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A systematic review of frameworks used to develop rehabilitation interventions for older adults.

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Abstract

Objectives

Rehabilitation interventions for older adults are complex as they involve a number of interacting components, have multiple outcomes of interest and are influenced by a number of contextual factors. The importance of rigorous intervention development prior to formal evaluation has been acknowledged and a number of frameworks have been developed. This review explored which frameworks have been used to guide the development of rehabilitation interventions for older adults.

Design

Systematic review.

Setting

Studies were not limited for inclusion based on setting.

Participants

Studies were included that featured older adults (>65 years of age).

Interventions

Studies were included that reported the development of a rehabilitation intervention.

Primary and secondary outcome measures

Data was extracted on study population, setting, type of intervention developed and frameworks used. The primary outcome of interest was the type of intervention development framework.

Results

Thirty-five studies were included. There was a range of underlying medical conditions including mild cognitive impairment and dementia (n=5), cardiac (n=4), stroke (n=3), falls (n=3), hip fracture (n=2), diabetes (n=2), breast cancer (n=1), Parkinson's disease (n=1), depression (n=1), chronic health

problems (n=1), osteoarthritis (n=1), leg ulcer (n=1), neck pain (n=1) and foot problems (n=1). The intervention types being developed included multicomponent, support-based, cognitive, physical activities, nursing-led, falls prevention and occupational therapy-led. Twelve studies (34%) did not report using a framework. Five frameworks were reported with the Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions being the most frequently cited (77%, n=17).

Conclusion

At present the MRC Framework is the most popular for developing rehabilitation interventions for older adults. Many studies do not report using a framework. Further, specific guidance to assist this complex field of rehabilitation research is required.

Key Words

Older adults, rehabilitation, intervention development

Article summary

- Rigorous intervention development prior to formal evaluation is important
- A number of frameworks have been developed but are inconsistently used or inconsistently reported
- PRISMA guidelines were followed for this systematic review
- An electronic database search aimed to capture all studies reporting intervention development
- Studies involving older people and specifically reporting the development of a rehabilitation intervention were included

Introduction

"*Rehabilitation is concerned with lessening the impact of disabling conditions*" (p677 (1) and is a complex process requiring a holistic approach that considers physical, social and psychological function. Rehabilitation interventions for older adults are complex as they involve a number of interacting components, are often tailored to individual needs, have multiple outcomes of interest and are influenced by a number of environmental and contextual factors (2).

The need to develop a robust evidence base for complex rehabilitation interventions has led to an increased focus on developing and evaluating these interventions. Interventions initially showing promise in small scale testing are often ineffective when scaled into large multicentre randomised-trials (RCT). For example, an in-patient falls prevention programme that was effective during an observational study (3), failed to prevent falls to a significant degree compared to a control in a multisite RCT (4). A review including this example, explored the reasons for the difference in outcomes, citing different contextual factors (staffing, length of stay) (5). However, whilst intervention development was reported by this example, a framework was not used and may have resulted in a lack of sound theoretical underpinning and understanding of the intervention mechanisms of action. The importance of rigorous intervention development prior to formal evaluation has been acknowledged by healthcare researchers in other fields (6) and a number of

frameworks have been developed. These frameworks include the Medical Research Council (MRC) guidance for developing and evaluating complex interventions (7), CReDECI (8), intervention mapping (9) and the 6SQuID (10). Although there are a number of intervention development frameworks, the lack of methodological detail and specificity to rehabilitation interventions may mean that researchers are using the frameworks in different ways or not using the frameworks at all.

Therefore the aims of this review were to a) to ascertain if, and which, intervention development frameworks are being used in older people rehabilitation research, and b) to explore how those frameworks are being used, what methods are employed, and how much detail is provided. This review will help researchers and clinicians to consider a range of frameworks for their studies and is the first step towards establishing more detailed guidance.

Methods

Inclusion criteria

Target population of intervention

Studies were included if their participants were older people who were >65 years (either through study inclusion criteria, mean sample age of study population, or are described as older or elderly).

Intervention

The interventions being developed or described focused on rehabilitation. The definition of rehabilitation used was "*the process of returning to a healthy or good way of life, or the process of helping someone to do this after they have been in prison, been very ill, etc. or the process of returning something to a good condition*" (11). To be a rehabilitation intervention the paper had to report that the intervention: involved the individual(s) being rehabilitated; consisted of more than one session to indicate a process; aimed to create a change in the individual(s)' state or ability from doing the intervention; took place either after something or to prevent something (e.g., an incident/illness); and was described or labelled as "rehabilitation" by the authors.

Types of studies

Studies were included if they stated an aim or intent to either report the intervention that had been developed or to document the process or synthesis as justification or background for the next stage of intervention testing. This included mixed method studies, randomised control trials (RCT), controlled clinical trials, experimental studies, qualitative based analysis studies, cohort, cross-sectional and case control studies. Study protocols were considered for inclusion, however, abstracts, thesis, dissertations, and conference proceedings were excluded due to the level of detail characteristic of these manuscripts (e.g., limited word counts with abstracts and significant word counts with thesis). Systematic reviews (all types) were included. Where possible if studies were part of a series of publications the other material available was sought and the most prominent paper detailing the intervention development process included.

Types of data and outcomes

Studies were included if they reported or described "intervention development" or "developing an intervention". Studies without a framework were included but only if sufficient detail on the intervention development process was presented. However, studies that claimed to report the development process of their intervention but did not include any details or material to confirm were excluded due to lack of data.

Studies were not limited nor selected according to their outcomes.

Search methods for identification of studies

The search strategy aimed to find both published and unpublished studies. A phased search strategy included search terms: "developing and evaluating complex interventions" (all fields), "development" OR "develop*" (title), "intervention" (title), "older" OR "old*" OR "elderly" (all fields).

Electronic searches

Initially, a limited search of MEDLINE and CINAHL was undertaken to identify and refine index terms used to describe relevant articles. Index terms and keywords were taken from known studies that reported their intervention development process and the search strategy refined to ensure these papers were captured.

A second full search using all identified keywords and index terms was then undertaken across relevant databases, including: The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue), MEDLINE, EMBASE, AMED, CINAHL and PsychINFO. A full search strategy is presented in Supplementary Material 1.

Searching other resources

The reference list of full text studies were searched for related material that could be included or were more relevant for data extraction.

Data collection and analysis

Selection of studies

Each study identified for inclusion was considered independently by two reviewers at all stages: title screening, abstract screening, and full paper review for inclusion. Discrepancies between reviewer's decisions were recorded and discussed between the other authors to achieve an outcome.

Data extraction and management

Data was extracted from the included papers using a bespoke data extraction tool, the main categories of which were; study population, setting, type of intervention developed and frameworks used. If a framework was cited then a more detailed review of the components used was completed. Microsoft Excel was used as the data management software and compiled into a single database once agreement of included studies and data extraction had been completed. The review has been reported according to PRISMA guidelines and a checklist completed (12).

Assessment of methodological quality in included studies

Included studies were not assessed for methodological quality. Considering the variety of study methods, different critical appraisal tools would have been required and comparison difficult. Assessment of the methodological quality of the studies would not influence their inclusion in the review nor add depth or justification to the review process.

Data synthesis

Data was collated and narratively described using tables and text.

Results

Thirty-five studies were included in the review for data extraction (13-47). The flow diagram depicting the number of studies identified and excluded at each stage is provided in Figure 1.

Description of the included studies

The most common population descriptor was community-dwelling or older adults of a certain age (16, 18, 26, 28, 30, 43, 44). Underlying conditions included mild cognitive impairment and dementia (n=5) (17, 27, 29, 31, 33), cardiac conditions (n=4) (14, 23-25), stroke (n=3) (21, 37, 39), falls and fear of falling (n=3) (20, 34, 47), hip fracture (n=2) (36, 38), diabetes (n=2) (13, 40, 41), breast cancer (19), Parkinson's disease (15), depression (22), chronic health problems (32), osteoarthritis (35), leg ulcer (42), neck pain (45) and foot problems (46).

The types of interventions reported were varied and included multicomponent (n=12) (13, 18, 22, 23, 25-28, 35, 38, 41, 44), support-based (n=5) (14, 15, 17, 29, 40), cognitive interventions (n=5) (30, 32, 33, 39, 47), physical activities (n=3) (16, 31, 45), nursing (n=2) (24, 42), falls prevention (20), occupational therapy (21), post-stroke care (37), podiatry (46) and dietary advice (36).

The included studies were from the UK (n=17) (13, 14, 16, 18, 19, 21, 30, 33-41, 46), Netherlands (n=6) (25, 26, 29, 43, 44, 47), USA (n=4) (17, 23, 24, 27), Canada (15), India (22), Germany (28, 45), Hong Kong (31), Italy (32), and Belgium (42). Ten studies were linked to other publications reporting the same intervention or other aspects of the development process (21, 24, 25, 27, 28, 30, 34, 38, 41, 42).

What frameworks were reported

Thirteen studies did not report using a framework to assist their intervention development (17, 20, 22-24, 27, 31, 33, 34, 36, 45, 47). In total five frameworks were reported. The Medical Research Council (MRC) guidance was the most frequently used (77%, n=17) (14, 18, 19, 21, 25, 26, 28, 29, 32, 35, 37-41, 46). The other frameworks were intervention mapping (n=3) (15, 43, 44), conceptual modelling (n=1) (30), intervention/programme theory (n=1) (16), and the Van Meijel model (n=1) (42).

What methods were used for the different framework sections

MRC guided studies

A variety of different methods were utilised in the different stages of the MRC guidance within the included studies (see Table 1). Most (14, 21, 26, 29, 37, 39-41) reported their intervention development process according to the three MRC framework stages. These are: 1) identifying the evidence base, 2) developing theory, and 3) modelling processes and outcomes. Some only referenced the guidance and did not report the stages as distinct phases (18, 19, 28, 35, 38, 46) or described their own stages (such as *evidence exploration*, *tune-up with experts*, and *fine tuning with patients*) (32). Three papers adapted and added a fourth stage their development process (13, 25, 39).

All except the study by Wylie (46) reported using a literature review in their development work. The literature review was most commonly used to identify relevant evidence or theories to underpin the intervention being developed (n=11). Other methods utilised included: expert consultation (n=2), qualitative interviews with either clinicians or patients (n=7), and observations or surveying patients (n=8).

A variety of terms were used to describe the second stage of their development process, with some categorising this as theoretical development, whereas others were focusing on modelling. There was a wide range of research methods reported in this second stage, including literature reviews (n=4), expert consultations (n=3), qualitative interviews and focus groups (n=4), observations (n=2), and pilot studies (n=5).

Nine studies then described a feasibility or modelling stage (13, 14, 21, 25, 26, 29, 32, 37, 39). This phase included pilot studies (n=3), qualitative focus groups and interviews (n=6), where data was collected. One study (26) reported eight different research methods at this stage including a Delphi consensus process.

The four studies that added a fourth stage into their development processes varied in terms used to describe it, including "pilot study" (13), "face validity" (25) and "assessing feasibility of the intervention" (39). Two of the studies reported completing a pilot or feasibility study within this stage (13, 39) whereas the third included expert meetings (25).

Other framework guided studies

Six studies used a variety of intervention development frameworks (15, 16, 30, 42-44). Reporting of the research methods used in these studies were varied even when the same framework was used (Table 2). Intervention Mapping (9) was used in three studies, one of which provided no detail on the methods used in each section (15), whereas the other two reported very detailed processes and methods (43, 44). Table 2 describes the different intervention development frameworks and the research methods used within each framework.

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)
MRC Guidance				
Avery, et al. (2016)	*Exploratory work* 1. Interview with GPs 2. Interactive workshop (patients)	*Identification of active intervention ingredients* 1. Systematic review	*Assessing usability* 1. Use by adults with type 2 diabetes 2. Structured interview	*Pilot Study* 1. Acceptability and feasibility (semi-structured interviews)
Barley, et al. (2012)	*Studies to inform intervention* 1. Systematic review 2. Qualitative study (clinicians and patients)	*Integration of findings* 1. Findings from the informative studies 2. Iterative evidence review	*Modelling of the intervention* 1. Focus group 2. Evidence review	
Bruce, et al. (2012)	1. Systematic reviews 2. Clinical guidelines review 3. Expert views 4. Observations (clinicians) 5. Piloting of manual (patients)			
Burgess, et al. (2008)	*Phase 0 (Theoretical)* 1. Review of literature 2. Expert consultation	*Phase I (Piloting and Modelling)* 1. Pilot study 2. Qualitative interviews with participants to explore acceptability		
Cunningham, et al. (2016)	*Identify evidence* 1. Review of literature (clinical guidelines, systematic reviews)	*Model the intervention for delivery* 1. Piloting of manual (patients)	*Test feasibility* 1. Piloting of intervention	
Ettema, et al. (2014)	*Identified existing evidence* 1. Systematic review	*Identified and developed theory* 1. Systematic review 2. Derived the questionnaire 3. Analytical study (patient characteristics/outcomes)	*Modelled process and outcomes* 1. In-depth interviews (patients) 2. Survey (clinicians)	*Face validity* 1. Expert meetings (national experts) 2. Expert meetings (clinicians)
Faes, et al. (2010)	*Existing evidence* 1. Literature reviews 2. Project team meetings	*Theoretical understanding* 1. Literature review 2. Focus groups (experts) 3. Interviews (patients and caregivers) 4. Observations 5. Expert meetings	*Intervention modelling* 1. Focus groups 2. Delphi surveys 3. Interviews (patients and caregivers) 4. Literature review 5. Project team meeting 6. Observations 7. Interviews (experts) 8. Expert consultations	

