

## REVIEW

**Developing complex interventions for nursing: a critical review of key guidelines**

Margarita Corry, Mike Clarke, Alison E While and Joan Lalor

**Aims and objectives.** To identify the most comprehensive approach to developing complex interventions for nursing research and practice.

**Background.** The majority of research in nursing is descriptive and exploratory in nature. There is an increasing professional and political demand for nurses to develop and provide evidence to support their practices. Nurses need to explore current practice and develop and test interventions to provide the evidence required for safe practice.

**Design.** A literature review using a systematic approach.

**Methods.** The review was carried out using four databases: CINAHL, PubMed, PsycINFO and BNI (2000–2011), and the search was limited to ‘brief interventions’ and complex intervention development (January 2000–September 2011). Included papers reported on guidelines for intervention development or ‘how’ an intervention was developed.

**Results.** Six papers reported on guidelines for developing interventions. There are many similarities between the guidelines with a similar pattern of guideline development in Europe and the USA. The only guideline reported to have been used in the development of interventions is the Medical Research Council framework (MRC) (A Framework for Developing and Evaluation of RCTs for Complex Interventions to Improve Health, 2000), with 9 of 14 papers that describe the development of an intervention reporting the use of this guideline. The other five papers did not mention the use of any guideline or framework.

**Conclusions.** The MRC (A Framework for Developing and Evaluation of RCTs for Complex Interventions to Improve Health, 2000) framework appears to be the most widely used guideline reported for developing complex interventions. Although the updated MRC (Developing and Evaluating Complex Interventions, 2008) framework adds considerably to the original MRC (A Framework for Developing and Evaluation of RCTs for Complex Interventions to Improve Health, 2000) framework, other guidelines contribute additional guidance which can inform the development of nursing interventions. These additional guidelines are presented in a model for developing complex interventions for nursing.

**Relevance to clinical practice.** The model will help nurses planning to develop nursing interventions as it provides additional and nursing-specific guidance to the MRC (Developing and Evaluating Complex Interventions, 2008) framework for the development of complex interventions for nursing practice.

**Key words:** complex interventions, frameworks, guidelines, literature review

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## Introduction

As nursing strives to strengthen the evidence base for practice, there is a move away from descriptive and exploratory research to the testing of new interventions and greater use of more evaluative research designs. The current drive for complex interventions is outlined by Richards and Borglin (2011, p. 531) who ‘...urge researchers in nursing to increase the volume of translational research by embracing new complex interventions research methods thinking’. They highlighted the non-benign nature of nursing practice and called for improved knowledge for nursing practice derived from a solid evidence base.

The paradigm war in nursing which has consumed researchers over the past 20 years has waned with the emergence of pragmatism and a greater acceptance of mixed methodologies. Although purists still argue against this, the increasing demands for quality in practice, the need for evidence to support effective practice and political demand for value for money has focused the debate, with researchers under increasing pressure to demonstrate how research outcomes support best practice. The randomised controlled trial (RCT) has long been heralded as the gold standard for research into the effects of interventions (Sackett *et al.* 1997). It is the only research design that allows researchers to ‘balance known and possibly unknown factors’ that may affect research outcomes (Watson *et al.* 2002, p. 132). Research outcomes from RCTs have high credibility and therefore greater potential to influence policy (Watson *et al.* 2002). Much published nursing research is descriptive and exploratory (Richards & Borglin 2011), but these research methodologies cannot provide the strong evidence needed to support well-informed choices based on the likely outcomes of nursing interventions. As in other areas of healthcare practice, nursing interventions must be based on evidence that the interventions and actions being implemented are likely to result in more good than harm. This is especially challenging given the complexity of many nursing activities. It is therefore incumbent on nurses to develop the knowledge and expertise to advance and embrace research methodologies that provide the highest form of evidence to support practice, so that choices are well informed and likely to lead to benefits for service users and society.

In an attempt to progress research in nursing, Richards and Borglin (2011), supported by eight European research funding bodies, urged the development of: ‘... “complex intervention thinking” in both experienced and the next generation of researchers in nursing’ (p. 531). As the drive for the advancement of nursing practice continues and

nurses identify areas of practice that require the development and testing of new procedures, they are looking to other disciplines for guidance on how to develop and test interventions. These disciplines include medicine, where much work has been undertaken regarding the development and testing of complex interventions. However, guidelines developed by other disciplines may not be readily applicable to nursing. Therefore, it is important that nurse researchers are aware of the range of guidelines available to them when developing nursing interventions and that they interpret guidelines produced by other disciplines from a nursing perspective.

## Methods

### Aim

To review published guidelines on the development of complex interventions in order to identify the most comprehensive approach to the development of complex interventions for nursing practice.

### Procedure

A systematic approach was used to identify guidelines for intervention development and to examine how researchers have used guidelines when developing interventions.

### Search strategy

The search was performed by MCo. using the four databases: CINAHL, PubMed, PsycINFO and BNI (2000–2011), in October 2011 and was limited to ‘brief interventions’ and complex intervention development and papers published between January 2000 and September 2011 (see Fig. 1). These search terms were retained as the ones most relevant for the purpose of the review (they captured the guidelines and were the ones most likely to describe the development of an intervention) following a scan of a broader search of the literature using the following search words: intervention, brief interventions, development, complex, testing, which were then combined to generate the following search strings: ‘intervention development’, ‘intervention testing’, ‘complex interventions’, and yielded unmanageable volumes of literature (which produced more than 88,000 hits). Papers that met the following inclusion criteria were selected: papers that described approaches to the development of complex intervention or reported ‘how’ an intervention was developed. All other research methodologies including feasibility and exploratory studies that did not

