>
- Postnatal Care- presenting the PRAM model. Plenary presentation. Royal College of Midwives Conference 2014.
- Postnatal care moving forward. RCM Think Tank Day 2015
- Bick D, Bowers J, Cheyne H, Harris F, Miller M, Mould M, Page M. Redesigning postnatal care with PRAM. The Sheila Kitzinger symposium at Green Templeton College. (2016)
- Bick D, Cheyne H, Harris F, Page M, Bowers, J, Mould G. Postnatal Care Symposium. 30th ICM Triennial Congress. Prague 2014
- Cheyne H Improving postnatal care. European Board & College of Obstetrics and Gynaecology Conference Glasgow 2014.
- Bower J, Cheyne H, Harris F, Miller M, Page M, Mould G, Bick D. Postnatal Resource Allocation Modelling in Postnatal Care. EURO Working Group on Operational Research Applied to Health Services will take place in Bath (UK) at the University of Bath from 30th July to 4th August 2017. <http://orahs.di.unito.it/>

Project Number:	MCH02.2
Status:	Complete
Project Title:	Right from the Start. A scoping study of the implementation of the GIRFEC practice model within Maternity Care in three contrasting sites across Scotland
Source of funding and total value of award:	Scottish Government Health Directorates, £36,6000
Value of funding to NMAHP RU:	£36,000
Principal investigator/co-applicants:	Cheyne H (PI) (University of Stirling).
NMAHP RU investigators:	Cheyne H, Cross B.
Workstream:	Maternal and Child Health
Start date:	January 2012
Duration:	18 Months

Aim(s):

To examine the place of strength based approaches within the integrated children's services policy in Scotland, "Getting It Right For Every Child".

Summary:

Strength based approaches draw on patient's strengths and perspectives to partner with them in their own care, recovery and problem solving. Their effectiveness in addressing complex health problems has a growing evidence base which has led to its incorporation within universal services in many countries. However, practitioners' understanding of strength based approaches and implementation strategies within universal services are under-researched. As these are complex interventions a methodology designed to capture complex dynamics such as a realist evaluation is particularly suited to investigating these developments. This study examined the place of strength based approaches within the integrated children's services policy in Scotland, "Getting It Right For Every Child". A case study approach, informed by Realist Evaluation, across three contrasting health board sites found that, whilst midwives reported adopting more open approaches to raising

sensitive issues with women, many midwives were unfamiliar with strength based approaches and were not drawing upon them, in contrast to a perception amongst managers that training and implementation was common. These findings suggest full implementation of strength based approaches within universal services require specific attention to training and embedded learning opportunities within practice.

Outcomes/Impact:

This study is an example of how small scale research can nevertheless bring together different components of an implementation strategy and identify emerging patterns resulting from the quality and sequencing of the components, thus moving beyond the reporting of micro-products without examining their relation to each other. As such, the study provides beneficial information for formative evaluation. The patterns identified also suggest topics to test across midwifery care training and professional development. This project led to the larger scale realist review of Early Years policy in Scotland (MCH02.3) and to the three 'Seamless Service' PhD studentships (MCH02.5).

Publications:

- Cross, B., Cheyne, H. and the Scottish Midwifery Research Collaboration. 2012. Right from the Start. A scoping study of the implementation of the GIRFEC practice model within Maternity Care in three contrasting sites across Scotland. Nursing, Midwifery and Allied Health Professions Research Unit. <http://www.nmahp-ru.ac.uk/research/reports/>

Other dissemination activity:

- Report to Scotland's Commissioner for Children and Young People www.cypcs.org.uk/ufiles/Approaches-to-engagement-with-children.pdf

Project Number:	MCH02.3
Status:	Report writing
Project Title:	Early years interventions to improve child health and wellbeing: what works, for whom and in what circumstances? A realist review (Scottish National Midwifery Research Programme)
Source of funding and total value of award:	Scottish Government Chief Nurse's Office, £80,000
Value of funding to NMAHP RU:	£80,000
Principal investigator/co-applicants:	Cheyne H (PI), Daniel B (University of Stirling).
NMAHP RU investigators:	Cheyne H, Coles E.
Workstream:	Maternal and Child Health
Start date:	December 2014
Duration:	24 Months

Aim(s):

To use realist methodology to demonstrate what works to improve child health and wellbeing and reduce inequalities in the early years. The main aims were to (i) critically examine the impact of early years interventions on the health and wellbeing of children; (ii) synthesise available data into a cohesive evidence base capturing the characteristics of effective interventions, the settings in which they are most likely to work, and the population groups for whom they are most effective; and (iii) translate findings into evidence-based, practical recommendations for policy-makers and practitioners.

Summary:

Taking a theory-driven realist review approach, the project synthesised interdisciplinary evidence to increase understanding about how and why early years interventions improve child health and wellbeing, by investigating mechanisms of change and outcomes generated within given contexts. Iterative project stages were (i) mapping early years policy and programmes in Scotland; (ii) stakeholder/expert consultation; (iii) case study of Getting it Right for

Every Child (GIRFEC), the Scottish Government's child wellbeing policy framework; (iv) developing a protocol for a realist review of the literature; (v) creation of a theoretical framework based on identified elements of effective interventions and causal links between programme activities and outcomes; (vi) reviewing a wide range of evidence and testing it against the theoretical framework.

Outcomes/Impact:

Production of an evidence-based framework and key recommendations to inform and support Scottish Government early years, children and families policy and practice, with anticipated longer-term impacts on child/family wellbeing, health inequalities and later life outcomes.

Publications:

- Coles, E., Cheyne, H., Rankin, J. and Daniel, B. (2016) 'Getting It Right for Every Child: A National Policy Framework to Promote Children's Wellbeing in Scotland, United Kingdom', *Milbank Quarterly*, 94(2): 334–365.
- Coles, E., Cheyne, H. and Daniel, B. (2015) 'Early years interventions to improve child health and wellbeing: what works, for whom and in what circumstances? Protocol for a realist review', *Systematic Reviews*, 4:79.

Other dissemination activity:

- Coles E, Cheyne H. (2017) 'What works to improve child wellbeing? From policy to programme theory to practitioners: Reflections on a realist journey', *International Conference for Realist Research, Evaluation and Synthesis: From Promise to Practice*, Brisbane, Australia, 24-26 October 2017.

Project Number:	MCH02.3
Status:	Complete
Project Title:	The Scottish Midwifery Research Collaboration: SMART
Source of funding and total value of award:	Scottish Government Health Directorate Chief Nurses Office, £299,765
Value of funding to NMAHP RU:	£299,765
Principal investigator/co-applicants:	Cheyne H, Abhyankar P (University of Stirling), Bryers H (NHS Highland), Deery R (University of West of Scotland), Humphrey T, McInnes R (Edinburgh Napier University), Rankin J (University of West of Scotland), Symon A (University of Dundee), Whitford H (University of Dundee), Williams B (Edinburgh Napier University).
NMAHP RU investigators:	Cheyne H, Williams B.
Workstream:	Maternal and Child Health
Start date:	September 2012
Duration:	60 Months

Aim(s):

To will safeguard and support midwifery research capacity and capability in Scotland. To provide and develop strategic midwifery research leadership and a coordinated approach to midwifery research in Scotland. To produce research outputs that will inform policy and practice and support REF submissions in partner institutions.

Summary:

Midwifery research is essential to the continued development of person-centred, safe and effective maternity care. Midwives have a pivotal role in the health and social care of mothers and babies. They are therefore ideally placed to implement existing effective interventions in efficient and woman-centred ways, and to develop and test new interventions and models of care. Prior to the award of this project funding (2012) there were relatively few experienced midwife researchers within Scotland who had the potential to obtain significant grant funding and who could be entered into the Research Excellence Framework (REF). Midwifery undergraduate (UG) student numbers had recently been reduced and the number of HEIs involved in UG midwifery education had, correspondingly, been

rationalised. This raised concern about potential loss of experienced midwife researchers and the longer term viability of midwifery research in Scotland. The Scottish Midwifery Research Collaboration is a joint HEI initiative, co-ordinated by the Nursing Midwifery and Allied Health Professions Research Unit (NMAHP RU). It brings together the lead midwife researchers from HEIs across Scotland with the aim of creating a critical mass of experienced researchers who have the skills and experience to develop and lead a sustainable programme of research in maternal and child health. The group was renamed SMART (Scottish Midwives Advancing Research Together) <http://smartmidwifery.org.uk/>.

Project funding supported regular meetings between group members and three research projects in Robert Gordon University (Mode of birth after caesarean section: Implementation of a tailored quality improvement intervention in Scotland.) University of Dundee (Alcohol in Pregnancy: validation of a sensitive diary-based questionnaire [Alco-Preg]) and University of Stirling (A realist review of early years interventions to improve child health and wellbeing) with co-investigators within and external to the collaboration.

Outcomes/Impact:

The three core funded research projects have been completed with paper writing and dissemination ongoing. Regular meetings have led to additional collaborations, grant applications and outputs e.g. a systematic review of evidence relating to clinical supervision. Almost all members of the group have benefited from high quality peer reviewed journal publications. The landscape of midwifery research in Scotland has now substantially changed. There are six professors of midwifery and the Mother and Infant Research Unit has now located in University of Dundee. The SMART group will now focus on capacity building of the next generation of midwifery researchers while continuing to collaborate on large scale grant applications.

Publications:

- Pollock A, Campbell P, Deery R, Fleming M, Rankin J, Sloan G & Cheyne H (2017) A systematic review of evidence relating to clinical supervision for nurses, midwives and allied health professionals (Forthcoming/ Available Online), *Journal of Advanced Nursing*.
- Symon, A., Rankin, J., Sinclair, H., Butcher, G., Barclay, K., Gordon, R., MacDonald, M. & Smith, L. (2017) Peri-conceptual and mid-pregnancy drinking: a cross-sectional assessment in two Scottish health board areas using a 7-day Retrospective Diary. *Journal of Advanced Nursing*. 73, 2, p. 375-385 11.
- Symon, A., Pringle, J., Downe, S., Hundley, V., Lee, E., Lynn, F., McFadden, A., McNeill, J., Renfrew, M., Ross-Davie, M., van Teijlingen, E. R., Whitford, H. & Alderdice, F. (2017) Antenatal care trial interventions: a systematic scoping review and taxonomy development of care models. *BMC Pregnancy and Childbirth*. 17, p. 1-16 16 p., 8.
- Symon A, Rankin, J., Butcher, G., Smith, L. & Cochrane, L. (2017) Evaluation of a retrospective diary for peri-conceptual and mid-pregnancy drinking in Scotland: a cross-sectional study. *Acta Obstetrica et Gynecologica Scandinavica*. 96, 1, p. 53-60 8.
- Symon, A., Pringle, J., Cheyne, H., Downe, S., Hundley,

V et al (2016). Midwifery-led antenatal care models: mapping a systematic review to an evidence-based quality framework to identify key components and characteristics of care. *BMC Pregnancy and Childbirth*, 16(1), 168.

- Coles E, Cheyne H, Rankine J, Daniel B (2016) Getting It Right for Every Child: A National Policy Framework to Promote Children's Well-being in Scotland, United Kingdom. *The Millbank Quarterly*. Volume 94, Issue 2, pages 334–365, June 2016.
- Coles E, Cheyne H, Daniel B (2015) Early years interventions to improve child health and wellbeing: what works, for whom and in what circumstances? Protocol for a realist review. *Systematic Reviews* 20154:79, DOI: 10.1186/s13643-015-0068-5.

Other dissemination activity:

Twitter @smartmidwifery

Project Number:	MCH02.4
Status:	Dissemination
Project Title:	The Scottish National Maternity Experience Programme
Source of funding and total value of award:	Scottish Government Health and Social Care Directorate, £105,065
Value of funding to NMAHP RU:	£105,065
Principal investigator/co-applicants:	Cheyne H (University of Stirling).
NMAHP RU investigators:	Cheyne H, Elders A, Hill D.
Workstream:	Maternal and Child Health
Start date:	July 2013
Duration:	45 months

Aim(s):

To provide comprehensive information about women's experiences of maternity care in Scotland as part of the Scottish Government Health and Social Care Directorates survey programme.

Summary:

The quality and safety of maternity services across Scotland are subject to scrutiny at local and national levels through the Scottish Patient Safety Programme, Maternity and Children's Quality Improvement Collaborative, and by measuring performance in relation to the Scottish Government HEAT target on antenatal access to care. However many important aspects of care quality can only be assessed by asking women about their experiences of care. Prior to 2013 there had been no national survey of women's maternity care experiences in Scotland since 1995. Since then maternity services have undergone considerable change both to organisation and infrastructure. Following recommendations of the national evaluation of the Scottish Government KCND programme the Scottish Government Health and Social Care Directorates and the NMAHP Research Unit worked together to instigate a programme of national maternity care surveys. The first survey was undertaken in 2013 and, with modifications to the survey

instrument and reporting, to include qualitative analysis repeated in 2015. The surveys in 2013 and 2015 used the questionnaire tested by the Care Quality Commission and used in the English national maternity survey programme, modified for use in the Scottish context. Surveys were distributed by an approved survey contractor to a random sample (10%) of women who gave birth in Scotland in February and March 2013 and 2015. Findings were provided at an individual NHS Board level and as national reports. Findings of both surveys indicated that in general women were satisfied with their maternity care and that HEAT targets for early access to maternity care were being met or surpassed in all NHS Boards. However important areas for improvement were highlighted. For example significant numbers of women lacked sufficient information regarding choice of place of birth. Many women reported receiving insufficient pain relief during labour and gave birth in sub optimal birth positions. In both surveys many women reported dissatisfaction with aspects of postnatal care including communication, kindness and respect and support for feeding choices.

Secondary analysis of data collected in the 2015 survey has been undertaken to examine whether women differed in the quality of care they experienced based on age, parity, geographical location, health or index of multiple deprivation.

Outcomes/Impact:

The two maternity surveys resulted in action plans for improvement in each of the 14 NHS Boards for example following the 2014 report NHS Forth Valley Forth Valley has launched an electronic format for women to request antenatal care. This enables women to self-refer by emailing the maternity booking bureau 24 hours per day to request their first midwife appointment and has provided enhanced breastfeeding support for mother following discharge. NHS Lanarkshire formed a maternity care action group comprising maternity staff; members of the public. NHS Tayside instigated improvement work on tackling the use of poor birthing positions.

The 2015 survey findings were included in the 2017 Scottish Government review of maternity and neonatal services. The Best Start: A Five-Year Forward Plan for Maternity and Neonatal Care in Scotland. <http://www.gov.scot/Topics/People/Young-People/child-maternal-health/neonatal-maternity-review>

'Kindness' concern in Scottish Maternity Care Survey 28th January 2014

<http://www.bbc.co.uk/news/uk-scotland-25926567>

Women praise maternity care 28th January 2014 <http://newsnet.scot/archive/women-praise-maternity-care/>

Publications:

- Cheyne H, Critchley A, Elders A, Hill D, Milburn E, Paterson A (2015) Having a baby in Scotland 2015: Listening to mothers. An Official Statistics Publication for Scotland. Available at: <http://www.gov.scot/Resource/0049/00490953.pdf>.
- Cheyne, H., Skar, S., Paterson, A., David, S., & Hodgkiss, F. (2014). Having a baby in Scotland 2013: Women's experiences of maternity care, volume 1: National results Scottish Government, NHS Scotland. Available from: <http://www.scotland.gov.uk/Publications/2014/01/8489>.

Other dissemination activity:

- Cheyne H, Elders A, Hill D, Milburn E. 2017 Is maternity care in Scotland equitable? Results of a national maternity care survey. 12th International Normal Labour and Birth Research Conference (Oral presentation).

Project Number:	MCH02.5
Status:	Ongoing
Project Title:	Achieving Seamless Services for Scotland's Children
Source of funding and total value of award:	Aberlour – Scotland's Children's Charity, NHS Forth Valley, Children in Scotland, Social Work Scotland, University of Stirling, £117,102
Value of funding to NMAHP RU:	£117,102
Principal investigator/co-applicants:	Cheyne H (PI), Daniel B (University of Stirling).
NMAHP RU investigators:	Cheyne H.
Workstream:	Maternal and Child Health
Start date:	May 2016
Duration:	36 Months

Aim(s):

The three 'seamless service' studentships address the ambition of the Scottish Government 'To make Scotland the best place in the world to grow up for all babies, children, mothers, fathers and families.' and are aligned with three objectives of the National Performance Framework: Our young people are successful learners, confident individuals, effective contributors and responsible citizens. Our children have the best start in life and are ready to succeed. We have improved the life chances for children, young people and families at risk.

Summary:

With policies such as Getting it right for every child, The Early Years Framework, National Parenting Strategy, Curriculum for Excellence and Better Health: Better Care, Scotland is in a potentially strong position to improve the lives of children. The Children and Young People (Scotland) Act 2014 has now enshrined the concept of wellbeing in statute, within the overarching framework of the SHANARRI Wellbeing indicators. Central to the Act is the aspiration that children's wellbeing is promoted, supported and safeguarded and that they receive seamless services, provided as far as possible by practitioners in education and health services who will assume the role of 'named persons' for children.

For children whose needs are beyond the scope or capacity of the named person service the Act provides for a single planning process supported by a Lead professional. These policies are being implemented against the background of the full scale reorganisation to integrate health and social care services across Scotland. This has provided a unique opportunity in Scotland for in-depth critical analysis of the impact of these developments as they unfold in a changing and challenging real – world context. These three studentships will each contribute to this agenda with distinct but interlinked research projects (one studentship addressing each of social work, education and health).

Project one: From every child to each: exploring the complexities of service provision for children with wellbeing needs in Scotland.

The current system for children's services in Scotland is built upon a range of policy and practice approaches. It sits among wider social, policy and political trends that influence whether and how services achieve the government's stated goal of being appropriate, proportionate – the right services at the right time for families. This study explores service provision where concerns arise around a child's wellbeing using a case study design.

Here, the case study in question is the network of children's service providers within a single local authority area, exploring elements of the general service environment and following individual casework where key actors in frontline service provision (social workers, health visitors, third sector staff, families and children) negotiate service provision. The study uses a range of qualitative methods, including repeat interviews with professionals, practitioners and service users; observations and reflective interviews around key meetings/events; and focus groups. The project explores the multiple perspectives through which the services to children are understood, and the practices through which the complexities of the case and its context are negotiated. The research is part of the wider Seamless Services research programme and its overarching questions of how ongoing reforms to Scottish children's services are unfolding, and whether Scotland's framework for children's services is helping to make children's lives better. The study is exploratory, and aims to understand how professionals, services, children and families negotiate services where concerns arise around a child's wellbeing which are below the thresholds for a child protection response. It uses a qualitative case study approach to answer three main questions: 1. How do different actors (practitioners, parents, children, families) negotiate issues around child wellbeing? 2. How do key contextual/structural elements, including social, policy and organisational factors, influence this? 3. What helps or hinders provision of proportionate, appropriate and timely services?

Project 2: Seamless Services: Learning how teachers practice and understand well-being through an exploration of how teachers communicate and document concerns about children's well-being.

This project aims to examine how classroom teachers understand and practice their role(s) as part of the multidisciplinary support network for children, in regard to child well-being within the Scottish education context. The objective is to examine the role of classroom teachers with regard to child well-being concerns, including the perceptions and communication practices of teachers around significant events and interprofessional work within the multidisciplinary support network for children. The project aims to produce a practical understanding of how teachers are currently

navigating the multidisciplinary support network and the ways in which their communication practices effect both interprofessional aspirations (joined-up working, integration) and, subsequently, well-being outcomes for children. This research project will use qualitative methods and a case study design to explore how teachers perceive, communicate about, and document well-being concerns and significant events in the classroom.

Project 3: Exploring the tensions of Getting it Right for Every Child
In keeping with the aspiration to make Scotland the best place to grow up, the Getting it Right for Every Child (GIRFEC) policy approach has been developed in Scotland since 2004 to promote young children's wellbeing. The two key principles within the GIRFEC are the promotion of early intervention practices as well as the seamless collaboration among stakeholders, such as families, educators, the police, social care and health services. Because the GIRFEC principles have been enshrined in law in the Children and Young People (Scotland) Act (2014) (Scottish Government, 2014), Health Visitors along with all the professionals working with families are required to adapt their practices to the new legislative changes at the ground level. From policy to practice, however, there are tensions brought up within GIRFEC. Due to the relatively new legislation, very little has been known about how professionals' new practices are perceived by Health Visitors, parents and young children, which creates a research gap in the literature.

This qualitative study aims to critically explore how professionals (mostly Health Visitors), parents and children understand and negotiate the tensions in GIRFEC between: 1. Promoting wellbeing and protecting from risk 2. Early intervention and reactive intervention 3. Integrated and independent services. The study will be a case study of one Scottish NHS Health Board using individual interviews and focus groups with key stakeholders including parents. To collect young children's views on the matter, creative methods i.e. drawing techniques, discussion on hypothetical scenarios (vignettes), unfinished sentences and postal boxes used with approximately 2-3 pre-schoolers (aged from 3-5) will take place.