Hinrichs, et al. (2013)	*Development* 1. Literature review 2. Cohort study (patients)		
Kerkhof, et al. (2016)	*Theoretical* 1. Literature reviews 2. Focus groups 3. Design of tool (users and stakeholders) 4. Mock-up and testing of app (patients) 5. Interviews 6. Development of theoretical framework and manual	*Modelling* 1. Pilot study 2. Interviews 3. Observational analysis 4. Case study (methods used) 5. Questionnaires 6. Inductive content analysis	*Exploratory trial* 1. Exploratory RCT 2. Literature search 3. Quantitative study 4. Qualitative evaluation
Menichetti and Graffigna (2016)	*Evidences exploration* 1. Systematic review	*Tune-up with experts* 1. Expert group discussion	*Fine tuning with patients* 1. Semi-structured interviews
Patel, et al. (2016)	1. Literature review 2. Pilot study 3. Process evaluation (observations of programme delivery, participant interviews)		
Redfern, et al. (2008)	*Pre-clinical phase* 1. Literature review 2. Analysis of current service 3. Interviews (patient representatives) 4. Observational study (patients) 5. Reviewing patient information leaflets	*Phase 1: Modelling* 1. Consensus meeting (researchers and experts) 2. Modification of data collection database 3. Developing computer algorithm 4. Development of patient intervention leaflets.	*Phase 2 Exploratory trial* 1. Pilot study (semi-structured interviews)
Roberts, et al. (2017)	*Development of the intervention (phase 1 of MRC)* 1. Realist literature review 2. Surveys (patients and rehabilitation teams) 3. Focus groups (patients and rehabilitation teams)		
Sadler, et al. (2017)	*Identifying existing evidence and theory* 1. Literature search	*Developing the theoretical foundation of the intervention* 1. Qualitative literature review 2. Interviews (patients, spouse, carers and professionals) 3. Stakeholder consultation (researchers,	*Modelling process and outcomes* 1. No formal method given "designed "	*Assessing feasibility of the intervention* 1. Feasibility study (questionnaires pre and post intervention, qualitative data from participants and professionals delivering

		clinicians and service users) 4. Scoping of literature	intervention).
Sturt, et al. (2006)	*Preclinical phase* 1. Literature search	*Phase I studies* 1. Iterative process between evidence and intervention components 2. Study (patients)	
Troughton, et al. (2016)	*Development "iterative process"* 1. Team and expert meetings 2. Literature review 3. Qualitative study (observation, telephone and face-to-face interviews and focus groups) 4. Pilot study (intervention)	*Feasibility and piloting* 1. Phased pilot study	
Wylie, et al. (2017)	1. Remodelling of intervention (feasible and acceptable in setting, refined recruitment processes and outcomes) 2. Pilot RCT (intervention)		

Table 1: Presentation of the methods used for each element of the MRC framework

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)	Methods used in IDF element (e)	Methods used in IDF element (f)
Intervention Mapping						
Beaudet, et al. (2015)	*Assessing needs and preferences* 1. Interviews (patients)	*Developing intervention* 1. Theory and model selection 2. Intervention proposal validation (patients and stakeholders)	*Formalising*	*Testing and evaluating* 1. Pilot testing (intervention)		
Stralen, et al. (2008)	*A needs assessment of the study population and the definition of programme objectives* 1. Literature search 2. Focus-group interviews (patients) 3. Interviews (stakeholders)	*Defining the performance objectives, specifying what changes are needed* 1. Literature review 2. Delphi study (experts) 3. Theoretical models review	*Selecting theory-based intervention methods and practical strategies to change health behaviour and its determinants* 1. Literature search 2. Search of existing interventions 3. Focus-group interviews (patients)	*Developing an intervention programme in which all strategies are integrated, as well as selecting, testing and producing intervention materials* 1. Brainstorming sessions (experts and patients)	*Developing a programme adoption and implementation plan* 1. Pilot study (implementation and recruitment)	*Anticipating a process and effect evaluation of the programme* 1. Process and effect evaluation
Walters, et al. (2015).	*Needs assessment* 1. Literature search 2. Survey 3. Project management group consultations 4. Interviews (experts)	*Programme objectives* 1. Survey 2. Literature search 3. Project management group consultations 4. Interviews (experts and workers)	*Theory-based methods and practical applications* 1. Literature search 2. Project management group consultations 3. Interviews (experts and workers)	*Programme plan* 1. Project management group consultations 2. Interviews (experts and workers) 3. Pilot study (training)	*Programme implementation* 1. Literature search 2. Consultation with stakeholders 3. Idea collection (workers and instructors)	*Evaluation plan* 1. Evaluation (questionnaire and discussion of workers and training)
Conceptual modelling						
Kingstone, et al. (2017)	*PPIE involvement*	*Development of conceptual model* 1. Interviews (patients and clinicians	*Agreement of conceptual model* 1. Consensus process (researchers)			
Intervention/programme theory						
Blamey, et	1. Logic model of					

al. (2013)	intervention theory		
Van Meijel model			
Van Hecke, et al. (2011).	*Collection of building blocks needed for the design of the intervention* 1. Literature review 2. Interviews (problem and needs analysis) 3. Focus groups (clinicians)	*Intervention design* 1. Expert commentary	*Validation of the nursing intervention* 1. Qualitative study (patients) 2. Evaluation

Table 2: Presentation of the methods used for each element of the other intervention development frameworks

Discussion

Principle findings

Thirty-five studies were included in the review for data extraction. Twelve studies did not cite a framework to assist their intervention development. Five frameworks were reported by the 23 studies who did use one. The MRC guidance was the most frequently used with 77% (n=17). The other four frameworks were intervention mapping, conceptual modelling, intervention/programme theory, and the Van Meijel model but these were only used in a small number of studies. Of the numerous potential frameworks researchers could be using this study highlights that most researchers felt that the MRC, is at present, the most appropriate for their use. Although the quality of the studies in this review was not measured against any standardised measure, the studies that used the MRC guidance provided considerably more details about the components of intervention development than the studies using other frameworks providing a greater degree of confidence that the results had been rigorously collected and not biased. This may indicate that the MRC is written in a way that helps researchers follow a process more easily. However, three studies also adapted and added to the MRC process, indicating that there are further aspects to consider that are not addressed in that guidance.

Strengths and weaknesses of this study

This review was conducted in line with PRISMA guidelines following a systematic process, using pre-defined eligibility criteria and independent assessment by two reviewers at each stage. As with all reviews, there may have been studies that were missed due to the parameters of the review, such as, the definition of rehabilitation that was used. Data extraction was completed using a standardised spreadsheet by all authors and despite regular review meetings there was discrepancy in the interpretation of research methods and the level of detail extracted. For example, what is counted as a "literature review" could for one study be a Cochrane review whilst for another it is a non-systematised narrative description of the field of research.

The findings of this review are limited by the information available about intervention development within the identified literature. It is acknowledged that many journals prefer to publish detail on the intervention content with little focus on the development process and this was evident in this review. Intervention development frameworks are a relatively recent development and studies conducted before the MRC guidance was introduced in 2000 may have had limited methodological literature to guide their intervention development. This review searched all literature from the date of inception of the electronic database and this search strategy may have biased the number of studies not reporting the use of a framework. It is anticipated that over the coming years there will be many more studies reporting the use of a framework and providing more details on that process. Details on the intervention development may not be through journal publications, but through online supplementary material, discussion series, study or institution websites, or online data repositories.

This review did not aim to report on the quality of the studies.

Strengths and weaknesses in relation to other studies

To our knowledge this is the first review of intervention development frameworks used in developing rehabilitation interventions for older people.

The MRC guidance (7) from the UK provides a structure to the development and evaluation process for complex interventions. However, the MRC guidance is brief and has been criticised for not dealing well with the complexity of complex interventions (48-50). Although the MRC framework

was the most commonly cited framework, the included papers provided varying levels of detail over how the framework was used, and a lack of clarity over whether all three stages of development were explored. The lack of consistency and detail may be a result of the limited practical guidance offered by the MRC framework. There were however common approaches used in the papers citing the MRC framework which included; literature reviews, consultation with stakeholders, interviews with patients and clinicians, consensus methodologies and pilot work. It is clear from this review that there is not a consistent approach to developing rehabilitation interventions for older adults and further work is needed to establish how, and which, research methods should be used within the different stages of intervention development.

Other frameworks to support intervention development include the 6SQUID which was based on the experiences of Wight and colleagues (10) in developing public health interventions. Although this framework provides more detail there is still a lack of methodological detail on how to undertake each element. It also has a public health focus which may not consider all aspects needed in the development of a complex rehabilitation intervention. In providing a rationale for the development of the 6SQUID framework, Wight and colleagues provided a summary and appraisal of existing intervention development frameworks in public health and included both the MRC framework and Intervention Mapping which were identified in this review. Intervention Mapping is an involved and detailed process (9) which may account for it being referred to in only three papers in this review. Mohler and colleagues (8) published criteria for reporting the development and evaluation of complex interventions (CREDECI) through a three-stage consensus process. This aimed to improve quality of the reporting on the underlying theory of an intervention, the components and interactions of an intervention as well as any contextual factors. Whilst its merits are acknowledged, the primary focus was on the evaluation phase and the criteria provide little detail on how to undertake the process of intervention development. The COM-B model and theoretical domains framework (51) is another intervention development framework that is becoming increasingly popular in the behaviour change literature but has not widely been used in rehabilitation research as yet.

Meaning and implications

Many studies did not use an intervention framework and in those that did there was a lack of consistent detail regarding the intervention development process. Rigorous intervention development is necessary to avoid costly trials of underdeveloped interventions that have no theoretical basis, however there is a distinct lack of practical guidance to help researchers determine when an intervention is sufficiently developed. It is acknowledged that each rehabilitation intervention is by its very nature complex and therefore reliant on the experience of the individuals developing it, as well as the context and circumstances it is to be delivered in. A rigid framework that dictates exactly how an intervention should be developed may therefore not be appropriate as it would not allow for the nuances of each individual intervention and the different approaches that may be more pertinent to their circumstances. Nevertheless there does appear a need to provide researchers with further detail on the indicators of good practice and what to consider when undertaking quality intervention development.

Recommendations

Following this review a number of recommendations can be made, including:

- Researchers should carefully plan and clearly detail the process of developing rehabilitation interventions for older people using a recognised framework such as MRC

- Rehabilitation journals need to welcome further detail on the intervention development process utilising online supplementary material
- A consensus process is needed to depict best practice and provide guidance on developing a rehabilitation intervention for older adults

Conclusion

The MRC guidance is the most popular framework being used by researchers developing rehabilitation interventions for older adults. However, many studies do not report using a framework to guide their development. Further, specific guidance to help researchers chose and use the best framework for their intervention are needed.

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Competing interests statement

The authors declare no competing interests.

Author contributions

The original idea for the review was provided by KRR and VB. VB and KRR completed the electronic searches. VB, KRR, VHM and JEH completed data extraction. KRR and VB drafted the paper. PAL, JEH and VHM edited the paper. All authors contributed to the final paper in intellectual content, design and writing.

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Data Statement

Data can be accessed through correspondence with the lead author.

Patient Involvement

Patients were not involved.

References

1. Young J. Rehabilitation and older people. BMJ: British Medical Journal. 1996;313(7058):677.
2. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ: British Medical Journal. 2007;334(7591):455.
3. Barker AL, Morello RT, Ayton DR, Hill KD, Landgren FS, Brand CA. Development of an implementation plan for the 6-PACK falls prevention programme as part of a randomised controlled trial: protocol for a series of preimplementation studies. Injury prevention. 2016;22(6):446-52.
4. Barker AL, Morello RT, Wolfe R, Brand CA, Haines TP, Hill KD, et al. 6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial. Bmj. 2016;352:h6781.
5. Slade SC, Carey DL, Hill A-M, Morris ME. Effects of falls prevention interventions on falls outcomes for hospitalised adults: protocol for a systematic review with meta-analysis. BMJ Open. 2017;7(11).
6. Walker MF, Hoffmann TC, Brady MC, Dean CM, Eng JJ, Farrin AJ, et al. Improving the development, monitoring and reporting of stroke rehabilitation research: Consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable. International Journal of Stroke. 2017;12(5):472-9.
7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337:979-83.
8. Mohler R, Bartoszek G, Kopke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): Guideline development. International Journal of Nursing Studies. 2012;49(1):40-6.
9. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory and evidence-based health education programs. Health Education & Behavior. 1998;25(5):545-63.
10. Wight D, Wimbush E, Jepson R, Doi L. Six Steps In Quality Intervention Development (6SQuID). J Epidemiol Community Health. 2015;0:1-6.
11. Cambridge Dictionary. Definition of "rehabilitation" - English Dictionary https://dictionary.cambridge.org/us/dictionary/english/rehabilitation: Cambridge University Press; 2018 [
12. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Annals of Internal Medicine. 2009;151(4):264-9.
13. Avery L, Charman SJ, Taylor L, Flynn D, Mosely K, Speight J, et al. Systematic development of a theory-informed multifaceted behavioural intervention to increase physical activity of adults with type 2 diabetes in routine primary care: Movement as Medicine for Type 2 Diabetes. Implementation Science. 2015;11(1):99.
14. Barley EA, Haddad M, Simmonds R, Fortune Z, Walters P, Murray J, et al. The UPBEAT depression and coronary heart disease programme: using the UK Medical Research Council framework to design a nurse-led complex intervention for use in primary care. BMC family practice. 2012;13(1):119.
15. Beaudet L, Ducharme F, L'Écuyer N, Chouinard S, Jodoin N, Panisset M. Development and evaluation of a dyadic intervention for elderly couples living with moderate-stage Parkinson disease. Applied Nursing Research. 2015;28(4):e21-e7.
16. Blamey AA, MacMillan F, Fitzsimons CF, Shaw R, Mutrie N. Using programme theory to strengthen research protocol and intervention design within an RCT of a walking intervention. Evaluation. 2013;19(1):5-23.
17. Brody AA, Guan C, Cortes T, Galvin JE. Development and testing of the Dementia Symptom Management at Home (DSM-H) program: An interprofessional home health care intervention to improve the quality of life for persons with dementia and their caregivers. Geriatr Nurs. 2016;37(3):200-6.

