

NMAHP Trialists

The Unit has developed a critical mass of **NMAHP Trialists** to support methodological developments in randomised controlled trials, including economic evaluation, of complex interventions relevant to the nursing, midwifery or allied health professions. Our trials are supported by the:

- **Trial Management Group:** consists of highly experienced trial managers and researchers
- **Quantitative Methods Group:** consists of experienced statisticians and data analysts
- **Qualitative Trialists:** researchers who use their qualitative skills to support the development of interventions; understanding of trial implementation; and understanding of trial outcomes.

Selected methodological publications:

- Cook, J., Elders, A., Boachie, C., Bassinga, T., Fraser, C., Altman, D., Boutron, I., Ramsay, C. and MacLennan, G. (2015) A systematic review of the use of an expertise-based randomised controlled trial design. *Trials*, 16, pp. 241.
- 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.
- Murray, J., Williams, B., Hoskins, G., Skar, S., McGhee, J., Treweek, S., Sniehotta, F., Sheikh, A., Brown, G., Hagen, S., Cameron, L., Jones, C. and Gauld, D. (2016) An interdisciplinary approach to developing visually mediated interventions to change behaviour; an asthma and physical activity intervention exemplar. *Pilot and Feasibility Studies (in Press)*.
- O’Cathain, A., Hodkinson, 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. Abstract only from doi: 10.1186/1745-6215-16-S2-O88.
- 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., 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.

Unit background:

The Nursing, Midwifery and Allied Health Professions Research Unit (NMAHP RU) is a multidisciplinary national research unit, funded by the Scottish Government Health Directorate Chief Scientist Office (CSO). It has academic bases within Glasgow Caledonian University and the University of Stirling.

Research programmes:

NMAHP RU focuses its activity on strong programmes of research that will impact on NMAHP practice and benefit patient and population health. These are: Interventions and Quality and Delivery of Care. This leaflet provides information on the Interventions Programme. Further information on the Quality and Delivery of Care Programme is available at www.nmahp-ru.ac.uk.

Find out more:

The Unit has a website: www.nmahp-ru.ac.uk

Here you can find details on all our recent research projects and publications and keep up to date with our latest news.

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Nursing, Midwifery and Allied Health Professions Research Unit

Interventions Programme

The main remit of this programme (Figure) is to evaluate NMAHP interventions, provide evidence of effectiveness, inform NMAHP practice and thereby improve patient outcomes.

The methodological work of the Interventions programme underpins evidence stages by improving effectiveness and efficiency. Progressive methodological approaches are used in the development and modelling of complex interventions within NMAHP clinical settings and maximising adherence to interventions so as to optimise impact.

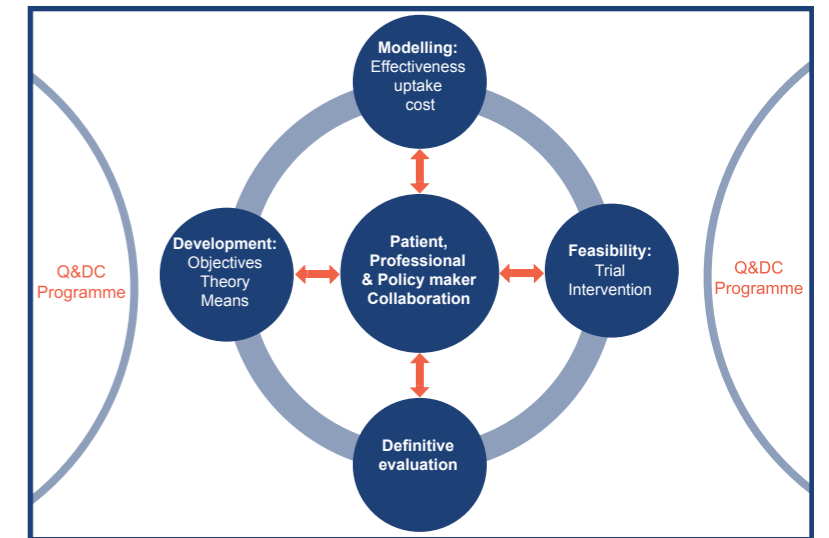


Figure: Interventions programme

Strategic aims:

- To undertake research (primary, secondary and implementation research) which addresses the effectiveness of NMAHP interventions in the NMAHP RU’s priority areas, with the ultimate aim of achieving health gain for the Scottish population and beyond.
- To undertake methodological research which improves our ability to successfully and efficiently evaluate NMAHP interventions and to maximise likely impact.
- To engage in cross-programme working with the NMAHP RU’s Quality & Delivery of Care programme to enhance our research in the phases of intervention development and translation of evidence relating to effective interventions.