Other dissemination activity:

- Calum Lindsay, Nikoletta Komvoki and Katherine Allen (2017) Child Wellbeing as Policy Concept: A Brief Discussion of Getting it Right for Every Child. Centre for Child Wellbeing and Protection. University of Stirling. <file:///C:/Users/hlc1/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/IE/WSC4OX-NO/29.5.2017%20Wellbeing%20briefing.pdf>
- Calum Lindsay (2017) From every child to each: exploring the complexities of child welfare service provision in Scotland. Children and Childhoods Conference 2017. University of Suffolk.

Project Number:	MCH02.6
Status:	Complete
Project Title:	Is there a relationship between ultrasound scanning ability and the visuospatial perception or psychomotor ability
Source of funding and total value of award:	College of Radiographers Industrial Partnership Scheme, £7,758
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Chapman E (PI), Gallagher H, Hagen S (Glasgow Caledonian University).
NMAHP RU investigators:	Hagen S.
Workstream:	Maternal and Child Health
Start date:	December 2010
Duration:	60 months

Aim(s):

This Professional Doctorate study aimed to explore relationships between visuospatial perception, psychomotor skills and scanning ability, and thus to identify evaluation techniques which may improve selection and recruitment of trainees.

Summary:

Competent sonography is thought to include a unique combination of skills not yet fully defined. This presents challenges when recruiting the correct people for training. Skills are thought to include visuospatial perception and psychomotor skills, but little is known about the relationship between these aptitudes and scanning ability. A sample of 30 experienced ultrasound practitioners and 30 trainees at commencement and on completion of training were administered eight tests of visuospatial perception and psychomotor skills, and their scanning ability was assessed pre (all) and post training (trainees only).

Outcomes/Impact:

No significant relationships were found between experienced practitioners' or trainees' visuospatial abili-

ties or psychomotor abilities and their scanning abilities. Results demonstrated that two of the visuospatial perception tests were not affected by training, and therefore may be measuring innate skills of the ultrasound practitioners. As ultrasound practitioners had not performed any of the tests previously, normative ranges of scores for each of the eight tests were established for this group. This included measures for psychomotor skills which added to the current body of knowledge for sonography. Although no significant correlations were found between participants' visuospatial perception or psychomotor abilities and scanning ability, performance on the Obstetric Structured Assessment Test (combining all the skills required) pre-training gave the best indication of post-training scanning performance. The Obstetric Structured Assessment Test may prove a useful tool for initial assessment of potential trainees but abilities will require further investigation.

Publications:

- Chapman E, Hagen S, Gallagher H. (2016) Is there a relationship between ultrasound scanning ability (sonography) and visuospatial perception or psychomotor ability? *Ultrasound* 24(4):214-221.

Project Number:	MCH02.7
Status:	Complete
Project Title:	Improving maternal and child health in Malawi: Rotary scholarship
Source of funding and total value of award:	The Rotary Foundation – Global Grant Scholarship, £25,408
Value of funding to NMAHP RU:	£6,520
Principal investigator/co-applicants:	Fraser M (PI), Styler M (Rotary Club of Dunblane), Limbe Malawi, Cheyne, H (University of Stirling).
NMAHP RU investigators:	Cheyne H.
Workstream:	Maternal and Child Health
Start date:	May 2014
Duration:	12 Months

Aim(s):

To support the Rotary Clubs of Limbe Malawi and Dunblane to apply for a Rotary Club Global Scholarship to enable a midwife from Malawi to undertake the Masters in Health Research at University of Stirling.

Summary:

The Rotary Midwifery Scholarship was awarded competitively to a senior midwife from Blantyre Malawi. Interviewed about her experience she said:

I was studying Masters in Health research to acquire knowledge and skills in research. My main goal was to be able to identify maternal and neonatal health problems and conduct research to come up with evidence based solutions to improve maternal and neonatal health in Malawi. I had a chance of working with senior researchers at the Nursing Midwifery and Allied Health Research Unit during my Health research placement, I was assigned to a research team on a defined research project. This helped me to apply the research knowledge and skills I gained theoretically to deepen my understanding and gain experience in health research skills. Whilst researching at Stirling, Apart from learning the research theory and skills, I have also learnt about the importance of using relevant research designs to come up with evidence based solutions. I have learnt about

approaches to Health research and that knowledge on complexities of research and creativity is very important and should be considered when conducting health research. For example, my research project is ‘implementation and evaluation of clean births practices during child birth to prevent puerperal sepsis at an urban maternity unit in Malawi’. The study considered importance of stake holder involvement who will analyse the practices and make judgements to come up with practices suitable for Malawi. To implement these practices, the study will use the Scottish patient safety quality improvement and behavioural change framework– currently being used in NHS to develop strategies which will be used to implement and finally evaluate the practices.

Outcomes/Impact:

The Scholarship midwife went on to become president of the College of Midwives in Malawi and continued to work with the Limbe Club in supporting maternity projects in Malawi <http://www.times.mw/limbe-rotary-club-boosts-health-sector/>

Other dissemination activity:

<http://www.rotary-ribi.org/clubs/page.php?PgID=473614&-ClubID=16>

Project Number:	MCH02.8
Status:	Complete
Project Title:	Making a difference for Mothers and babies. Midwifery research in Scotland
Source of funding and total value of award:	Scottish Government, Chief Nursing Office, £8,500
Value of funding to NMAHP RU:	£8,500
Principal investigator/co-applicants:	Cheyne H (PI) (University of Stirling).
NMAHP RU investigators:	Cheyne H.
Workstream:	Maternal and Child Health
Start date:	-
Duration:	1 day conference

Aim(s):

The aim of this conference was to present the results of the evaluation of the Keeping Childbirth Natural and Dynamic programme, the RCM PhD fellowship- Measuring the quantity and quality of midwifery support of women during labour and childbirth. And to provide a platform to showcase midwifery research undertaken by colleagues across Scotland.

The NHS in Scotland is committed to providing a maternity care service for all women that is person centred, safe and effective and to ensuring that every child has the best possible start in life. Research is fundamental to safe and effective care and continuous healthcare improvement and needs to be at the heart of midwifery practice. Several major research projects in maternity care have recently been undertaken in Scotland, including the evaluation of Keeping Childbirth Natural and Dynamic and the 1st RCM PhD fellowship on Midwifery support in labour. The conference provided the opportunity for midwives, service managers, policy makers and researchers to come together to hear about some of the research which had recently been completed. The main purpose of the conference was to present and discuss findings of the Realist Evaluation of the KCND programme, a major initiative in maternity care in Scotland and the findings of the RCM PhD fellowship on support in labour. The conference also included presentations on the

Birth Place Study in England, and from researchers from the newly formed Scottish midwifery research collaboration – co-ordinated by the NMAHP research unit. The conference was attended by 150 midwives, maternity service managers, policy makers and educators.

Publications:

- Abhyankar P, Cheyne H, Maxwell M, Harris FM, McCourt C (2013) A realist evaluation of a normal birth programme, Evidence Based Midwifery, 11 (4), pp. 112-119.
- Cheyne, H, Abhyankar P, and McCourt C. (2013) Empowering change: Realist evaluation of a Scottish Government programme to support normal birth. Midwifery 29.10: 1110-1121.
- Ross-Davie, M, Cheyne, H, Niven, C (2013) Measuring the quality and quantity of professional intrapartum support: testing a computerised systematic observation tool in the clinical setting. BMC pregnancy and childbirth 13.1: 163.
- Ross-Davie, Mary C. "Measuring the quantity and quality of midwifery support of women during labour and childbirth: The development and testing of the 'Supportive Midwifery in Labour Instrument'." (2012). <http://hdl.handle.net/1893/9796>
- Ross-Davie, Mary, et al. "Midwifery support in labour: how important is it to stay in the room?" The practising midwife 17.6 (2014): 19-22.

SUPPORTING HEALTHY CHOICES AND BEHAVIOURS FOR MATERNAL AND CHILD HEALTH

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We had three sessions altogether as far as I can remember which involved getting people in from quite a wide geographical area, but I think they felt it was really worthwhile. We certainly did. We felt we contributed. I mean, there's no point in having these experiences if nobody learns from them and if the researchers can learn from them and if we can help to improve research and improve the outcomes for future patients, that is a great bonus that you haven't been through all this for nothing.

”

Project Number:	MCH03.1
Status:	Complete
Project Title:	Development of a theory and evidence informed intervention to promote smoking cessation during pregnancy using narrative, text-messages and images as modes of delivery
Source of funding and total value of award:	Chief Scientist Office PhD studentship, £53,555
Value of funding to NMAHP RU:	£53,555
Principal investigator/co-applicants:	Williams B (PI), Steele M (PhD Student), Cheyne H (University of Stirling).
NMAHP RU investigators:	Steele M (PhD Student), Williams B, Cheyne H.
Workstream:	Maternal and Child Health
Start date:	March 2011
Duration:	48 Months

Aim(s):

To develop an intervention to promote smoking cessation during pregnancy and complete initial feasibility testing.

and heuristic evaluation were used to determine the acceptability and usability of the intervention for the target group of pregnant smokers.

Summary:

A three-part literature review, two qualitative studies, and the development of an intervention to promote smoking cessation during pregnancy were completed.

Central to the design of the research was the creation of the theoretical basis which was developed in line with recommendations from the MRC Framework for Complex Interventions (Craig et al. 2008, Campbell et al. 2000).

To develop the theoretical underpinning for the intervention, a three part literature review was undertaken. For part one, qualitative and quantitative studies were re-analysed to complete a mixed-methods secondary analysis of the active ingredients of interventions to promote smoking cessation during pregnancy. Part two consisted of an exploration of psychological models and constructs which are likely to predict or influence smoking behaviour during pregnancy. The final part was a discussion regarding the modes of delivery by which an intervention could feasibly be delivered.

Qualitative interviews were then carried out with participants from stakeholder groups to fill in gaps in literature and determine the acceptability and feasibility of the proposed intervention. The intervention was created using the theoretical basis developed from the findings. Further qualitative interviews, a focus group,

Outcomes/Impact:

Initial testing of the intervention has demonstrated feasibility and acceptability. CSO have granted further funding for final development and a pilot trial.

Other dissemination activity:

Posters:

- Steele, M. E., Cheyne, H., Williams, B. (2016, August) A logic model outlining the processes involved in an intervention for smoking cessation during pregnancy. Poster presented at the European Health Psychology Society & BPS Division of Health Psychology Annual Conference 2016, Aberdeen.
- Steele, M. E., Cheyne, H., Williams, B. (2015, December) Development of a theory and evidence informed intervention to promote smoking cessation during pregnancy using narrative, text-messages and images as modes of delivery. Poster presented at the UK Society for Behavioural Medicine Annual Conference 2015, Newcastle (winner of a best poster prize).

Oral presentations:

- Steele, M. E., Cheyne, H., Williams, B. (2012, December) Identifying the elements which act as facilitators for smoking cessation during pregnancy in successful or unsuccessful RCTs: a cross study synthesis. Oral presentation given at the UK Society for Behavioural Medicine Annual Conference 2012, Manchester.
- Steele, M. E., Cheyne, H., Williams, B. (2013, March) Identifying the elements which act as facilitators for smoking cessation during pregnancy in RCTs of interventions to promote smoking cessation during pregnancy. Oral presentation given at the Royal College of Nursing Annual Conference 2013, Belfast.

Project Number:	MCH03.2
Status:	Complete
Project Title:	Antenatal physical activity: women's experiences and the acceptability of antenatal walking groups
Source of funding and total value of award:	Paths to Health, £2,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Shepherd A (PI) (University of Stirling).
NMAHP RU investigators:	McInnes R.
Workstream:	Maternal and Child Health
Start date:	July 2010
Duration:	12 Months

Aim(s):

To explore women's experiences of PA during a recent pregnancy, understand the barriers and determinants of antenatal PA and explore the acceptability of antenatal walking groups for further development.

Summary:

Regular physical activity (PA) can be beneficial to pregnant women, however, many women do not adhere to current PA guidelines during the antenatal period. Patient and public involvement is essential when designing antenatal PA interventions in order to uncover the reasons for non-adherence and non-engagement with the behaviour, as well as determining what type of intervention would be acceptable.

Methods:

Seven focus groups were undertaken with women who had given birth within the past five years. Focus groups were transcribed and analysed using a grounded theory approach. Relevant and related behaviour change techniques (BCTs), which could be applied to future interventions, were identified using the BCT taxonomy.

Results:

Women's opinions and experiences of PA during pregnancy were categorised into biological/physical (including tiredness and morning sickness), psychological (fear of harm to

baby and self-confidence) and social/environmental issues (including access to facilities). Although antenatal walking groups did not appear popular, women identified some factors which could encourage attendance (e.g. childcare provision) and some which could discourage attendance (e.g. walking being boring). It was clear that the personality of the walk leader would be extremely important in encouraging women to join a walking group and keep attending. Behaviour change technique categories identified as potential intervention components included social support and comparison of outcomes (e.g. considering pros and cons of behaviour).

Conclusions:

Women's experiences and views provided a range of considerations for future intervention development, including provision of childcare, involvement of a fun and engaging leader and a range of activities rather than just walking. These experiences and views relate closely to the Health Action Process Model which, along with BCTs, could be used to develop future interventions. The findings of this study emphasise the importance of involving the target population in intervention development and present the theoretical foundation for building an antenatal PA intervention to encourage women to be physically active throughout their pregnancies.

MCH03.2

Development of a theory and evidence informed intervention to promote smoking cessation during pregnancy using narrative, text-messages and images as modes of delivery

Publications:

Currie S, McInnes R, Gray C, Styles M, Shepherd AJ (2016). Antenatal physical activity: a qualitative study exploring women's experiences and the acceptability of a walking group. *BMC Pregnancy and Childbirth* 2016, 16:182

Project Number:	MCH03.3
Status:	Complete
Project Title:	PETER-FEST: Proactive telephone care for breastfeeding women delivered by a feeding support team in a rural community
Source of funding and total value of award:	NHS Grampian, £18,490
Value of funding to NMAHP RU:	£3,584.50
Principal investigator/co-applicants:	Humphrey T (PI)(Robert Gordon University), Hoddinott P (University of Stirling), Belizzi M(NHS Grampian), Lau A (Robert Gordon University), Penman K (NHS Grampian).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Maternal and Child Health
Start date:	October 2012
Duration:	12 Months

Aim(s):

To evaluate the feasibility of proactive, dedicated telephone care for breastfeeding women in a rural community setting.

Research Questions:

1. Is it feasible for a dedicated feeding team, who are existing members of maternity and health visiting teams, to provide a proactive telephone support service for breastfeeding women for up to six weeks, within existing resources?
2. Have women who have initiated breastfeeding had an observation of a complete breastfeed within 24 hours or birth or transfer home?
3. Do women accept and are they satisfied with proactive telephone feeding care?
4. What are women's views and experiences of pro-active telephone feeding care?
5. What are the views and experiences of involved and less involved staff about delivering pro-active telephone care to breastfeeding women?
6. What are the opportunities and barriers to implementing the above intervention?

Summary:

Scottish Government has adopted the World Health Organisation (WHO) recommendation that infants should be exclusively breastfeed for the first six months of life, yet fewer than 1% of mothers in Scotland choose to do this. The policy is based on growing evidence about the short and long term health gains of breastfeeding compared to formula feeding, as well as positive effects on parenting, cognitive development and educational attainment. Government is also committed to reducing health inequalities and recommends targeted support to those who most need it.

The PETERFEST study builds on the promising FEST pilot trial, also funded by NHS Grampian and published in BMJ Open (Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. on behalf of the FEST project team. The FEeding Support Team (FEST) trial of proactive telephone support for breastfeeding women living in disadvantaged areas. BMJ Open 2012;2:2 e000652 doi:10.1136/bmjopen-2011-000652; Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. on behalf of the FEST project team. Process evaluation for the FEeding Support Team (FEST) trial of proactive telephone support for breastfeeding women living in disadvantaged areas. BMJ Open 2012;2:2 e001039 doi:10.1136/bmjopen-2012-001039).

It provides preparatory work for a full trial grant application of the FEST intervention. FEST showed that proactive telephone care for breastfeeding women by a dedicated team has promise as a low cost, effective intervention for improving breastfeeding outcomes. In the FEST pilot trial proactive telephone intervention was delivered by a dedicated team of maternity care assistants led by a midwife to women living in more disadvantaged areas of Grampian. What remains uncertain is whether this approach can be implemented effectively into routine community based care (i.e. not delivered by a dedicated infant feeding team) within existing resources. This was tried in the small rural town of Peterhead. A proposal for a multi-centre full randomised trial has been submitted to NIHR HTA Board on two occasions and was unsuccessful. A third attempt to NIHR HS&DR is planned in 2018.

Outcomes/Impact:

The study showed that the intervention was feasible, women were satisfied with the breastfeeding support that they received and the staff enjoyed delivering the intervention, although sometimes struggled to fit it into the working day. It facilitated a continuing relationship with staff beyond the 2 week intervention period. However, the logistical problems of commencing the intervention in the community after discharge from hospital, making timely contact with women and the reduced reach of the intervention compared to the original FEST pilot trial meant that this was a less feasible alternative than the intervention delivered by a dedicated maternity hospital feeding team.

Other dissemination activity:

Humphrey T, Lau, A, Penman K, Bellizzi M, Hoddinott P. Proactive telephone care for breastfeeding women in a rural setting. International Conference of Midwifery June 2014, Prague.

Humphrey T, Lau, A, Penman K, Bellizzi M, Hoddinott P. Proactive telephone care for breastfeeding women in a rural setting. Scottish Public Health Annual Conference. November 2013.

Project Number:	MCH03.4
Status:	Complete
Project Title:	A randomised controlled trial of proactive breastfeeding telephone support for mothers of preterm infants
Source of funding and total value of award:	VR/Formas/VINNOVA/FAS; Center for Clinical Research Dalarna; Orebro-Uppsala Regional Research Council; Magn Bergvall's Foundation and Little Baby's Fund, Sweden, £204,765
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Flacking R (PI) Hoddinott P (University of Stirling), Dalarna University, Ericsson J (Uppsala University), Eriksson M (Uppsala University, Sweden), Hagberg L (Uppsala University), Hellström-Westas L (Uppsala University).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Maternal and Child Health
Start date:	December 2012
Duration:	36 Months

Aim(s):

The aim with this multi-centre RCT was to assess the effectiveness and cost-effectiveness of proactive or reactive telephone support to mothers of preterm infants for up to 14 days after hospital discharge from neonatal units.

1. Is additional proactive (health service initiated) telephone breastfeeding support offered to mothers of preterm infants after hospital discharge more effective than reactive (mother initiated) telephone support at increasing the proportion of mothers who are exclusively breastfeeding 8 weeks after discharge?
2. Is proactive/reactive telephone breastfeeding support cost-effective compared to reactive breastfeeding support (usual care)?

Summary:

For preterm infants admitted to a Neonatal Intensive Care Unit (NICU), there is a dose-response effect for breast milk, in that greater benefits are achieved with exclusive and longer duration of breastfeeding. Unlike term infants, for preterm infants the time before the infant can exclusively breastfeed varies, depending on gestational age. Many mothers may therefore cease breastfeeding during the first months after discharge from the NICU. The transition to the home environment has been described as difficult due to lack of support, lack of skills, and unsolved feeding

problems. Particularly vulnerable are infants of mothers with lower socioeconomic status who are less likely to continue to breastfeed.

The Swedish team of academic Neonatal and Pediatric nurses approached Pat Hoddinott to collaborate so that they could replicate some of the successful components of the promising FEST trial of proactive telephone support which Pat led in the UK. (Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. on behalf of the FEST project team. The FEeding Support Team (FEST) trial of proactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ Open* 2012;2:2 e000652 doi:10.1136/bmjopen-2011-000652; Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. on behalf of the FEST project team. Process evaluation for the FEeding Support Team (FEST) trial of proactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ Open* 2012;2:2 e001039 doi:10.1136/bmjopen-2012-001039.) This is the first study to deliver a telephone support trial to mothers of preterm infants. The proactive feeding support was delivered as part of routine care by breastfeeding support teams across 6 neonatal units in Sweden.

Outcomes/Impact:

In this trial, 493 mothers with a premature infant were randomised to receive either proactive telephone support or usual care. Fewer mothers were breastfeeding than anticipated and fewer were recruited than expected, so the trial was underpowered. The proactive support was not associated with increased exclusive breastfeeding prevalence eight weeks following discharge from a NICU. However, mothers who received proactive support showed significantly lower parental stress. Partial breastfeeding at discharge, low educational level, and longer length of stay in the NICU increased the risk for ceasing breastfeeding during the infants first year of life. It was concluded that the 2 week intervention may not have been long enough to make a difference to feeding outcomes for this particularly vulnerable group of mothers and babies.