18. Bruce J, Ralhan S, Sheridan R, Westacott K, Withers E, Finnegan S, et al. The design and development of a complex multifactorial falls assessment intervention for falls prevention: The Prevention of Falls Injury Trial (PreFIT). BMC Geriatr. 2017;17(1):116.
19. Burgess C, Bish A, Hunter H, Salkovskis P, Michell M, Whelehan P, et al. Promoting early presentation of breast cancer: development of a psycho-educational intervention. Chronic Illn. 2008;4(1):13-27.
20. Claflin S. Development of a home care falls prevention and intervention program. J Clin Outcomes Manage. 2005;12(12):637-42.
21. Cunningham P, Turton AJ, Van Wijck F, Van Vliet P. Task-specific reach-to-grasp training after stroke: development and description of a home-based intervention. Clin Rehabil. 2016;30(8):731-40.
22. Dias A, Azariah F, Cohen A, Anderson S, Morse J, Cuijpers P, et al. Intervention development for the indicated prevention of depression in later life: The "DIL" protocol in Goa, India. Contemporary clinical trials communications. 2017;6:131-9.
23. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and Testing of an Intervention to Improve Outcomes for Partners Following Receipt of an Implantable Cardioverter Defibrillator in the Patient. Advances in Nursing Science. 2012;35(4):359-77.
24. Duffy JR, Hoskins LM, Dudley-Brown S. Development and Testing of a Caring-based Intervention for Older Adults With Heart Failure. J Cardiovasc Nurs. 2005;20(5):325-33.
25. Ettema RG, Hoogendoorn ME, Kalkman CJ, Schuurmans MJ. Development of a nursing intervention to prepare frail older patients for cardiac surgery (the PREDOCS programme), following phase one of the guidelines of the Medical Research Council. Eur J Cardiovasc Nurs. 2014;13(6):494-505.
26. Faes MC, Reelick MF, Esselink RA, Rikkert MGO. Developing and evaluating complex healthcare interventions in geriatrics: the use of the medical research council framework exemplified on a complex fall prevention intervention. J Am Geriatr Soc. 2010;58(11):2212-21.
27. Gildengers AG, Butters MA, Albert SM, Anderson SJ, Dew MA, Erickson K, et al. Design and implementation of an intervention development study: Retaining Cognition while Avoiding Late-Life Depression (ReCALL). The American Journal of Geriatric Psychiatry. 2016;24(6):444-54.
28. Hinrichs T, Brach M, Bucchi C, Moschny A, Wilm S, Thiem U, et al. An exercise programme for community-dwelling, mobility-restricted and chronically ill older adults with structured support by the general practitioner's practice (HOMEfit). Z Gerontol Geriatr. 2013;46(1):56-63.
29. Kerkhof YJ, Graff MJ, Bergsma A, de Vocht HH, Dröes R-M. Better self-management and meaningful activities thanks to tablets? Development of a person-centered program to support people with mild dementia and their carers through use of hand-held touch screen devices. International psychogeriatrics. 2016;28(11):1917-29.
30. Kingstone T, Burroughs H, Bartlam B, Ray M, Proctor J, Shepherd T, et al. Developing a community-based psycho-social intervention with older people and third sector workers for anxiety and depression: a qualitative study. BMC family practice. 2017;18(1):77.
31. Lai CK, Lai DL, Ho JS, Wong KK, Cheung DS. Interdisciplinary collaboration in the use of a music-with-movement intervention to promote the wellbeing of people with dementia and their families: Development of an evidence-based intervention protocol. Nursing & health sciences. 2016;18(1):79-84.
32. Menichetti J, Graffigna G. "PHE in Action": Development and Modeling of an Intervention to Improve Patient Engagement among Older Adults. Frontiers in psychology. 2016;7:1405.
33. O'Sullivan M, Coen R, O'Hora D, Shiel A. Cognitive rehabilitation for mild cognitive impairment: developing and piloting an intervention. Aging, Neuropsychology, and Cognition. 2015;22(3):280-300.
34. Parry S, Bamford C, Deary V, Finch T, Gray J, MacDonald C, et al. Cognitive–behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial–the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study. Health Technol Assess. 2016;20(56):1-206.

35. Patel S, Heine PJ, Ellard DR, Underwood M. Group exercise and self-management for older adults with osteoarthritis: a feasibility study. Primary health care research & development. 2016;17(3):252-64.
36. Price RJ, McMurdo ME, Anderson AS. A personalized snack-based intervention for hip fracture patients: development, feasibility and acceptability. Journal of human nutrition and dietetics. 2006;19(2):139-45.
37. Redfern J, Rudd AD, Wolfe CD, McKevitt C. Stop Stroke: development of an innovative intervention to improve risk factor management after stroke. Patient education and counseling. 2008;72(2):201-9.
38. Roberts JL, Din NU, Williams M, Hawkes CA, Charles JM, Hoare Z, et al. Development of an evidence-based complex intervention for community rehabilitation of patients with hip fracture using realist review, survey and focus groups. BMJ open. 2017;7(10):e014362.
39. Sadler E, Sarre S, Tinker A, Bhalla A, McKevitt C. Developing a novel peer support intervention to promote resilience after stroke. Health & social care in the community. 2017;25(5):1590-600.
40. Sturt J, Whitlock S, Hearnshaw H. Complex intervention development for diabetes self-management. J Adv Nurs. 2006;54(3):293-303.
41. Troughton J, Chatterjee S, Hill SE, Daly H, Martin Stacey L, Stone MA, et al. Development of a lifestyle intervention using the MRC framework for diabetes prevention in people with impaired glucose regulation. Journal of Public Health. 2016;38(3):493-501.
42. Van Hecke A, Verhaeghe S, Grypdonck M, Beele H, Flour M, Defloor T. Systematic development and validation of a nursing intervention: the case of lifestyle adherence promotion in patients with leg ulcers. J Adv Nurs. 2011;67(3):662-76.
43. van Stralen MM, Kok G, de Vries H, Mudde AN, Bolman C, Lechner L. The Active plus protocol: systematic development of two theory-and evidence-based tailored physical activity interventions for the over-fifties. BMC Public Health. 2008;8(1):399.
44. Walters ME, Dijkstra A, de Winter AF, Reijneveld SA. Development of a training programme for home health care workers to promote preventive activities focused on a healthy lifestyle: an intervention mapping approach. BMC health services research. 2015;15(1):263.
45. Wiedemann AM, von Trott P, Luedtke R, Reisshauer A, Willich SN, Witt CM. Developing a qigong intervention and an exercise therapy for elderly patients with chronic neck pain and the study protocol. Complementary Medicine Research. 2008;15(4):195-202.
46. Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, et al. Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study). BMC Geriatr. 2017;17(1):143.
47. Zijlstra GR, Tennstedt SL, van Haastregt JC, van Eijk JTM, Kempen GI. Reducing fear of falling and avoidance of activity in elderly persons: The development of a Dutch version of an American intervention. Patient Education and Counseling. 2006;62(2):220-7.
48. Anderson R. New MRC guidance on evaluating complex interventions. BMJ: British Medical Journal (Online). 2008;337.
49. Kernick D. Guidelines perpetuate inappropriate methods. BMJ: British Medical Journal (Online). 2008;337.
50. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. International Journal of Nursing Studies. 2013;50(5):587-92.
51. Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. Needed: physician leaders. 2014;26:146.

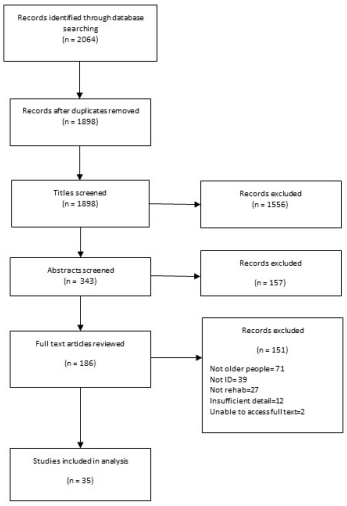

Figure 1: Flow diagram

338x190mm (96 x 96 DPI)

Supplementary Material 1: Example of search strategy

Search strategy for MEDLINE (1996+)

a)	"developing and evaluating complex interventions" (all fields)
b)	"development" OR "develop*" (title)
c)	"intervention" (title)
d)	B) and C)
e)	A or D
f)	"older" OR "old*" OR "elderly" (all fields)
g)	E and F

Reporting checklist for systematic review and meta-analysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA reporting guidelines, and cite them as:

Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

		Reporting Item	Page Number
	#1	Identify the report as a systematic review, meta-analysis, or both.	1
Structured summary	#2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	1-2
Rationale	#3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	#4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
Protocol and registration	#5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	n/a

Eligibility criteria	#6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	3
Information sources	#7	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	4
Search	#8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	See note 1
Study selection	#9	State the process for selecting studies (i.e., for screening, for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta-analysis).	4
Data collection process	#10	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	4
Data items	#11	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	4
Risk of bias in individual studies	#12	Describe methods used for assessing risk of bias in individual studies (including specification of whether this was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	4
Summary measures	#13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Planned methods of analyis	#14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	4
Risk of bias across studies	#15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	#16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
Study selection	#17	Give numbers of studies screened, assessed for eligibility, and	Figure 1

		included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	#18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	5
Risk of bias within studies	#19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	n/a
Results of individual studies	#20	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	5-11
Synthesis of results	#21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	5-11
Risk of bias across studies	#22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	#23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
Summary of Evidence	#24	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	12
Limitations	#25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	12-13
Conclusions	#26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14
Funding	#27	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	14

Author notes

1. Supplementary Material 1

BMJ Open

A systematic review of frameworks used to develop rehabilitation interventions for older adults.

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Keywords:	older adults, rehabilitation, intervention development, REHABILITATION MEDICINE

A systematic review of frameworks used to develop rehabilitation interventions for older adults.

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Word Count: 3094

Abstract

Objectives

Rehabilitation interventions for older adults are complex as they involve a number of interacting components, have multiple outcomes of interest and are influenced by a number of contextual factors. The importance of rigorous intervention development prior to formal evaluation has been acknowledged and a number of frameworks have been developed. This review explored which frameworks have been used to guide the development of rehabilitation interventions for older adults.

Design

Systematic review.

Setting

Studies were not limited for inclusion based on setting.

Participants

Studies were included that featured older adults (>65 years of age).

Interventions

Studies were included that reported the development of a rehabilitation intervention.

Primary and secondary outcome measures

Data was extracted on study population, setting, type of intervention developed and frameworks used. The primary outcome of interest was the type of intervention development framework.

Results

Thirty-five studies were included. There was a range of underlying medical conditions including mild cognitive impairment and dementia (n=5), cardiac (n=4), stroke (n=3), falls (n=3), hip fracture (n=2), diabetes (n=2), breast cancer (n=1), Parkinson's disease (n=1), depression (n=1), chronic health

problems (n=1), osteoarthritis (n=1), leg ulcer (n=1), neck pain (n=1) and foot problems (n=1). The intervention types being developed included multicomponent, support-based, cognitive, physical activities, nursing-led, falls prevention and occupational therapy-led. Twelve studies (34%) did not report using a framework. Five frameworks were reported with the Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions being the most frequently cited (77%, n=17).

Conclusion

At present the MRC Framework is the most popular for developing rehabilitation interventions for older adults. Many studies do not report using a framework. Further, specific guidance to assist this complex field of rehabilitation research is required.

Key Words

Older adults, rehabilitation, intervention development

Article summary

- Rigorous intervention development prior to formal evaluation is important
- A number of frameworks have been developed but are inconsistently used or inconsistently reported
- PRISMA guidelines were followed for this systematic review
- An electronic database search aimed to capture all studies reporting intervention development
- Studies involving older people and specifically reporting the development of a rehabilitation intervention were included

Introduction

"*Rehabilitation is concerned with lessening the impact of disabling conditions*" (p677 (1) and is a complex process requiring a holistic approach that considers physical, social and psychological function. Rehabilitation interventions for older adults are complex as they involve a number of interacting components, are often tailored to individual needs, have multiple outcomes of interest and are influenced by a number of environmental and contextual factors (2).

The need to develop a robust evidence base for complex rehabilitation interventions has led to an increased focus on developing and evaluating these interventions. Interventions initially showing promise in small scale testing are often ineffective when scaled into large multicentre randomised-trials (RCT). For example, an in-patient falls prevention programme that was effective during an observational study (3), failed to prevent falls to a significant degree compared to a control in a multisite RCT (4). A review including this example, explored the reasons for the difference in outcomes, citing different contextual factors (staffing, length of stay) (5). However, whilst intervention development was reported by this example, a framework was not used and may have resulted in a lack of sound theoretical underpinning and understanding of the intervention mechanisms of action. The importance of rigorous intervention development prior to formal evaluation has been acknowledged by healthcare researchers in other fields (6) and a number of

frameworks have been developed. These frameworks include the Medical Research Council (MRC) guidance for developing and evaluating complex interventions (7), Criteria for Reporting the Development and Evaluation of Complex Interventions (CReDECI) (8), intervention mapping (9) and the 6 Steps in Quality Intervention Development (6SQuID) (10). Although there are a number of intervention development frameworks, the lack of methodological detail and specificity to rehabilitation interventions may mean that researchers are using the frameworks in different ways or not using the frameworks at all.

Therefore the aims of this review were to a) to ascertain if intervention development frameworks are being used in older people rehabilitation research, b) to document which frameworks have been used and c) to explore how those frameworks are being used, what methods are employed, and how much detail is provided. This review will help researchers and clinicians to consider a range of frameworks for their studies and is the first step towards establishing more detailed guidance.

Methods

Inclusion criteria

Target population of intervention

Studies were included if their participants were older people who were >65 years (either through study inclusion criteria, mean sample age of study population, or are described as older or elderly).

Intervention

The interventions being developed or described focused on rehabilitation. The definition of rehabilitation used was "*the process of returning to a healthy or good way of life, or the process of helping someone to do this after they have been in prison, been very ill, etc. or the process of returning something to a good condition*" (11). To be a rehabilitation intervention the paper had to report that the intervention: involved the individual(s) being rehabilitated; consisted of more than one session to indicate a process; aimed to create a change in the individual(s)' state or ability from doing the intervention; took place either after something or to prevent something (e.g., an incident/illness); and was described or labelled as "rehabilitation" by the authors.

Types of studies

Studies were included if they stated an aim or intent to either report the intervention that had been developed or to document the process or synthesis as justification or background for the next stage of intervention testing. This included mixed method studies, randomised control trials (RCT), controlled clinical trials, experimental studies, qualitative based analysis studies, cohort, cross-sectional and case control studies. Systematic reviews (all types) were considered for inclusion so reference lists could be explored for further studies that may not have been identified in the search strategy. Types of publications were also considered. Study protocols were considered for inclusion, however, abstracts, thesis, dissertations, and conference proceedings were excluded due to the level of detail characteristic of these manuscripts (e.g., limited word counts with abstracts and significant word counts with thesis). Where possible if studies were part of a series of publications the other material available was sought and the most prominent paper detailing the intervention development process included.

Types of data and outcomes

Studies were included if they reported or described "intervention development" or "developing an intervention". Studies without a framework were included but only if they met the predetermined criteria that sufficient information and detail on the intervention development process or methods was presented. Studies that claimed to have completed an intervention development process but did not include any information on the process or method were excluded due to lack of data. All studies were assessed for inclusion by two authors and any discrepancy on the decision of a paper was discussed by all authors to reach a group consensus.