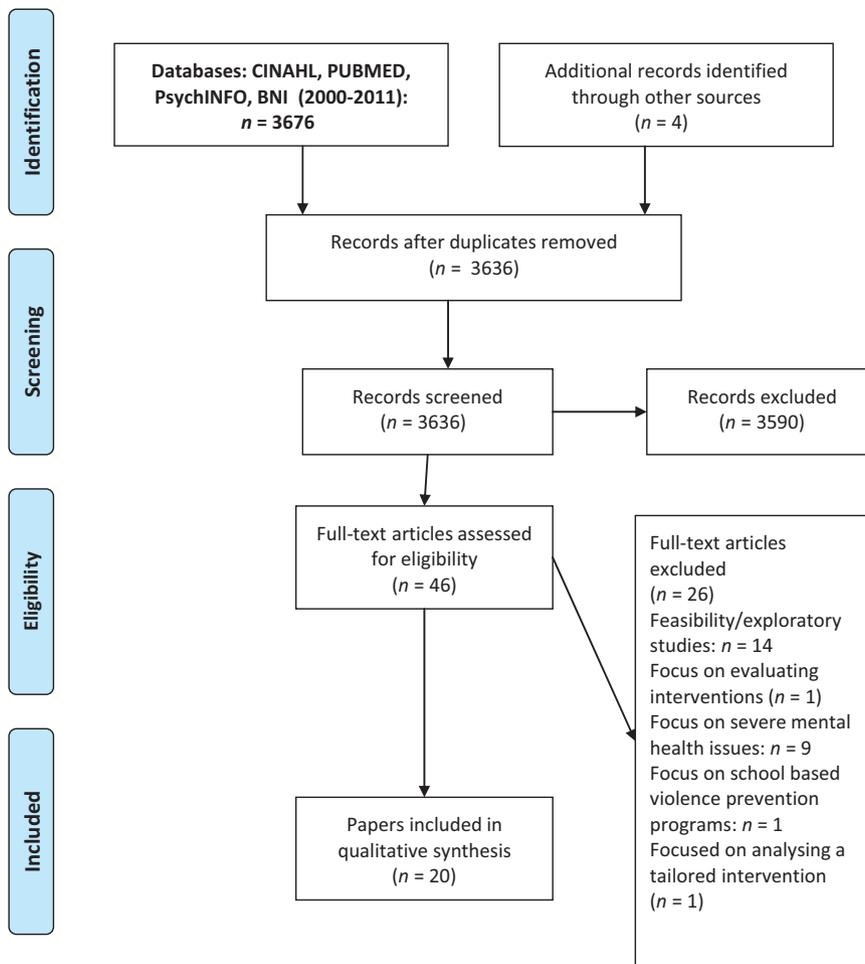


Figure 1 Flow diagram.

report on the process of developing a complex intervention were excluded. Papers that reported the development of complex interventions relating to alcohol or substance abuse, suicide or severe mental illnesses involving multiple professions across healthcare and social care sectors which are unique to mental health were also excluded. The reference lists of the selected papers were hand-searched for additional studies that met the inclusion criteria.

## Results

Six of the twenty papers reported on intervention development (Table 1). Bradley *et al.* (1999) reported on an approach to develop and evaluate complex interventions in health services research. Two reported the use of the Medical Research Council (MRC) framework (Craig *et al.* 2008, Campbell-Yeo *et al.* 2009), and three reported approaches to the development of nursing interventions (Conn *et al.* 2001, Whittemore & Grey 2002, Van Meijel *et al.* 2004). One of the papers was authored in the USA, one in South America and one in the Netherlands.

The development of complex interventions is presented in terms of levels (Bradley *et al.* 1999), phases (Whittemore & Grey 2002, Campbell *et al.* 2007, Craig *et al.* 2008), and stages or building blocks (Van Meijel *et al.* 2004), with Conn *et al.* (2001) providing an overview of the issues for consideration in intervention design (see Table 1).

While the papers differ in presentation, they have many similarities, for example each recommended that attention should be given to the early stages of intervention development. The levels presented by Bradley *et al.* (1999) were echoed and built upon in the frameworks and guidelines of later publications. Over time, however, more emphasis has been placed on the early phase of intervention development and testing and the need to ground the intervention clearly within the descriptive and theoretical research, with greater attention to the process of intervention delivery. For example, the MRC (2000) framework was updated in 2008 to remedy the limitations of the original version which included a less linear approach to evaluation, integration of process and outcome evaluation and tailoring of interventions to local contexts (Craig *et al.*

Table 1 Papers presenting approaches/models to intervention development

| Author, Country, Year                      | Definition   | Details of the guidance/framework  |
|--|--|--|
| Bradley <i>et al.</i> (1999)<br>UK         | Propose three levels for defining a complex intervention: 'the evidence and theory which inform the intervention, the tasks and processes involved in applying the theoretical principles, and the people with whom, and context within which, the intervention is operationalised' (p. 712) | Uses a case study approach to present the 'Southampton heart integrated care programme'<br>Levels:<br>Level 1: theory and evidence underpinning the intervention (e.g. target population, service provision, management of behaviour change within the programme, best practice in enabling behaviour change among practitioners and patients, using guidelines and psychological models<br>Level 2: defines essential tasks and processes required for operationalisation in these areas at a generalisable level<br>Level 3: defines who would do what local elements that are specific to a local setting   |
| Campbell <i>et al.</i> (2007)<br>UK        | Complex interventions are 'built up from a number of components, which may act both independently and interdependently' (Office of National statistics, 2000, cited by Campbell <i>et al.</i> 2007, p. 455)  | Provides suggestions for flexible use of the MRC (2000) framework stepwise approach to intervention development<br>Suggests combining phases 0–2 of the MRC (2000) framework into a large iterative activity, rather than as sequential stages   |
| Conn <i>et al.</i> (2001)<br>South America | No specific definition given   | Provides guidance on the following: <ul style="list-style-type: none"> <li>• Theoretical underpinnings of interventions</li> <li>• Rigorous meta-analysis can inform intervention design and should be considered along with conceptual frameworks</li> <li>• Intervention targeted for population</li> <li>• Intervention specificity/generality and individualised treatments</li> <li>• Single or bundled interventions</li> <li>• Intervention delivery (need to consider): Interventionists (carefully selected attributes); extent of intervention burden imposed on participants; identifying acceptable subject adherence; clarifying mode of delivery; setting for intervention delivery; timing of the intervention; treatment dose issue; duration of delivery; robustness (increase dose); attrition (balance dose/ timing with participant demand and risk of attrition); intervention intensity</li> </ul> |
| Craig <i>et al.</i> (2008)<br>UK           | Complex interventions are: '... interventions that contain several interacting components, but they have other characteristics that evaluators should take into account (outlines them in box 1)' (p. 979)   | Provides details on why the MRC framework guidelines were revised<br>Outlines how the MRC (2008) framework guidelines address the limitations of the MRC (2000) framework guidelines: <ul style="list-style-type: none"> <li>• Greater attention to early phase of piloting and development work; less linear model of evaluation process; integration of process and outcome evaluation; recognition that complex interventions may work best if they are tailored to local contexts rather than completely standardised; &gt; use of the insights provided by the theory of complex adaptive systems</li> <li>• Also recommended methods other than RCT for evaluation of complex interventions</li> </ul>   |

Table 1 (Continued)

| Author, Country, Year                              | Definition   | Details of the guidance/framework   |
|--|--|---|
| Van Meijel <i>et al.</i> (2004)<br>the Netherlands | No definition given  | <p>Presents the model for developing evidence-based nursing interventions by the Nursing Science Department at Utrecht University</p> <p>Model comprises 4 stages (provides a detailed overview of the stages):</p> <ul style="list-style-type: none"> <li>• Problem definition</li> <li>• Accumulation of building blocks for intervention design (problem analysis, needs analysis, current practice analysis)</li> <li>• Intervention design</li> <li>• Intervention validation</li> </ul> <p>Key points: stages are considered building block stages; during the stages, literature review is required; problem analysis, needs analysis, current practice analysis may/may not be necessary; research needs to consider the nature of problem intervention aims to alter; nature of the intervention and stage of knowledge about the intervention and related subject areas</p> |
| Whittemore and Grey (2002)<br>USA                  | No definition given<br>Presents guidelines for nursing interventions (integrating the National Institutes of Health Phases of Clinical Trials (NIH) clinical guidelines with elements specific to nursing interventions) | <p>Presents guidelines for nursing interventions (integrating the National Institutes of Health (NIH) Phases of Clinical Trials clinical guidelines with elements specific to nursing interventions)</p> <p>Phases</p> <p>Phase 1: Basic research (to establish content, strength and timing of intervention, to establish outcome measures)</p> <p>Phase 2: Pilot research (to refine intervention and outcome measures)</p> <p>Phase 3: Efficacy clinical trial (to determine clinical efficacy)</p> <p>Phase 4: Effectiveness clinical trials (to determine clinical effectiveness: analysis of effect in clinical practice; determine clinical utility; cost analysis)</p> <p>Phase 5: Effects on public health (to determine effects on public health). Involves wide-scale implementation</p>   |

2008). In addition, the guidelines recommended the use of a range of methods of evaluation, one of which was the RCT.