The main outcomes paper has been submitted to *Acta Paediatrica* and the secondary outcomes paper has been submitted to *Maternal and Child Nutrition*. The study has had impact in Sweden, because it has demonstrated that breastfeeding rates for premature infants are lower than previously reported. This led to further research now published by the Swedish team to look at the changes in the prevalence of breastfeeding in preterm infants discharged from neonatal units. It has raised the profile of the need to address health inequalities in exclusive breastfeeding after discharge from neonatal units.

In the UK, this trial confirms that there is equipoise about whether additional proactive telephone support is effective and cost-effective for improving breastfeeding outcomes after birth. It therefore supports the case for seeking funding from NIHR for a full trial of the promising FEST pilot trial intervention.

Publications:

- Ericson, J., Eriksson, M., Hellström-Westas, L., Hagberg, L., Hoddinott, P. and Flacking, R. (2013) The effectiveness of proactive telephone support provided to breastfeeding mothers of preterm infants: study protocol for a randomized controlled trial. *BMC Pediatrics*, 13, pp. 73.

Other dissemination activity:

- Ericsson, J., Hellström-Westas, L., Eriksson, M., Hoddinott, P., Flacking, R. The effectiveness of proactive telephone support provided to breastfeeding mothers of preterm infants: a randomized controlled trial. 7th International Conference on Maternal and Infant Nutrition and Nurture. Dalarna, Sweden. 24-26 August 2016.
- Is proactive breastfeeding effective? Study protocol for a randomized controlled trial. Ericson, J., Eriksson, M., Hellström-Westas, L., Hagberg, L., Hoddinott, P., Flacking, R. Nordic Conference on Advances in Health Care Science Research, Turku, Finland, November 12th-13th 2014.
- Ericson, J., Eriksson, M., Hellström-Westas, L., Hagberg, L., Hoddinott, P., Flacking, R. The Effectiveness Of Proactive Telephone Support Provided To Breastfeeding Mothers Of Preterm Infants: Study Protocol For A Randomized Controlled Trial. Council of International Neonatal Nurses (COINN). Belfast. Sept. 2013

Project Number:	MCH03.5
Status:	In Progress
Project Title:	Assets-based feeding help Before and After birth (ABA): feasibility study for improving breastfeeding initiation and continuation
Source of funding and total value of award:	NIHR- Public Health Research Programme, £328,980
Value of funding to NMAHP RU:	£11,238.00
Principal investigator/co-applicants:	Kate Jolly (PI) (University of Birmingham) Hoddinott P (University of Stirling), Daniels J (University of Birmingham), Dykes F (University of Central Lancashire), Ingram J (University of Bristol), MacArthur C (University of Birmingham), Roberts T, (University of Birmingham), Sitch A (University of Birmingham), Thomson G (University of Central Lancashire), Trickey H (University of Cardiff), Dombrowski S.U (University of Stirling).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Maternal and Child Health
Start date:	November 2016
Duration:	24 Months

Aim(s):

To assess the feasibility of delivering a new ABA infant feeding helper intervention within a feasibility randomised controlled trial.

Objectives:

1. To adapt existing peer support services to provide a new infant feeding helper intervention, underpinned by theory and evidence, with service user and provider input.
 2. To undertake a feasibility RCT of the new feeding helper role compared with usual care (control group) for women living in areas of low breastfeeding prevalence.
 3. To determine levels of uptake and engagement with the intervention; to describe socio-economic/demographic profiles to ascertain reach and explore health inequalities.
 4. To describe care received by the reactive 'usual care group' in relation to feeding method.
 5. To assess fidelity of intervention delivery, any contamination and explore feedback from feeding helpers to improve fidelity if required.
 6. To assess whether women are willing to be recruited and randomised; whether the expected recruitment rate for a subsequent full scale effectiveness RCT is feasible and to identify successful recruitment strategies.
 7. To explore mothers' and feeding helpers' perceptions of the intervention, trial participation and processes.
 8. To explore the acceptability and fidelity of the intervention when delivered by paid and volunteer feeding helpers.
 9. To assess acceptability and integration of the intervention to other providers of maternity, postnatal and social care.
 10. To explore the relative value of the individual feeding support versus the community integration elements to inform the design of a future trial.
 11. To provide estimates of the variability in the primary outcome to enable sample size calculation for a definitive trial.
 12. To measure the features of the feeding helper provision and service utilisation which would underpin the cost-effectiveness of the intervention and determine the feasibility of data collection.
- To test the components of the proposed RCT to determine the feasibility of the protocol.

Summary:

Breastfeeding can improve the health of mothers and infants, but the UK has low rates, with marked socio-economic inequalities. Whilst peer support services have been effective in some settings, trials of peer support in the UK have not improved breastfeeding rates. Qualitative research suggests that many women are alienated by the focus on breastfeeding. This feasibility study proposes to change from breastfeeding focussed interactions to respecting a woman's feeding choices, inclusion of behaviour change theory, an increased intensity of contacts, particularly in the two weeks after birth when many women cease to breastfeed. This will take place alongside an assets-based approach. An assets-based approach is about focusing on the positive capability of individuals and communities, rather than solely on their needs, deficits and problems. It is essentially about recognising and making the most of people's strengths, to 'redress the balance between meeting needs and nurturing the strengths and resources of people and communities', with a corresponding shift in focus from the determinants of illness to the determinants of health and wellbeing. Pat Hoddinott had the original idea for the study, which builds on the findings of the promising FEST pilot trial (Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. on behalf of the FEST project team. The FEeding Support Team (FEST) trial of proactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ Open* 2012;2:2 e000652 doi:10.1136/bmjopen-2011-000652; Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. on behalf of the FEST project team. Process evaluation for the FEeding Support Team (FEST) trial of proactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ Open* 2012;2:2 e001039 doi:10.1136/bmjopen-2012-001039).

Publications:

A protocol paper for the feasibility trial has been accepted for publication in *BMJ Open*:

- Jolly K, Ingram J, Clark J, Johnson D, Trickey H, Thomson G, Dombrowski SU, Sitch A, Dykes F, Feltham M, Darwent K, MacArthur C, Roberts T, Hoddinott P. Protocol for a feasibility trial for improving breastfeeding initiation and continuation: Assets-based infant feeding help Before and After birth (ABA). *BMJ Open* 2017 (In press)

Project Number:	MCH03.6
Status:	In Progress
Project Title:	(Phase II) A women-centred, tailored SMS-delivered multi-component intervention for weight loss and maintenance of weight loss in the postpartum period: intervention adaptation and pilot RCT
Source of funding and total value of award:	NIHR- Public Health Research Programme, £483,040
Value of funding to NMAHP RU:	£14,895.00
Principal investigator/co-applicants:	McKinley M. (PI- The Queen's University of Belfast), Anderson A (University of Dundee), Cardwell C (The Queen's University of Belfast), Dombrowski S (University of Stirling), Free C (London School of Hygiene & Tropical Medicine), Holmes V (The Queen's University of Belfast), Kee F (The Queen's University of Belfast), McIntosh E (University of Glasgow), Woodside J (The Queen's University of Belfast), Young I (The Queen's University of Belfast).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Maternal and Child Health
Start date:	November 2016
Duration:	32 Months

Objectives:

- To assess and refine the txt2stop logic model for weight loss and maintenance of weight loss. Txt 2 stop is an automated smoking cessation programme delivered via mobile phone text messaging by C Free, which is effective, cost-effective and has been implemented across the NHS.
- To adapt the SMS intervention for use in the context of weight loss and maintenance of weight loss in postpartum women.
- To develop the protocol for a pilot trial of the SMS intervention.
- To conduct a pilot RCT to: trial recruitment and randomisation strategies; examine fidelity of implementation and acceptability of the intervention; identify valid and PPI acceptable research instruments to be used in a full trial; provide variability data on the primary endpoints (weight loss and maintenance of weight loss) on which to base a formal power calculation for a definitive trial; and, to assess outcome data collection processes.
- To assess pilot data in relation to pre-defined stop/go criteria for a full trial
- Based on the data from the pilot study, if proceeding to a full trial is warranted: To develop a protocol for a multicentre RCT to evaluate the effectiveness of a tailored SMS-based intervention for weight loss and maintenance of weight loss in postpartum women.

Summary:

Obesity has nearly doubled worldwide since 1980 and this has implications for maternal health. Excessive gestational weight gain and postpartum weight retention are established predictors of long term obesity. Systematic review evidence and NICE guidance both highlight gaps in knowledge about effective and appropriate weight management interventions in women during the postpartum period.

Phase 1: Intervention adaptation of the text2stop text automated messages and development of protocol for the pilot trial: This used an iterative process conducted in conjunction with postpartum women in order to develop a woman-centred, tailored SMS intervention that facilitates a self-directed approach to behaviour change.

Phase 2: (in progress). The pilot study is a parallel group RCT conducted at one site (Belfast). Eligibility: women from birth until 2 years postnatal, uniparous or multiparous, with postpartum BMI >25 kg/m².

The intervention group will receive the SMS intervention; the control group will be an 'active control' and will receive SMS messages related to child care and child development.

The 12 month pilot intervention (sufficient to allow examination of weight loss as well as a 3-6 month 'maintenance' period for most participants) will have data collection taking place at 3, 6, and 12 months.

Outcomes/Impact:

The primary outcome of the pilot trial will be to provide a decision regarding the feasibility of proceeding to a multi-centre RCT to fully test the intervention. This decision will be based on an assessment of quantitative and qualitative data. Stop/go criteria for proceeding to a full trial are based on acceptability and feasibility outcomes:

- Acceptability of the intervention and 'active control' (satisfaction rating, qualitative views)
- Feasibility of recruitment – successful recruitment - at least 80% of pilot study target
- Retention rate consistent with other weight loss interventions in this target group, i.e. at least 65% in intervention group and 60% in control group (2,3,4)

- Evidence of positive indicative effects - change in anthropometric measures over time

In addition questionnaires will be used to collect 4-day food diary to assess dietary intake, other lifestyle behaviours - physical activity, sedentary behaviour, smoking, alcohol, measures to inform future trial economic analysis, theory-based mediators of behaviour change including self efficacy, motivation, social support, self-regulation, habit formation and child-related outcomes - infant feeding (breastfeeding behaviour and weaning) and growth. A process evaluation using qualitative interviews will seek women's experiences of being in the pilot trial and fidelity of the SMS intervention delivery will be assessed.

Publications:

The protocol is available on the NIHR website.

INNOVATIONS IN SERVICES, SYSTEMS AND ROLES



ISSR01

PRE-HOSPITAL EMERGENCY CARE

Project Number:	ISSR01.1
Status:	Complete
Project Title:	A national prevalence survey of impaired awareness of hypoglycaemia in patients who have been attended by the Scottish Ambulance Service due to a severe hypoglycaemic event
Source of funding and total value of award:	Scottish Ambulance Service, £3,021
Value of funding to NMAHP RU:	£3,021
Principal investigator/co-applicants:	Duncan EAS (PI), Fitzpatrick D (University of Stirling), Dougall N (Edinburgh Napier University)
NMAHP RU investigators:	Duncan EAS, Fitzpatrick D, Dougall N.
Workstream:	Innovations in Services, Systems and Roles
Start date:	January 2016
Duration:	8 Months

Objectives:

To compare the experiences of people who are affected by diabetes related hypoglycaemia and either do or do not require an emergency attendance; and to measure the prevalence of impaired awareness of hypoglycaemia in patients who are attended by an ambulance service due to a severe hypoglycaemic event.

Summary:

The qualitative interview study was undertaken with 31 people with diabetes (Types 1 and 2) resident in the central belt of Scotland. The prevalence survey was a national study of 590 Scottish Ambulance Service patients who had experienced a severe hypoglycaemic emergency. Considerable differences in impaired awareness were found in the experiences of participants who did or did not require the ambulance service to treat their severe hypoglycaemic events. Those who required an ambulance reported fewer warning signs and symptoms. The prevalence of impaired awareness of hypoglycaemia in ambulance service call outs is more than twice that found in the general population of people with Diabetes. This study was the first to demonstrate that the prevalence of impaired awareness of hypoglycaemia in patients who are attended by an ambulance service clinician due to a severe

hypoglycaemic event is more than double that which is found in the general diabetic population. The findings contribute to an understanding of why some people require an ambulance to assist with a severe hypoglycaemic event, while the majority do not. These findings can be used to shape future pre-hospital clinical practice and empirical and theory based intervention development globally.

Outcomes/Impact:

This study has informed the development of a Programme Grant application to improve outcomes for patients who experience a hypoglycaemic emergency.

Other dissemination activity:

- Duncan EAS, Fitzpatrick D A study of the prevalence of impaired awareness of hypoglycaemia in people who have had a severe hypoglycaemic emergency and been attended by the ambulance service. EMS 2017. Copenhagen. May 2017
- Duncan EAS, Fitzpatrick D A study of the prevalence of impaired awareness of hypoglycaemia in people who have had a severe hypoglycaemic emergency and been attended by the ambulance service. EMS999 Research Forum. Bristol. March 2017

Project Number:	ISSR01.2
Status:	Complete
Project Title:	Impact of Hypoglycaemia on healthcare services
Source of funding and total value of award:	Novo Nordisk, £76,061
Value of funding to NMAHP RU:	£2,500
Principal investigator/co-applicants:	Leese C (PI) (University of Dundee), Wang H (University of Dundee), Donnan P (University of Dundee), Duncan EAS (University of Stirling), Fitzpatrick D (Scottish Ambulance Service/University of Stirling) Firer B, (Edinburgh University), Leese G (University of Dundee)
NMAHP RU investigators:	Duncan EAS, Fitzpatrick D.
Workstream:	Innovations in Services, Systems and Roles
Start date:	May 2014
Duration:	12 Months

Aim(s):

This population-based data-linkage cohort study aimed to ascertain whether a temporal change has occurred in the incidence rates of hypoglycemia requiring emergency medical services in people with types 1 and 2 diabetes.

Summary:

Almost 20 years ago, the frequencies of severe hypoglycemia requiring emergency medical treatment were reported in people with types 1 and 2 diabetes in the Tayside region of Scotland. With subsequent improvements in the treatment of diabetes, concurrent with changes in the provision of emergency medical care, a decline in the frequency of severe hypoglycemia could be anticipated. The study population comprised all people with diabetes in Tayside, Scotland over the period 1 January 2011 to 31 December 2012. Patients' data from different healthcare sources were linked anonymously to measure the incidence rates of hypoglycemia requiring emergency medical services that include treatment by ambulance staff and in hospital emergency departments, and necessitated hospital admission. These were compared with data recorded in 1997–1998 in the same region.

In January 2011 to December 2012, 2029 people in Tayside had type 1 diabetes and 21,734 had type 2 diabetes, compared to 977 and 7678, respectively, in June 1997 to May 1998. In people with type 2 diabetes, the proportion treated with sulfonylureas had declined from 36.8 to 22.4% ($p < 0.001$), while insulin-treatment had increased from 11.7 to 18.7% ($p < 0.001$). The incidence rate of

hypoglycemia requiring emergency medical treatment had significantly fallen from 0.115 (95% CI: 0.094–0.136) to 0.082 (0.073–0.092) events per person per year in type 1 diabetes ($p < 0.001$), and from 0.118 (0.095–0.141) to 0.037 (0.003–0.041) in insulin-treated type 2 diabetes ($p = 0.008$). However, the absolute annual number of hypoglycemia events requiring emergency treatment was 1.4-fold higher. Although from 1998 to 2012 the incidences of hypoglycemia requiring emergency medical services appeared to have declined by a third in type 1 diabetes and by two thirds in insulin-treated type 2 diabetes, because the prevalence of diabetes was higher (2.7 fold), the number of severe hypoglycemia events requiring emergency medical treatment was greater.

Outcomes/Impact:

- This study has informed the development of a Programme Grant application to improve outcomes for patients who experience a hypoglycaemic emergency.

Publications:

- Wang, H., Donnan, P. T., Leese, C. J., Duncan, E., Fitzpatrick, D., Frier, B. M., & Leese, G. P. (2017). Temporal changes in frequency of severe hypoglycemia treated by emergency medical services in types 1 and 2 diabetes: a population-based data-linkage cohort study. *Clinical Diabetes and Endocrinology*, 3(1), 7.

Project Number:	ISSR01.3
Status:	Complete
Project Title:	Using record linkage analysis to inform the development of an improved care pathway(s) for psychiatric and self-harm emergencies currently transferred by ambulance to Emergency Departments
Source of funding and total value of award:	Chief Scientist Office £30,000 + Scottish Ambulance Service £3,510
Value of funding to NMAHP RU:	£33,510
Principal investigator/co-applicants:	Duncan E (PI), N Dougal N, Evans J, Skar S, Best C, Fitzpatrick D (University of Stirling), Corfield A (NHS Greater Glasgow and Clyde), Stark C (NHS Highland), Wojcik W (NHS Lothian), Goldie I (Mental Health Foundation), White C (Metal Health Foundation, Patient Involvement Rep), Snooks H (Swansea University), Maxwell M (University of Stirling).
NMAHP RU investigators:	Duncan E, Dougal N, Skar S, Fitzpatrick D, Maxwell M.
Workstream:	Innovations in Services, Systems and Roles
Start date:	September 2015
Duration:	12 Months

Aim(s):

We looked at what happened to people seen by the ambulance service (SAS) for a psychiatric or self-harm emergency in Scotland in 2011. We wanted to understand what happened to them and what their health outcomes were. This information will help to improve care, access to specialist mental health services and reduce unnecessary Emergency Department attendance for these people.

Summary:

We analysed patient records that linked ambulance, Emergency Department and hospital data. This is the first study to report the epidemiology of emergency ambulance attendances for mental health emergencies including self-harm, including linked record outcomes. People attended by ambulance service were most often transported to and discharged from an Emergency Department with no known follow-up (4566 calls; 51%). Combining this with calls that

were attended by the ambulance service but not transported to hospital (n=1003) accounted for 62% of all mental health ambulance emergencies. Though most people were only attended once, repeat calls within 12 months were relatively common (n=3,238, 47.6%). People who were transported to ED but then self-discharged before completion of treatment were statistically more likely to make another mental health emergency call to ambulances service within the same year (Pearson chi square =5.24, p=0.02). And people were more likely to self-discharge themselves from the Emergency Department if they were intoxicated with alcohol (person chi squared=35.4, p<0.001). Within 12 months of their first emergency call, 279 people (4.1%) had died, 97 (35%) recorded as suicide.

Outcomes/Impact:

The importance of the study findings for health policy and health service delivery has been recognised. Representatives from the Mental Welfare Commission attended a stakeholder workshop and reported the study findings to their Chief Executive Officer. The Principal Investigator (Edward Duncan) met with leaders of the Scottish Government Mental Health Improvement Program and others in October 2016. The importance of the study results were recognised and the program members' emphasised that the results would further refine their thinking about strategic action. Presentation of the paper at a national emergency medical service conference in Bristol (March 2017) was awarded with the (£1000) prize for best quality research to fund presentation of the paper at the Australian PAIC Conference.

Stakeholder workshop:

A stakeholder workshop was held to: - 1) present and discuss the findings of the linked data analysis and consider the relevance of these data for future practice, policy and research (RQ5); and 2) use the study findings and participants' expert knowledge in a process mapping exercise [1] to develop potential improved care pathway(s)/intervention(s). Workshop participants [n=35] came from a wide range of backgrounds:- Scottish Ambulance Service; Emergency Departments; Primary Care; Social Work; Police Scotland; The Mental Welfare Commission; 3rd sector organisations; University Sector. Almost all (93%, n=27) participants perceived the study findings to be 'very useful' or 'quite useful' in understanding the patient population. Almost all (90%, n=22) participants found the data to be 'very useful' to 'quite useful' in developing evidence-informed alternative care pathways. Twenty-four people (75%) reported that using data-informed care pathway process mapping was a highly to extremely useful method to identify potential care pathway/intervention development opportunities.