Studies were not limited nor selected according to their outcomes.

Search methods for identification of studies

The search strategy aimed to find both published and unpublished studies. A phased search strategy included search terms: "developing and evaluating complex interventions" (all fields), "development" OR "develop*" (title), "intervention" (title), "older" OR "old*" OR "elderly" (all fields).

Electronic searches

Initially, a limited search of MEDLINE and CINAHL was undertaken to identify and refine index terms used to describe relevant articles. Index terms and keywords were taken from known studies that reported their intervention development process and the search strategy refined to ensure these papers were captured.

A second full search using all identified keywords and index terms was then undertaken across relevant databases, including: The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue), MEDLINE, EMBASE, AMED, CINAHL and PsychINFO. The search was completed in October 2017. A full search strategy is presented in Supplementary Material 1.

Searching other resources

The reference list of full text studies were searched for related material that could be included or were more relevant for data extraction.

Data collection and analysis

Selection of studies

Each study identified for inclusion was considered independently by two reviewers at all stages: title screening, abstract screening, and full paper review for inclusion. Discrepancies between reviewer's decisions were recorded and discussed between the other authors to achieve an outcome.

Data extraction and management

Data was extracted from the included papers using a bespoke data extraction tool, the main categories of which were; study population, setting, type of intervention developed and frameworks used. If a framework was cited then a more detailed review of the components used was completed. Microsoft Excel was used as the data management software and compiled into a single database once agreement of included studies and data extraction had been completed. The review has been reported according to PRISMA guidelines and a checklist completed (12).

Assessment of methodological quality in included studies

Included studies were not assessed for methodological quality. Considering the variety of study methods, different critical appraisal tools would have been required and comparison difficult. Assessment of the methodological quality of the studies would not influence their inclusion in the review nor add depth or justification to the review process.

Data synthesis

Data was collated and narratively described using tables and text.

Patient and Public Involvement

Patients were not involved.

Results

Thirty-five studies were included in the review for data extraction (13-47). The flow diagram depicting the number of studies identified and excluded at each stage is provided in Figure 1.

Description of the included studies

The most common population descriptor was community-dwelling or older adults of a certain age (16, 18, 26, 28, 30, 43, 44). Underlying conditions included mild cognitive impairment and dementia (n=5) (17, 27, 29, 31, 33), cardiac conditions (n=4) (14, 23-25), stroke (n=3) (21, 37, 39), falls and fear of falling (n=3) (20, 34, 47), hip fracture (n=2) (36, 38), diabetes (n=2) (13, 40, 41), breast cancer (19), Parkinson's disease (15), depression (22), chronic health problems (32), osteoarthritis (35), leg ulcer (42), neck pain (45) and foot problems (46).

The types of interventions reported were varied and included multicomponent (n=12) (13, 18, 22, 23, 25-28, 35, 38, 41, 44), support-based (n=5) (14, 15, 17, 29, 40), cognitive interventions (n=5) (30, 32, 33, 39, 47), physical activities (n=3) (16, 31, 45), nursing (n=2) (24, 42), falls prevention (20), occupational therapy (21), post-stroke care (37), podiatry (46) and dietary advice (36).

The included studies were from the UK (n=17) (13, 14, 16, 18, 19, 21, 30, 33-41, 46), Netherlands (n=6) (25, 26, 29, 43, 44, 47), USA (n=4) (17, 23, 24, 27), Canada (15), India (22), Germany (28, 45), Hong Kong (31), Italy (32), and Belgium (42). Ten studies were linked to other publications reporting the same intervention or other aspects of the development process (21, 24, 25, 27, 28, 30, 34, 38, 41, 42).

What frameworks were reported

Thirteen studies did not report using a framework to assist their intervention development (17, 20, 22-24, 27, 31, 33, 34, 36, 45, 47). In total five frameworks were reported. The Medical Research Council (MRC) guidance was the most frequently used (77%, n=17) (14, 18, 19, 21, 25, 26, 28, 29, 32, 35, 37-41, 46). The other frameworks were intervention mapping (n=3) (15, 43, 44), conceptual modelling (n=1) (30), intervention/programme theory (n=1) (16), and the Van Meijel model (n=1) (42). Descriptions and key references for the frameworks are provided in Supplementary Material 2.

What methods were used for the different framework sections

MRC guided studies

A variety of different methods were utilised in the different stages of the MRC guidance within the included studies (see Table 1). Most (14, 21, 26, 29, 37, 39-41) reported their intervention development process according to the three MRC framework stages. These are: 1) identifying the evidence base, 2) developing theory, and 3) modelling processes and outcomes. Some only referenced the guidance and did not report the stages as distinct phases (18, 19, 28, 35, 38, 46) or described their own stages (such as *evidence exploration*, *tune-up with experts*, and *fine tuning with patients*) (32). Three papers adapted and added a fourth stage their development process (13, 25, 39).

All except the study by Wylie (46) reported using a literature review in their development work. The literature review was most commonly used to identify relevant evidence or theories to underpin the intervention being developed (n=11). Other methods utilised included: expert consultation (n=2), qualitative interviews with either clinicians or patients (n=7), and observations or surveying patients (n=8).

A variety of terms were used to describe the second stage of their development process, with some categorising this as theoretical development, whereas others were focusing on modelling. There was a wide range of research methods reported in this second stage, including literature reviews (n=4), expert consultations (n=3), qualitative interviews and focus groups (n=4), observations (n=2), and pilot studies (n=5).

Nine studies then described a feasibility or modelling stage (13, 14, 21, 25, 26, 29, 32, 37, 39). This phase included pilot studies (n=3), qualitative focus groups and interviews (n=6), where data was collected. One study (26) reported eight different research methods at this stage including a Delphi consensus process.

The four studies that added a fourth stage into their development processes varied in terms used to describe it, including "pilot study" (13), "face validity" (25) and "assessing feasibility of the intervention" (39). Two of the studies reported completing a pilot or feasibility study within this stage (13, 39) whereas the third included expert meetings (25).

Other framework guided studies

Six studies used a variety of intervention development frameworks (15, 16, 30, 42-44). Reporting of the research methods used in these studies were varied even when the same framework was used (Table 2). Intervention Mapping (9) was used in three studies, one of which provided no detail on the methods used in each section (15), whereas the other two reported very detailed processes and methods (43, 44). Table 2 describes the different intervention development frameworks and the research methods used within each framework.

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)
MRC Guidance				
Avery, et al. (2016)	*Exploratory work* 1. Interview with GPs 2. Interactive workshop (patients)	*Identification of active intervention ingredients* 1. Systematic review	*Assessing usability* 1. Use by adults with type 2 diabetes 2. Structured interview	*Pilot Study* 1. Acceptability and feasibility (semi-structured interviews)
Barley, et al. (2012)	*Studies to inform intervention* 1. Systematic review 2. Qualitative study (clinicians and patients)	*Integration of findings* 1. Findings from the informative studies 2. Iterative evidence review	*Modelling of the intervention* 1. Focus group 2. Evidence review	
Bruce, et al. (2012)	1. Systematic reviews 2. Clinical guidelines review 3. Expert views 4. Observations (clinicians) 5. Piloting of manual (patients)			
Burgess, et al. (2008)	*Phase 0 (Theoretical)* 1. Review of literature 2. Expert consultation	*Phase I (Piloting and Modelling)* 1. Pilot study 2. Qualitative interviews with participants to explore acceptability		
Cunningham, et al. (2016)	*Identify evidence* 1. Review of literature (clinical guidelines, systematic reviews)	*Model the intervention for delivery* 1. Piloting of manual (patients)	*Test feasibility* 1. Piloting of intervention	
Ettema, et al. (2014)	*Identified existing evidence* 1. Systematic review	*Identified and developed theory* 1. Systematic review 2. Derived the questionnaire 3. Analytical study (patient characteristics/outcomes)	*Modelled process and outcomes* 1. In-depth interviews (patients) 2. Survey (clinicians)	*Face validity* 1. Expert meetings (national experts) 2. Expert meetings (clinicians)
Faes, et al. (2010)	*Existing evidence* 1. Literature reviews 2. Project team meetings	*Theoretical understanding* 1. Literature review 2. Focus groups (experts) 3. Interviews (patients and caregivers) 4. Observations 5. Expert meetings	*Intervention modelling* 1. Focus groups 2. Delphi surveys 3. Interviews (patients and caregivers) 4. Literature review 5. Project team meeting 6. Observations 7. Interviews (experts) 8. Expert consultations	

Hinrichs, et al. (2013)	*Development* 1. Literature review 2. Cohort study (patients)			
Kerkhof, et al. (2016)	*Theoretical* 1. Literature reviews 2. Focus groups 3. Design of tool (users and stakeholders) 4. Mock-up and testing of app (patients) 5. Interviews 6. Development of theoretical framework and manual	*Modelling* 1. Pilot study 2. Interviews 3. Observational analysis 4. Case study (methods used) 5. Questionnaires 6. Inductive content analysis	*Exploratory trial* 1. Exploratory RCT 2. Literature search 3. Quantitative study 4. Qualitative evaluation	
Menichetti and Graffigna (2016)	*Evidences exploration* 1. Systematic review	*Tune-up with experts* 1. Expert group discussion	*Fine tuning with patients* 1. Semi-structured interviews	
Patel, et al. (2016)	1. Literature review 2. Pilot study 3. Process evaluation (observations of programme delivery, participant interviews)			
Redfern, et al. (2008)	*Pre-clinical phase* 1. Literature review 2. Analysis of current service 3. Interviews (patient representatives) 4. Observational study (patients) 5. Reviewing patient information leaflets	*Phase 1: Modelling* 1. Consensus meeting (researchers and experts) 2. Modification of data collection database 3. Developing computer algorithm 4. Development of patient intervention leaflets.	*Phase 2 Exploratory trial* 1. Pilot study (semi-structured interviews)	
Roberts, et al. (2017)	*Development of the intervention (phase 1 of MRC)* 1. Realist literature review 2. Surveys (patients and rehabilitation teams) 3. Focus groups (patients and rehabilitation teams)			
Sadler, et al. (2017)	*Identifying existing evidence and theory* 1. Literature search	*Developing the theoretical foundation of the intervention* 1. Qualitative literature review 2. Interviews (patients, spouse, carers and professionals) 3. Stakeholder consultation (researchers,	*Modelling process and outcomes* 1. No formal method given "designed "	*Assessing feasibility of the intervention* 1. Feasibility study (questionnaires pre and post intervention, qualitative data from participants and professionals delivering

		clinicians and service users) 4. Scoping of literature	intervention).
Sturt, et al. (2006)	*Preclinical phase* 1. Literature search	*Phase I studies* 1. Iterative process between evidence and intervention components 2. Study (patients)	
Troughton, et al. (2016)	*Development "iterative process"* 1. Team and expert meetings 2. Literature review 3. Qualitative study (observation, telephone and face-to-face interviews and focus groups) 4. Pilot study (intervention)	*Feasibility and piloting* 1. Phased pilot study	
Wylie, et al. (2017)	1. Remodelling of intervention (feasible and acceptable in setting, refined recruitment processes and outcomes) 2. Pilot RCT (intervention)		

Table 1: Presentation of the methods used for each element of the MRC framework

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)	Methods used in IDF element (e)	Methods used in IDF element (f)
Intervention Mapping						
Beaudet, et al. (2015)	*Assessing needs and preferences* 1. Interviews (patients)	*Developing intervention* 1. Theory and model selection 2. Intervention proposal validation (patients and stakeholders)	*Formalising*	*Testing and evaluating* 1. Pilot testing (intervention)		
Stralen, et al. (2008)	*A needs assessment of the study population and the definition of programme objectives* 1. Literature search 2. Focus-group interviews (patients) 3. Interviews (stakeholders)	*Defining the performance objectives, specifying what changes are needed* 1. Literature review 2. Delphi study (experts) 3. Theoretical models review	*Selecting theory-based intervention methods and practical strategies to change health behaviour and its determinants* 1. Literature search 2. Search of existing interventions 3. Focus-group interviews (patients)	*Developing an intervention programme in which all strategies are integrated, as well as selecting, testing and producing intervention materials* 1. Brainstorming sessions (experts and patients)	*Developing a programme adoption and implementation plan* 1. Pilot study (implementation and recruitment)	*Anticipating a process and effect evaluation of the programme* 1. Process and effect evaluation
Walters, et al. (2015).	*Needs assessment* 1. Literature search 2. Survey 3. Project management group consultations 4. Interviews (experts)	*Programme objectives* 1. Survey 2. Literature search 3. Project management group consultations 4. Interviews (experts and workers)	*Theory-based methods and practical applications* 1. Literature search 2. Project management group consultations 3. Interviews (experts and workers)	*Programme plan* 1. Project management group consultations 2. Interviews (experts and workers) 3. Pilot study (training)	*Programme implementation* 1. Literature search 2. Consultation with stakeholders 3. Idea collection (workers and instructors)	*Evaluation plan* 1. Evaluation (questionnaire and discussion of workers and training)
Conceptual modelling						
Kingstone, et al. (2017)	*PPIE involvement*	*Development of conceptual model* 1. Interviews (patients and clinicians	*Agreement of conceptual model* 1. Consensus process (researchers)			
Intervention/programme theory						
Blamey, et	1. Logic model of					

al. (2013)	intervention theory		
Van Meijel model			
Van Hecke, et al. (2011).	*Collection of building blocks needed for the design of the intervention* 1. Literature review 2. Interviews (problem and needs analysis) 3. Focus groups (clinicians)	*Intervention design* 1. Expert commentary	*Validation of the nursing intervention* 1. Qualitative study (patients) 2. Evaluation

Table 2: Presentation of the methods used for each element of the other intervention development frameworks

Discussion

Principle findings

Thirty-five studies were included in the review for data extraction. Twelve studies did not cite a framework to assist their intervention development. Five frameworks were reported by the 23 studies who did use one. The MRC guidance was the most frequently used with 77% (n=17). The other four frameworks were intervention mapping, conceptual modelling, intervention/programme theory, and the Van Meijel model but these were only used in a small number of studies. Of the numerous potential frameworks researchers could be using this study highlights that most researchers felt that the MRC, is at present, the most appropriate for their use. Although the quality of the studies in this review was not measured against any standardised measure, the studies that used the MRC guidance provided considerably more details about the components of intervention development than the studies using other frameworks providing a greater degree of confidence that the results had been rigorously collected and not biased. This may indicate that the MRC is written in a way that helps researchers follow a process more easily. However, three studies also adapted and added to the MRC process, indicating that there are further aspects to consider that are not addressed in that guidance.