Achieving impact:

The Interventions programme capitalises on commissioned calls, priority setting information and other opportunities in pursuing impact on practice with research undertaken. The following criteria are used to ensure maximum impact:

- selecting high impact areas
- within NMAHP domains
- with potential for future implementation
- with high patient priority
- relevant to policy
- value for money



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Improving health through research

Examples of current projects:

Early phase theory building, intervention development and feasibility trials

Systematic reviews

Systematic reviews to synthesise current evidence are a fundamental initial stage for workstreams within the Interventions programme, and NMAHP RU has specific expertise relating to systematic reviews of complex nursing and rehabilitation interventions. NMAHP RU is highly experienced in synthesising quantitative and qualitative evidence covering a range of clinical areas and interventions. We produce and maintain a high number of Cochrane systematic reviews, and are a lead producer of Cochrane systematic reviews of stroke rehabilitation interventions. NMAHP RU has growing expertise in overviews (reviews of reviews), leading the first overviews completed by Cochrane Stroke Group and Cochrane Incontinence Group, and developing innovative methodological solutions to the challenges of this evolving review method. NMAHP RU have implemented novel strategies to actively involve patients, carers and health professionals in carrying out systematic reviews, to ensure that synthesised evidence is accessible and clinically relevant. Ongoing work in collaboration with Cochrane Consumers and Cochrane Training seeks to establish resources to support effective and meaningful public involvement within systematic reviews.

Patient Centred Assessment Method (PCAM)

This study will assess the feasibility for conducting a cluster RCT in primary care settings of the PCAM intervention. This intervention aims to enable practice nurses to conduct a biopsychosocial assessment of the needs of patients living with long term conditions (particularly needs that may hinder patient engagement in better self-care) and to develop an action plan to address these needs.



Recovery versus Mindfulness models for Depression (ReMoDe)

Guidelines support early intervention for recurrence of depression with pharmacological and psychological interventions, including Mindfulness Based Cognitive Therapy (MBCT) usually delivered via NHS settings. Self-help peer support, such as Wellness Recovery Action Planning (WRAP), has become an increasingly important approach in recovery from depression. WRAP offers care and support through voluntary input of non-professionals in their delivery and offers a potentially cost-effective mechanism. ReMoDe is a feasibility study leading to a trial of the effectiveness of MBCT versus WRAP in comparing outcomes, delivery, sustainability and cost-benefits.



Secondary uses of data

Use of a trial repository to establish scale of clinical problems and need for intervention

VISTA-Rehab is part of the Virtual International Stroke Trials Archive (VISTA). The aim of the project is to collate anonymised data from completed stroke trials and provide access to these data to investigators for novel exploratory analyses. The archive has 8 sections, each focussing on a specific part of stroke research; VISTA-Rehab is the section which deals with stroke rehabilitation. Currently, there are few effective therapies for stroke. The development of interventions takes time and money and may not result in a positive outcome. By using data from existing resources such as VISTA-Rehab to answer research questions, pilot design methods and assess feasibility, stroke researchers can make informed decisions before proceeding to costly randomised controlled trials.



REhabilitation and recovery of peopLE with Aphasia after StrokeE (RELEASE)

Aphasia (impairment of language post-stroke) impacts on the ability to speak, understand speech, read and write and affects approximately one third of stroke survivors. As a result of our recent research we know that speech and language therapy for aphasia after stroke improves language recovery. However, the specific patient, stroke, aphasia and therapy factors which optimize recovery and rehabilitation are unclear. The aim of the NIHR funded RELEASE project (HS&DR-1404/22) is to create a large, international database of individual participant datasets (>2500) from pre-existing aphasia research to determine the extent that individual stroke, aphasia and intervention characteristics contribute to recovery. Using the results of this project we hope to progress our understanding of how to maximise recovery by optimising speech and language interventions to suit specific groups of stroke survivors with aphasia after stroke.