Conference Presentations:

- Duncan EAS, Best C, Dougall D, Skar S, Evans J, Corfield A, Goldie I, Maxwell M, Snooks H, Stark C, White C, Wojcik W. Investigating the population characteristics, processes and outcomes of pre-hospital psychiatric and self-harm emergencies in Scotland: a national record linkage study. Paramedics Australasia International Conference (PAIC), Melbourne. November 2017.
- Duncan EAS, Best C, Dougall D, Skar S, Evans J, Corfield A, Goldie I, Maxwell M, Snooks H, Stark C, White C, Wojcik W. Psychiatric Emergencies in prehospital care: an invisible and unmet need. MQ Data Science Meeting. Manchester. March 2017.
- Duncan EAS, Best C, Dougall D, Skar S, Evans J, Corfield A, Goldie I, Maxwell M, Snooks H, Stark C, White C, Wojcik W. Investigating the population characteristics, processes and outcomes of pre-hospital psychiatric and self-harm emergencies in Scotland: a national record linkage study. Informatics for Health. Manchester. April 2017.
- Duncan EAS, Best C, Dougall D, Skar S, Evans J, Corfield A, Goldie I, Maxwell M, Snooks H, Stark C, White C, Wojcik W. Investigating the population characteristics, processes and outcomes of pre-hospital psychiatric and self-harm emergencies in Scotland: a national record linkage study. EMS999 Research Forum. Bristol. March 2017 .
- Duncan EAS Psychiatric emergencies in prehospital emergency care: an invisible and unmet need? Invited Annual School Lecture. Plymouth University. October 2016.

Project Number:	ISSR01.4
Status:	Complete
Project Title:	Consensus on the items and quantities of clinical equipment required to deal with a mass casualties big bang incident: an national Delphi study
Source of funding and total value of award:	Department of Health, £48,976
Value of funding to NMAHP RU:	£48,976
Principal investigator/co-applicants:	Duncan EAS (University of Stirling), Colver K (Scottish Ambulance Service), Swingler K (University of Stirling), Stephenson J (National Ambulance Service resilience Unit), Abhyankar P (University of Stirling)
NMAHP RU investigators:	Duncan EAS.
Workstream:	Innovations in Services, Systems and Roles
Start date:	September 2012
Duration:	12 Months

Aim(s):

To develop an expert consensus opinion of the essential items and minimum quantities of clinical equipment that is required to treat 100 people at the scene of a big bang mass casualties event.

Summary:

A three round modified Delphi study was conducted with 32 experts using a specifically developed web-based platform. Individuals were invited to participate if they had personal clinical experience of providing a pre-hospital emergency medical response to a mass casualties incident, or had responsibility in health emergency planning for mass casualties incidents and were in a position of authority within the sphere of emergency health planning. Each item's importance was measured on a 5-point Likert scale. The quantity of items required was measured numerically. Data were analysed using nonparametric statistics. Experts achieved consensus on a total of 134 items (54%) on completion of the study. Experts did not reach consensus on 114 (46%) items. Median quantities and interquartile ranges of the items, and their recommended quantities were identified and are presented.

This study is the first to produce an expert consensus on the items and quantities of clinical equipment that are required to treat 100 people at the scene of a big bang mass casualties event. The findings can be used, both in the UK and internationally, to support decision makers in the planning of equipment for such incidents.

Outcomes/Impact:

A stakeholder workshop was held with key stakeholders from the 4 home nations; Government policy advisors and members of several ambulance services across the UK. The workshop refined the list, considering items that did not reach consensus. The revised list of equipment is now used in the planning for future equipment procurement in both Scotland and England.

Publications:

Duncan EAS, Colver K, Dougall N, Swingler K, Stephenson J, & Abhyankar P (2014) Consensus on items and quantities of clinical equipment required to deal with a mass casualties big bang incident: a national Delphi study. BMC emergency medicine, 14(1), 5.

DEVELOPMENT AND EVALUATION OF INNOVATIONS IN DEVELOPING SERVICES, SYSTEMS AND ROLES

Project Number:	ISSR02.1
Status:	In Progress
Project Title:	Scottish Person Centredness Improvement Collaboration (Scopic)
Source of funding and total value of award:	Scottish Government, £977,116
Value of funding to NMAHP RU:	£616,791
Principal investigator/co-applicants:	Duncan EAS (University of Stirling), Colver K (Scottish Ambulance Service), Swingle K (University of Stirling), Stephenson J (National Ambulance Service resilience Unit), Abhyanakar P (University of Stirling)
NMAHP RU investigators:	Maxwell M, Duncan E, Carina Hibberd, Hagen S.
Workstream:	Innovations in Services, Systems and Roles
Start date:	February 2012
Duration:	72 Months

Aim(s):

1. To develop and evaluate evidenced interventions to support improved person-centredness.
2. To contribute to improving and embedding patient-reported outcomes and experience across NHS Scotland as stated within the Quality Strategy.

Summary:

The project was split into two studies: Improving Patients Experience of Care Study (IPEC) & Neuro-rehabilitation Outcomes Measurement System (NROMS).

IPEC: This mixed methods study ran parallel evaluations of Releasing Time to Care (NHS Tayside) (RTC™plus) and the Caring Behaviours Assurance System (CBAS™) with an embedded realist process evaluation. It sought to test the impact of these two interventions upon staff and patient outcomes, through quasi-experimental stepped wedge designs involving 30 wards (15 each intervention) over six three month phases. The study was not designed to compare the interventions. RTC™plus was delivered by the local NHS practice development team. The “plus” aspect involved a locally developed readiness for change and team feedback element delivered before RTC™. The three

month implementation phase, covered implementation of the three core RTC™ units (further units were available). For RTC™plus this indicated that:

1. The key aims and objectives, and core messages were understood by staff on the wards.
2. There was a mixed response to the facilitation provided with mixed views being expressed about the credibility, knowledge, and supportiveness of the facilitators.
3. RTC-Plus was perceived by staff as successful in 4 wards, had a mixed response in 4 wards, and was perceived unsuccessful in 2 further wards.
4. Most interviewees perceived that their ward was not staffed to a level that makes full engagement in the initiatives possible.

The CBAS™ model involved training of three quality champions (across nursing grades) on each ward. Wards selected target outcomes from across the 7 “C”s of caring and quality champions then led each ward team to achieve those outcomes. For CBAS™ this indicated that:

1. The key aims and objectives, and core messages of CBAS™ were well received by the people who received the facilitator training.
2. Training was extremely well received by all participants.
3. Facilitators perceived as knowledgeable, credible and highly supportive.
4. CBAS™ was perceived by staff as successful in 2 wards, as having a mixed response in 9 wards, and as unsuccessful in 2 further wards. Staff's perception of success was not supported by the quantitative data. However, in the wards where the realist evaluation predicted a poor response we found a statistically significant worsening in two of the three primary outcomes.
5. Despite the perceived quality and credibility of the training, the ability of CBAS™, to penetrate and change ward culture in its current form appears limited at best.

There were several shared lessons from the evaluation of both interventions. Consideration should be given to targeting of these interventions to ward settings where it addresses the needs of a particular ward at that given moment in time. We propose three key mechanism of action: Fit; Mode of Delivery; and Mechanisms of Action. The support and influence of the senior charge nurse was integral to successful change. And the relationship with the ward based agents of implementation (either practice development staff or local champions) was key in terms of engagement, communication and respect.

NROMS: This mixed methods formative project worked collaboratively with NHS Fife to develop and evaluate of a person-centred outcomes system for neuro-rehabilitation. Rehabilitation of patients is a crucial component of effective healthcare delivery, particularly within a context of an aging population and associated multi-morbidities. Given the impact that rehabilitation can have on people's lives, and the scale of rehabilitation services being delivered, it is essential that the interventions being delivered are appropriately evaluated. Patient-reported outcome measurements should enable the impact of rehabilitation on patients' lives to be monitored and maintained, which in turn could inform future service provision. This is essential to achieve and maintain effective, safe and person-centred care in accordance with

the Scottish Government's quality strategy. To ensure such high quality evaluation and monitoring, key outcomes to be monitored must be decided upon. These must be: meaningful and important to both service users and the multi-disciplinary team; valid; reliable; sensitive to change; and useful to inform practice. However, the reality is that selecting which area of rehabilitation to evaluate, and which outcome measures to use to achieve this is challenging and can act as a barrier to routine outcome measurement in practice. The NROMS project began by consulting with local patients and Scottish neuro-rehabilitation staff to identify their outcome priorities. A multi-disciplinary, clinical working group then rationalised that list of priorities (protecting patient choices) to form a list of key targets. The research team conducted a systematic review to identify validated outcomes which mapped against these targets and the working group used this map to identify a list of core outcome measures which could be used across the patient rehabilitation journey. In collaboration with NHS eHealth, an intranet data system was developed and implemented in steps on 2 organisationally different, neuro-rehabilitation, in-patient wards. A realist evaluation used longitudinal, brief interviews with staff across a range of disciplines and seniority to understand the implementation process.

Outcomes/Impact:

IPEC

1. Provision of a clear theoretical and operational definition of all interventions tested so that these can, whether in full or in part, be replicated accurately in other clinical contexts.
2. Provision of an assessment of the effectiveness of these interventions on patient experience, and, where possible, subsequent behavioral and clinical outcomes.
3. Detail of the degree to which the effectiveness of any of the interventions tested may be dependent on specific aspects of the clinical or organisational context. This will aid an assessment as to whether replication of the intervention(s) will be likely to lead to similar benefits elsewhere and thus aid and promote successful implementation elsewhere.

NROMS

1. A functioning outcomes data system; a literature review of neurological outcome measures mapped to the ICF.
2. A practical guide to implementing the system on further wards
3. A theoretical understanding of implementation using Normalisation Process Theory.

It is anticipated that the NROMS system will lead to improvements in direct patient care, multi-disciplinary working, quality improvement and audit and may act as a platform for future research. The quality of the data for these uses is currently being assessed.

- Hibberd C, Duncan E, Baldie D, Maxwell M, Jones M, Rattray J, Williams B. (2016). Symposium. RCN International Research Conference.
- Hibberd C, Torrens R, Sutherland B. (2016) Shared Outcomes in Neurorehabilitation - supporting person centred care and multi-disciplinary working - the Neurorehabilitation Outcomes Management System (NROMS). Talk. RCN International Research Conference.

Publications:

- Claire Torrens, Carina Hibberd, Pauline Campbell, Ben Sutherland. Linking research and practice through the ICF framework: a systematic review of outcome measures in neurorehabilitation. PROSPERO 2016:CRD42016041293 Available from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016041293

Reports and papers are currently in preparation.

Presentations:

- Duncan EAS Understanding and measuring the role of context when implementing ward-based improvement interventions. SISCC Improvement/Implementation Science Capacity and Capability-building Seminar Series. University of Stirling. October 2016
- Duncan EAS Understanding and measuring the role of context when implementing ward-based improvement interventions. Implementation Science Seminar Series. Glasgow Caledonian University. September 2016
- Duncan EAS A Realist Evaluation of an augmented version of Releasing Time to Care. Symposium presentation. RCN International Nursing Research Conference and Exhibition, April 2016, Edinburgh
- Hibberd C (2013) Selecting outcome measures to test the effectiveness of two complex interventions to improve nurse and patient experience of care. Presentation. RCN International Research Conference.

Project Number:	ISSR02.2
Status:	Complete
Project Title:	A qualitative evaluation of the Govan SHIP: a social and health integration partnership project
Source of funding and total value of award:	Glasgow South Health & Social Care Partnership, £37,000
Value of funding to NMAHP RU:	£37,000
Principal investigator/co-applicants:	Harris F (PI), Maxwell M, McGregor J (University of Stirling), Mercer S (University of Glasgow).
NMAHP RU investigators:	Harris F (PI), Maxwell M, McGregor J.
Workstream:	Innovations in Services, Systems and Roles
Start date:	January 2016
Duration:	12 Months

Aim(s):

The evaluation aims were to:

1. identify the barriers, facilitators and potential solutions to social work integration
2. explore the benefits and challenges of health and social care integration
3. develop recommendations for future integrated working

Summary:

Govan SHIP was developed to respond to the needs of patients with complex health and social needs living in the most deprived general practices in Scotland. The ongoing pilot/demonstration project is being implemented within Govan Health Centre, with the key aims of addressing the inverse care law via an integration model. The evaluation explored the key components of this model: linked social work (SW) and social care workers (SCWs), GP extra time and multidisciplinary team working (MDTs).

The evaluation drew on an ethnographic approach, informed by realist evaluation and normalisation process theory. The evaluation explored implementation processes and experiences as an outcomes-based evaluation is being undertaken as a separate study.

MDT working, SW, SCW involvement and the additional

time allocated to GPs worked in synergy to create an integrated model of working that shows promise for addressing the inverse care law. The extra time allows GPs to plan and address complex health and social needs, also drawing on the expertise of colleagues from other sectors within MDT meetings. The SW involvement in GHC met with key challenges that mainly arose from a lack of understanding of the current social work role, different perceptions of risk and vulnerability as well as a lack of knowledge about the eligibility criteria for access to services referred via SW. However, practice staff benefited from learning about these issues, resulting in GPs developing more incisively written referral requests that were more likely to meet SW criteria, as well as gaining an understanding of what patient issues might be better served by access to services within the third sector.

SCWs linked to GHC are a recent innovation that shows promise. There have already been examples of joint/collaborative working with practice/community-based staff that highlight the benefit to patients of working in an integrated way to prevent crises before they occur. The MDTs have also been adapted over time, revealing the propensity for the SHIP project team to learn and adapt the model over time. As the organisation and management of MDTs improves in efficiency, and with greater involvement of professionals across social work, secondary care and the third sector, the MDT offers a potential platform for integrated working.

The SHIP project met with challenges known to have affected integration projects elsewhere, namely, issues related to bringing together two formerly distinct sectors. However, there have been considerable benefits in gaining the knowledge and understanding crucial to moving forward with the integration agenda. As the SHIP project continues to evolve there are some key recommendations arising from this report that are worthy of consideration:

- The integration model would be better served by a wider constituency of professionals involved in planning and development going forward. Representation should go beyond GPs and SWs to include SCWs, nursing, AHPs and key third sector organisations.
- There needs to be a stronger focus on planning prior to implementation in order to maximise staff engagement
- Key learning, achievements and successes should be shared with all associated staff

Outcomes/Impact:

The report to the funders will be hosted on the Scottish School of Primary Care website in order to maximise learning from this evaluation.

Publications:

- Harris F, Maxwell M, McGregor J, Mercer S. (2017) A qualitative evaluation of the Govan SHIP: a social and health integration partnership project, Report to Glasgow City Health and Social Care Partnership (South).
- McGregor J, Mercer S, Harris FM. (2016) Health Benefits of Primary Care Social Work for Adults with Complex Health and Social Needs: A Systematic Review, *Health & Social Care in the Community*, doi:10.1111/hsc.12337 [epub ahead of print]. <http://onlinelibrary.wiley.com/doi/10.1111/hsc.12337/full>

Project Number:	ISSR02.3
Status:	In Progress
Project Title:	The Evaluation of the Implementation of Advanced Nurse Practitioner Roles in Primary Care
Source of funding and total value of award:	Scottish School of Primary Care, £120,000
Value of funding to NMAHP RU:	£120,000
Principal investigator/co-applicants:	Wells M (PI), Maxwell M, Cunningham M, Strachan H, Hoskins G (Stirling University).
NMAHP RU investigators:	Wells M, Maxwell M, Cunningham M, Strachan H, Hoskins G.
Workstream:	Innovations in Services, Systems and Roles
Start date:	April 2017
Duration:	18 Months

Aim(s):

1. To identify stakeholders' experiences of the introduction, implementation and evaluation of existing and new ANP roles funded by the PCTR projects in Scotland.
2. To examine the impacts of ANP roles and how these are measured, in relation to the anticipated outcomes.
3. To explore, from different key stakeholders' perspectives, the barriers and facilitators to the introduction, implementation and evaluation of ANP roles across different primary care contexts.
4. To examine the transferability of the results of the evaluation, based on our understandings about what works for whom, in what circumstances and contexts, for different types of current and emerging ANP roles across Primary Care in NHS Scotland.

Summary:

The evaluation of the implementation of Advanced Nurse Practitioner (ANP) roles is one of the six case studies chosen by the Scottish Government, as part of the Scottish School of Primary Care's evaluation of new models of delivering primary care services that are being trialed across Scotland with support from the Primary Care Transformation Fund (PCTF).

Our evaluation seeks to understand the nature of ANP roles in Scotland, the new models of primary care that they support and their intended impact on the: service user, organisation, team and ANPs themselves. We will assess the mechanisms and contextual factors that impact on the delivery and outcomes associated with the implementation of ANP roles, therefore seeking not only to answer what the new service is (ANP roles in Primary Care) but also to answer the question of why the service works, for whom and in what circumstance. Methods include a systematic review of ANP roles, and in-depth case studies involving key informants in a range of Health Boards across Scotland.

Outcomes/Impact:

The results of this evaluation will inform future new models of delivering primary care services and the long-term sustainability of these roles. A close working relationship with the current strategic initiative 'Transforming Nursing roles', which aims to ensure a consistent approach to developing Advanced Practitioners in all specialties across Scotland, will ensure that learning can be maximized across both initiatives.

Project Number:	ISSR02.4
Status:	Complete
Project Title:	Qualitative baseline evaluation of community hub pilots in NHS Fife and NHS Forth Valley
Source of funding and total value of award:	NHS Health Scotland, £22,693
Value of funding to NMAHP RU:	£22,693
Principal investigator/co-applicants:	Harris F (PI), Maxwell M (University of Stirling).
NMAHP RU investigators:	Harris F, Maxwell M.
Workstream:	Innovations in Services, Systems and Roles
Start date:	February 2017
Duration:	5 months

Aim(s):

The aim of this qualitative study was to explore the barriers and facilitators to designing and implementing the Community Hub-GP Fellow model and the potential impact on the delivery of care at (or close to) home.

Summary:

The Community Hub- GP Fellow (CHGP) model was an innovative response to the need to find new ways of meeting the care needs of the increasing numbers of older people with complex needs. Delivering care within the community, reducing hospital admissions and facilitating early discharge were some of the key aims that might be addressed by providing a bridge between primary and secondary care. The new role of GP Fellow was devised to facilitate the Community Hub model, where GPs would receive additional training that would prepare them to act to bridge the primary-secondary care gap. A small pilot scheme was implemented, recruiting GPs to be located within NHS Fife and NHS Forth Valley.

Key facilitators for implementation included the existence of a CHGP 'champion' who was in place from inception and development of the model through to ongoing implementation. Another facilitator was the workplace training provided in one site, where the Fellows rotated around secondary care specialties, gaining experience and establishing

relationships that may well enhance their ability to act as a bridge between sectors in the future. Potentially a key contextual factor that may facilitate future implementation is the input of geriatricians into the community team, which allows a greater range of treatment options to be delivered in patients' homes and may facilitate a stronger working relationship between GP Fellows and secondary care staff.

Challenges to implementation experienced by both sites were a lack of lead in time, with implementation started before full planning of the role and how it would be operationalised had been addressed. Problems experienced by the GP Fellows included a lack of workspace facilities, no role clarity, and the lack of choice in allocation to General Practices. Furthermore, communication about the CHGP model had not reached those individuals likely to come into contact with the GP Fellows within the community. Other issues which led to early resignations in one site had been addressed prior to recruiting their replacements, illustrating how this Health Board has responded and adapted to early implementation issues. Other more intractable issues include the incompatibility of primary and secondary care information systems that result in double or even triple recording of healthcare activity into multiple databases. The ongoing development and implementation of the CHGP model would benefit from cross sector input, particularly from geriatricians who are not routinely involved in steering this model in either site.

While there have been challenges to implementing the CHGP model, nevertheless many participants commented positively about its' potential and expressed an enthusiasm to continue with it. This included the GP Fellows themselves, who felt that the role presented an exciting new career path in General Practice. Perceived benefits of the CHGP model included improving the patient journey by increasing timely access to outpatient diagnostic tests and thereby reducing the likelihood of hospital admission.

Outcomes/Impact:

The report to the funders will be shared with the Scottish Government who have funded the CHGP pilot in order to improve services for people with complex needs. The evaluation will inform further development and implementation of this innovation in primary care delivery and organisation.

Publications:

- Harris F, Booth H, Wade S, Maxwell M. (2017) Qualitative baseline evaluation of community hub pilots in NHS Fife and NHS Forth Valley, Report to NHS Health Scotland.

Project Number:	ISSR02.5
Status:	Complete
Project Title:	Using “Good Goals” to improve children’s occupational therapy services: a feasibility study of a multifaceted intervention
Source of funding and total value of award:	Chief Scientist Office, £70,396
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Kolehmainen N (PI), MacLennan G, Tennent L (University of Aberdeen), Duncan EAS (University of Stirling), Duncan EM, Ryan SB, McKee L (University of Aberdeen), Francis JJ (University of Aberdeen).
NMAHP RU investigators:	Duncan EAS.
Workstream:	Innovations in Services, Systems and Roles
Start date:	April 2010
Duration:	12 Months

Aim(s):

Investigated the use of Good Goals in one children’s therapy context, specifically children’s occupational therapy. The specific objectives were to: (1) identify factors related (qualitatively and/or statistically) to the uptake and adoption of the Good Goals intervention; (2) investigate perceived changes in service delivery and actual changes in therapists’ goal setting during the uptake and early adoption of Good Goals; and (3) evaluate the cost of delivering and adopting Good Goals.