Strengths and weaknesses of this study

This review was conducted in line with PRISMA guidelines following a systematic process, using pre-defined eligibility criteria and independent assessment by two reviewers at each stage. As with all reviews, there may have been studies that were missed due to the parameters of the review, such as, the definition of rehabilitation that was used. Data extraction was completed using a standardised spreadsheet by all authors and despite regular review meetings there was discrepancy in the interpretation of research methods and the level of detail extracted. For example, what is counted as a "literature review" could for one study be a Cochrane review whilst for another it is a non-systematised narrative description of the field of research.

The findings of this review are limited by the information available about intervention development within the identified literature. It is acknowledged that many journals prefer to publish detail on the intervention content with little focus on the development process and this was evident in this review. Intervention development frameworks are a relatively recent development and studies conducted before the MRC guidance was introduced in 2000 may have had limited methodological literature to guide their intervention development. This review searched all literature from the date of inception of the electronic database and this search strategy may have biased the number of studies not reporting the use of a framework. It is anticipated that over the coming years there will be many more studies reporting the use of a framework and providing more details on that process. Details on the intervention development may not be through journal publications, but through online supplementary material, discussion series, study or institution websites, or online data repositories.

This review did not report on the quality of the studies. Whilst quality assessments are standard practice in systematic reviews, reviews which aim to scope the literature do not require this component (48). The intention of this review was to make comment on the current state of the literature relating to intervention development. Studies were not included or excluded based on their quality, but on their detail of the intervention development process and methods.

Strengths and weaknesses in relation to other studies

To our knowledge this is the first review of intervention development frameworks used in developing rehabilitation interventions for older people.

The MRC guidance (7) from the UK provides a structure to the development and evaluation process for complex interventions. However, the MRC guidance is brief and has been criticised for not dealing well with the complexity of complex interventions (49-51). Although the MRC framework was the most commonly cited framework, the included papers provided varying levels of detail over how the framework was used, and a lack of clarity over whether all three stages of development were explored. The lack of consistency and detail may be a result of the limited practical guidance offered by the MRC framework. There were however common approaches used in the papers citing the MRC framework which included; literature reviews, consultation with stakeholders, interviews with patients and clinicians, consensus methodologies and pilot work. It is clear from this review that there is not a consistent approach to developing rehabilitation interventions for older adults and further work is needed to establish how, and which, research methods should be used within the different stages of intervention development.

Other frameworks to support intervention development include the 6SQUID which was based on the experiences of Wight and colleagues (10) in developing public health interventions. Although this framework provides more detail there is still a lack of methodological detail on how to undertake each element. It also has a public health focus which may not consider all aspects needed in the development of a complex rehabilitation intervention. In providing a rationale for the development of the 6SQUID framework, Wight and colleagues provided a summary and appraisal of existing intervention development frameworks in public health and included both the MRC framework and Intervention Mapping which were identified in this review. Intervention Mapping is an involved and detailed process (9) which may account for it being referred to in only three papers in this review. Mohler and colleagues (8) published criteria for reporting the development and evaluation of complex interventions (CREDECI) through a three-stage consensus process. This aimed to improve quality of the reporting on the underlying theory of an intervention, the components and interactions of an intervention as well as any contextual factors. Whilst its merits are acknowledged, the primary focus was on the evaluation phase and the criteria provide little detail on how to undertake the process of intervention development. The COM-B model and theoretical domains framework (52) is another intervention development framework that is becoming increasingly popular in the behaviour change literature but has not widely been used in rehabilitation research as yet.

Meaning and implications

Many studies did not use an intervention framework and in those that did there was a lack of consistent detail regarding the intervention development process. Rigorous intervention development is necessary to avoid costly trials of underdeveloped interventions that have no theoretical basis, however there is a distinct lack of practical guidance to help researchers determine when an intervention is sufficiently developed. It is acknowledged that each rehabilitation intervention is by its very nature complex and therefore reliant on the experience of the individuals developing it, as well as the context and circumstances it is to be delivered in. A rigid framework that dictates exactly how an intervention should be developed may therefore not be appropriate as it would not allow for the nuances of each individual intervention and the different approaches that may be more pertinent to their circumstances. Nevertheless there does appear a need to provide researchers with further detail on the indicators of good practice and what to consider when undertaking quality intervention development.

Recommendations

Following this review a number of recommendations can be made, including:

- Researchers should carefully plan and clearly detail the process of developing rehabilitation interventions for older people using a recognised framework such as MRC
- Rehabilitation journals need to welcome further detail on the intervention development process utilising online supplementary material
- A consensus process is needed to depict best practice and provide guidance on developing a rehabilitation intervention for older adults

Conclusion

The MRC guidance is the most popular framework being used by researchers developing rehabilitation interventions for older adults. However, many studies do not report using a framework to guide their development. Further, specific guidance to help researchers chose and use the best framework for their intervention are needed.

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Competing interests statement

The authors declare no competing interests.

Author contributions

The original idea for the review was provided by KRR and VB. VB and KRR completed the electronic searches. VB, KRR, VHM and JEH completed data extraction. KRR and VB drafted the paper. PAL, JEH and VHM edited the paper. All authors contributed to the final paper in intellectual content, design and writing.

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Data Statement

Data can be accessed through correspondence with the lead author.

References

1. Young J. Rehabilitation and older people. BMJ: British Medical Journal. 1996;313(7058):677.
2. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ: British Medical Journal. 2007;334(7591):455.
3. Barker AL, Morello RT, Ayton DR, Hill KD, Landgren FS, Brand CA. Development of an implementation plan for the 6-PACK falls prevention programme as part of a randomised controlled trial: protocol for a series of preimplementation studies. Injury prevention. 2016;22(6):446-52.
4. Barker AL, Morello RT, Wolfe R, Brand CA, Haines TP, Hill KD, et al. 6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial. Bmj. 2016;352:h6781.
5. Slade SC, Carey DL, Hill A-M, Morris ME. Effects of falls prevention interventions on falls outcomes for hospitalised adults: protocol for a systematic review with meta-analysis. BMJ Open. 2017;7(11).
6. Walker MF, Hoffmann TC, Brady MC, Dean CM, Eng JJ, Farrin AJ, et al. Improving the development, monitoring and reporting of stroke rehabilitation research: Consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable. International Journal of Stroke. 2017;12(5):472-9.
7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337:979-83.
8. Mohler R, Bartoszek G, Kopke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): Guideline development. International Journal of Nursing Studies. 2012;49(1):40-6.
9. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory and evidence-based health education programs. Health Education & Behavior. 1998;25(5):545-63.
10. Wight D, Wimbush E, Jepson R, Doi L. Six Steps In Quality Intervention Development (6SQuID). J Epidemiol Community Health. 2015;0:1-6.
11. Cambridge Dictionary. Definition of "rehabilitation" - English Dictionary https://dictionary.cambridge.org/us/dictionary/english/rehabilitation: Cambridge University Press; 2018 [
12. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Annals of Internal Medicine. 2009;151(4):264-9.
13. Avery L, Charman SJ, Taylor L, Flynn D, Mosely K, Speight J, et al. Systematic development of a theory-informed multifaceted behavioural intervention to increase physical activity of adults with type 2 diabetes in routine primary care: Movement as Medicine for Type 2 Diabetes. Implementation Science. 2015;11(1):99.
14. Barley EA, Haddad M, Simmonds R, Fortune Z, Walters P, Murray J, et al. The UPBEAT depression and coronary heart disease programme: using the UK Medical Research Council framework to design a nurse-led complex intervention for use in primary care. BMC family practice. 2012;13(1):119.
15. Beaudet L, Ducharme F, L'Écuyer N, Chouinard S, Jodoin N, Panisset M. Development and evaluation of a dyadic intervention for elderly couples living with moderate-stage Parkinson disease. Applied Nursing Research. 2015;28(4):e21-e7.
16. Blamey AA, MacMillan F, Fitzsimons CF, Shaw R, Mutrie N. Using programme theory to strengthen research protocol and intervention design within an RCT of a walking intervention. Evaluation. 2013;19(1):5-23.
17. Brody AA, Guan C, Cortes T, Galvin JE. Development and testing of the Dementia Symptom Management at Home (DSM-H) program: An interprofessional home health care intervention to improve the quality of life for persons with dementia and their caregivers. Geriatr Nurs. 2016;37(3):200-6.

18. Bruce J, Ralhan S, Sheridan R, Westacott K, Withers E, Finnegan S, et al. The design and development of a complex multifactorial falls assessment intervention for falls prevention: The Prevention of Falls Injury Trial (PreFIT). BMC Geriatr. 2017;17(1):116.
19. Burgess C, Bish A, Hunter H, Salkovskis P, Michell M, Whelehan P, et al. Promoting early presentation of breast cancer: development of a psycho-educational intervention. Chronic Illn. 2008;4(1):13-27.
20. Claflin S. Development of a home care falls prevention and intervention program. J Clin Outcomes Manage. 2005;12(12):637-42.
21. Cunningham P, Turton AJ, Van Wijck F, Van Vliet P. Task-specific reach-to-grasp training after stroke: development and description of a home-based intervention. Clin Rehabil. 2016;30(8):731-40.
22. Dias A, Azariah F, Cohen A, Anderson S, Morse J, Cuijpers P, et al. Intervention development for the indicated prevention of depression in later life: The "DIL" protocol in Goa, India. Contemporary clinical trials communications. 2017;6:131-9.
23. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and Testing of an Intervention to Improve Outcomes for Partners Following Receipt of an Implantable Cardioverter Defibrillator in the Patient. Advances in Nursing Science. 2012;35(4):359-77.
24. Duffy JR, Hoskins LM, Dudley-Brown S. Development and Testing of a Caring-based Intervention for Older Adults With Heart Failure. J Cardiovasc Nurs. 2005;20(5):325-33.
25. Ettema RG, Hoogendoorn ME, Kalkman CJ, Schuurmans MJ. Development of a nursing intervention to prepare frail older patients for cardiac surgery (the PREDOCS programme), following phase one of the guidelines of the Medical Research Council. Eur J Cardiovasc Nurs. 2014;13(6):494-505.
26. Faes MC, Reelick MF, Esselink RA, Rikkert MGO. Developing and evaluating complex healthcare interventions in geriatrics: the use of the medical research council framework exemplified on a complex fall prevention intervention. J Am Geriatr Soc. 2010;58(11):2212-21.
27. Gildengers AG, Butters MA, Albert SM, Anderson SJ, Dew MA, Erickson K, et al. Design and implementation of an intervention development study: Retaining Cognition while Avoiding Late-Life Depression (ReCALL). The American Journal of Geriatric Psychiatry. 2016;24(6):444-54.
28. Hinrichs T, Brach M, Bucchi C, Moschny A, Wilm S, Thiem U, et al. An exercise programme for community-dwelling, mobility-restricted and chronically ill older adults with structured support by the general practitioner's practice (HOMEfit). Z Gerontol Geriatr. 2013;46(1):56-63.
29. Kerkhof YJ, Graff MJ, Bergsma A, de Vocht HH, Dröes R-M. Better self-management and meaningful activities thanks to tablets? Development of a person-centered program to support people with mild dementia and their carers through use of hand-held touch screen devices. International psychogeriatrics. 2016;28(11):1917-29.
30. Kingstone T, Burroughs H, Bartlam B, Ray M, Proctor J, Shepherd T, et al. Developing a community-based psycho-social intervention with older people and third sector workers for anxiety and depression: a qualitative study. BMC family practice. 2017;18(1):77.
31. Lai CK, Lai DL, Ho JS, Wong KK, Cheung DS. Interdisciplinary collaboration in the use of a music-with-movement intervention to promote the wellbeing of people with dementia and their families: Development of an evidence-based intervention protocol. Nursing & health sciences. 2016;18(1):79-84.
32. Menichetti J, Graffigna G. "PHE in Action": Development and Modeling of an Intervention to Improve Patient Engagement among Older Adults. Frontiers in psychology. 2016;7:1405.
33. O'Sullivan M, Coen R, O'Hora D, Shiel A. Cognitive rehabilitation for mild cognitive impairment: developing and piloting an intervention. Aging, Neuropsychology, and Cognition. 2015;22(3):280-300.
34. Parry S, Bamford C, Deary V, Finch T, Gray J, MacDonald C, et al. Cognitive–behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial–the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study. Health Technol Assess. 2016;20(56):1-206.

35. Patel S, Heine PJ, Ellard DR, Underwood M. Group exercise and self-management for older adults with osteoarthritis: a feasibility study. Primary health care research & development. 2016;17(3):252-64.
36. Price RJ, McMurdo ME, Anderson AS. A personalized snack-based intervention for hip fracture patients: development, feasibility and acceptability. Journal of human nutrition and dietetics. 2006;19(2):139-45.
37. Redfern J, Rudd AD, Wolfe CD, McKevitt C. Stop Stroke: development of an innovative intervention to improve risk factor management after stroke. Patient education and counseling. 2008;72(2):201-9.
38. Roberts JL, Din NU, Williams M, Hawkes CA, Charles JM, Hoare Z, et al. Development of an evidence-based complex intervention for community rehabilitation of patients with hip fracture using realist review, survey and focus groups. BMJ open. 2017;7(10):e014362.
39. Sadler E, Sarre S, Tinker A, Bhalla A, McKevitt C. Developing a novel peer support intervention to promote resilience after stroke. Health & social care in the community. 2017;25(5):1590-600.
40. Sturt J, Whitlock S, Hearnshaw H. Complex intervention development for diabetes self-management. J Adv Nurs. 2006;54(3):293-303.
41. Troughton J, Chatterjee S, Hill SE, Daly H, Martin Stacey L, Stone MA, et al. Development of a lifestyle intervention using the MRC framework for diabetes prevention in people with impaired glucose regulation. Journal of Public Health. 2016;38(3):493-501.
42. Van Hecke A, Verhaeghe S, Grypdonck M, Beele H, Flour M, Defloor T. Systematic development and validation of a nursing intervention: the case of lifestyle adherence promotion in patients with leg ulcers. J Adv Nurs. 2011;67(3):662-76.
43. van Stralen MM, Kok G, de Vries H, Mudde AN, Bolman C, Lechner L. The Active plus protocol: systematic development of two theory-and evidence-based tailored physical activity interventions for the over-fifties. BMC Public Health. 2008;8(1):399.
44. Walters ME, Dijkstra A, de Winter AF, Reijneveld SA. Development of a training programme for home health care workers to promote preventive activities focused on a healthy lifestyle: an intervention mapping approach. BMC health services research. 2015;15(1):263.
45. Wiedemann AM, von Trott P, Luedtke R, Reisshauer A, Willich SN, Witt CM. Developing a qigong intervention and an exercise therapy for elderly patients with chronic neck pain and the study protocol. Complementary Medicine Research. 2008;15(4):195-202.
46. Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, et al. Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study). BMC Geriatr. 2017;17(1):143.
47. Zijlstra GR, Tennstedt SL, van Haastregt JC, van Eijk JTM, Kempen GI. Reducing fear of falling and avoidance of activity in elderly persons: The development of a Dutch version of an American intervention. Patient Education and Counseling. 2006;62(2):220-7.
48. Grant MJ, Booth A. A typology of reviews: an analysis of 14 review types and associated methodologies. Health Information & Libraries Journal. 2009;26(2):91-108.
49. Anderson R. New MRC guidance on evaluating complex interventions. BMJ: British Medical Journal (Online). 2008;337.
50. Kernick D. Guidelines perpetuate inappropriate methods. BMJ: British Medical Journal (Online). 2008;337.
51. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. International Journal of Nursing Studies. 2013;50(5):587-92.
52. Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. Needed: physician leaders. 2014;26:146.