A similar pattern of knowledge development using laboratory-type approaches to research into the more complex healthcare environment exists across developed healthcare systems. In South America, Conn *et al.* (2001) set out the principles of nursing intervention design, which were followed up by Whittemore and Grey (2002) drawing upon the biomedical framework of 'The National Institutes of Health Phases of Clinical Trials'

adapted to the nursing context. The National Institutes of Health Phases of Clinical Trials as presented by Whittemore and Grey (2002) differed significantly from that of the MRC (2000) framework. The MRC framework uses the term 'pre-clinical (theoretical)' and has four phases leading to the development and testing of an intervention, while the National Institutes of Health Phases of Clinical Trials presents a four-phased approach to testing a new biomedical or behavioural intervention with no guidance on how to develop the intervention. Whittemore and Grey (2002) emphasised the importance

of grounding the research within theory and previous research. In the Netherlands, Van Meijel *et al.* (2004) published their model for the development and testing of nursing interventions at a similar time. The similarities and differences between the five structured frameworks reported are presented in Table 2.

**Papers reporting on the development of interventions**

The review identified 14 papers that reported the development of interventions rather than setting out general processes ( $n = 8$ , UK;  $n = 3$ , USA;  $n = 1$ , Ireland;  $n = 1$ , the Netherlands;  $n = 1$ , Australia) (see Table 3). The papers fall into two categories, namely interventions designed to provide support to a target population (Finlayson *et al.* 2008, Katz *et al.* 2008, King *et al.* 2009) and management of chronic illness (Hardeman *et al.* 2005, Robinson *et al.* 2005, Blackwood 2006, Byrne *et al.* 2006, Sturt *et al.* 2006, Murchie *et al.* 2007, Alexopoulos *et al.* 2008, Lovell *et al.* 2008, Redfern *et al.* 2008, Faes *et al.* 2010, Reavley *et al.* 2010).

The supportive interventions included an intervention to target behavioural and psychosocial risk factors among pregnant African American women (Katz *et al.* 2008), an educational programme for caregivers of people ageing with MS and continuity of care in patients with cancer (King *et al.* 2009).

The interventions to manage chronic illness included improving treatment adherence and outcomes in chronic

obstructive pulmonary disease (COPD) (Alexopoulos *et al.* 2008), promoting secondary prevention of coronary heart disease (Byrne *et al.* 2006), weaning patients from mechanical ventilation in intensive care (Blackwood 2006), fall prevention (Faes *et al.* 2010), promoting increased physical activity for individuals among those at high risk of type 2 diabetes (Hardeman *et al.* 2005), an integrated follow-up intervention for cutaneous melanoma (Murchie *et al.* 2007) and promoting risk factor management after stroke (Redfern *et al.* 2008).

Nine of the papers referred to the MRC framework for complex interventions (Hardeman *et al.* 2005, Robinson *et al.* 2005, Blackwood 2006, Byrne *et al.* 2006, Sturt *et al.* 2006, Murchie *et al.* 2007, Lovell *et al.* 2008, Redfern *et al.* 2008, Faes *et al.* 2010); five of these were UK studies that used the MRC framework to develop their interventions (Robinson *et al.* 2005, Blackwood 2006, Sturt *et al.* 2006, Murchie *et al.* 2007, Redfern *et al.* 2008), and two indicated their use of the framework (Hardeman *et al.* 2005, Lovell *et al.* 2008). The MRC framework was also used to inform intervention development in studies from Ireland (Byrne *et al.* 2006) and the Netherlands (Faes *et al.* 2010). Five papers reporting the development of interventions did not refer to the MRC framework or specify the use of any other framework to guide the development of the intervention ( $n = 3$ , USA;  $n = 1$ , UK;  $n = 1$ , Australia) (see Table 3). Table 4 describes the use of key components of intervention development (use of literature, use of theory

Table 2 Outline of the guidelines for developing complex interventions (updated from Blackwood 2006)

|  | Bradley et al. 1999  | MRC (2000)                                     | Whittemore and Grey (2002)             | Van Meijel et al. (2004)  | MRC (2008)*   |
|--|--|--|--|---|---|
|  <p><b>KEY COMPONENTS OF THE GUIDELINES</b></p> | Defining the Intervention<br>Level 1: Theory & evidence<br>Level 2: Essential tasks and processes involved | Pre-clinical phase<br>Phase 1: Modelling phase | Phase 1: Basic research                | Problem definition<br>Building blocks<br><ul style="list-style-type: none"> <li>➢ Literature review</li> <li>➢ Problem analysis</li> <li>➢ Needs analysis</li> <li>➢ Practice analysis</li> </ul> | Development<br><ul style="list-style-type: none"> <li>➢ Identifying the evidence base</li> <li>➢ Identifying/developing theory</li> <li>➢ Modelling process &amp; outcomes</li> </ul> |
|  | Level 3: People & contexts<br>Piloting the intervention  | Phase 2: Exploratory trial phase               | Phase 2: Pilot research                | Intervention design<br>Intervention validation  | Feasibility/piloting<br><ul style="list-style-type: none"> <li>➢ Testing procedures</li> <li>➢ Estimating recruitment and retention</li> <li>➢ Determining sample size</li> </ul>     |
|  | Evaluating the intervention<br>RCT and qualitative methods   | Phase 3: Definitive RCT phase                  | Phase 3: Efficacy clinical trial       | RCT   | Evaluation<br><ul style="list-style-type: none"> <li>➢ Assessing effectiveness</li> <li>➢ Understanding the change process</li> <li>➢ Assessing cost-effectiveness</li> </ul>         |
|  |  | Long term implementation Phase                 | Phase 4: Effectiveness clinical trials |   | Implementation<br><ul style="list-style-type: none"> <li>➢ Dissemination</li> <li>➢ Surveillance and monitoring</li> <li>➢ Long term follow-up</li> </ul>                             |
|  |  |  | Phase 5: Effects on public health      |   |   |

RCT: Randomised Controlled Trial  
 \*Series of stages (may not follow a linear or cyclical sequence)