Summary:

Access and equity in children’s therapy services may be improved by directing clinicians’ use of resources toward specific goals that are important to patients. A practice-change intervention (titled ‘Good Goals’) was designed to achieve this. This study investigated uptake, adoption, and possible effects of that intervention in children’s occupational therapy services. Mixed methods case studies (n=3 services, including 46 therapists and 558 children) were conducted. The intervention was delivered over 25 weeks through face-to-face training, team workbooks, and ‘tools for change’.

Data were collected before, during, and after the intervention on a range of factors using interviews, a focus group, case note analysis, routine data, document analysis, and researchers’ observations. Factors related to uptake and adoptions were: mode of intervention delivery, competing demands on therapists’ time, and leadership by service manager. Service managers and therapists reported that the intervention: helped therapists establish a shared rationale for clinical decisions; increased clarity in service provision; and improved interactions with families and schools. During the study period, therapists’ behaviours changed: identifying goals, odds ratio 2.4 (95% CI 1.5 to 3.8); agreeing goals, 3.5 (2.4 to 5.1); evaluating progress, 2.0 (1.1 to 3.5). Children’s LoT decreased by two months [95% CI -8 to +4 months] across the services. Cost per therapist trained ranged from £1,003 to £1,277, depending upon service size and therapists’ salary bands. Good Goals is a promising quality improvement intervention that can be delivered and adopted in practice and may have benefits. Further research is required to evaluate its: (i) impact on patient outcomes, effectiveness, cost-effectiveness, and (ii) transferability to other clinical contexts.

Publications:

- Kolehmainen N, MacLennan G, Ternent L, Duncan EAS, Duncan EM, Ryan S, McKee L, Francis J. (2012) Using shared goal setting to improve access and equity: a mixed methods study of the Good Goals intervention in children’s occupational therapy. *Implementation Science*. 7:76. doi: 10.1186/1748-5908-7-76.

Conference Presentations:

- Kolehmainen N, Francis J, Duncan E, Duncan EM, MacLennan G, McKee L Changing healthcare professionals’ caseload management: development and pilot of a behaviour change intervention, UK Society for Behavioural Medicine Annual Meeting, December, 2010, London.
- Kolehmainen N, Francis J, Duncan E, McKee L, Grant, A. Good Goals: supporting therapists to manage caseloads. Allied Health Professions’ children and young people network (AHP CYP) Launch event, 21 October, Perth, UK 2009. (Poster).
- Kolehmainen N, Duncan EM, MacLennan G, Duncan EAS, McKee L, Ternent L, Dorward M, Fayed N, Kay D, Francis JJ Implementation research in allied health care: the Good Goals programme. *Improving Quality in Health Care: translating Evidence into Practice*, 2012, Edinburgh.
- Kolehmainen N, MacLennan G, Ternent L, Duncan EAS, Duncan EM, Ryan SB, McKee L, Francis J. Improving shared goal setting: a multi-level mixed methods study of the Good Goals intervention. *European Academy of Childhood Disability*. October 2013, Newcastle.
- BB. Kolehmainen N, MacLennan G, Ternent L, Duncan EAS, Duncan EM, Ryan SE, McKee L, Francis JJ Multi-level case studies in development of complex interventions. *2nd Clinical Trials Methodology Conference*, November 2013, Edinburgh.

Project Number:	ISSR02.6
Status:	Complete
Project Title:	Evaluating the impact of mental health nursing initiatives in Scotland: the 3 R's.
Source of funding and total value of award:	Scottish Government Chief Nursing Officer, £45,000
Value of funding to NMAHP RU:	£45,000
Principal investigator/co-applicants:	Maxwell M (PI) (University of Stirling), Kelly F (Scottish Government), Rutherford A (University of Stirling).
NMAHP RU investigators:	Maxwell, M.
Workstream:	Long Term Conditions Management
Start date:	February 2012
Duration:	12 Months

Aim(s):

The main aim of the study was to explore from mental health nurses, senior NHS Board staff, HEI staff and mental health nursing students' perspectives, how current the 3 R's and its associated action plans remain at the forefront of everyday practice and teaching; and how should the 3 R's be taken forward into the future. Additional aims:

1. To explore mental health nurses, senior NHS Board staff, HEI staff and mental health nursing students' perspectives the impact of the 3 R's on:

- the working environment
- patient care and recovery oriented practice

2. To explore how the 3 R's are implemented in teaching (for HEI staff and students only).

Summary:

A qualitative study of key NHS and Higher Education Institute (HEI) stakeholder views on the impact and continuing relevance of the 3 R's. This included mental health nursing teams in 2 NHS Boards, senior NHS staff invited from across all NHS Boards, and HEI staff and students from 3 HEI's delivering mental health nursing in Scotland.

Key recommendations were produced covering:

- Promoting positive care practices
- Evidence of quality improvement
- Supervision
- Professional development
- Future priorities/focus for 3R's

The 3Rs provides a foundation for the role of mental health nursing but now needs to use this foundation to clarify its distinct role and function within health and social care integration. This will likely drive any new action points that are required for this changing environment. Any future direction for the 3Rs or related strategies and activity must be complimentary and integrated with any existing or planned policies, initiatives, or products.

Whilst the 3 R's must be maintained as the foundation of mental health nursing and as a professional goal, it is not recommended to re-refresh or return to the same activities and action points as have been previously emphasised and re-freshed. Links with other agencies to help the NHS deliver Recovery based services to patients should be encouraged. Examples such as the Branching Out scheme could be extended or act as a model for other similar initiatives.

Outcomes/Impacts:

A report was submitted to the CNO for consideration within future policies relating to nursing and mental health nursing and education.

Publications:

Margaret Maxwell, Theresa Ikegwuonu. Scoping the impact and continuing relevance of the Rights, Relationships and Recovery (3 Rs) in mental health nursing. Final Report July 2014.

Project Number:	ISSR02.7
Status:	In Progress
Project Title:	Revolutionising psychological trauma care: providing the final details for an NIHR application for a robust evaluation of effectiveness, reach and context dependence of a novel Scottish government funded model of care
Source of funding and total value of award:	Chief Scientist Office, £29,691
Value of funding to NMAHP RU:	£12,500
Principal investigator/co-applicants:	Karatzias T (PI), Williams B, Dougal N, (Edinburgh Napier University), Fyvie C (Rivers Centre).
NMAHP RU investigators:	Hibberd C, Maxwell M.
Workstream:	Innovations in Services, Systems and Roles
Start date:	June 2017
Duration:	6 Months

Aim(s):

1. To develop a programme model which will inform a full evaluation
2. To identify valid, meaningful outcomes for a full evaluation
3. To identify valid, meaningful comparator datasets for a full evaluation.

Summary:

The impact of psychological trauma on physical and mental health is well known, although current models of care are failing to meet clients' needs. A new model of care, supported and financed by the Scottish Government, will be tested for the very first time in the Rivers Centre for Traumatic Stress. The model joins up health, social care and third sector services to deliver holistic trauma care across the lifespan. The current project is providing evidence and understanding to support

A funding application to NIHR for a full evaluation. We require information, including evidence of feasibility, recruitment, optimum impact/outcome measures, datasets and sample size calculation to refine our design and provide a robust case for funding.

Outcomes/Impact:

1. An NIHR funding application for a full evaluation
2. Feedback into the initial development of the service, potentially facilitating improvement.

Project Number:	ISSR02.8
Status:	Incomplete
Project Title:	Shared decision-making in treatment evaluation
Source of funding and total value of award:	Alliance for Self-care Network Seed funding, £2,491
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Bugge C (PI), Abhyankar P (University of Stirling), Crispin V (University of West of Scotland), Burton C (University of Sheffield).
NMAHP RU investigators:	Abhyankar P.
Workstream:	Innovations in Services, Systems and Roles
Start date:	March 2015
Duration:	6 Months

Aim(s):

To identify and appraise research papers that investigate patient involvement in treatment evaluation. The review aimed to support the development of a grant application for a study investigating patient involvement in treatment evaluation.

Summary:

Shared Decision Making, at all stages of the patient journey, is a key component of person centred health care and is enshrined in NHS policies. To date, research into shared decision making has largely focused on one-off, prospective discussions about starting treatment, often involving hypothetical risks – for instance of side effects or complications. There has been little research into how clinicians and patients make shared evaluations of existing treatment and use this to decide on subsequent treatment, a process we call “Shared Treatment Evaluation”.

Through this review, we aimed to assess the current state of evidence on patient involvement in treatment evaluation.

We searched Pubmed, CINAHL, EMBASE, Social Science Citation Index; Medline; PsycINFO using free text and index search terms related to ‘patient participation in decision making’ (e.g. patient participation, involvement,

shared decision making) and ‘treatment evaluation’ (e.g. treatment/medication review, treatment outcome, review consultations) combined with AND. The databases were searched from inception to 13th Feb 2015. Studies were included if they were primary or secondary research, focussed on patient-professional interaction, and reported data on evaluation of an existing treatment in any clinical context. Publications were excluded if they were theoretical papers, commentaries, non-peer reviewed, if data on evaluation of treatment could not be separated from other data, if there was no mention of data collected at treatment evaluation stage, included participants under 18 or people with cognitive incapacity. All titles were reviewed by one member of the team to eliminate any that were obviously irrelevant. Abstracts of potentially relevant titles were screened by the same member against inclusion-exclusion criteria. Any papers proceeding to full text review were reviewed by two members of the team.

A total of 11 papers met the inclusion criteria. Data were extracted on study objectives, design, theory, setting, population, treatment being evaluated, how treatment was evaluated, data analysis, findings and authors’ conclusions.

The review and the subsequent grant application, however, remained incomplete for several reasons. First, the review found it difficult to identify research specifically addressing this issue, which made it difficult to develop a clear rationale for a proposal focussing on shared treatment evaluation that would result in a fundable application. Second, there were no resources (e.g. staff time, funding to sustain RA) to complete the review.

This review and plans for a grant application however remain ongoing. It was recently handed over to the team member at University of Sheffield who may be progressing this with a PhD studentship.

Project Number:	ISSR02.9
Status:	Complete
Project Title:	Evaluation of the Scottish Recovery Indicator Tool (SRI1 and SRI2)
Source of funding and total value of award:	Scottish Recovery Network/ Scottish Government, £30,000
Value of funding to NMAHP RU:	£30,000
Principal investigator/co-applicants:	Maxwell M (PI), MacGregor A, Dougall N, Harris F (University of Stirling)
NMAHP RU investigators:	Maxwell M, Dougall N, Harris F.
Workstream:	Innovations in Services, Systems and Roles
Start date:	October 2011
Duration:	10 Months

Aim(s):

The main aim of the SRI 2 evaluation was:

- To establish the types of impact that result from the use of the SRI 2 in different areas of practice.

The SRI 2 evaluation addressed the following objectives:

- To assess the impact of the SRI 2 on the knowledge (e.g. in relation to recovery), beliefs and practices of network participants
- To establish the impact of the SRI 2 on team culture and service environment, including its impact in NHS settings as well as the voluntary sector
- To identify perceptions of the impact of the SRI 2 in responding to individual service user needs
- To explore some aspects of the process of implementation of the SRI 2 in relation to how change is achieved in the different service environments

To compare, as far as possible, the results of the SRI 1 and SRI 2 evaluations.

Summary:

A mixed methods study was adopted to capture the impact of the SRI 2 using baseline and follow-up survey data and qualitative interviews with network participants.

At follow-up, focus groups were also convened in order to explore the implementation of SRI 2 within a service or team setting. The SRI 2 study was conducted using participants from the regional SRI 2 Learning Networks. These consisted of three regional networks: North, West, South and East.

Although it was only possible to examine immediate and short-term impacts of SRI 2, the overwhelmingly positive feedback given by NHS and voluntary sector staff suggests that SRI 2 does indeed have a major role to play in promoting the recovery agenda as well as wider service development.

Outcomes/Impact:

Report submitted to the Scottish Recovery Network and Scottish Government to inform further roll-out of the SRI2 across Scotland.

Publications:

- Evaluation of the Scottish Recovery Indicator 2 (SRI2). Andy MacGregor, Susan Reid, Margaret Maxwell, Nadine Dougall and Fiona Harris. ScotCen Social Research 2013.

Project Number:	ISSR02.10
Status:	In Progress
Project Title:	(Phase IV) A theoretically informed exploration of practice change in speech and language therapy
Source of funding and total value of award:	ESRC PhD Studentship (Health Pathway), £54,780.00
Value of funding to NMAHP RU:	£54,780.00
Principal investigator/co-applicants:	Nicoll N (PI) (University of Stirling).
NMAHP RU investigators:	Nicoll A, Maxwell M, Williams B.
Workstream:	Innovations in Services, Systems and Roles
Start date:	October 2013
Duration:	48 Months

Aim(s):

To explain, from a practice perspective:

1. What 'practice change' is
2. What it really takes to change practice
3. Why there are different trajectories of change

Research question: How and why have speech and language therapists changed their practice with children with speech sound disorders?

Summary:

Healthcare professionals such as speech and language therapists are expected to change their practice throughout their career. However there is a lack of knowledge from a practice perspective of what this entails. As a consequence, therapists, managers and commissioners lack empirical evidence on which to base decisions about enabling practice change. In addition, intervention researchers lack basic sociological research around implementation that could inform their research designs, reporting and impact.

This case-based sociological inquiry includes a qualitative synthesis of studies where speech and language therapists explained the work of their practice in depth, and a primary qualitative study focused on one high-usage client group,

children with speech sound difficulties (SSD). Forty two speech and language therapists from three NHS areas and independent practice in Scotland participated in individual interviews or self-organised pairs or focus groups to discuss in depth how and why they had changed their practice with these children.

Six cases of practice change (Transforming; Redistributing; Venturing; Personalising; Delegating; Refining) and a 10-element layered complex intervention model were identified. The work invested across four key aspects of the practice context (Intervention; Candidacy; Caseload; Service) explained how practice had come to be one way rather than another.

Outcomes/Impact:

Among its practical applications, this research could help services plan more realistic practice change and contribute to speech and language therapy education. It also has potential to contribute to methodological discussions around complex interventions and their context.

Publications:

Anticipating around 6 papers will be prepared for peer-reviewed Journals.

Accepted presentations:

- Nicoll A, Maxwell M and Williams B. What does it take to change practice with children with speech sound difficulties? Royal College of Speech and Language Therapists conference, 27-28 September 2017, Glasgow.
- Nicoll A, Maxwell M and Williams B. What is a complex intervention for children with speech sound difficulties? Royal College of Speech and Language Therapists conference, 27-28 September 2017, Glasgow.

Presentations:

- Nicoll A. A qualitative study of practice change in speech and language therapy. Council for Allied Health Professions Research (CAHPR) North East Symposium, 1 September 2016, Perth.
- Nicoll A. Conceptualising practice change. Royal College of Speech and Language Therapists Research Champions' Day, 1 July 2016, London.
- Nicoll A. Putting qualitative analysis into practice. Stirling University Faculty of Health Sciences and Sport postgraduate conference, 23 March 2016, Stirling.
- Nicoll A. What's your transcription theory? Realism Leeds pre-conference event for PhDs/ECRs, 3 November 2015, Leeds.
- Nicoll A. Stop, get ready, go: negotiating complex junctions in the early stages of attempting a meta-ethnography. British Sociological Association Applied Qualitative Health Research Symposium on Qualitative Health Research in Practice, 13 May 2015, York.

Other:

Nicoll, A. Twitter rotation curator of @WeSpeechies (chat #7) on topic 'Making a change in your practice – what does it take?' 20-26 April 2014

Project Number:	ISSR02.11
Status:	Completed
Project Title:	Development and Validation of the 'valuing people as individuals scale' VPAIS
Source of funding and total value of award:	NHS Tayside, £25,000
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Jones M (PI), MacGillivray S, Rattray J (University of Dundee), Williams B (University of Stirling).
NMAHP RU investigators:	Williams B.
Workstream:	Innovations in Services, Systems and Roles
Start date:	July 2010
Duration:	24 Months

Aim(s):

To update and re-validate the Valuing Patients as Individuals Scale for use as a patient appraisal of received healthcare.

Summary:

Background: Healthcare in the United Kingdom and beyond is required to deliver high quality, person-centred care that is clinically effective and safe. However, patient experience is not uniform, and complaints often focus on the way patients have been treated. Legislation in United Kingdom requires health services to gather and use patients' evaluations of care to improve services.

Design: This study uses scoping literature reviews, cognitive testing of questionnaire items with patient and healthcare staff focus groups, and exploratory factor analysis.

Methods/Setting/Participants: Data were collected from 790 participants across 34 wards in two acute hospitals in one National Health Service Health Board in Scotland from September 2011–February 2012. Ethics and Research and Development approval were obtained.

Results: Fifty six unique items identified through literature review were added to 72 original Valuing Patients as Individuals Scale items. Face validity interviews removed ambiguous or low relevance items leaving 88 items for

administration to patients. Two hundred and ninety questionnaires were returned, representing 37% response rate, 71 were incomplete. Thus 219 complete data were used for Exploratory Factor Analysis with varimax orthogonal rotation. This revealed a 31 item, three factor solution, Care and Respect; Understanding and Engagement; Patient Concerns, with good reliability, concurrent and discriminant validity in terms of gender. A shortened 10 item measure based on the top 3 or 4 loading items on each scale was comparable.

Conclusions: The Updated Valuing Patients as Individuals Scale is sufficiently developed to capture patient appraisals of received care.

Outcomes/Impact:

Too early to say as paper only just published in 2017. The short scale version is now being routinized in real-time evaluation of patient experience contributing to this United Kingdom, National Health Service setting meeting its policy and legislative requirements.

Publications:

- Jones M, Baldie D, Rattray J, Williams B. Assessing person-centredness: Developing the updated Valuing Patients as Individuals Scale (uVPAIS) for use in an adult, acute hospital setting using Exploratory Factor Analysis. (2017) Journal of Clinical Nursing. DOI: 10.1111/jocn.13845

Project Number:	ISSR02.12
Status:	Completed
Project Title:	ECCO oncopolicy project: Systematic review
Source of funding and total value of award:	European Oncology Nursing Society (EONS) and European CanCer Organisation (ECCO), £22,488
Value of funding to NMAHP RU:	£22,488
Principal investigator/co-applicants:	Campbell P (PI) (Glasgow Caledonian University), Wells M (University of Stirling), Torrens C (Glasgow Caledonian University).
NMAHP RU investigators:	Campbell P, Wells M, Torrens C.
Workstream:	Innovations in Services, Systems and Roles
Start date:	July 2016
Duration:	8 Months

Aim(s):

To identify, appraise and synthesize the available evidence relating to the value and impact of cancer nursing on patient experience and outcomes.

Summary:

Cancer nurses play a central role in caring for individuals diagnosed and living with and beyond cancer. However, in some countries across Europe, there is little recognition of the value of cancer nursing. There is an emerging literature that recognizes the importance of cancer nurses in caring for people with cancer; however, a systematic review examining the impact and value of cancer nursing across the cancer spectrum was lacking.

This systematic review identified published studies and on-going trials by searching multiple electronic databases (Medline, AMED, Epistemonikos, CINAHL, Embase, Cochrane Central Register of Controlled, DARE, HTA, CDSR), clinical trial registries (WHO ICTRP) from 01 January 2000 to 30 May 2016. RCTs, quasi-RCT and CBA studies were included. Key information relating to the intervention was extracted in accordance with the Template for Intervention Description and Replication (TIDieR) guidelines. Cancer nursing roles were defined using the Canadian Association of Nurses in Oncology (CANO)

definition for generalist, specialist and advanced oncology nurses. Interventions were classified using the OMAHA nursing intervention classification.

The search identified 22450; screened 16169 abstracts and considered 925 full papers, of which 518 studies were excluded. This resulted in 316 reports of 214 unique studies that were eligible for inclusion within our qualitative synthesis. Cancer nursing interventions were classified as: Case management (n=38); Surveillance (n= 27); Teaching, counselling and guidance (n=131); and Treatment and procedures (n = 18). The review has highlighted that evidence for certain cancer groups and stages of the cancer care continuum is limited.

Outcomes/Impact:

This is the first systematic review to focus on cancer nursing across all stages of the cancer continuum. It fulfils the first stage of the Recognising European Cancer Nursing (RECaN) project, funded by the European Cancer Organisation and European Oncology Nursing Society. The findings of this review inform the second and third stages of the RECaN project: a multiple case study of cancer nursing across four contrasting European countries (Stage 2) and a policy initiative to engage with policy makers across Europe to strengthen the education, recognition and contribution of cancer nurses in European countries (Stage 3).

Publications:

- Campbell P, Torrens C, Kelly D, Charalambous A, Domenech-Climent N, Nohavova I, Ostlund U, Patiraki E, Salisbury D, Sharp L, Wiseman T, Oldenmenger W, Wells M Recognising European Cancer Nursing: Protocol for a systematic review and meta-analysis of the evidence of effectiveness and value of cancer nursing *Journal of Advanced Nursing* (in press).