Figure Legend

Figure 1:

Flow diagram depicting the number of studies identified and excluded at each stage (each stage of the review process is depicted by a box in a sequential design as suggested by PRISMA (12)).

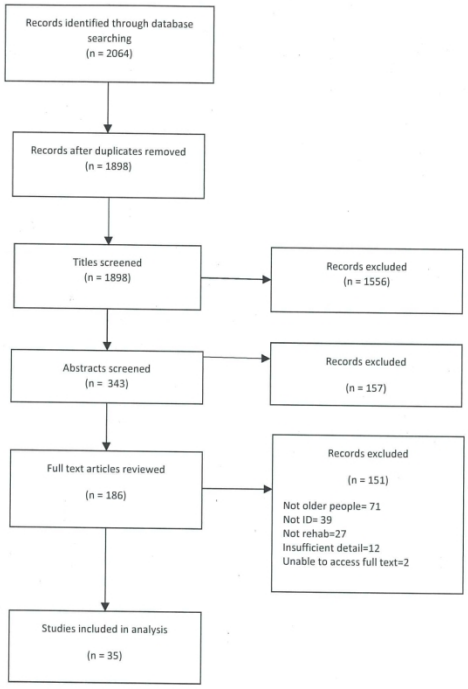

Figure 1: Flow diagram depicting the number of studies identified and excluded at each stage (each stage of the review process is depicted by a box in a sequential design as suggested by PRISMA (12)).

209x298mm (300 x 300 DPI)

Supplementary Material 1: Example of search strategy

Search strategy for MEDLINE (1996+)

a)	"developing and evaluating complex interventions" (all fields)
b)	"development" OR "develop*" (title)
c)	"intervention" (title)
d)	B) and C)
e)	A or D
f)	"older" OR "old*" OR "elderly" (all fields)
g)	E and F

Supplementary Material 2: Descriptions of the intervention development frameworks included in the review.

Name of framework	Description	Key reference(s) or website
Medical Research Council Guidance	The Medical Research Council guidance is a published framework for evaluating complex interventions. Its original 2000 guidance was updated in 2008 and suggests a non-linear phased sequence.	Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008, 337:a1655.
Intervention Mapping	Intervention Mapping is a six-stepped method going from identifying the problem through to solving the problem and is focused on behaviour change interventions. It is a self-described protocol which can aid the development of these types of interventions.	Bartholomew LK, Parcel GS, Kok G, Gottlieb NH, Fernández ME. Planning Health Promotion Programs - An Intervention Mapping Approach. 3rd ed. San Francisco: CA: Jossey-Bass; 2011. https://interventionmapping.com/
Conceptual Modelling	Conceptual modelling is a term used in multiple fields (e.g., business, computing, social sciences and health research). A conceptual model is a model or diagrammatic representation of the rationale, process and/or outcomes. It has been used in health research previously and examples are given.	E.g., Wagner E, Austin B, Von Korff M: Organizing care for patients with chronic illness. *Milbank Q* 1996, 74:511–543. Gask et al., Improving access to psychosocial interventions for common mental health problems in the United Kingdom: narrative review and development of a conceptual model for complex interventions. BMC Health Serv Res. 2012;12(1):249.
Programme Theory	Programme theory is a term that has been used by evaluators to describe the theory underpinning a programme, such as a social or health intervention. Programme theory also refers to a specific concept used within realistic evaluation.	Weiss CH (1998) Evaluation: Methods for Studying Programs and Policies. Upper Saddle River, NJ: Prentice Hall. Pawson R and Tilley N (1997) Realistic Evaluation. London: SAGE.
Van Meijel Model	The Van Meijel model was first reported in 2004 and was established in response to the development of a nursing-based intervention. The model uses four stages from defining the problem through to validating the intervention.	Van Meijel B., Gamel C., van Swieten-Duijfjes B. & Grypdonck M.H. (2004) The development of evidence-based nursing interventions: methodological considerations. *Journal of Advanced Nursing* 48, 84–92.

Reporting checklist for systematic review and meta-analysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA reporting guidelines, and cite them as:

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		Reporting Item	Page Number
	#1	Identify the report as a systematic review, meta-analysis, or both.	1
Structured summary	#2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	1-2
Rationale	#3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	#4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
Protocol and registration	#5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	n/a

Eligibility criteria	#6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	3
Information sources	#7	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	4
Search	#8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	See note 1
Study selection	#9	State the process for selecting studies (i.e., for screening, for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta-analysis).	4
Data collection process	#10	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	4
Data items	#11	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	4
Risk of bias in individual studies	#12	Describe methods used for assessing risk of bias in individual studies (including specification of whether this was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	4
Summary measures	#13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Planned methods of analyis	#14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	4
Risk of bias across studies	#15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	#16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
Study selection	#17	Give numbers of studies screened, assessed for eligibility, and	Figure 1

		included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	#18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	5
Risk of bias within studies	#19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	n/a
Results of individual studies	#20	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	5-11
Synthesis of results	#21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	5-11
Risk of bias across studies	#22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	#23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
Summary of Evidence	#24	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	12
Limitations	#25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	12-13
Conclusions	#26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14
Funding	#27	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	14

Author notes

1. Supplementary Material 1

BMJ Open

A systematic review of frameworks used to develop rehabilitation interventions for older adults.

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A systematic review of frameworks used to develop rehabilitation interventions for older adults.

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Abstract

Objectives

Rehabilitation interventions for older adults are complex as they involve a number of interacting components, have multiple outcomes of interest and are influenced by a number of contextual factors. The importance of rigorous intervention development prior to formal evaluation has been acknowledged and a number of frameworks have been developed. This review explored which frameworks have been used to guide the development of rehabilitation interventions for older adults.

Design

Systematic review.

Setting

Studies were not limited for inclusion based on setting.

Participants

Studies were included that featured older adults (>65 years of age).

Interventions

Studies were included that reported the development of a rehabilitation intervention.

Primary and secondary outcome measures

Data was extracted on study population, setting, type of intervention developed and frameworks used. The primary outcome of interest was the type of intervention development framework.

Results

Thirty-five studies were included. There was a range of underlying medical conditions including mild cognitive impairment and dementia (n=5), cardiac (n=4), stroke (n=3), falls (n=3), hip fracture (n=2), diabetes (n=2), breast cancer (n=1), Parkinson's disease (n=1), depression (n=1), chronic health

problems (n=1), osteoarthritis (n=1), leg ulcer (n=1), neck pain (n=1) and foot problems (n=1). The intervention types being developed included multicomponent, support-based, cognitive, physical activities, nursing-led, falls prevention and occupational therapy-led. Twelve studies (34%) did not report using a framework. Five frameworks were reported with the Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions being the most frequently cited (77%, n=17).

Conclusion

At present the MRC Framework is the most popular for developing rehabilitation interventions for older adults. Many studies do not report using a framework. Further, specific guidance to assist this complex field of rehabilitation research is required.

Key Words

Older adults, rehabilitation, intervention development

Article summary

- Rigorous intervention development prior to formal evaluation is important
- A number of frameworks have been developed but are inconsistently used or inconsistently reported
- PRISMA guidelines were followed for this systematic review
- An electronic database search aimed to capture all studies reporting intervention development
- Studies involving older people and specifically reporting the development of a rehabilitation intervention were included

Introduction

"*Rehabilitation is concerned with lessening the impact of disabling conditions*" (p677 (1) and is a complex process requiring a holistic approach that considers physical, social and psychological function. Rehabilitation interventions for older adults are complex as they involve a number of interacting components, are often tailored to individual needs, have multiple outcomes of interest and are influenced by a number of environmental and contextual factors (2).

The need to develop a robust evidence base for complex rehabilitation interventions has led to an increased focus on developing and evaluating these interventions. Interventions initially showing promise in small scale testing are often ineffective when scaled into large multicentre randomised-trials (RCT). For example, an in-patient falls prevention programme that was effective during an observational study (3), failed to prevent falls to a significant degree compared to a control in a multisite RCT (4). A review including this example, explored the reasons for the difference in outcomes, citing different contextual factors (staffing, length of stay) (5). However, whilst intervention development was reported by this example, a framework was not used and may have resulted in a lack of sound theoretical underpinning and understanding of the intervention mechanisms of action. The importance of rigorous intervention development prior to formal evaluation has been acknowledged by healthcare researchers in other fields (6) and a number of

frameworks have been developed. These frameworks include the Medical Research Council (MRC) guidance for developing and evaluating complex interventions (7), Criteria for Reporting the Development and Evaluation of Complex Interventions (CReDECI) (8), intervention mapping (9) and the 6 Steps in Quality Intervention Development (6SQuID) (10). Although there are a number of intervention development frameworks, the lack of methodological detail and specificity to rehabilitation interventions may mean that researchers are using the frameworks in different ways or not using the frameworks at all.

Therefore the aims of this review were to a) to ascertain if intervention development frameworks are being used in older people rehabilitation research, b) to document which frameworks have been used and c) to explore how those frameworks are being used, what methods are employed, and how much detail is provided. This review will help researchers and clinicians to consider a range of frameworks for their studies and is the first step towards establishing more detailed guidance.

Methods

Inclusion criteria

Target population of intervention

Studies were included if their participants were older people who were >65 years (either through study inclusion criteria, mean sample age of study population, or are described as older or elderly).

Intervention

The interventions being developed or described focused on rehabilitation. The definition of rehabilitation used was "*the process of returning to a healthy or good way of life, or the process of helping someone to do this after they have been in prison, been very ill, etc. or the process of returning something to a good condition*" (11). To be a rehabilitation intervention the paper had to report that the intervention: involved the individual(s) being rehabilitated; consisted of more than one session to indicate a process; aimed to create a change in the individual(s)' state or ability from doing the intervention; took place either after something or to prevent something (e.g., an incident/illness); and was described or labelled as "rehabilitation" by the authors.

Types of studies

Studies were included if they stated an aim or intent to either report the intervention that had been developed or to document the process or synthesis as justification or background for the next stage of intervention testing. This included mixed method studies, randomised control trials (RCT), controlled clinical trials, experimental studies, qualitative based analysis studies, cohort, cross-sectional and case control studies. Systematic reviews (all types) were considered for inclusion so reference lists could be explored for further studies that may not have been identified in the search strategy. Types of publications were also considered. Study protocols were considered for inclusion, however, abstracts, thesis, dissertations, and conference proceedings were excluded due to the level of detail characteristic of these manuscripts (e.g., limited word counts with abstracts and significant word counts with thesis). Where possible if studies were part of a series of publications the other material available was sought and the most prominent paper detailing the intervention development process included.

Types of data and outcomes

Studies were included if they reported or described "intervention development" or "developing an intervention". Studies without a framework were included but only if they met the predetermined criteria that sufficient information and detail on the intervention development process or methods was presented. Studies that claimed to have completed an intervention development process but did not include any information on the process or method were excluded due to lack of data. All studies were assessed for inclusion by two authors and any discrepancy on the decision of a paper was discussed by all authors to reach a group consensus.

Studies were not limited nor selected according to their outcomes.

Search methods for identification of studies

The search strategy aimed to find both published and unpublished studies. A phased search strategy included search terms: "developing and evaluating complex interventions" (all fields), "development" OR "develop*" (title), "intervention" (title), "older" OR "old*" OR "elderly" (all fields).

Electronic searches

Initially, a limited search of MEDLINE and CINAHL was undertaken to identify and refine index terms used to describe relevant articles. Index terms and keywords were taken from known studies that reported their intervention development process and the search strategy refined to ensure these papers were captured.

A second full search using all identified keywords and index terms was then undertaken across relevant databases, including: The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue), MEDLINE, EMBASE, AMED, CINAHL and PsychINFO. The search was completed in October 2017. A full search strategy is presented in Supplementary Material 1.

Searching other resources

The reference list of full text studies were searched for related material that could be included or were more relevant for data extraction.

Data collection and analysis

Selection of studies

Each study identified for inclusion was considered independently by two reviewers at all stages: title screening, abstract screening, and full paper review for inclusion. Discrepancies between reviewer's decisions were recorded and discussed between the other authors to achieve an outcome.

Data extraction and management

Data was extracted from the included papers using a bespoke data extraction tool, the main categories of which were; study population, setting, type of intervention developed and frameworks used. If a framework was cited then a more detailed review of the components used was completed. Microsoft Excel was used as the data management software and compiled into a single database once agreement of included studies and data extraction had been completed. The review has been reported according to PRISMA guidelines and a checklist completed (12).

Assessment of methodological quality in included studies

Included studies were not assessed for methodological quality. However, each study was critiqued according to the latest reporting standards for the development and evaluation of complex interventions in healthcare (CReDECI2) (13). Assessment of the reporting standard of the studies would not influence their inclusion in the review.

Data synthesis

Data was collated and narratively described using tables and text.

Patient and Public Involvement

Patients were not involved.

Results

Thirty-five studies were included in the review for data extraction (14-48). The flow diagram depicting the number of studies identified and excluded at each stage is provided in Figure 1.