Table 3 Papers reporting on the development of an intervention

| Author, Country, Year                   | Purpose of intervention   | Approach to intervention development  | Comment   |
|---|---|---|---|
| Alexopoulos <i>et al.</i> (2008)<br>USA | To improving treatment adherence and outcomes in COPD   | Review of literature on various aspects of the problem: geriatric depression, need for a behavioural approach, adherence-enhancement intervention in depressed COPD patients, the need for integrated treatment<br>From the above topics devised a treatment model for depression, disability and treatment adherence<br>Preclinical phase  | Does not use a specific framework. Presents the model based on literature reviewed<br>Provides a case example   |
| Blackwood (2006)<br>UK                  | Nurse-led intervention for weaning patients from mechanical ventilation in IC<br>Aims of study: to develop and implement nurse-directed weaning protocols and to evaluate its impact on patient outcomes and nursing practice | Established evidence for implementing nurse-directed protocolised weaning from literature and from this identified the key components of the intervention; explored theories of change and behavioural management and from this made a list of factors deemed critical to successful implementation of clinical change, constructed a checklist of necessary factors to take into account during implementation of the intervention<br>Phase 1 (modelling phase)<br>Used observation (observation of the weaning process with 54 patients where the intervention was to be introduced to assess feasibility of devising protocols); semi-structured interview (with ICU consultants explore their views on weaning, usage of weaning protocols, nursing role in the process. This helped identify aids and barriers to developing weaning protocols and their introduction to practice); questionnaire survey (of ICU nurses to determine their knowledge of weaning (inform education package), attitudes towards the use of protocols in practice and what they considered essential in the weaning protocols)<br>Phase 2 (exploratory phase): exploratory trial employing quasi-experimental, non-equivalent group design. Two ICU (one nurse-led weaning, other traditional approach) | Used the MRC (2000) framework guidelines to develop the intervention<br>Intervention complex because: included practitioner behaviours, parameters of behaviour and methods of organising and delivering those behaviours<br>Provides a background and rationale for the intervention (evidence role of consultant, possible value to weaning protocols (also provides contrary evidence), link to national health service modernisation agency |

Table 3 (Continued)

| Author, Country, Year                 | Purpose of intervention   | Approach to intervention development  | Comment   |
|---------------------------------------|---|---|---|
| Byrne <i>et al.</i> (2006)<br>Ireland | Healthcare intervention to promote secondary prevention of coronary heart disease | <p>Preclinical phase</p> <p>Literature relating to secondary prevention of CHD, outlined key components of previous successful interventions and barriers to the provision and uptake of secondary prevention</p> <p>Looked at theories on health behaviour (theories on lifestyle/behaviour change)</p> <p>Phase 1 (modelling phase)</p> <p>Questions relating to participant experience of and attitude towards key intervention components identified from the literature and findings were used in modelling the pilot intervention; focus group findings confirmed the importance of tailoring the intervention to individual practices and patients; practitioners indicated a need to address the factors of time and financial limitations; findings from exploratory qualitative work were used to add detail to three intervention components identified from the literature</p> <p>Phase 2 (exploratory phase)</p> <p>Pilot testing the preliminary intervention</p> | <p>Used the MRC (2000) framework guidelines to develop the intervention</p> <p>Provides a case report of intervention development</p> |

Table 3 (Continued)

| Author, Country, Year                        | Purpose of intervention              | Approach to intervention development  | Comment  |
|--|--------------------------------------|---|--|
| Faes <i>et al.</i> (2010)<br>the Netherlands | Complex fall prevention intervention | <p data-bbox="392 743 416 1182"><i>Preclinical phase</i>: integrated with phase 1 Phase 1 (modelling phase)</p> <ul data-bbox="453 743 564 1182" style="list-style-type: none"> <li>• Defined and quantified the target population</li> <li>• Defined health outcome</li> <li>• Reviewed literature to understand pathways that cause and sustain the problem</li> </ul> <p data-bbox="571 911 595 1182">Identified outcome measures</p> <p data-bbox="601 785 679 1182">Based on reviewed literature predicted major confounders, barriers and strategic design challenges</p> <p data-bbox="686 785 710 1182">Took on board expert views and opinions</p> <p data-bbox="716 814 740 1182">Project team agreed on various aspects of design, including carers, outcomes to be measured and theory to be used</p> <ul data-bbox="810 743 922 1182" style="list-style-type: none"> <li>• Specific intervention points and behaviour change techniques decided upon</li> <li>• Project team decided on the total number, frequency and duration of the sessions of the intervention (based on two Delphi interviews, earlier literature review, expert opinion); identified barriers to application of intervention from experts and review; planned strategies for randomisation, blinding, recruitment, adherence, outcome measures and analysis</li> </ul> <p data-bbox="1098 919 1121 1182">Phase 2 (exploratory phase)</p> <ul data-bbox="1128 646 1329 1182" style="list-style-type: none"> <li>• Tested the feasibility of the recruitment process, intervention and measurement; explicitly trained the instructors to deliver the intervention in the pilot study; a guide was written for patients and carers; recruitment issues were identified</li> <li>• Goes on to describe phase 3: evaluation of the intervention using a multicentre RCT</li> </ul> | Used the MRC (2000) framework guidelines to develop the intervention |

Table 3 (Continued)

| Author, Country, Year                 | Purpose of intervention  | Approach to intervention development  | Comment  |
|---------------------------------------|--|---|--|
| Finlayson <i>et al.</i> (2008)<br>USA | Three-phase, cross-sectional, mixed method approach  | <p>Phase 1: 303 carers of people with multiple sclerosis were interviewed (asked to identify typical caregiving activities and challenges, as well as their educational and training needs)</p> <p>Phase 2: a systematic review of existing caregiver education programmes to determine which programmes best address the needs identified in phase 2</p> <p>Phase 3: development of a new programme using a series of steps (establishing guiding principles; determining the overarching goals and objectives of the programme; selecting the theoretical models to guide the implementation process and selection and sequencing of content; identifying tools to measure the expected programme outcomes; determining a preliminary structure for the programme; developing and refining the modules)</p> | Did not use a specific framework to guide the study but described the study in terms of 'phases'   |
| Hardeman <i>et al.</i> (2005)<br>UK   | Illustrates the approach using a case study with individuals at high risk of type 2 diabetes | <p>Argues that a comprehensive causal modelling approach starts with a simple generic model linking behaviour and disease determinants in a causal pathway. The model is tailored to characteristics of the target population, social context, target behaviour and health or disease outcomes</p> <p>Contains four levels: behavioural determinants, behaviour, physiological and biochemical variables and health outcomes</p> <p>Theory and evidence are used to guide the selection of behavioural determinants, intervention and measurement points and behaviour change techniques, which are indicated in one graphical representation</p>   | <p>Presents a causal modelling approach to the development of theory-based intervention for RCT evaluation, focusing on the first two phases of the MRC (2000) framework guidelines</p> <p>They use the term 'causal modelling' to mean the development of a specific causal model to guide the design of a programme to support behaviour change for trial evaluation</p> |