Other dissemination activity:

Oral presentations at International conferences - European Cancer Congress (ECCO2017), Amsterdam (January 2017), RCN International Research Conference, Oxford (April 2017) and European Society of Medical Oncology (ESMO2017), Madrid (September 2017). The review has also been registered on the PROSPERO database.

METHODS



Project Number:	M01.1
Status:	Complete
Project Title:	Developing meta-ethnography reporting guidelines and standards for research (eMERGe)
Source of funding and total value of award:	NIHR HS & DR £298,450
Value of funding to NMAHP RU:	£222,535
Principal investigator/co-applicants:	France E (PI), Duncan E, Maxwell M, Ring N, Jepson R (University of Stirling), Turley R (Cardiff University), Noyes J (Bangor University).
NMAHP RU investigators:	Cunningham M, Uny I, Roberts R.
Workstream:	Methods
Start date:	June 2015
Duration:	24 Months

Aim(s):

The eMERGe project aimed to create evidence based meta-ethnography reporting guidance, by answering the following research questions:

1. What are the existing recommendations and guidance for conducting and reporting each process in a meta-ethnography, and why?
2. What good practice principles can we identify in meta-ethnography conduct and reporting to inform recommendations and guidance?
3. From the good practice principles, what standards can we develop in meta-ethnography conduct and reporting to inform recommendations and guidance?

What is the consensus of experts and other stakeholders on key standards and domains for reporting meta-ethnography in an abstract and main report/publication?

Summary:

Meta-ethnography is a complex and commonly used method of qualitative evidence synthesis. Previous research has identified that the quality of reporting of published meta-ethnographies is often poor and this has limited the utility of meta-ethnography findings to influence policy and practice. The eMERGe reporting guidance has been

developed following a thorough and recommended approach.

The eMERGe project has produced a guidance table, detailed explanatory notes, and training material for reporting meta-ethnographies. The guidance was developed with the help and support of an international Project Advisory Group of key stakeholders - including one of the founders of meta-ethnography, Prof George Noblit – who were involved in all aspects of the project.

Outcomes/Impact:

The project team has developed detailed explanatory notes and training materials to support the use of the reporting guidance. Meta-ethnography is an evolving qualitative evidence synthesis methodology with huge potential to contribute evidence for policy and practice. The impact of this guidance should be to improve the quality and completeness of meta-ethnography reporting, to enable stakeholders to assess the credibility of meta-ethnography findings, and to increase the usability of meta-ethnography findings to influence policy and practice.

M01.1 Developing meta-ethnography reporting guidelines and standards for research (eMERGE)

Publications:

- Uny, I., France, E.F., Noblit, G.W. (2017). Steady and delayed: explaining the different development of meta-ethnography in health care and education. *Ethnography and Education*. 12 (2).243-257
- France, E. F., Ring, N., Noyes, J., Maxwell, M., Jepson, R., Duncan, E. & Uny, I. (2015). Protocol-developing meta-ethnography reporting guidelines (eMERGE). *BMC medical research methodology*, 15(1), 103.

The guidance paper has been submitted and is under review for simultaneous publication in five journals – *Journal of Advanced Nursing*, *PLOS One*, *BMC Medical Research Methodology*, *Psycho-oncology* and *Review of Education*.

Other dissemination activity:

A range of online training material has been created to support the project output, hosted on the project website www.emergeproject.org. This material includes a glossary of terms, exemplars for each of the reporting criteria in the guidance table, and four films featuring members of the project team explaining meta-ethnography and how to use the guidance.

The project team held a webinar in May 2017 'Introducing the New Meta-ethnography Reporting Guidance – what it is and how to use it'. This one hour, free, webinar gave an overview of why the reporting guidance is needed, what format the guidance takes, and how to use the guidance, and gave attendees to opportunity to ask questions. Fifty people from around the world attended the webinar. Attendees included PhD students and academics.

Conferences:

- Oral presentation at the International Institute for Qualitative Methods 15th Annual Qualitative Methods Conference, Glasgow, UK, 3-5 May 2016
- Oral presentation at the Global Evidence Summit, Cape Town, South Africa, 13-16 September 2017

Project Number:	M01.2
Status:	In Progress
Project Title:	Identifying and assessing different approaches to developing complex interventions (INDEX study)
Source of funding and total value of award:	MRC, £380,033
Value of funding to NMAHP RU:	£91,528
Principal investigator/co-applicants:	O’Cathain A (PI) (University of Sheffield), Duncan E, Hoddinott P (University of Stirling), Croot L (University of Sheffield), Turner K (University of Bristol), Yardley L (Universities of Southampton/Oxford).
NMAHP RU investigators:	Hoddinott P, Duncan E, Rousseau N.
Workstream:	Methods
Start date:	April 2016
Duration:	24 Months

Aim(s):

To produce guidance for researchers on how to develop complex interventions to improve health or health care outcomes.

Objectives:

1. Identify and describe the different approaches taken to intervention development, the rationales for their use, and any implications for the future utility of the interventions.
2. Compare and contrast different intervention development approaches, and their methods of data collection and analysis, considering strengths and limitations overall and for different contexts.
3. Understand the history and challenges of intervention development from the perspectives of experienced researchers and wider stakeholders.
4. Measure stakeholder consensus on the key aspects of intervention development and explore the reasons for any lack of consensus.

Offer guidance to researchers on good practice, with examples from different approaches.

Summary:

Researchers, the public, patients, industry, charities and health care providers can all be involved in the development or design of new interventions to improve health and health care. There is increasing recognition of the importance of carefully developing and evaluating complex interventions so that there is an increased chance of interventions being effective within trials, and being adopted widely in the real world.

The INDEX project builds on the methodological expertise in intervention development of the Unit’s Pat Hoddinott and Edward Duncan (stroke rehabilitation). The collaboration arose through the CONDUCT II MRC funded methods for trials hub [M01.4, M01.6] and links to Pat Hoddinott’s guest editor role on BMC Pilot and Feasibility Studies to host a series on intervention development (Hoddinott P. A new era for intervention development studies. *Pilot and Feasibility Studies*. 2015; 1:36. DOI: 10.1186/s40814-015-0032-0).

INDEX has three phases: systematic reviews of the methodological literature and primary intervention development research; qualitative interview study led by Pat Hoddinott with researchers engaged in intervention development and wider stakeholders (directors of funding boards, PPI on

M01.2 Identifying and assessing different approaches to developing complex intervention (INDEX study)

funding panels, policy decision makers and journal editors); and reaching consensus using a Delphi approach led by Edward Duncan and using an e-platform he developed with Computing Science at University of Stirling

Publications:

- Sworn, K., O’Cathain, A., Croot, L., Duncan, E., Hoddinott, P., Turner, K. and Yardley, L. (2017) A systematic review of the different approaches to intervention development. *Trials*, 18 (Supl 1), pp. 126.

Other dissertation activity:

- Sworn, K., O’Cathain, A., Croot, L., Duncan, E., Hoddinott, P., Turner, K. and Yardley, L. (2017) A systematic review of the different approaches to intervention development. Poster presentation. Society for Clinical Trials/International Clinical Trials Methodology Conference, Liverpool, May 2017.
- O’Cathain A, Hoddinott P, Duncan E, Yardley L, Turner K, Croot E, Sworn K, Rousseau N. Identifying and assessing different approaches to developing complex interventions: An introduction to the INDEX Study. Society for Social Medicine Conference (workshop). Manchester. 6-8 Sept 2017.

Project Number:	M01.3
Status:	In Progress
Project Title:	A Scottish improvement science research, development and knowledge translation collaborating centre (SISCC)
Source of funding and total value of award:	Chief Scientist Office, Scottish Funding Council, NHS Education for Scotland, and the Health Foundation (joint funding), £3,250,000
Value of funding to NMAHP RU:	£250,000
Principal investigator/co-applicants:	Renfrew M (PI) (University of Dundee), Maxwell M, Cheyne H, O'Carroll R (University of Stirling), Williams B (Edinburgh Napier University), Morris J (Glasgow Caledonian University), Allyson (NHS Tayside), Clarkson J, Davey P, Guthrie B, Kroll T, MacGillivray S, Sullivan F (University of Dundee), Nathwani D, O'Connor P (NHS Tayside), Marr C, Ramsay C (University of Aberdeen), Davies H (St Andrew's University), Walker J (Perth and Kinross Council), Stark C (NHS Highland).
NMAHP RU investigators:	Maxwell M, Cheyne H, Morris J, Frost J, Coles E.
Workstream:	Methods
Start date:	June 2014
Duration:	5 years

Aim(s):

The Scottish Improvement Science Collaborating Centre is funded to strengthen the evidence base for improving the quality of care sustainably and at scale. It is intended that programmes of work will generate new knowledge to support improvement activities within health and social care; building capacity and capability through a cross-sectoral platform.

Summary:

SISCC is a collaboration involving more than 100 organisations and over 200 individuals across Scotland and beyond. Its work is informed by 7 advisory groups including PPI. It has held 14 engagement events with over 250 participants and has 30+ projects completed or on-going. Work across the SISCC research themes (behavior change, context, capacity and capability, improvement science methods,

spread and sustainability) informs the implementation and evaluation of our improvement projects (maternal and child health, older people's health and wellbeing, and knowledge into action at scale) and all of its work has been planned to overlap and synergise as all components are needed to inform and deliver effective sustainable change at scale and pace.

SISCC draws on expertise across multiple academic disciplines, and from the experience of those with direct experience of delivering improvement activity in health and social care. In all of its methods work it includes practitioners and public stakeholders. Its focus has been on synthesising current approaches to improvement and implementation science and on developing the methods, theories, instruments and measures needed to design, test and evaluate large-scale change. SISCC research themes and improvement programmes and their progress are described in detail on the website <https://siscc.dundee.ac.uk/>

Publications:

- Behaviour Change (2016) - Dombrowski SU, Campbell P, Frost H, Pollock A, McLellan J, MacGillivray S, Gavine A, Maxwell M, O'Carroll R, Cheyne H, Presseau J, Williams B. (2016) Interventions for sustained healthcare professional behaviour change: a protocol for an overview of reviews. *Systematic Reviews* 5:173. DOI: 10.1186/s13643-016-0355-9.
- DQIP (2011) - Guthrie B, et al. High risk prescribing in primary care patients particularly vulnerable to adverse drug events: cross sectional population database analysis in Scottish general practice. *BMJ* 2011;342: d3514
- DQIP (2015) - Guthrie, B., Dreischulte, T. et al, The rising tide of polypharmacy and drug-drug interactions: population database analysis 1995–2010. *BMC Med.* 2015; 13:7
- DQIP (2016) - Dreischulte T., et al, 2016. Safer Prescribing-A Trial of Education, Informatics, and Financial Incentives. *New England Journal of Medicine*, 374(11), pp. 1053-1064
- DQIP (2016) - Guthrie, B, et al. Data feedback and behavioural change intervention to improve primary care prescribing safety (EFIPPS): multicentre, three arm, cluster randomised controlled trial, *BMJ* (2016). DOI: 10.1136/bmj.i4079
- Older People Health & Well Being - Physical Activity (2017) - Zubala A., MacGillivray S., Frost H., Kroll T., Skelton, D.A., Gavine A., Gray N.M., Toma M. & Morris J. Promotion of physical activity interventions for community dwelling older adults: A review of reviews.

Poster presentations:

- Improvement Science Methods (2016) - The purpose, design and use of balancing measures in quality and safety improvement - NHS Scotland 2016.
- Improvement Science Methods (2016) - The purpose, design and use of balancing measures in quality and safety improvement - HIS 4th Annual Research Symposium 2016.
- Capacity & Capability (2017) - Medical students as agents of change: a qualitative exploratory study - HIS 5th Annual Research Symposium 2017.

- Spread & Sustainability (2017) - Co-creating a framework for conceptualising sustainable change at scale: combining expertise from improvement initiatives across the UK - HIS 5th Annual Research Symposium 2017.

Presentations:

- Effectiveness of Motivational Interviewing on Adult Behaviour Change: An Overview Of Reviews - Dr Stephan U Dombrowski- EHPS 2016.
- Long-term effects of healthcare professional behaviour change interventions: a systematic review of Cochrane reviews- Julie McLellan - EHPS 2016.
- Introduction to SISCC..... the story so far - Professor Mary Renfrew- SISCC Consortium April 2017.
- Improvement & behaviour change - Professor Brian Williams- SISCC Consortium April 2017.
- Optimising management of patients at risk of preventable drug side effects (DQIP2) - Dr Tobias Dreischulte - SISCC Consortium April 2017.
- Motivating change - Professor Mary Renfrew on behalf of Dr Jenna Breckenridge - SISCC Consortium April 2017 (awaiting publication).
- Balancing measures or a 'balanced accounting' of both intended and unintended consequences of improvement interventions? - Dr Madalina Toma - SISCC Consortium April 2017 (awaiting publication)
- Students as change agents - Diane Campbell on behalf of Professor Peter Davey- SISCC Consortium April 2017.
- Transformative Innovation in Health & Social Care - Dr Margaret Hannah- SISCC Consortium April 2017.
- Structured, Supported Engagement - Dr Cameron Stark - SISCC Consortium April 2017.
- Motivating Change: Learning for T

Project Number:	M01.4
Status:	In Progress
Project Title:	(Phase 1) Guidance to optimise pilot study design and conduct: a joint HTMR and NIHR HTA 'research on research' proposal
Source of funding and total value of award:	MRC Methodology Panel, £24,510.00
Value of funding to NMAHP RU:	£0
Principal investigator/co-applicants:	Blazeby J (PI) Avery K (University of Bristol), Blatch-Jones (nee Young) A (University of Southampton), Bond C (University of Aberdeen), Coleman C (Queen Mary University London), Duley L (University of Nottingham), Eldridge S (Queen Mary University of London), Gamble C (University of Liverpool), Hopewell S (University of Oxford), Lancaster G (Lancaster University), O'Cathain A (University of Sheffield), Thabane L (McMaster University Ontario), Williamson P (University of Liverpool).
NMAHP RU investigators:	Hoddinott P.
Workstream:	Methods
Start date:	February 2017
Duration:	12 Months

Aim(s):

To provide clear guidance for trialists to inform the selection and design of pilot work prior to a definitive/main randomised controlled trial assessing the effect of an intervention, and to provide guidance for selection of progression in RCTs with an internal pilot design.

Summary:

There are a growing number of studies described as pilot or feasibility studies by their authors. Research has indicated that many of these pilot and feasibility studies are poorly designed, conducted, and reported. This builds on a programme of work that Pat Hoddinott collaborated on including the development of a CONSORT extension guideline, and work on the role of qualitative research in these studies. In addition, Pat Hoddinott is an associate editor of the new BMC journal, "Pilot and Feasibility Studies", which is

becoming established. There are several key unanswered questions in this field. In particular there has been no work focusing on when researchers should use internal or external pilot study design, and when qualitative research or non-randomised work is required before a main trial. Also, for studies with an internal pilot phase little is known about the selection and reporting of key progression criteria and this is critical to determine main trial success and funding.

NIHR HTA funded internal pilot studies will be analysed to explore their decision making in relation to progression criteria, qualitative interviews will be undertaken and a two-day event will be held in spring 2018. The first meeting day will consist of presentations by the team and discussion. Day two will consist of a smaller working group who will together will write guidance on how to optimise pilot study design and how to select an external pilot RCT, internal pilot design and/or non-randomised feasibility work.

Project Number:	M01.5
Status:	Complete
Project Title:	Developing theory based behaviour change interventions to minimise drop-out in randomised trials (Systematic Techniques to Enhance Retention in RCTs: The STEER Project)
Source of funding and total value of award:	Chief Scientist Office, £199,858
Value of funding to NMAHP RU:	£3,690
Principal investigator/co-applicants:	Gillies K (PI) (University of Aberdeen), Bower P (University of Manchester), Francis J (City University), MacLennan G (Aberdeen CTU), Newlands R (University of Aberdeen), Treweek S (University of Aberdeen), Wells M, Witham M (Tayside CTU), Young B (University of Liverpool).
NMAHP RU investigators:	Wells M.
Workstream:	Methods
Start date:	August 2017
Duration:	20 months

Aim(s):

To develop and pilot theoretically-informed, participant-centred, evidence-based behaviour change interventions to improve retention in trials.

Summary:

Randomised controlled trials are the cornerstone of evidence-based healthcare as they provide unbiased estimates of the benefits and harms of treatment if conducted rigorously. It is common for many trial participants (sometimes more than 20%) to drop out before the trial finishes. Moreover, 50% of trials have loss to follow up of over 11%. This study will use an established theoretical framework (Theoretical Domains Framework, TDF) to inform the development of targeted retention interventions for use in future trials. Five 'host' trials with poor retention (e.g. those with more than 15% missing primary outcome data) from the portfolios of Trials Units will be purposively selected. Semi-structured interviews with participants who have dropped out, or considered dropping out, of these host trials will be conducted.

The barriers and enablers to retention that are reported by trial stakeholders will be linked to retention-relevant domains of the TDF and used to identify specific behaviour change techniques. Co-production workshops will then be held to develop retention interventions.

Outcomes/Impact:

If successful, these interventions will directly lead to an improved evidence base on which clinical care treatment choices are made.

Project Number:	M01.6
Status:	In Progress
Project Title:	(Phase II) ConDuCT-II Hub. Collaboration and innovation for difficult and complex randomised controlled trials in invasive procedures.
Source of funding and total value of award:	£1,979,501.00
Value of funding to NMAHP RU:	£18,706.00
Principal investigator/co-applicants:	Blazeby J (PI) (University of Bristol), Hollingsworth W, Donovan J, Brookes ST, Welton N, Lane A, Higgins J, Noble S, Hollinghurst S, Metcalfe C, Sterne J, Thom J, Campbell R, Tilling K, O’Cathain A (University of Sheffield), Heawood A, Mills N, Montgomery AA, Peters T, Wiles N, Macefield R, Rogers C, Cook JA (University of Oxford), Huxtable R, Avery K, Savovic J, Salisbury C (all University of Bristol unless otherwise stated)
NMAHP RU investigators:	Hoddinott P.
Workstream:	Methods
Start date:	April 2013
Duration:	60 Months

Aim(s):

To develop and implement research methods that will lead to marked improvements in the successful prioritisation, design, conduct and completion of RCTs.

Summary:

The ConDuCT Hub was established in April 2009 based at the University of Bristol is part of an established environment and infrastructure to ensure continued close collaboration with other MRC Hubs for Trials Methodology Research (HTMRs), UKCRC-registered Clinical Trials Units (CTUs) and other relevant groups which focus on improving the conduct of RCTs.

The CONDUCT II Hub funding focuses on four themes:

- Theme 1: Prioritisation and design of trials for cost effectiveness analysis
- Theme 2: Integrative and dynamic research methods to optimise recruitment to RCTs

- Theme 3: Trial conduct and feasibility study design
- Theme 4: Trial outcomes: selection, reporting and integration into decision-making

Pat Hoddinott is one of three external co-applicants on this University of Bristol research methods hub project and contributes mainly to Themes 2 and 3.

Outcomes/Impact:

The CONDUCT II hub has met pre-specified objectives and performance metrics in the MRC funding application. These are numerous and many are available on the Hub website <http://www.bristol.ac.uk/social-community-medicine/centres/conduct2/>

The impact for NMAHP-RU has been a raised profile for the trials methodology work undertaken by the unit amongst the trial methodology community. Through this collaboration, the Unit’s Pat Hoddinott and Edward Duncan are co-applicants on the MRC funded INDEX study [M01.2],

Pat is a co-applicant on a MRC funded study to develop guidance to optimise pilot study design and conduct [M01.4] which follows Pat's provision of qualitative methods input into the CONSORT guidance extension for pilot and feasibility trials (see below). Pat is also a collaborator on a MRC funded small grant to develop a medical work force that designs, participates in, and implements findings of trials to improve evidence based practice. This is a case study in surgery, with the intention of in future extending the learning to the primary care workforce and beyond. The Unit's Brian Williams was invited by Prof Jane Blazeby to deliver a keynote talk at the Royal College of Surgeons in 2014. The MRC Hub Collaboration has enhanced Pat's reputation in the field of Pilot and feasibility studies, and as a result she was invited to be Guest Editor of a special series on intervention development in *Pilot and Feasibility Studies*, a sister journal of *Trials*.