Description of the included studies

The most common population descriptor was community-dwelling or older adults of a certain age (17, 19, 27, 29, 31, 44, 45). Underlying conditions included mild cognitive impairment and dementia (n=5) (18, 28, 30, 32, 34), cardiac conditions (n=4) (15, 24-26), stroke (n=3) (22, 38, 40), falls and fear of falling (n=3) (21, 35, 48), hip fracture (n=2) (37, 39), diabetes (n=2) (14, 41, 42), breast cancer (20), Parkinson's disease (16), depression (23), chronic health problems (33), osteoarthritis (36), leg ulcer (43), neck pain (46) and foot problems (47).

The types of interventions reported were varied and included multicomponent (n=12) (14, 19, 23, 24, 26-29, 36, 39, 42, 45), support-based (n=5) (15, 16, 18, 30, 41), cognitive interventions (n=5) (31, 33, 34, 40, 48), physical activities (n=3) (17, 32, 46), nursing (n=2) (25, 43), falls prevention (21), occupational therapy (22), post-stroke care (38), podiatry (47) and dietary advice (37).

The included studies were from the UK (n=17) (14, 15, 17, 19, 20, 22, 31, 34-42, 47), Netherlands (n=6) (26, 27, 30, 44, 45, 48), USA (n=4) (18, 24, 25, 28), Canada (16), India (23), Germany (29, 46), Hong Kong (32), Italy (33), and Belgium (43). Ten studies were linked to other publications reporting the same intervention or other aspects of the development process (22, 25, 26, 28, 29, 31, 35, 39, 42, 43).

The reporting standard of the included studies was mixed with an average score of 4.4 (range=1-13) out of 13. All reported elements of the development and pilot phase of the checklist with only four studies reporting the evaluation stage (27, 35-36, 44). A table of the reporting standards for all included studies are provided in Supplementary Material 2.

What frameworks were reported

Thirteen studies did not report using a framework to assist their intervention development (18, 21, 23-25, 28, 32, 34, 35, 37, 46, 48). In total five frameworks were reported. The Medical Research Council (MRC) guidance was the most frequently used (77%, n=17) (15, 19, 20, 22, 26, 27, 29, 30, 33, 36, 38-42, 47). The other frameworks were intervention mapping (n=3) (16, 44, 45), conceptual modelling (n=1) (31), intervention/programme theory (n=1) (17), and the Van Meijel model (n=1) (43). Descriptions and key references for the frameworks are provided in Supplementary Material 3.

What methods were used for the different framework sections

MRC guided studies

A variety of different methods were utilised in the different stages of the MRC guidance within the included studies (see Table 1). Most (15, 22, 27, 30, 38, 40-42) reported their intervention development process according to the three MRC framework stages. These are: 1) identifying the evidence base, 2) developing theory, and 3) modelling processes and outcomes. Some only referenced the guidance and did not report the stages as distinct phases (19, 20, 29, 36, 39, 47) or described their own stages (such as *evidence exploration*, *tune-up with experts*, and *fine tuning with patients*) (33). Three papers adapted and added a fourth stage their development process (14, 26, 40).

All except the study by Wylie (47) reported using a literature review in their development work. The literature review was most commonly used to identify relevant evidence or theories to underpin the intervention being developed (n=11). Other methods utilised included: expert consultation (n=2), qualitative interviews with either clinicians or patients (n=7), and observations or surveying patients (n=8).

A variety of terms were used to describe the second stage of their development process, with some categorising this as theoretical development, whereas others were focusing on modelling. There was a wide range of research methods reported in this second stage, including literature reviews (n=4), expert consultations (n=3), qualitative interviews and focus groups (n=4), observations (n=2), and pilot studies (n=5).

Nine studies then described a feasibility or modelling stage (14, 15, 22, 26, 27, 30, 33, 38, 40). This phase included pilot studies (n=3), qualitative focus groups and interviews (n=6), where data was collected. One study (27) reported eight different research methods at this stage including a Delphi consensus process.

The four studies that added a fourth stage into their development processes varied in terms used to describe it, including "pilot study" (14), "face validity" (26) and "assessing feasibility of the intervention" (40). Two of the studies reported completing a pilot or feasibility study within this stage (14, 40) whereas the third included expert meetings (26).

Other framework guided studies

Six studies used a variety of intervention development frameworks (16, 17, 31, 43-45). Reporting of the research methods used in these studies were varied even when the same framework was used (Table 2). Intervention Mapping (9) was used in three studies, one of which provided no detail on the methods used in each section (16), whereas the other two reported very detailed processes and methods (44, 45). Table 2 describes the different intervention development frameworks and the research methods used within each framework.

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)
MRC Guidance				
Avery, et al. (2016)	*Exploratory work* 1. Interview with GPs 2. Interactive workshop (patients)	*Identification of active intervention ingredients* 1. Systematic review	*Assessing usability* 1. Use by adults with type 2 diabetes 2. Structured interview	*Pilot Study* 1. Acceptability and feasibility (semi-structured interviews)
Barley, et al. (2012)	*Studies to inform intervention* 1. Systematic review 2. Qualitative study (clinicians and patients)	*Integration of findings* 1. Findings from the informative studies 2. Iterative evidence review	*Modelling of the intervention* 1. Focus group 2. Evidence review	
Bruce, et al. (2012)	1. Systematic reviews 2. Clinical guidelines review 3. Expert views 4. Observations (clinicians) 5. Piloting of manual (patients)			
Burgess, et al. (2008)	*Phase 0 (Theoretical)* 1. Review of literature 2. Expert consultation	*Phase I (Piloting and Modelling)* 1. Pilot study 2. Qualitative interviews with participants to explore acceptability		
Cunningham, et al. (2016)	*Identify evidence* 1. Review of literature (clinical guidelines, systematic reviews)	*Model the intervention for delivery* 1. Piloting of manual (patients)	*Test feasibility* 1. Piloting of intervention	
Ettema, et al. (2014)	*Identified existing evidence* 1. Systematic review	*Identified and developed theory* 1. Systematic review 2. Derived the questionnaire 3. Analytical study (patient characteristics/outcomes)	*Modelled process and outcomes* 1. In-depth interviews (patients) 2. Survey (clinicians)	*Face validity* 1. Expert meetings (national experts) 2. Expert meetings (clinicians)
Faes, et al. (2010)	*Existing evidence* 1. Literature reviews 2. Project team meetings	*Theoretical understanding* 1. Literature review 2. Focus groups (experts) 3. Interviews (patients and caregivers) 4. Observations 5. Expert meetings	*Intervention modelling* 1. Focus groups 2. Delphi surveys 3. Interviews (patients and caregivers) 4. Literature review 5. Project team meeting 6. Observations 7. Interviews (experts) 8. Expert consultations	

Hinrichs, et al. (2013)	*Development* 1. Literature review 2. Cohort study (patients)			
Kerkhof, et al. (2016)	*Theoretical* 1. Literature reviews 2. Focus groups 3. Design of tool (users and stakeholders) 4. Mock-up and testing of app (patients) 5. Interviews 6. Development of theoretical framework and manual	*Modelling* 1. Pilot study 2. Interviews 3. Observational analysis 4. Case study (methods used) 5. Questionnaires 6. Inductive content analysis	*Exploratory trial* 1. Exploratory RCT 2. Literature search 3. Quantitative study 4. Qualitative evaluation	
Menichetti and Graffigna (2016)	*Evidences exploration* 1. Systematic review	*Tune-up with experts* 1. Expert group discussion	*Fine tuning with patients* 1. Semi-structured interviews	
Patel, et al. (2016)	1. Literature review 2. Pilot study 3. Process evaluation (observations of programme delivery, participant interviews)			
Redfern, et al. (2008)	*Pre-clinical phase* 1. Literature review 2. Analysis of current service 3. Interviews (patient representatives) 4. Observational study (patients) 5. Reviewing patient information leaflets	*Phase 1: Modelling* 1. Consensus meeting (researchers and experts) 2. Modification of data collection database 3. Developing computer algorithm 4. Development of patient intervention leaflets.	*Phase 2 Exploratory trial* 1. Pilot study (semi-structured interviews)	
Roberts, et al. (2017)	*Development of the intervention (phase 1 of MRC)* 1. Realist literature review 2. Surveys (patients and rehabilitation teams) 3. Focus groups (patients and rehabilitation teams)			
Sadler, et al. (2017)	*Identifying existing evidence and theory* 1. Literature search	*Developing the theoretical foundation of the intervention* 1. Qualitative literature review 2. Interviews (patients, spouse, carers and professionals)	*Modelling process and outcomes* 1. No formal method given " designed "	*Assessing feasibility of the intervention* 1. Feasibility study (questionnaires pre and post intervention, qualitative data from participants

		3. Stakeholder consultation (researchers, clinicians and service users) 4. Scoping of literature	and professionals delivering intervention).
Sturt, et al. (2006)	*Preclinical phase* 1. Literature search	*Phase I studies* 1. Iterative process between evidence and intervention components 2. Study (patients)	
Troughton, et al. (2016)	*Development "iterative process"* 1. Team and expert meetings 2. Literature review 3. Qualitative study (observation, telephone and face-to-face interviews and focus groups) 4. Pilot study (intervention)	*Feasibility and piloting* 1. Phased pilot study	
Wylie, et al. (2017)	1. Remodelling of intervention (feasible and acceptable in setting, refined recruitment processes and outcomes) 2. Pilot RCT (intervention)		

Table 1: Presentation of the methods used for each element of the MRC framework

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)	Methods used in IDF element (e)	Methods used in IDF element (f)
Intervention Mapping						
Beaudet, et al. (2015)	*Assessing needs and preferences* 1. Interviews (patients)	*Developing intervention* 1. Theory and model selection 2. Intervention proposal validation (patients and stakeholders)	*Formalising*	*Testing and evaluating* 1. Pilot testing (intervention)		
Stralen, et al. (2008)	*A needs assessment of the study population and the definition of programme objectives* 1. Literature search 2. Focus-group interviews (patients) 3. Interviews (stakeholders)	*Defining the performance objectives, specifying what changes are needed* 1. Literature review 2. Delphi study (experts) 3. Theoretical models review	*Selecting theory-based intervention methods and practical strategies to change health behaviour and its determinants* 1. Literature search 2. Search of existing interventions 3. Focus-group interviews (patients)	*Developing an intervention programme in which all strategies are integrated, as well as selecting, testing and producing intervention materials* 1. Brainstorming sessions (experts and patients)	*Developing a programme adoption and implementation plan* 1. Pilot study (implementation and recruitment)	*Anticipating a process and effect evaluation of the programme* 1. Process and effect evaluation
Walters, et al. (2015).	*Needs assessment* 1. Literature search 2. Survey 3. Project management group consultations 4. Interviews (experts)	*Programme objectives* 1. Survey 2. Literature search 3. Project management group consultations 4. Interviews (experts and workers)	*Theory-based methods and practical applications* 1. Literature search 2. Project management group consultations 3. Interviews (experts and workers)	*Programme plan* 1. Project management group consultations 2. Interviews (experts and workers) 3. Pilot study (training)	*Programme implementation* 1. Literature search 2. Consultation with stakeholders 3. Idea collection (workers and instructors)	*Evaluation plan* 1. Evaluation (questionnaire and discussion of workers and training)
Conceptual modelling						
Kingstone, et al. (2017)	*PPIE involvement*	*Development of conceptual model* 1. Interviews (patients and clinicians	*Agreement of conceptual model* 1. Consensus process (researchers)			
Intervention/programme theory						

Blamey, et al. (2013)	1. Logic model of intervention theory		
Van Meijel model			
Van Hecke, et al. (2011).	*Collection of building blocks needed for the design of the intervention* 1. Literature review 2. Interviews (problem and needs analysis) 3. Focus groups (clinicians)	*Intervention design* 1. Expert commentary	*Validation of the nursing intervention* 1. Qualitative study (patients) 2. Evaluation

Table 2: Presentation of the methods used for each element of the other intervention development frameworks

Discussion

Principle findings

Thirty-five studies were included in the review for data extraction. Twelve studies did not cite a framework to assist their intervention development. Five frameworks were reported by the 23 studies who did use one. The MRC guidance was the most frequently used with 77% (n=17). The other four frameworks were intervention mapping, conceptual modelling, intervention/programme theory, and the Van Meijel model but these were only used in a small number of studies. Of the numerous potential frameworks researchers could be using this study highlights that most researchers felt that the MRC, is at present, the most appropriate for their use. Although the quality of the studies in this review was not measured against any standardised measure, the studies that used the MRC guidance provided considerably more details about the components of intervention development than the studies using other frameworks providing a greater degree of confidence that the results had been rigorously collected and not biased. This may indicate that the MRC is written in a way that helps researchers follow a process more easily. However, three studies also adapted and added to the MRC process, indicating that there are further aspects to consider that are not addressed in that guidance.

Strengths and weaknesses of this study

This review was conducted in line with PRISMA guidelines following a systematic process, using pre-defined eligibility criteria and independent assessment by two reviewers at each stage. As with all reviews, there may have been studies that were missed due to the parameters of the review, such as, the definition of rehabilitation that was used. Data extraction was completed using a standardised spreadsheet by all authors and despite regular review meetings there was discrepancy in the interpretation of research methods and the level of detail extracted. For example, what is counted as a "literature review" could for one study be a Cochrane review whilst for another it is a non-systematised narrative description of the field of research.

The findings of this review are limited by the information available about intervention development within the identified literature. It is acknowledged that many journals prefer to publish detail on the intervention content with little focus on the development process and this was evident in this review. Intervention development frameworks are a relatively recent development and studies conducted before the MRC guidance was introduced in 2000 may have had limited methodological literature to guide their intervention development. This review searched all literature from the date of inception of the electronic database and this search strategy may have biased the number of studies not reporting the use of a framework. It is anticipated that over the coming years there will be many more studies reporting the use of a framework and providing more details on that process. Details on the intervention development may not be through journal publications, but through online supplementary material, discussion series, study or institution websites, or online data repositories.

This review did not report on the quality of the studies. Whilst quality assessments are standard practice in systematic reviews (49), there is not yet a quality assessment tool for intervention development studies. The intention of this review was to make comment on the current state of the literature relating to intervention development. Studies were not included or excluded based on their quality, but on their detail of the intervention development process and methods. A critique against the reporting standards was included as a compromise and to compare the included studies to the recognised publishing standards.