Table 3 (Continued)

| Author, Country, Year             | Purpose of intervention  | Approach to intervention development   | Comment   |
|-----------------------------------|--|--|---|
| Katz <i>et al.</i> (2008)<br>USA  | Intervention to target behavioural and psychosocial risk factors among pregnant African American women | <p>Intervention is based on previous literature on risk factors and interventions</p> <p>Outlines the delivery of the intervention, timing, location, recruitment and retention</p> <p>Provides details on measure used, then some brief information on results</p>  | <p>Does not use a particular framework</p> <p>Does not appear to engage participants in the development of the intervention – all literature presented</p>  |
| King <i>et al.</i> (2009)<br>UK   | Intervention to improve experienced continuity of care in patients with cancer                         | <p>Two palliative clinics and three MD team meetings were observed at a hospice. Conducted semi-structured interviews with staff and patients to inform timing of the people to target and context within which to deliver the intervention and obtain professional and patient's views on the acceptability and practicability of delivering and receiving the intervention</p> <p>Developed the continuity assessment (the intervention) through two iterations</p> <p>Version 1: a continuity assessment composed of four domains that we had developed in earlier work – planned that assessment completed by clinicians and presented at MDT meetings to inform team decision-making. Nurses felt strongly insufficient time to help patients complete the assessment</p> <p>Concluded that continuity assessment should be entirely patient-focused – developed a second version</p> <p>Version 2: for patient self-completion (contained 18 items from earlier work, six additional items from version 2)</p> <p>Used state to determine items of low reliability that were dropped = 17 items in final version</p> | <p>Does not use a particular framework</p> <p>Study conducted in breast, lung and colorectal cancer services at four North London NHS Trusts</p>  |
| Lovell <i>et al.</i> (2008)<br>UK | Guided self-help intervention for depression in primary care   | <p>Preclinical phase: does not refer to this phase (commences at phase 1)</p> <p>Phase 1 (modelling phase): Uses meta-regression synthesis combined with a consensus process (32 international experts) to interpret the evidence and deal with the ambiguities</p>  | <p>Paper describes the modelling phase of the MRC (2000) framework guidelines used to develop a guided self-help intervention for depression in primary care and reports data from an exploratory RCT of the intervention</p> |

Table 3 (Continued)

| Author, Country, Year                     | Purpose of intervention   | Approach to intervention development  | Comment  |
|---|---|---|--|
| Murchie <i>et al.</i> (2007)<br>UK        | Integrated follow-up programme for cutaneous melanoma                                     | The preclinical and phase 1 occurred simultaneously over a period of approximately 18 months. They became increasingly structured using the following three techniques: Iterative literature review; steering group; semi-structured telephone interviews<br>Synthesised the evidence and the final proposed programme eventually emerged in a form that the researchers believed would function in real life<br>Carried out an operationalisation prepiloting exercise where GPs made minor recommendations  | Used the MRC (2000) framework guidelines to develop the intervention |
| Reavley <i>et al.</i> (2010)<br>Australia | A workplace programme development that integrates health promotion and disease management | Used structured concept mapping to help specify programme principles, aspects of service delivery and constituent elements to develop the potential components of the model (termed 'the programme logic')<br>Concept mapping was completed from the views of 45 participants invited to workshop for their expertise and current active participation in the field along with other elements (the outcome hierarchies produced at the group session and key practice and evidence-based elements of successful educational interventions) to inform the development of a programme logic model | Does not use a particular framework                                  |

Table 3 (Continued)

| Author, Country, Year              | Purpose of intervention                                     | Approach to intervention development   | Comment  |
|------------------------------------|---|--|--|
| Redfern <i>et al.</i> (2008)<br>UK | Intervention to improve risk factor management after stroke | <p>Preclinical phase</p> <p>Reviewed existing literature to analyse patterns of secondary prevention; investigate patient understanding of secondary prevention; observe how secondary prevention strategies were delivered by healthcare professionals; review education materials currently used for stroke secondary prevention</p> <p>Mapped patterns of risk factor management practices in the area where the intervention was to be delivered; identified barriers and facilitators to risk factor management from the perspective of both healthcare practitioners and patients; reviewed the quality of existing patient information leaflets providing secondary prevention information and advice</p> <p>Phase 1 (modelling phase)</p> <p>Findings from the preclinical phase above were used to design an intervention. To do this, the authors considered the data, sought wider agreement, proposed embedding the intervention in an existing population register, developed a computerised algorithm, developed an information package for patients and healthcare professionals, developed the stop stroke intervention and provides an outline of the intervention itself</p> <p>Phase 2 (exploratory phase)</p> <p>Stroke survivors were not randomised – focus was on testing procedures and gaining feedback on the patient and professional information literature rather than testing trial outcomes. All problems encountered in the process were documented</p> <p>Two weeks after distribution, semi-structured interviews were conducted to find out whether patients and professionals had received the intervention, what they had understood from the advice provided and what actions they had taken as a result of the advice</p> | <p>Authors sought to investigate the problem of poor management of secondary prevention from multiple perspectives</p> <p>Used the MRC (2000) framework guidelines to develop the intervention</p> <p>Reports phases 1–3 of the development of a novel intervention to improve risk factor management after stroke</p> |

Table 3 (Continued)

| Author, Country, Year               | Purpose of intervention                                      | Approach to intervention development   | Comment   |
|-------------------------------------|--|--|---|
| Robinson <i>et al.</i> (2005)<br>UK | To facilitate coping skills in new carers of stroke patients | <p>Preclinical phase</p> <p>Literature review to identify needs of carers (identified five distinct areas that carers need support)</p> <p>Identifies coping theory and a cognitive behavioural model to form the theoretical basis</p> <p>Developed a theoretically based outline for a six-session small group course, which incorporated the identified needs based on four main themes</p> <p>Phase 1 (exploratory phase)</p> <p>One-to-one semi-structured interviews with a purposive sample of informal carers of patients with first ever stroke using topic guide by project team. Course was refined following phase 1 (analysis of interviews) to include greater focus on issues of importance to carers (loss of control, emotional issues, self-care and support)</p> <p>Phase 2 (exploratory phase)</p> <p>Course advertised (leaflets and posters) in primary and secondary care. Delivered two courses. Five carers participated in 1st course. Two weeks afterwards one-to-one taped interviews were conducted to explore their views about the content, appropriateness and delivery of the course. Following analysis of these interviews and minor adjustments to the course, it was rolled out for a further seven carers who completed a satisfaction questionnaire</p> <p>Participants unanimously positive about the course in general and the handbook</p> | Used the Medical Research Council (2000) framework guidelines to develop the intervention |

Table 3 (Continued)

| Author, Country, Year            | Purpose of intervention   | Approach to intervention development  | Comment  |
|----------------------------------|---|---|--|
| Sturt <i>et al.</i> (2006)<br>UK | Self-efficacy goal achievement<br>nursing intervention for type<br>2 diabetes | <p><i>Preclinical phase</i> (literature analysis and findings from parallel studies)</p> <p>Phase 1 (modelling phase): small trial of the intervention (with two nurses and eight patients with two practice nurses and eight patients according to eligibility criteria) to evaluate feasibility, identify appropriate outcome measures for future trials and improve components</p> <p>Provided half-day training focusing on measuring self-efficacy, self-efficacy theory, training manual given (encouraged to refer to this during the delivery period to enhance own mastery experiences of delivering the intervention). Nurses exchanged contact details (peer support)</p> <p>Intervention: SEGA, four consultations held at monthly intervals. Patient and practice nurse focused on goal setting and achievement informed by self-efficacy theory. Each consultation designed to last 20–30 minutes</p> | Used the MRC (2000) framework guidelines to develop the intervention |

COPD, chronic obstructive pulmonary disease; RCT, randomised controlled trial.

and intervention modelling) in papers reporting on the development of an intervention.