Definitive randomised controlled trials

Optimising pelvic floor exercises to achieve long-term benefits (OPAL)

Intensive pelvic floor muscle training (PFMT) may be more effective than basic PFMT for female stress and mixed urinary incontinence (UI), but how best to intensify PFMT, to optimise benefit, is unclear. Adding biofeedback is one option which shows potential but the research evidence is unclear. We address this uncertainty in the OPAL multicentre trial by investigating the clinical and cost-effectiveness of basic PFMT versus biofeedback-mediated intensive PFMT. We hypothesise biofeedback will increase PFMT adherence and effectiveness, leading to greater reductions in UI at 2 years.



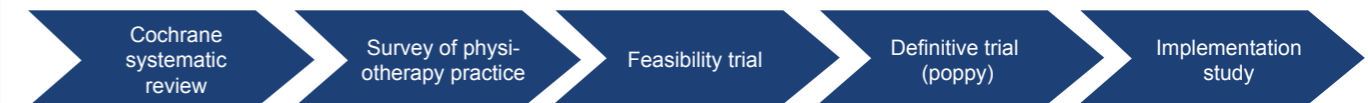
Abdominal Massage for Neurogenic Bowel Dysfunction in People with Multiple Sclerosis (AMBER)

Bowel Dysfunction (constipation and/or faecal incontinence) is common in people with multiple sclerosis (MS), and is rated as the most severe impact of their disease above wheelchair dependence. Despite this, current treatment options are limited, poorly evaluated and complex. The AMBER study is a multicentre, NIHR HTA-funded trial to determine if abdominal massage, undertaken by a carer or the patient themselves, is an effective treatment of constipation in people with MS. There are also qualitative, process evaluation and economical components to the trial which will aid implementation should the intervention prove to be effective. We aim to recruit 200 people with MS to the study with results due in summer 2017.



Pelvic organ prolapse - from systematic review to implementation via definitive trial

One workstream that demonstrates the benefits of taking a long-term focussed approach from inception of an idea through to clinical implementation phase is that of the Pelvic Organ Prolapse portfolio of work. The workstream started with a Cochrane review of prolapse management focusing on Pelvic Floor Muscle Training (PFMT) published in 2004, followed by further Cochrane reviews in tandem with a UK survey, published in 2004, of practice amongst >500 women's health physiotherapists. The survey and review findings informed a feasibility study, which in turn led to a definitive international multicentre trial of PFMT for prolapse (POPPY), carried out between 2007-11. A follow-up survey of practice assessed the impact of the evidence generated, and an implementation study (PROPEL) has now been funded to explore different models of translating the evidence into clinical practice in line with the POPPY trial findings.



Methodological PhD studies

Methods of optimising the development of complex health interventions: exploring existing and potential new modelling approaches

NMAHP interventions are usually complex in nature, with multicentre interacting components, requiring a distinct development phase prior to trial. The aims of this study include identification and developing a taxonomy of modelling techniques and processes currently adopted in the development of complex interventions; to gain researcher accounts regarding experience and associated pros and cons of different techniques; to attempt to link the appropriateness of different modelling approaches to different types of complex health interventions, based on the elements and data gathered to develop the taxonomy; to assess some of the gaps in the evidence base on the validity and usefulness of varied processes identified.

Recruitment to stroke rehabilitation trials

Accurate estimates of recruitment to clinical trials can be challenging. Randomised controlled clinical trials strive to recruit the minimum number of participants required to have confidence in the statistical analysis and trial results. Where recruitment does not progress as planned, trials either extend their recruitment timelines (requiring additional trial funding), are terminated early due to poor recruitment or are completed but their findings are inconclusive. We aim to examine the recruitment rates to stroke rehabilitation trials over the last 10 years and consider the impact of any specific stroke rehabilitation trial characteristics or design features on recruitment. Our findings will inform the development, planning and design of future stroke rehabilitation trials in terms of resources required, timelines and recruitment procedures likely to optimise recruitment.