A Scottish Collaboration of NMAHP Trialists:

The Intervention Programme is involved in supporting trialists in Scotland through a Scottish Collaboration of NMAHP Trialists: aSCeNT

"A cross-disciplinary platform to support methodological developments in randomised controlled trials of complex, nursing, midwifery or allied health professions interventions"

aSCeNT was established in recognition of the challenge of doing NMAHP trials and provides a platform for support and exchange of ideas by NMAHP trialists and methodologists. aSCeNT aims to enhance and optimise methodological approaches to the evaluation of complex NMAHP interventions within RCTs, as well as the development phase leading to RCTs themselves. aSCeNT is led by a vision to maximize valued patient outcomes within the NMAHP domain and prioritises development and support of high quality NMAHP trials, irrespective of the professional or disciplinary background of the trialists themselves.

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. Following the Unit's successful 2010 Scientific Review, its activity was consolidated into two new programmes: 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.

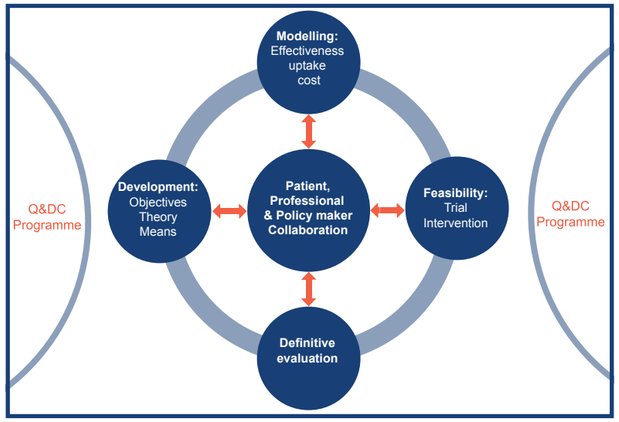


Figure: Interventions programme

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

nmahp-ru
Nursing, Midwifery and Allied Health Professions Research Unit

Improving health through research
CHIEF SCIENTIST OFFICE

Project examples:

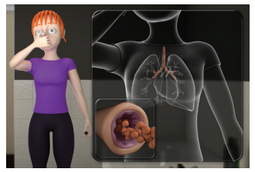
Early phase theory building, intervention development and feasibility trials

Systematic reviews

Systematic reviews to synthesise current evidence are a fundamental initial stage for workstreams within the Interventions programme. NMAHP RU is a lead producer of Cochrane systematic reviews of stroke rehabilitation interventions, and projects have recently included a number of Cochrane reviews relating to upper limb function, aphasia, vision and cognition after stroke. Cochrane Overviews are a relatively new product from the Cochrane Collaboration, and provide a summary of evidence from more than one systematic review. NMAHP RU is completing the first Cochrane overview carried out in collaboration with the Cochrane Stroke Group. This will synthesise all evidence relating to interventions for upper limb problems after stroke as well as highlight important methodological lessons for future NMAHP overviews.

Intervention modelling experiment

Can visualisation encourage physical activity in patients with asthma? Asthma and low physical activity levels could be addressed through the development of an interactive educational visual intervention for use by primary care staff, children with asthma and their parents. A theory-informed animation has been developed to enable young people to visualise lungs, bronchi and the mechanism of asthma as well as the differences between asthma and breathlessness due to inactivity, and the impact of preventer and alleviator inhalers. The animations will be formally evaluated in this study with an intervention modelling experiment prior to a difinitive controlled trial.



Feasibility study

Guidelines support early intervention for recurrence 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 (Recovery versus Mindfulness models for Depression) is a feasibility study leading to a trial of the effectiveness of MBCT versus WRAP in comparing outcomes, delivery, sustainability and cost-benefits.

srn Scottish Recovery Network

ACTION ON DEPRESSION
Scotland's national charity for depression

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.

OPAL
optimising pelvic floor exercises to achieve longterm benefits

Case study: Pelvic organ prolapse - from systematic review to implementation via definitive RCT (POPPY)

One workstream in the Interventions Programme 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 was kick-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 in 2003. The survey and review findings informed a feasibility study, which in turn led to a definitive international multicentre RCT of PFMT for prolapse (POPPY), carried out between 2007-11. An implementation study is in planning to investigate best mechanisms for changing clinical practice in line with the POPPY trial findings.

poppy

Cochrane systematic review → Survey of physiotherapy practice → Feasibility trial → Definitive trial (poppy) → Implementation strategy

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 6 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.

VISTA Rehab

Database Of Research In Stroke (DORIS)

DORIS (www.askDORIS.org) aims to promote evidence based stroke rehabilitation.
This is achieved by enabling easy access to a database of evidence, including national guidelines, systematic reviews and international stroke trials. This database can be interrogated to answer new research questions or answer existing research questions more effectively. DORIS was developed by NMAHP RU, but is now maintained by the Cochrane Stroke Group.

DORIS database of research in stroke

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.

Developing rigorous, accurate and acceptable methods of measuring patient adherence to home or community based allied health professional interventions

The extent to which patients adhere to a therapeutic regimen in clinical trials forms an important part of assessing the acceptability and effectiveness of interventions. However, there is no 'gold-standard' method of measuring patient adherence. This project aims to review the quality of current methods of assessing adherence to prescribed therapeutic regimens; to assess the utility of measurement methods for the different parameters of interventions; to identify gaps within this evidence base; and to develop a valid, reliable and acceptable method of measuring patient adherence to home and community based allied health professional interventions.

Selected methodological publications:

- Williams, B., Coyle, J., Anderson, A., Burrows, E., Barton, K. Can theory be embedded in visual interventions to promote self-management? A proposed model and worked example. *International Journal of Nursing Studies* 2012 49:12 p.1598-609. doi: 10.1016/j.ijnursu.2012.07.005
- Wells, M., Williams, B., Treweek, S., Coyle, J., Taylor, J. Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials* 2012, 13:95 doi:10.1186/1745-6215-13-95
- Hagen, S., Williams, B. 2011, "Trials and Tribulations. Public Service Review", *UK Science and Technology,* no. 4.
- Brady, M. C., Stott, D. J., Norrie, J., Chalmers, C., St George, B., Sweeney, P. M., 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 http://www.trialsjournal.com/content/12/1/168
- Hagen, S., Stark, D., Glazener, C., Sinclair, L., Ramsay, I. A randomised controlled trial of pelvic floor muscle training for stage I and II pelvic organ prolapse. *International Urogynecology Journal.* 2009; 20: 45-51.