The nine papers using the MRC framework referred to previous research. Most of these ( $n = 6$ ) identified a theory that guided the development of the intervention (Hardeman *et al.* 2005, Robinson *et al.* 2005, Blackwood 2006, Byrne *et al.* 2006, Sturt *et al.* 2006, Faes *et al.* 2010), but its use was unclear in two of the papers (Robinson *et al.* 2005, Sturt *et al.* 2006) and two papers (Murchie *et al.* 2007, Redfern *et al.* 2008) made no reference to the use of theory. Two papers (Robinson *et al.* 2005, King *et al.* 2009) were unclear about the modelling phase of the intervention, and two (Robinson *et al.* 2005, Sturt *et al.* 2006) did not report consideration of intervention acceptability to participants.

## Discussion

The MRC framework (2000) appeared to be the most widely used guideline for the development of complex interventions. The different guidelines for the development of complex interventions have many similarities but vary in consistency and depth regarding the grounding of the intervention in a conceptual framework and previous research evidence. There is also recognition that the acceptability and process of delivery of the intervention should be considered during the early phases and for exploratory testing to proceed definitive testing. The key steps in intervention development can be categorised as follows: integrating theory and research, building and modelling (representing) the intervention, determining acceptability and planning, and intervention delivery. These steps and the key activities required for each step as identified from the selected papers are represented in Fig. 2. A number of important activities required for intervention delivery, for example the need to identify the goal of the intervention, build the intervention and take cognisance of the scope of nursing practice, which are implicit in the MRC framework (2008) guidelines, are highlighted, so that nurses can be aware of their importance when developing complex interventions for nursing research and practice.

### Integrating theory and research

Grounding the intervention in a well-tested theoretical framework creates the foundation on which further development of the intervention hinges. To increase the likelihood of having a measurable impact on key outcomes, it is important that the conceptual/theoretical framework has empirical support and the important constructs of the framework form the core of, and are fully integrated into,

Table 4 Underpinning components to interventions

| Key components of intervention development  | Used MRC framework<br>( <i>n</i> = 9) | Did not use the MRC framework<br>( <i>n</i> = 5) |
|---|---------------------------------------|--|
| Use of literature: referred to previous research/existing knowledge                       | <i>n</i> = 9                          | <i>n</i> = 4                                     |
| Theory: identified a theory   | <i>n</i> = 6                          | <i>n</i> = 1                                     |
| Theory: absent or unclear   | <i>n</i> = 4                          | <i>n</i> = 3                                     |
| Modelling the intervention:<br>unclear on modelling phase                                 | <i>n</i> = 2                          | <i>n</i> = 3                                     |
| Modelling: explication<br>of the approach take<br>to phase 1 'modelling'<br>interventions | Poorly explicated                     | Does not use<br>the word<br>'modelling'          |

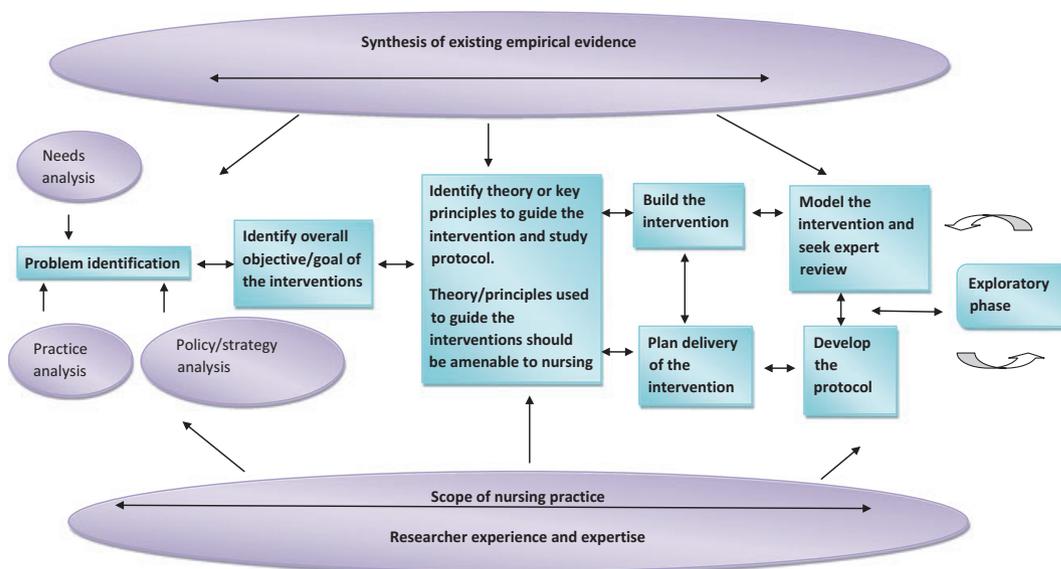


Figure 2 Model for developing complex interventions in nursing.

all parts of the intervention. In this way, the intervention can 'reflect the key constructs of interest in the conceptual framework' (Conn *et al.* 2001, p. 434). The conceptual framework, therefore, comprises the theoretical underpinnings of the interventions and gives guidance to operational procedures, such as the selection of the target population and the type of intervention(s) required, that is, single or groups (termed as bundled) (Conn *et al.* 2001).

The importance of grounding within a theoretical framework and prior research has been recognised since the late 1990s when researchers first began exploring intervention development and testing of particular interventions that were complex and did not fit the traditional model for drug testing. Although Bradley *et al.* (1999) did not use the term 'conceptual framework', they referred to the use of models to determine the best way to bring about change and the value of theory to early intervention development. This is

exemplified in the levels that they presented for defining a complex intervention '...the evidence and theory which inform the intervention, the tasks and processes involved in applying the theoretical principles, and the people with whom, and context within which, the intervention is operationalised' (p. 712). Similarly, Van Meijel *et al.* (2004) did not use the term 'conceptual framework' but emphasised the use of literature to inform the early phases in order to define the nature of the intervention and the problem that the intervention aims to alter. The term 'building blocks' was used to describe the stages of intervention development, with reference to the need for literature reviews during the stages, so that evidence as to what is already known about the intervention can be considered or topics related to the intervention explored (Van Meijel *et al.* 2004). The need for a strong theoretical base and well-defined problem was also emphasised by Whittmore and Grey (2002), and

this is reflected in phase 1 of the guidelines presented (see Table 2). Commenting on the MRC framework, Campbell *et al.* (2007) noted that prior research can help define the extent of the problem, clarify the gap between the problem and solution and inform the planning stage together with expert opinion.