Publications:

- O'Cathain, A., Hoddinott, P., Lewin, S., Thomas, K., Young, B., Adamson, J., Jansen, Y., Mills, N., Moore, G. and Donovan, J. (2015) Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot and Feasibility Studies*, 1, pp. 32.
- O'Cathain, A., Hoddinott, P., Lewin, S., Thomas, K., Young, B., Adamson, J., Jansen, Y., Mills, N., Moore, G. and Donovan, J. (2015) Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Trials*, 16 (Supplement 2), pp. 088.
- Hoddinott, P., O'Cathain, A., Boyer, I. and Oliver, S. (2015) Qualitative methods and patient and public involvement in trials: opportunities and pitfalls. *Trials*, 16 (Supplement 2), pp. 75.
- Hoddinott, P. (2015) A new era for intervention development studies. *Pilot and Feasibility Studies*, 1, pp. 36.
- Eldridge, S., Chan, C., Campbell, M., Bond, C., Hopewell, S., Thabane, L.L.G., Altman, D., Bretz, F., Campbell, M., Cobo, E., Craig, P., Davidson, P., Groves, T., Gumedze, F., Hewison, J., Hirst, A., Hoddinott, P., Lamb, S., Lang, T., McColl, E., O'Cathain, A., Shanahan, D., Sutton, C. and Tugwell, P. (2016) CONSORT 2010 Statement: extension to randomised pilot and feasibility trials. *Bmj*, 335, pp. i5239.
- Eldridge, S., Chan, C., Campbell, M., Bond, C., Hopewell, S., Thabane, L., Lancaster, G., Altman, D., Bretz, F., Campbell, M., Cobo, E., Craig, P., Davidson, P., Groves, T., Gumedze, F., Hewison, J., Hirst, A., Hoddinott, P., Lamb, S., Lang, T., McColl, E., O'Cathain, A., Shanahan, D., Sutton, C. and Tugwell, P. (2016) Consort 2010 statement: extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies*, 2, pp. 64.

Other dissemination activity:

- Hoddinott P, O'Cathain A, Donovan J, Blazeby J. Society for Clinical Trials (SCT), USA International Webinar: Applying Qualitative Methods to Maximize Impact in Feasibility Studies for Randomised Controlled Trials: 1st December 2016. 9 Available on SCT website
- Donovan J, O'Cathain A, Hoddinott P, Mills N, Young B. Can Qualitative Research Methods Revolutionize the Design and Conduct of Randomized Clinical Trials? Hoddinott P: Why qualitative researchers should lead trials of complex interventions – evidence for the need to understand and refine intervention components from breast-feeding trials. SCT conference workshop. Boston, USA. May 2013
- O'Cathain, A., Hoddinott, P., Lewin, S., Thomas, K., Young, B., Adamson, J., Jansen, Y., Mills, N., Moore, G. and Donovan, J. (2015) Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. 3rd International Clinical Trials Methodology Conference, Glasgow, November 2015.
- Hoddinott, P., O'Cathain, A., Boyer, I. and Oliver, S. (2015) Qualitative methods and patient and public involvement in trials: opportunities and pitfalls. (Poster presentation) 3rd International Clinical Trials Methodology Conference, Glasgow, November 2015
- Hoddinott P, keynote. Maximising the value of combining qualitative research and randomised controlled trials. Workshop on qualitative methods applied to trials. University of Sheffield. November 2012.

Project Number:	M01.7
Status:	In Progress
Project Title:	Methods and strategies for the development of optimised complex health interventions: exploring existing and potential new approaches
Source of funding and total value of award:	Glasgow Caledonian University, £58,000
Value of funding to NMAHP RU:	£58,000
Principal investigator/co-applicants:	Levati S (PI), Hagen S (Glasgow Caledonian University), Wells M (University of Stirling), Donaldson C (Glasgow Caledonian University)
NMAHP RU investigators:	Levati S (PhD Student), Hagen S, Wells M, Donaldson C.
Workstream:	Methods
Start date:	October 2012
Duration:	72 months

Aim(s):

1. To identify and describe the various optimisation techniques and processes currently used in complex intervention development.
2. To gain insider accounts regarding the detailed experience and associated pros and cons of different techniques
3. To assess and potentially address some of the gaps in the evidence base to support the validity and usefulness of varied processes identified.

Summary:

This study examines current methods and guidelines in relation to the development and optimisation of complex interventions (including those falling within the domain of nursing and the allied health professions) and move towards integrating or developing new techniques. To date a systematic scoping review of the literature has been completed and published, along with a qualitative case study involving researchers who have developed complex health interventions, the data for which are currently being analysed. A focus group was recently held to explore the development of tool to guide researchers regarding optimisation methods to use in future studies.

Outcomes/Impact:

The study will provide a new definition of optimisation within the current context of complex health interventions development, together with recommendations to conduct future development studies.

Publications:

- Levati S, Campbell P, Frost R, Dougall N, Wells M, Donaldson C, Hagen S. Optimisation of complex health interventions prior to a randomised controlled trial: a scoping review of strategies used. Pilot and feasibility studies. 2016 Mar 15;2(1):17.
- Levati, S, Donaldson C, Wells M, Hagen S. Researchers' experiences of optimising complex health interventions before full-scale RCTs: results from an exploratory multiple case study. *Trials*. 2015 16(Suppl 2):O29.

Other dissemination activity:

- 3rd International Clinical Trials Methodology Conference (Glasgow, UK) 2015: Researchers' experiences of optimising complex health interventions before full-scale RCTs: results from a multiple case study (oral presentation).

Researching Complex Interventions in Health: The State of the Art – Conference 2015 (Exeter, UK): Can complex interventions be optimised before moving to a definitive RCT? Strategies and methods currently used (invited speaker).

EANS Summer Conference (Barcelona, Spain) 2015: Optimising complex interventions prior to an RCT: an exploration of current strategies and their influence on trials (poster presentation/Best poster award)

Project Number:	M01.8
Status:	Complete
Project Title:	ACTIVE - Authors and consumers together impacting of evidence
Source of funding and total value of award:	Cochrane Training and Innovation Fund, £14,877
Value of funding to NMAHP RU:	£14,877
Principal investigator/co-applicants:	Pollock A (PI), Campbell P (Glasgow Caledonian University), Morris J (University of Dundee), Goodare H (Lay Member), Hill S (La Trobe University Australia), Nunn J (La Trobe University Australia), Struthers C (University of Oxford), Synnot A (La Trobe University Australia)
NMAHP RU investigators:	Pollock A, Campbell P.
Workstream:	Methods
Start date:	April 2016
Duration:	12 months

Aim(s):

The ACTIVE project aimed to bring together evidence, information and resources about the active involvement of people (such as Cochrane Consumers) in systematic review. The goal was to help Cochrane review authors have meaningful active involvement in systematic reviews, specifically by providing learning content to support the development of an online learning resource relating to how to involve people within systematic reviews.

Summary:

To address these aims we have:

- Carried out a comprehensive systematic review to find reports of active involvement in published reviews. The protocol for this has been published in the journal *Research Involvement and Engagement*. The full results of this review are being prepared for journal publication.
- Interviewed 13 people who have been involved in reviews where there was active involvement. These interviews have been audio-recorded and transcribed.
- Brought together the results of the review and the

interviews to create the structure and content of the online learning resource. We are contributing to ongoing discussions and work to develop, test and finalise this learning resource.

Outcomes/Impact:

Key outcome from this project is the development of a Cochrane Training online learning resource aimed at helping systematic review authors involve people in their reviews. This is due to be launched at the Global Evidence Summit (Capetown) in September 2017.

Publications:

- Pollock, A., Campbell, P., Struthers, C., Synnot, A., Nunn, J., Hill, S., Goodare, H., Watts, C. and Morley, R. (2017) Stakeholder involvement in systematic reviews: a protocol for a systematic review of methods, outcomes and effects. *Research Involvement and Engagement*, 3, pp. 9.
- Pollock, A., Campbell, P., Struthers, C., Synnot, A., Nunn, J., Hill, S., Goodare, H., Watts, C. and Morley, R. (2017) Stakeholder involvement in systematic reviews: a systematic review of methods (in preparation)

Other dissemination activity::

- Cochrane Learning Live webinar, October 2016
- Workshop at UK Cochrane Meeting, March 2017
- Submissions accepted for Global Evidence Summit, Cape Town, September 2017:
 - Workshop: Effective stakeholder engagement is beneficial to research – but HOW do you do it? Practical guidance and resources for authors, editors and researchers to support successful stakeholder involvement in systematic reviews
 - Long platform presentation: How are stakeholders involved in systematic reviews? Findings from a systematic review of methods.
 - Poster presentation: “A complete shift in ownership”: valuing contributions from consumers and other stakeholders in systematic reviews
- Workshop, Cochrane Australia Learning Week: “Engaging consumers and other stakeholders in systematic reviews” <http://learningweek.cochrane.org.au/index.php/courses/#kt>

NMAHP POLICY & PRACTICE DEVELOPMENT & RESEARCH CAREER DEVELOPMENT

Project Number:	PPRC01.1
Status:	In Progress
Project Title:	Clinical Academic Nursing & Midwifery Research Careers for Scotland
Source of funding and total value of award:	Chief Nurses Office Scotland, £1,500,000
Value of funding to NMAHP RU:	£1,314,317
Principal investigator/co-applicants:	Maxwell M (PI), Williams B, Hoskins G (University of Stirling).
NMAHP RU investigators:	Maxwell M, Hoskins G.
Workstream:	NMAHP Policy & Practice Development & Research Career Development
Start date:	January 2012
Duration:	4 years

Aim(s):

To encourage high quality nursing and midwifery research in order to address and support a number of contemporary policy drivers and strategies.

Summary:

Developing and sustaining future clinical academic positions not only depends on common high level strategic commitment between the HEIs and the NHS, but also significant financial resource at a time of fiscal constraint. There is also a need to foster engagement and commitment at all levels if a clinical academic framework is to be accepted and sustained within practice. This means influencing the current clinical culture to appreciate and value the benefits for patient care and outcomes that come from embedding academics and research activity within clinical areas. Given that it can take a number of years to train and develop high quality nurse research staff we must therefore ensure that we:

- Provide supportive environments that raise the standard of research to the very highest level, and ensure that clinical academics feel valued, rewarded and committed to an on-going clinical-academic career.

- Retain and/or re-engage those trained to date who have a demonstrable ability and commitment to furthering nursing research.
- Ensure that we have an efficient means of identifying the high quality clinical academics of tomorrow, prior to more substantial training and investment in them.

Such a focus not only ensures that any funding invested is efficiently used but, through the improved identification of the right people, maximises the likelihood that their research activities will be income generating via externally funded grants, HEIs' REF (Research Excellence Framework) returns, and a Health Board's NHS Support for Science allocation.

Outcomes/Impact:

To address the challenges we have focused on four mutually supportive strands of activity:

1. Financial support for up to 15 aspiring nurse researchers through studentships and funded places on the Master of Nursing in Clinical Research programme at Edinburgh University during 2013-14 academic session.
2. Award of 4 re-engagement/retention fellowships (3 general/open and 1 dedicated to learning disabilities).

3. A nursing/midwifery research and clinical academic forum, with a strategic and support role, and a means for formalising NHS links to research. This includes creation of a framework for embedding clinical academic posts within the NHS.

4. Research development for consultant NMAHPs.

Each strand has multiple layers of activity and continues to evolve. Strategic outcomes from the activities include the development of research capacity and capability of clinical academic NMAHPs in Scotland, and enhancement of the environment within which they are identified, developed and retained. Such capacity and capability would support the evidence base to develop safe, effective and person-centred services within the NHS in Scotland.

Publications:

- Hoskins G, Waterton J, Williams B. Developing a Strategy Supportive of NMAHP Research & Research Skills in Scotland. Report from the CARC summit held on 04/02/15. Submitted to CNO 2015
- Waterton J, Hoskins G, Williams B. Developing a Strategy Supportive of NMAHP Research & Research Skills in Scotland. Vision statement. Submitted to the CNO 2015.
- Brian Williams & Lesley Holdsworth. Developing NMAHP Research & Research Skills in Scotland: Considerations to inform an Action Plan: Summary Paper prepared and presented to CNO 2016.
- Mathieson A, Waterton J & Hoskins G. A clinical academic approach for nurses, midwives and allied health professionals. It's a no-brainer! In press. 2017

Project Number:	PPRC01.2
Status:	Complete
Project Title:	The Carnegie Centenary Professorship for Professor James C Coyne
Source of funding and total value of award:	Carnegie Trust for the Universities of Scotland, £40,000
Value of funding to NMAHP RU:	£40,000
Principal investigator/co-applicants:	Harris F (PI) (University of Stirling), Coyne J (University of Pennsylvania), Maxwell M (University of Stirling).
NMAHP RU investigators:	Harris F, Maxwell M.
Workstream:	NMAHP Policy & Practice Development & Research Career Development
Start date:	March 2015
Duration:	5 Months

Aim(s):

To share Professor Coyne's internationally recognised research expertise for the benefit of the NMAHP Research Unit and the wider academic community in Scotland.

Summary:

The Carnegie Centenary Professorships are competitive, prestigious awards that target scholars with significant international reputations whose period of tenure in Scotland is likely to be of benefit to the wider academic community. Professor Coyne is one of the most published and highly cited clinical health psychologists in the United States with a long-standing, international reputation. In 2003, ISI Web of Science recognised him as one of the 225 most cited psychologists and psychiatrists in the world. At the time of his visit, he was a Professor of Psychology in Psychiatry, a Senior Fellow at the Leonard Davis Institute, and Director of Behavioural Oncology at the Abramson Cancer Center at the Perelman School of Medicine, the University of Pennsylvania. He has a secondary appointment as Professor of Health Psychology at the University of Groningen, Netherlands, where his responsibilities include teaching the writing of high impact scientific papers and coaching European Research Council Award finalists.

Outcomes/Impact:

During this professorship, Professor Coyne contributed to life in NMAHP Research Unit as an active participant in the monthly meetings of the Implementation Science Group and contributed support and expertise to research students in both the Universities of Stirling and St. Andrews via advising sessions and critical appraisal training. He provided supportive advice and comments to numerous staff on academic papers and grants and delivered six lectures in locations across Scotland from Edinburgh to Inverness. Students and staff alike benefited from his writing workshop (delivered over two sessions in each of five locations) and also provided senior staff within the NMAHP Research Unit with a coaching session on EU grant funding. Professor Coyne also collaborated on a number of papers within Stirling (both published and in development) as well as with colleagues in other HEI's in Scotland.

Publications:

- Harris FM, Maxwell M, O'Connor R, Coyne J, Arensman E, Coffey C, Koburger N, Gusmao R, Costa S, Szekeley A, Cserhati Z, McDaid D, Audenhove C, Heferl U. (2016) Exploring Synergistic Interactions And Catalysts In Complex Interventions: Longitudinal, Mixed Methods Case Studies Of An Optimised Multi-Level Suicide Prevention Intervention In Four European Countries (Ospi-Europe), BMC Public Health, :268. DOI: 10.1186/s12889-016-2942-z.

Other dissemination activity:

- Lecture: Most positive findings in psychology are false: an activist perspective, Medical School, University of St. Andrews.
- Glasgow Sceptics Lecture: Positive psychology is for rich people, public engagement in psychology
- Aberdeen Sceptics Lecture: Are most positive findings in psychology false? Public engagement in psychology.
- Carnegie Public Lecture: Why routine screening doesn't reduce depression in the community, University of Stirling.
- Café Scientifique: A sceptical look at positive psychology, public engagement lecture and discussion, Inverness.
- Maurice Bloch Lecture, Institute for Health & Well-being, University of Glasgow

2

PART 2: PUBLICATIONS

NMAHP-RESEARCH UNIT PUBLICATIONS 2010-2017



- Ali, M., MacIsaac, R., Quinn, T., Bath, P., Veenstra, D., Xu, Y., Brady, M., Patel, A., Lees, K. and on behalf of the VISTA Collaborators. (2017) Dependency and health utilities in stroke: Data to inform cost-effectiveness analyses. *European Journal of Stroke* (in Press).
- Arba, F., Ali, M., Quinn, T., Hankey, G., Lees, K., Inzitari, D. and VISTA Collaboration. (2017) Lacunar Infarcts, Depression, and Anxiety Symptoms One Year after Stroke. *25* (4), pp. 831-834.
- Avenell, A., Stewart, F., Boyers, D., Douglas, F., Archibald, D., van Teijlingen, E., Hoddinott, P. and Boachie, C. (2017) Sex can affect participation, engagement, and adherence in trials (letter). *Bmj*, 355.
- Berlin, N., Goldzahl, L., Bauld, L., Hoddinott, P. and Berlin, I. (2017) Public acceptability of financial incentives to reward pregnant smokers who stop smoking: a United Kingdom - France comparison. *European Journal of Health Economics* (in Press).
- Dall, P., Stark, D. and Hagen, S. (2017) Training physiotherapists to use the Pelvic Organ Prolapse Quantification (POP-Q) system. *Journal of Pelvic Obstetric and Gynaecological Physiotherapy* (in Press).
- Forbes, G., Loudon, K., Treweek, S., Taylor, S. and Eldridge, S. (2017) Understanding the applicability of results from primary care trials: lessons learned from applying PRECIS-2 *J Clin Epidemiol* (e-Pub Ahead of Print) Doi: 10.1016/j.jclinepi.2017.06.007.
- Hagen, S. (2017) Should we screen for prolapse symptoms in primary care? *BJOG: An International Journal of Obstetrics & Gynaecology*, 124 (3), pp. 520.
- Hagen, S., Glazener, C., McClurg, D., Macarthur, C., Elders, A., Herbison, P., Wilson, D., Toozs-Hobson, P., Hemming, C., Hay-Smith, J., Collins, M., Dickson, S. and Logan, J. (2017) Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial. *The Lancet*, 389 (10067), pp. 393-402.
- Hoddinott, P., Dombrowski, S., van der Pol, M., Kee, F., Grindle, M., Gray, C., Avenell, A. and McKinley, M. on behalf of the research team. (2017) Opportunities and pitfalls encountered when using the template for intervention description and replication (TIDIER) to develop a complex intervention to reduce obesity in men. *Trials*, 18 (suppl 1), pp. 249.
- Loudon, K., Zwarenstein, M., Sullivan, F., Donnan, P., Gágyor, I., Hobbelen, H., Althabe, F., Krishnan, J. and Treweek, S. (2017) The PRECIS - 2 tool has good inter - rater reliability and reasonable discriminant validity. *J Clin Epidemiol*, 16 (30601-1), pp. S0895-4356.
- MacIsaac, R., Ali, M., Taylor-Rowan, M., Rodgers, H., Lees, K., Quinn, T. and VISTA Collaborators. (2017) Use of a 3-Item Short-Form Version of the Barthel Index for Use in Stroke: Systematic Review and External Validation. *Stroke*, 48 (3), pp. 618-623.
- McClurg, D., Goodman, K., Hagen, S., Harris, F., Treweek, S., Emmanuel, A., Norton, C., Coggrave, M., Doran, S., Norrie, J., Donnan, P., Mason, H. and Manoukian, S. (2017) Abdominal massage for neurogenic bowel dysfunction in people with multiple sclerosis (AMBER - Abdominal Massage for Bowel Dysfunction Effectiveness Research)-study protocol for a randomised controlled trial. *Trials*, 18, pp. 150.

Pollock, A., Campbell, P., Brunton, G., Hunt, H. and Estcourt, L. (2017) Selecting and implementing overview methods: implications from five exemplar overviews. *Systematic Reviews* (e-Pub Ahead of Print) Doi: 10.1186/s13643-017-0534-3, *Systematic Reviews*.

Pollock, A., Campbell, P., Deery, R., Fleming, M., Rankin, J., Sloan, G. and Cheyne, H. (2017) A systematic review of evidence relating to clinical supervision for nurses, midwives and allied health professionals. *J Adv Nurse* (e-Pub Ahead of Print) Doi: 10.1111/jan.13253.

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Riemsma, R., Hagen, S., Kirschner-Hermanns, R., Norton, C., Wijk, H., Andersson, K., Chapple, C., Spinks, J., Wagg, A., Hutt, E., Misso, K., Deshpande, S., Kleijnen, J. and Milsom, I. (2017) Can incontinence be cured? - A systematic review of cure rates. *BMC Medicine*, 15 (1), pp. 63.

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Shepherd, A., Mackay, W. and Hagen, S. (2017) Washout policies in long-term indwelling urinary catheterisation in adults. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD004012. DOI: 10.1002/14651858.CD004012.pub5.

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Wells, M., Aitchison, P., Harris, F., Ozakinci, G., Radley, A., Bauld, L., Entwistle, V., Munro, A., Haw, S., Culbard, B. and Williams, B. (2017) Barriers and facilitators to smoking cessation in a cancer context: A qualitative study of patient, family and professional views. *BMC Cancer* (in Press).

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Zwarenstein, M., Treweek, S. and Loudon, K. (2017) PRECIS-2 helps researchers design more applicable RCTs while CONSORT Extension for Pragmatic Trials helps knowledge users decide whether to apply them. *Journal of Clinical Epidemiology* (e-Pub Ahead of Print) Doi: 10.1016/j.jclinepi.2016.10.010.