However, theories may not always be readily available to guide intervention development, with evidence for an intervention being refined through the modelling phase (MRC 2008). Reavley *et al.* (2010) presented an example of the inter-relationship between the stages of intervention development by describing how the theory underpinning the intervention was identified from the workshops with experts and those active in the field and from which the guiding principles underpinning the programme were identified. This is important to consider in the discipline of nursing, where theories to guide interventions may not be readily available and researchers may be tempted to draw on theories and conceptual frameworks from other disciplines. Conn *et al.* (2001) cautioned against the use of theories that are not amenable to nursing interventions and noted that doing so is likely to lead to an intervention that does not impact on study outcomes. It is therefore important that nurses develop interventions based on theories relevant to and within the scope of nursing practice and therefore amenable to nursing intervention. It is equally important that the study outcome measures are congruent with the theoretical underpinnings of the intervention and therefore also amenable to nursing intervention.

### Building and representing the intervention

In general, the selected papers reported this stage of complex intervention development as crucial but varied in the language that they used and the level of guidance given. The MRC framework includes this step in phase 1 (modelling the intervention), while Van Meijel *et al.* (2004) referred to building the intervention, but their discussion focused primarily upon how the model could be used to guide the intervention, with little guidance on how to actually build an intervention. They also proposed that attention at this stage should also be given to feasibility of the intervention for practice. It is argued that the most challenging part of a complex intervention is defining the actual intervention itself, with standardisation of the content and delivery of the intervention (MRC 2000). To achieve this level of standardisation, the MRC (2000) contended that the critical components of the intervention and their relationship with each other must be identified using informal or formal methods. Informal methods

included what they described as ‘paper and pencil’, while the more formal approach included simulation and computer modelling through to primary data gathering, for example through survey and qualitative interviews, focus groups or field work (MRC 2000, 2008). The guidance on modelling is scant, and the recently updated MRC framework (MRC 2008) contributes little further guidance.

The lack of clarity regarding what is meant by this phase of intervention development is evident in the papers outlining the development of interventions using the MRC framework. In the MRC framework (2000, 2008), phase 1 is termed ‘modelling’. It is, however, also the phase in which the intervention is built and issues pertaining to ‘acceptability’ are determined. Researchers using the MRC framework tend to focus on the building of the intervention and on determining acceptability, with little attention to the ‘modelling’ of the intervention through simulation or other methods, as recommended by the framework guidelines or through case study design. Although primary data gathering is recommended by the MRC (2000, 2008) in this phase of intervention development, no guidance is provided as to the focus that researchers should have when gathering data for the purpose of ‘modelling’ an intervention.

Many researchers appear to interpret phase 1 as the phase in which the intervention is developed and refined in the light of data gathered during this phase through interviews (focus group/individual), observation of current practice, survey findings or the opinion of ‘experts’. For example, Blackwood (2006) used a combination of practice observation, interviews and questionnaires to model the intervention and observed the weaning process with 54 patients to assess the feasibility of the intervention protocol. The exploratory work was described as helping to ‘...define further the components and to determine how they related to one another by enabling their function and specific form to be refined’ (p. 616). Similarly, Faes *et al.* (2010) used exploratory work to determine the number, frequency and duration of the sessions within their intervention, although they did not fully report the resultant ‘model’.

Lovell *et al.* (2008) described the modelling phase in terms of using evidence synthesis, namely quantitative (meta-regression) and qualitative (meta-synthesis) reviews and a consensus process to interpret the evidence and clarify ambiguities as part of protocol development of the guided self-help, while Sturt *et al.* (2006) reported using the theoretical and empirical evidence from a preclinical phase to build a complex intervention in phase 1. In phase 1, they also carried out a small trial of the intervention, evaluated its feasibility, identified appropriate outcome measures for future trials and improved the components with two nurses

and eight patients. Similarly, Byrne *et al.* (2006) interpreted the modelling phase in terms of obtaining the views of stakeholders to inform the development of the intervention. Exploratory qualitative work in the form of focus groups was used to add detail to the components identified in the preclinical phase, with the findings also informing the practical aspects of delivery and the identification of potential barriers to implementation such as time and financial limitations.

Robinson *et al.* (2005) and Murchie *et al.* (2007) appeared to be the only researchers who devised/built the intervention prior to modelling. Robinson *et al.* (2005) developed the intervention in the preclinical phase, before a qualitative study to explore the experiences of carers and their views of the proposed intervention. From this, they obtained consensus regarding how to deliver the intervention and identified what it was like for carers living with a person with stroke. Thus, qualitative work was used to refine the intervention. Although Murchie *et al.* (2007) stated that in the preclinical phase, knowledge should be used to formulate theory which informs a potential intervention that is modelled in the next phase, they did not delineate clearly between the two phases, and they recommended that 'the first two phases are used iteratively and simultaneously when developing complex health care interventions' (p. 283). This view supports the MRC (2000), where the two phases are inter-related. However, this lack of delineation, with Murchie *et al.* (2007) appearing to use an integrative literature review and steering group in the preclinical phase to develop the intervention, which was then modelled using semi-structured telephone interviews with nine patients and 14 general practitioners regarding feasibility, desirability, benefits, pitfalls and essential components of the intervention and piloted with two GPs to assess feasibility and barriers to implementation, makes it difficult to determine their conceptualisation of phase 1 (modelling).

From the selected papers, it is evident that researchers vary in their interpretation of the concept of intervention modelling. In an attempt to explicate the modelling process further, Hardeman *et al.* (2005) presented a causal modelling approach as a way in which researchers can justify the theory selection in the absence of detail on how to activate phase 1 of the MRC framework. While this approach to intervention development may work well in relation to health outcomes where theories to guide change in health-related behaviour are more readily available, it fails to acknowledge the challenges that some researchers may encounter when theories do not exist to guide intervention development or where the evidence or theory underpinning

the intervention may need to be refined through the modelling phase itself.

The MRC (2000) framework acknowledged that the theoretical phase and phase 1 (modelling) are inter-related, and this was depicted in the process of intervention development in a number of the selected papers, where the theoretical and modelling phases were merged (e.g. Lovell *et al.* 2008, King *et al.* 2009, Faes *et al.* 2010). It is also acknowledged that theories may not always exist to guide intervention development, and the evidence or theory underpinning the intervention may be refined through the modelling phase (MRC framework 2000). This was evident in Faes *et al.*'s 2010 study, where the original fall intervention was not implemented because it was necessary to adapt it by reverting to earlier phases of the framework following phase 2 feasibility testing. Similarly, Lovell *et al.* (2008) commenced at phase 1, but it is clear from their description of the intervention development that the evidence underpinning the intervention was derived from a combination of quantitative meta-regression and qualitative meta-synthesis reviews.

### Determining acceptability and planning

Determining acceptability and planning is an essential component of intervention development and includes the views of key stakeholders and experts. Carefully selected experts can help to determine the potential for an intervention to affect key outcomes (Conn *et al.* 2001) and can also provide guidance on the acceptability of the intervention to all parties. This, along with evidence from previous research in the initial steps, will inform planning for the delivery of intervention. Table 5 sets out the key questions to establish during the planning phase.

During the planning phase, the best method to evaluate the intervention needs to be considered. The importance of integrating the use of both quantitative and qualitative approaches to evaluating complex interventions was discussed by Bradley *et al.* (1999). More recently, the need to consider approaches other than the RCT has been adopted by the MRC (Craig *et al.* 2008).

### Intervention delivery

Essential components of intervention delivery are guided by the theoretical and planning steps in the process and must be considered before initial testing. Failure to ground the intervention delivery in the literature and theory applied to and amenable to the discipline, along with inadequate initial modelling of the intervention, may lead to an inability

**Table 5** Questions to ask when planning the intervention

---

|   |
|---|
| What are the key attributes of the interventionist and who should that person be? (Conn <i>et al.</i> 2001)   |
| What dose of the intervention is necessary to achieve an effect? (Conn <i>et al.</i> 2001, Whittemore & Grey 2002)  |
| What is the optimum time for intervention delivery i.e. optimum stage of illness to intervene? (Conn <i>et al.</i> 2001, Whittemore & Grey 2002)                                  |
| What level of adherence is required to achieve the outcome, frequency and duration for intervention delivery? (Conn <i>et al.</i> 2001)   |
| Can/should the intervention be tailored to individuals and contexts? (Conn <i>et al.</i> 2001, Craig <i>et al.</i> 2008)  |
| Will one intervention achieve the expected outcome or is there a requirement for more than one intervention and if so how will this impact on outcomes? (Conn <i>et al.</i> 2001) |
| Is the setting appropriate and how does it impact on the delivery of the intervention? (Conn <i>et al.</i> 2001)  |
| What are the best approaches, methods and instruments to measure outcomes? (Bradley <i>et al.</i> 1999, Craig <i>et al.</i> 2008)   |

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to detect the benefits and harms of an intervention. When delivering the intervention, there needs to be clarity on what constitutes the intervention. Answers are needed to the key questions outlined in Table 5, and consideration must be given as to how the participant intervention burden will be determined so that the impact of a potentially powerful intervention can be identified. Conn *et al.* (2001) noted that the potentially important effects of an intervention might be concealed by selective participant attrition due to intervention burden. Consideration must also be given to the setting in which the intervention will be delivered. Initial testing of the intervention can then commence and may comprise a series of pilot studies, known as exploratory studies, which include preliminary testing and refinement of the intervention and study protocol, and exploring the potential contribution of the intervention, including its cost-effectiveness.

Although six of the studies did not report using the MRC framework for complex interventions, some studies were grounded in the literature and theory (e.g. Alexopoulos *et al.* 2008, Finlayson *et al.* 2008). Others developed the interventions drawing upon previous research with no reference to theory (for example, Katz *et al.* 2008) or developed interventions using focus groups, interviews or workshops with participants or professionals (for example, King *et al.* 2009, Reavley *et al.* 2010) or a combination of these approaches (for example, Finlayson *et al.* 2008). Unlike the interventions developed using the MRC framework, there was little emphasis on modelling and testing for acceptability in the development stages of these interventions. Alexopoulos *et al.* (2008) outlined a case example, while

Finlayson *et al.* (2008) and Reavley *et al.* (2010) appear to incorporate stakeholder involvement as part of their intervention development although they did not use the term 'modelling'. Reavley *et al.* (2010) referred to a literature review and a workshop with participants who had expertise and actively engaged in the field. Similarly, Finlayson *et al.* (2008) used phase 1 interviews with caregivers to inform their intervention design. In contrast, the case example presented by Alexopoulos *et al.* (2008) provides a more thorough example of intervention modelling in line with the MRC framework.

The varying foci of the interventions and subsequent exploratory studies make comparison between studies using and not using the MRC framework problematic. In both groups of selected papers, there was evidence of some outcomes that were both positive and negative, and there was also evidence of ongoing testing of the interventions or plans to do so in a number of papers. However, the studies using the MRC framework reported more emphasis on the initial exploratory work prior to testing for outcomes and the ongoing refinement of the intervention together with testing for feasibility during exploratory work prior to testing for outcomes. Initial exploratory work ensures that large-scale trials are not embarked upon before essential refinement of the intervention, and knowledge regarding its acceptability to participants and overall feasibility of carrying out a trial are considered. In this way, limited resources are less likely to be wasted on large-scale trials which are fundamentally flawed from the outset.

As the MRC framework provides broad guidelines that must be interpreted for use within a particular discipline, application of phases 1 and 2 provides a number of challenges, especially for those new to intervention development. First, reviewing the literature and identifying a theory as set out in the MRC framework (2000, 2008) requires nurse researchers to ensure that the selected theories and models are relevant to a nursing intervention. Second, the definition of the term 'modelling' (phase 1) is incomplete because modelling is defined as '... delineating an intervention's components and how they inter-relate and how active components of a complex package may relate to either surrogate or final outcomes. "Modelling" refers to the possibility that this phase is paper-based, for example, computer simulations' (MRC 2000, p. 4), with no further details on the more recent MRC (2008) framework. Indeed, phase 1 involves more than just representing the intervention with protocol development for phase 2. For some researchers, it also includes testing for acceptability, although this is not captured in the MRC (2000) definition

of the term 'modelling'. Despite the inclusion of case studies in the updated guidelines (MRC 2008), guidance on 'how' to model remains scant, especially relating to the modelling of interventions in areas of complex clinical practice. However, these limitations can be offset by avoiding a slavish adherence to the MRC framework and incorporating the views of others (Conn *et al.* 2001, Whittemore & Grey 2002, Van Meijel *et al.* 2004) to inform the phases of the MRC framework especially the modelling phase. Figure 2 presents a potential model for nurse researchers to guide their research planning, so that they design well-developed interventions for testing.

## Conclusion

The most widely used guidelines for evaluating complex interventions in health appear to be that of the MRC framework (2000), with the 2008 update incorporating a number of improvements to the earlier MRC (2000) framework. Most researchers consider research evidence and, to a lesser extent, the importance of theory in the development of complex interventions. The review suggests that interventions developed using the MRC framework tend to present a more comprehensive account of intervention development, giving greater attention to the importance of theory and modelling of the intervention. However, the model presented in Fig. 2 will help nurse researchers to create well-developed nursing interventions.

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## Relevance to clinical practice

Nurses have a responsibility to ensure that practice is based on the best available evidence. Guidelines for developing and testing complex interventions are constantly evolving. The model presented here for developing complex interventions in nursing is based on a synthesis of the guidelines reviewed. The model complements the MRC (framework) guidelines and will help nurses to ensure that decisions made in the process of developing and early phase testing of interventions in nursing are considered in terms of the scope of nursing practice.

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Study design: MCo and AW; data collection and analysis: MCo and MC and manuscript preparation: MCo, MC, AW, JL.

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## Conflict of interest

None.

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