- Arba, F., Quinn, T., Hankey, G., Inzitari, D., Ali, M. and Lees KR on behalf of the VISTA Collaboration. (2017) Cerebral small vessel disease, medial temporal lobe atrophy and long-term cognitive status in patients with ischaemic stroke and transient ischaemic attack. *European Journal of Neurology*, 24 (2), pp. 276-282.
- Armstrong, L., Shepherd, A. and Harris, F. (2017) An evaluation of methods used to teach quality improvement to undergraduate healthcare students to inform curriculum development within pre-registration nurse education: a systematic review and narrative synthesis. *International Journal of Nursing Studies* (e-Pub Ahead of Print) Doi: 10.1016/j.ijnurstu.2017.05.005.
- Astbury, R., Shepherd, A. and Cheyne, H. (2017) Working in partnership: the application of shared decision-making to health visitor practice. *Journal of Clinical Nursing*, 26 (1-2), pp. 215-244.
- Colquhoun, H., LaMontagne, M., Fiander, M., Duncan, E. and Grimshaw, J. (2017) A systematic review of interventions to increase the use of standardized outcome measures by rehabilitation professionals *Clinical Rehabilitation*, 31 (3), pp. 299-309.
- Cunningham, M. and Wells, M. (2017) Qualitative Analysis of 6961 free-text comments from the first National Cancer Patient Experience Survey in Scotland. *BMJOpen* (e-Pub Ahead of Print) Doi: 10.1136/bmjopen-2016-015726.
- Stead, M., Parkes, T., Nicoll, A., Wilson, S., Burgess, C., Eadie, D., Fitzgerald, N., Mckell, J., Reid, G., Jepson, R., McAteer, J. and Bauld, L. (2017) Delivery of alcohol brief interventions in community-based youth work settings: exploring feasibility and acceptability in a qualitative study. *BMC Public Health*, 17, pp. 357.
- Uny, I., France, E. and Noblit, G. (2017) Steady and delayed: explaining the different development of meta-ethnography in health care and education. *Ethnography and Education*, 12 (2), pp. 243-257.
- Wells, M. and King, E. (2017) Patient Adherence to Swallowing Exercises in Head and Neck Cancer. *Current Opinion in Otolaryngology & Head & Neck Surgery* (e-Pub Ahead of Print) Doi: 10.1097/MOO.0000000000000356.

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Dumoulin, C., Hunter, K., Moore, K., Bradley, C., Burgio, K., Hagen, S., Imamura, M., Thakar, R., Williams, K. and Chambers, T. (2016) Conservative Management for female urinary incontinence and pelvic organ prolapse Review 2013: Summary of the 5th International Consultation on Incontinence. *Neurourology and Urodynamics*, 35 (1), pp. 15-20.

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- louafkaoui, P., Young, L., Newlands, R., Duncan, E.M., Elders, A., Clarkson, J.E. and Ramsay, C.R. (2016) An Audit and Feedback Intervention for Reducing Antibiotic Prescribing in General Dental Practice: The RAPiD Cluster Randomised Controlled Trial. *PLoS Med*, 13 (8), pp. e1002115.
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- Frost, R., McClurg, D., Brady, M. and Williams, B. (2016) Optimising the validity and completion of adherence diaries; a multiple case study and randomised crossover trial. *Trials*, 17 (1), pp. 489.
- Glazener, C., Constable, L., Hemming, C., Breeman, S., Elders, A., Cooper, K., Freeman, R., Smith, A., Hagen, S., McDonald, A., McPherson, G., Montgomery, I., Kilonzo, M., Boyers, D., Goulao, B. and Norrie, J. (2016) Two parallel, pragmatic, UK multicentre, randomised controlled trials comparing surgical options for upper compartment (vault or uterine) pelvic organ prolapse (the VUE Study): study protocol for a randomised controlled trial *Trials*, 17, pp. 441.
- Glazener, C., Breeman, S., Elders, A., Hemming, C., Cooper, K., Freeman, R., Smith, A., Reid, F., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., McDonald, A., McPherson, G., MacLennan, G., Norrie, J. and [for the PROSPECT study group]. (2016) Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). *The Lancet*, 389 (10067), pp. 381-392.
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- Hagen, S., Stark, D. and Dougall, I. (2016) A survey of prolapse practice in UK women's health physiotherapists: what has changed in the last decade? *Int Urogynecol J*, 27 (4), pp. 579-585.
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- Levati, S., Campbell, P., Frost, R., Dougall, N., Wells, M., Donaldson, C. and Hagen, S. (2016) Optimisation of complex health interventions prior to a randomised controlled trial: a scoping review of strategies used. *Pilot and Feasibility Studies*, 2, pp. 17.

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Details of publications in the top 5% of all research outputs scored by Altmetric

Altmetric assigns each publication a coloured donut; the donut gives a quick visual indicator of the attention a publication has received. The number inside the donut is the 'attention score'. The colours around the donut edge indicate the type of mentions.

There is no formal method to say what a 'good score' is, but in general, if an article scores 20 or more then it's doing far better than most of its contemporaries

(<https://help.altmetric.com/support/solutions/articles/6000060970-putting-the-altmetric-attention-score-in-context>).

The information below gives details of the publications with scores in the top 5% of Altmetric scores. The also includes shows the ranking of each publication's score in comparison to publications from the same journal.



Brady, M. C., Kelly, H., Godwin, J., Enderby, P., & Campbell, P. (2016). Speech and language therapy for aphasia following stroke. *Cochrane Database of Systematic Reviews*, 6, Art. No.: CD000425. doi:10.1002/14651858.CD000425.pub4

- In the top 1% of all research outputs scored by Altmetric



Pollock, A., Campbell, P., Deery, R., Fleming, M., Rankin, J., Sloan, G., & Cheyne, H. (2017). A systematic review of evidence relating to clinical supervision for nurses, midwives and allied health professionals. *Journal of Advanced Nursing*, 73(8), 1825–1837. doi:10.1111/jan.13253

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- One of the highest-scoring outputs for its age in this journal: #2



Robertson, R., Robertson, A. R. R., Jepson, R., & Maxwell, M. (2012). Walking for depression or depressive symptoms: a systematic review and meta-analysis. *Mental Health and Physical Activity (MENPA)*, 5(1), 66-75. doi:10.1016/j.mhpa.2012.03.002

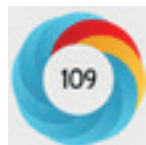
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Luce, A., Cash, M., Hundley, V., Cheyne, H., van Teijlingen, E., & Angell, C. (2016). "Is it realistic?" the portrayal of pregnancy and childbirth in the media. *BMC Pregnancy and Childbirth*, 16(1), 40. doi:10.1186/s12884-016-0827-x

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Details of publications in the top 5% of all research outputs scored by Altmetric



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Glazener, C. M. A., Breeman, S., Elders, A., Hemming, C., Cooper, K. G., Freeman, R. M., . . . Norrie, J. (2016). Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). *The Lancet*, 389(10067), 381-392. doi:10.1016/S0140-6736(16)31596-3

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Fitzgerald, N., Angus, K., Elders, A., Andrade, M., Raistrick, D., Heather, N., & McCambridge, J. (2016). Weak evidence on nalmefene creates dilemmas for clinicians and poses questions for regulators and researchers. *Addiction*, 111(8), 1477-1487. doi:10.1111/add.13438

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Fearn, N., Kelly, J., Callaghan, M., Graham, K., Loudon, L., Harbour, R., . . . Treweek, S. (2016). What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. *BMC Health Services Research*, 16, 74. doi:10.1186/s12913-016-1319-4

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- Highest-scoring output for its age in this journal: #1

Details of publications in the top 5% of all research outputs scored by Altmetric



Haddow, G., King, E., Kunkler, I., & McLare, D. (2015). Cyborgs in the Everyday: Masculinity and Biosensing Prostate Cancer. *Science as Culture*, 24(4), 484-506. doi:10.1080/09505431.2015.1063597

- In the top 2% of all research outputs scored by Altmetric
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Eldridge, S., Chan, C., Campbell, M., Bond, C., Hopewell, S., Thabane, L., . . . Tugwell, P. (2016). CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies*, 2, 64. doi:10.1186/s40814-016-0105-8

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- Highest-scoring output for its age in this journal: #1



Eldridge, S., Chan, C., Campbell, M., Bond, C., Hopewell, S., Thabane, L. L. G., . . . Tugwell, P. (2016). CONSORT 2010 Statement: extension to randomised pilot and feasibility trials. *British Medical Journal*, 335, i5239. doi:10.1136/BMJ.i5239

- In the top 2% of all research outputs scored by Altmetric



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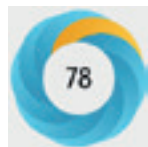
- In the top 2% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2



Shepherd, A. J., Cheyne, H., Kennedy, S., McIntosh, C., Style, s. M., & Niven, C. A. (2010). The Purple Line as a measure of labour progress. A longitudinal Study. *BMC Pregnancy and Childbirth*, 10, 54. doi:10.1186/1471-2393-10-54

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- One of the highest-scoring outputs for its age in this journal: #2

Details of publications in the top 5% of all research outputs scored by Altmetric



O’Cathain, A., Hoddinott, P., Lewin, S., Thomas, K. J., Young, B., Adamson, J., . . . Donovan, J. L. (2015). Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot and Feasibility Studies*, 1, 32. doi:10.1186/s40814-015-0026-y

- In the top 2% of all research outputs scored by Altmetric
- Highest-scoring output from this journal: #1



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- In the top 2% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1



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- In the top 2% of all research outputs scored by Altmetric



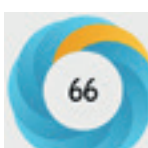
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- In the top 2% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1



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- In the top 2% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2



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Details of publications in the top 5% of all research outputs scored by Altmetric



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- In the top 2% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1



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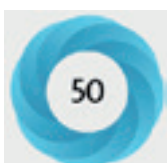
Worrall, L., Simmons-Mackie, N., Wallace, S., Rose, T., Hallowell, B., Kong, A., . . . Brady, M. C. (2016). "Let's call it "aphasia": Rationales for eliminating the term "dysphasia". *International Journal of Stroke*, 11(8), 848-851. doi:10.1177/1747493016654487

- In the top 3% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1



Pollock, A., Campbell, P., Baer, G., Choo, P. L., Morris, J., & Forster, A. (2015). User-involvement in a Cochrane systematic review: using structured methods to enhance the clinical relevance, usefulness and usability of a systematic review update. *Systematic Reviews*, 4, 55. doi:10.1186/s13643-015-0023-5

- In the top 3% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #3



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- In the top 3% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1

Details of publications in the top 5% of all research outputs scored by Altmetric



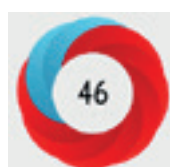
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- In the top 3% of all research outputs scored by Altmetric



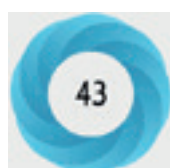
Pollock, A., Baer, G., Campbell, P., Choo, P. L., Forster, A., Morris, J., . . . Langhorne, P. (2014). Physical rehabilitation approaches for the recovery of function and mobility following stroke. *Cochrane Database of Systematic Reviews*, 4, Art. No.: CD001920. doi:10.1002/14651858.CD001920.pub3

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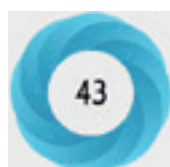
Glazener, C., Elders, A., MacArthur, C., Lancashire, R. J., Herbison, P., Hagen, S., . . . Wilson, D. (2013). Childbirth and prolapse: long term associations with the symptoms and objective measurement of pelvic organ prolapse. *BJOG: An International Journal of Obstetrics and Gynaecology*, 120(2), 161-168. doi:10.1111/1471-0528.12075

- In the top 3% of all research outputs scored by Altmetric



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- In the top 3% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2



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- In the top 3% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #3



Hoddinott, P. (2015). A new era for intervention development studies. *Pilot and Feasibility Studies*, 1, 36. doi:10.1186/s40814-015-0032-0

- In the top 3% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1

Details of publications in the top 5% of all research outputs scored by Altmetric



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- In the top 3% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #5



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- In the top 4% of all research outputs scored by Altmetric



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- In the top 4% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #5



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- In the top 4% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2



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- Highest-scoring output for its age in this journal: #1



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- In the top 4% of all research outputs scored by Altmetric
- Highest-scoring output from this journal: #1

Details of publications in the top 5% of all research outputs scored by Altmetric



Brady, M. C., Frederick, A., & Williams, B. (2013). People with aphasia: capacity to consent, research participation and intervention inequalities. *International Journal of Stroke*, 8(3), 193-196. doi:10.1111/j.1747-4949.2012.00900.x

- In the top 4% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1



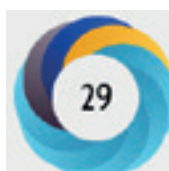
Harris, F. M., Maxwell, M., O'Connor, R., Coyne, J. C., Arensman, E., Coffey, C., . . . Hegerl, U. (2016). Exploring synergistic interactions and catalysts in complex interventions: longitudinal, mixed methods case studies of an optimised multi-level suicide prevention intervention in four European countries (Ospi-Europe). *BMC Public Health*, 16, 268. doi:10.1186/s12889-016-2942-z

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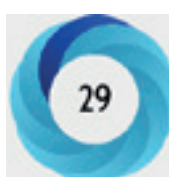
MacArthur, C., Wilson, D., Herbison, P., Lancashire, R. J., Hagen, S., Toozs-Hobson, P., . . . Glazener, C. (2016). Urinary incontinence persisting after childbirth: extent, delivery history and effects in a 12 year longitudinal cohort study. *BJOG: An International Journal of Obstetrics and Gynaecology*, 123, 1022-1029. doi:10.1111/1471-0528.13395

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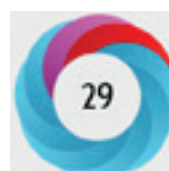
Dougall, N., Maayan, N., Soares-Weiser, K., McDermott, L. M., & McIntosh, A. (2015). Transcranial magnetic stimulation (TMS) for schizophrenia. *Cochrane Database of Systematic Reviews*, 8, Art no.: CD006081. doi:10.1002/14651858.CD006081.pub2

- In the top 4% of all research outputs scored by Altmetric



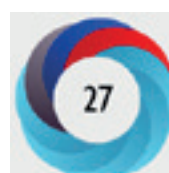
Avenell, A., Robertson, C., Boachie, C., Stewart, F., Archibald, D., Douglas, F., . . . van Teijlingen, E. (2016). Sex based subgroup differences in randomized controlled trials: empirical evidence from Cochrane meta-analyses (letter). *British Medical Journal*, 355. doi:10.1136/bmj.i5826

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Hoddinott, P., Morgan, H., MacLennan, G., Sewel, K., Thomson, G., Bauld, L., . . . Campbell, M. (2014). Public acceptability of financial incentives for smoking cessation in pregnancy and breastfeeding: a survey of the British public. *BMJ Open*, 4(7), e005524. doi:10.1136/BMJopen-2014-005524

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Details of publications in the top 5% of all research outputs scored by Altmetric



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- In the top 4% of all research outputs scored by Altmetric



France, E. F., Ring, N., Thomas, R., Noyes, J., Maxwell, M., & Jepson, R. A. (2014). A methodological systematic review of what's wrong with meta-ethnography reporting. *BMC Medical Research Methodology*, 14, 119. doi:10.1186/1471-2288-14-119

- In the top 4% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1



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- Highest-scoring output for its age in this journal: #1



Mercer, S. W., Jani, B. D., Maxwell, M., Wong, S. Y. S., & Watt, G. C. M. (2012). Patient enablement requires physician empathy: a cross-sectional study of general practice consultations in areas of high and low socioeconomic deprivation in Scotland. *BMC Family Practice*, 13, 6. doi:10.1186/1471-2296-13-6

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- One of the highest-scoring outputs for its age in this journal: #2



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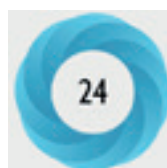
- In the top 5% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1

Details of publications in the top 5% of all research outputs scored by Altmetric



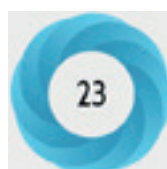
Symon, A., Pringle, J., Cheyne, H., Downe, S., Hundley, V., Lee, E., . . . van Teijlingen, E. (2016). Midwifery-led antenatal care models: mapping a systematic review to an evidence-based quality framework to identify key components and characteristics of care. *BMC Pregnancy and Childbirth*, 16(1), 168. doi:10.1186/s12884-016-0944-6

- In the top 5% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #5



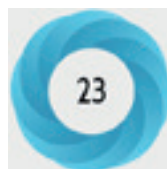
Colquhoun, H., LaMontagne, M., Fiander, M., Duncan, E. A. S., & Grimshaw, J. (2017). A systematic review of interventions to increase the use of standardized outcome measures by rehabilitation professionals. *Clinical Rehabilitation*, 31(3), 299-309. doi:10.1177/0269215516644309

- In the top 5% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2



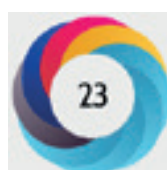
Bowers, J., & Cheyne, H. (2016). Reducing the length of postnatal hospital stay: implications for cost and quality of care. *BMC Health Services Research*, 16(1), 16. doi:10.1186/s12913-015-1214-4.

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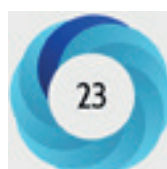
Thomson, G., Crossland, N., Morgan, H., Bauld, L., Dykes, F., & Hoddinott, P. (2014). Unintended Consequences of Incentive Provision for Behaviour Change and Maintenance around Childbirth. *Plos One*, 9(10), e111322. doi:10.1371/journal.pone.0111322

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Glazener, C., Boachie, C., Buckley, B., Cochran, C., Dorey, G., Grant, A., . . . N'Dow, J. (2011). Urinary incontinence in men after formal one-to-one pelvic-floor muscle training following radical prostatectomy or transurethral resection of the prostate (MAPS): two parallel randomised controlled trials. *The Lancet*, 378(9788), 328-337. doi:10.1016/S0140-6736(11)60751-4

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Doi, L., Jepson, R., & Cheyne, H. (2015). A realist evaluation of an antenatal programme to change drinking behaviour of pregnant women. *Midwifery*, 31(10), 965-972. doi:10.1016/j.midw.2015.06.007

- In the top 5% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2

Details of publications in the top 5% of all research outputs scored by Altmetric



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- In the top 5% of all research outputs scored by Altmetric



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- In the top 5% of all research outputs scored by Altmetric



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- In the top 5% of all research outputs scored by Altmetric



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- In the top 5% of all research outputs scored by Altmetric



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- In the top 5% of all research outputs scored by Altmetric
- One of the highest-scoring outputs for its age in this journal: #2



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- In the top 5% of all research outputs scored by Altmetric



Allan, J. L., Farquharson, B., Johnston, D. W., Jones, M. C., Choudhary, C. J., & Johnston, M. (2014). Stress in telephone helpline nurses is associated with failures of concentration, attention and memory, and with more conservative referral decisions. *British Journal of Psychology*, 105(2), 200-213. doi:10.1111/bjop.12030

- In the top 5% of all research outputs scored by Altmetric
- Highest-scoring output for its age in this journal: #1

Details of publications in the top 5% of all research outputs scored by Altmetric



Cook, J. A., Elders, A., Boachie, C., Bassinga, T., Fraser, C., Altman, D. G., . . . MacLennan, G. S. (2015). A systematic review of the use of an expertise-based randomised controlled trial design. *Trials*, 16, 241. doi:10.1186/s13063-015-0739-5

- In the top 5% of all research outputs scored by Altmetric



Lowrie, R., Morrison, G., Lees, R., Grant, C. H., Johnson, C., MacLean, F., . . . Macdonald, S. (2015). Research is 'a step into the unknown': an exploration of pharmacists' perceptions of factors impacting on research participation in the NHS. *BMJ Open*, 5, e009180. doi:10.1136/BMJ-Open-2015-009180

- In the top 5% of all research outputs scored by Altmetric

Publications cited in online policy documents

It can be difficult to determine the influence of research work on policy. Altmetric monitors a number of online policy documents and so allows some citing of NMAHP publications to be identified but does not include all possible policy documents. We have added some further known policy documents in the field of stroke to this altmetric analysis.



Herd, C., Tomlinson, C. L., Deane, K. H. O., Brady, M. C., Smith, C., & Clarke, C. E. (2012). Comparison of speech and language therapy techniques for speech problems in Parkinson's disease. *Cochrane Database of Systematic Reviews*, 2, Art. No.: CD002814. doi:10.1002/14651858.CD002814

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Parkinson's disease in adults: Appendix G - Excluded studies, 2017, <https://www.nice.org.uk/guidance/ng71/evidence>



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