Strengths and weaknesses in relation to other studies

To our knowledge this is the first review of intervention development frameworks used in developing rehabilitation interventions for older people.

The MRC guidance (7) from the UK provides a structure to the development and evaluation process for complex interventions. However, the MRC guidance is brief and has been criticised for not dealing well with the complexity of complex interventions (50-52). Although the MRC framework was the most commonly cited framework, the included papers provided varying levels of detail over how the framework was used, and a lack of clarity over whether all three stages of development were explored. The lack of consistency and detail may be a result of the limited practical guidance offered by the MRC framework. There were however common approaches used in the papers citing the MRC framework which included; literature reviews, consultation with stakeholders, interviews with patients and clinicians, consensus methodologies and pilot work. It is clear from this review that there is not a consistent approach to developing rehabilitation interventions for older adults and further work is needed to establish how, and which, research methods should be used within the different stages of intervention development.

Other frameworks to support intervention development include the 6SQUID which was based on the experiences of Wight and colleagues (10) in developing public health interventions. Although this framework provides more detail there is still a lack of methodological detail on how to undertake each element. It also has a public health focus which may not consider all aspects needed in the development of a complex rehabilitation intervention. In providing a rationale for the development of the 6SQUID framework, Wight and colleagues provided a summary and appraisal of existing intervention development frameworks in public health and included both the MRC framework and Intervention Mapping which were identified in this review. Intervention Mapping is an involved and detailed process (9) which may account for it being referred to in only three papers in this review. Mohler and colleagues (8) published criteria for reporting the development and evaluation of complex interventions (CREDECI) through a three-stage consensus process. This aimed to improve quality of the reporting on the underlying theory of an intervention, the components and interactions of an intervention as well as any contextual factors. Whilst its merits are acknowledged, the primary focus was on the evaluation phase and the criteria provide little detail on how to undertake the process of intervention development. The COM-B model and theoretical domains framework (53) is another intervention development framework that is becoming increasingly popular in the behaviour change literature but has not widely been used in rehabilitation research as yet.

Meaning and implications

Many studies did not use an intervention framework and in those that did there was a lack of consistent detail regarding the intervention development process. Rigorous intervention development is necessary to avoid costly trials of underdeveloped interventions that have no theoretical basis, however there is a distinct lack of practical guidance to help researchers determine when an intervention is sufficiently developed. It is acknowledged that each rehabilitation intervention is by its very nature complex and therefore reliant on the experience of the individuals developing it, as well as the context and circumstances it is to be delivered in. A rigid framework that dictates exactly how an intervention should be developed may therefore not be appropriate as it would not allow for the nuances of each individual intervention and the different approaches that may be more pertinent to their circumstances. Nevertheless there does appear a need to provide researchers with further detail on the indicators of good practice and what to consider when undertaking quality intervention development.

Recommendations

Following this review a number of recommendations can be made, including:

- Researchers should carefully plan and clearly detail the process of developing rehabilitation interventions for older people using a recognised framework such as MRC
- Rehabilitation journals need to welcome further detail on the intervention development process utilising online supplementary material
- A consensus process is needed to depict best practice and provide guidance on developing a rehabilitation intervention for older adults

Conclusion

The MRC guidance is the most popular framework being used by researchers developing rehabilitation interventions for older adults. However, many studies do not report using a framework to guide their development. Further, specific guidance to help researchers chose and use the best framework for their intervention are needed.

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Competing interests statement

The authors declare no competing interests.

Author contributions

The original idea for the review was provided by KRR and VB. VB and KRR completed the electronic searches. VB, KRR, VHM and JEH completed data extraction. KRR and VB drafted the paper. PAL, JEH and VHM edited the paper. All authors contributed to the final paper in intellectual content, design and writing.

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Data Statement

Data can be accessed through correspondence with the lead author.

References

1. Young J. Rehabilitation and older people. BMJ: British Medical Journal. 1996;313(7058):677.
2. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ: British Medical Journal. 2007;334(7591):455.
3. Barker AL, Morello RT, Ayton DR, Hill KD, Landgren FS, Brand CA. Development of an implementation plan for the 6-PACK falls prevention programme as part of a randomised controlled trial: protocol for a series of preimplementation studies. Injury prevention. 2016;22(6):446-52.
4. Barker AL, Morello RT, Wolfe R, Brand CA, Haines TP, Hill KD, et al. 6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial. Bmj. 2016;352:h6781.
5. Slade SC, Carey DL, Hill A-M, Morris ME. Effects of falls prevention interventions on falls outcomes for hospitalised adults: protocol for a systematic review with meta-analysis. BMJ Open. 2017;7(11).
6. Walker MF, Hoffmann TC, Brady MC, Dean CM, Eng JJ, Farrin AJ, et al. Improving the development, monitoring and reporting of stroke rehabilitation research: Consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable. International Journal of Stroke. 2017;12(5):472-9.
7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337:979-83.
8. Mohler R, Bartoszek G, Kopke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): Guideline development. International Journal of Nursing Studies. 2012;49(1):40-6.
9. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory and evidence-based health education programs. Health Education & Behavior. 1998;25(5):545-63.
10. Wight D, Wimbush E, Jepson R, Doi L. Six Steps In Quality Intervention Development (6SQuID). J Epidemiol Community Health. 2015;0:1-6.
11. Cambridge Dictionary. Definition of "rehabilitation" - English Dictionary https://dictionary.cambridge.org/us/dictionary/english/rehabilitation: Cambridge University Press; 2018 [
12. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Annals of Internal Medicine. 2009;151(4):264-9.
13. Möhler R, Köpke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2). Trials. 2015;16(1):204.
14. Avery L, Charman SJ, Taylor L, Flynn D, Mosely K, Speight J, et al. Systematic development of a theory-informed multifaceted behavioural intervention to increase physical activity of adults with type 2 diabetes in routine primary care: Movement as Medicine for Type 2 Diabetes. Implementation Science. 2015;11(1):99.
15. Barley EA, Haddad M, Simmonds R, Fortune Z, Walters P, Murray J, et al. The UPBEAT depression and coronary heart disease programme: using the UK Medical Research Council framework to design a nurse-led complex intervention for use in primary care. BMC family practice. 2012;13(1):119.
16. Beaudet L, Ducharme F, L'Écuyer N, Chouinard S, Jodoin N, Panisset M. Development and evaluation of a dyadic intervention for elderly couples living with moderate-stage Parkinson disease. Applied Nursing Research. 2015;28(4):e21-e7.
17. Blamey AA, MacMillan F, Fitzsimons CF, Shaw R, Mutrie N. Using programme theory to strengthen research protocol and intervention design within an RCT of a walking intervention. Evaluation. 2013;19(1):5-23.
18. Brody AA, Guan C, Cortes T, Galvin JE. Development and testing of the Dementia Symptom Management at Home (DSM-H) program: An interprofessional home health care intervention to improve the quality of life for persons with dementia and their caregivers. Geriatr Nurs. 2016;37(3):200-6.

19. Bruce J, Ralhan S, Sheridan R, Westacott K, Withers E, Finnegan S, et al. The design and development of a complex multifactorial falls assessment intervention for falls prevention: The Prevention of Falls Injury Trial (PreFIT). BMC Geriatr. 2017;17(1):116.
20. Burgess C, Bish A, Hunter H, Salkovskis P, Michell M, Whelehan P, et al. Promoting early presentation of breast cancer: development of a psycho-educational intervention. Chronic Illn. 2008;4(1):13-27.
21. Claflin S. Development of a home care falls prevention and intervention program. J Clin Outcomes Manage. 2005;12(12):637-42.
22. Cunningham P, Turton AJ, Van Wijck F, Van Vliet P. Task-specific reach-to-grasp training after stroke: development and description of a home-based intervention. Clin Rehabil. 2016;30(8):731-40.
23. Dias A, Azariah F, Cohen A, Anderson S, Morse J, Cuijpers P, et al. Intervention development for the indicated prevention of depression in later life: The "DIL" protocol in Goa, India. Contemporary clinical trials communications. 2017;6:131-9.
24. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and Testing of an Intervention to Improve Outcomes for Partners Following Receipt of an Implantable Cardioverter Defibrillator in the Patient. Advances in Nursing Science. 2012;35(4):359-77.
25. Duffy JR, Hoskins LM, Dudley-Brown S. Development and Testing of a Caring-based Intervention for Older Adults With Heart Failure. J Cardiovasc Nurs. 2005;20(5):325-33.
26. Ettema RG, Hoogendoorn ME, Kalkman CJ, Schuurmans MJ. Development of a nursing intervention to prepare frail older patients for cardiac surgery (the PREDOCS programme), following phase one of the guidelines of the Medical Research Council. Eur J Cardiovasc Nurs. 2014;13(6):494-505.
27. Faes MC, Reelick MF, Esselink RA, Rikkert MGO. Developing and evaluating complex healthcare interventions in geriatrics: the use of the medical research council framework exemplified on a complex fall prevention intervention. J Am Geriatr Soc. 2010;58(11):2212-21.
28. Gildengers AG, Butters MA, Albert SM, Anderson SJ, Dew MA, Erickson K, et al. Design and implementation of an intervention development study: Retaining Cognition while Avoiding Late-Life Depression (ReCALL). The American Journal of Geriatric Psychiatry. 2016;24(6):444-54.
29. Hinrichs T, Brach M, Bucchi C, Moschny A, Wilm S, Thiem U, et al. An exercise programme for community-dwelling, mobility-restricted and chronically ill older adults with structured support by the general practitioner's practice (HOMEfit). Z Gerontol Geriatr. 2013;46(1):56-63.
30. Kerkhof YJ, Graff MJ, Bergsma A, de Vocht HH, Dröes R-M. Better self-management and meaningful activities thanks to tablets? Development of a person-centered program to support people with mild dementia and their carers through use of hand-held touch screen devices. International psychogeriatrics. 2016;28(11):1917-29.
31. Kingstone T, Burroughs H, Bartlam B, Ray M, Proctor J, Shepherd T, et al. Developing a community-based psycho-social intervention with older people and third sector workers for anxiety and depression: a qualitative study. BMC family practice. 2017;18(1):77.
32. Lai CK, Lai DL, Ho JS, Wong KK, Cheung DS. Interdisciplinary collaboration in the use of a music-with-movement intervention to promote the wellbeing of people with dementia and their families: Development of an evidence-based intervention protocol. Nursing & health sciences. 2016;18(1):79-84.
33. Menichetti J, Graffigna G. "PHE in Action": Development and Modeling of an Intervention to Improve Patient Engagement among Older Adults. Frontiers in psychology. 2016;7:1405.
34. O'Sullivan M, Coen R, O'Hora D, Shiel A. Cognitive rehabilitation for mild cognitive impairment: developing and piloting an intervention. Aging, Neuropsychology, and Cognition. 2015;22(3):280-300.
35. Parry S, Bamford C, Deary V, Finch T, Gray J, MacDonald C, et al. Cognitive–behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial–the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study. Health Technol Assess. 2016;20(56):1-206.

36. Patel S, Heine PJ, Ellard DR, Underwood M. Group exercise and self-management for older adults with osteoarthritis: a feasibility study. Primary health care research & development. 2016;17(3):252-64.
37. Price RJ, McMurdo ME, Anderson AS. A personalized snack-based intervention for hip fracture patients: development, feasibility and acceptability. Journal of human nutrition and dietetics. 2006;19(2):139-45.
38. Redfern J, Rudd AD, Wolfe CD, McKevitt C. Stop Stroke: development of an innovative intervention to improve risk factor management after stroke. Patient education and counseling. 2008;72(2):201-9.
39. Roberts JL, Din NU, Williams M, Hawkes CA, Charles JM, Hoare Z, et al. Development of an evidence-based complex intervention for community rehabilitation of patients with hip fracture using realist review, survey and focus groups. BMJ open. 2017;7(10):e014362.
40. Sadler E, Sarre S, Tinker A, Bhalla A, McKevitt C. Developing a novel peer support intervention to promote resilience after stroke. Health & social care in the community. 2017;25(5):1590-600.
41. Sturt J, Whitlock S, Hearnshaw H. Complex intervention development for diabetes self-management. J Adv Nurs. 2006;54(3):293-303.
42. Troughton J, Chatterjee S, Hill SE, Daly H, Martin Stacey L, Stone MA, et al. Development of a lifestyle intervention using the MRC framework for diabetes prevention in people with impaired glucose regulation. Journal of Public Health. 2016;38(3):493-501.
43. Van Hecke A, Verhaeghe S, Grypdonck M, Beele H, Flour M, Defloor T. Systematic development and validation of a nursing intervention: the case of lifestyle adherence promotion in patients with leg ulcers. J Adv Nurs. 2011;67(3):662-76.
44. van Stralen MM, Kok G, de Vries H, Mudde AN, Bolman C, Lechner L. The Active plus protocol: systematic development of two theory-and evidence-based tailored physical activity interventions for the over-fifties. BMC Public Health. 2008;8(1):399.
45. Walters ME, Dijkstra A, de Winter AF, Reijneveld SA. Development of a training programme for home health care workers to promote preventive activities focused on a healthy lifestyle: an intervention mapping approach. BMC health services research. 2015;15(1):263.
46. Wiedemann AM, von Trott P, Luedtke R, Reisshauer A, Willich SN, Witt CM. Developing a qigong intervention and an exercise therapy for elderly patients with chronic neck pain and the study protocol. Complementary Medicine Research. 2008;15(4):195-202.
47. Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, et al. Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study). BMC Geriatr. 2017;17(1):143.
48. Zijlstra GR, Tennstedt SL, van Haastregt JC, van Eijk JTM, Kempen GI. Reducing fear of falling and avoidance of activity in elderly persons: The development of a Dutch version of an American intervention. Patient Education and Counseling. 2006;62(2):220-7.
49. Grant MJ, Booth A. A typology of reviews: an analysis of 14 review types and associated methodologies. Health Information & Libraries Journal. 2009;26(2):91-108.
50. Anderson R. New MRC guidance on evaluating complex interventions. BMJ: British Medical Journal (Online). 2008;337.
51. Kernick D. Guidelines perpetuate inappropriate methods. BMJ: British Medical Journal (Online). 2008;337.
52. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. International Journal of Nursing Studies. 2013;50(5):587-92.
53. Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. Needed: physician leaders. 2014;26:146.

Figure Legend

Figure 1:

Flow diagram depicting the number of studies identified and excluded at each stage (each stage of the review process is depicted by a box in a sequential design as suggested by PRISMA (12)).

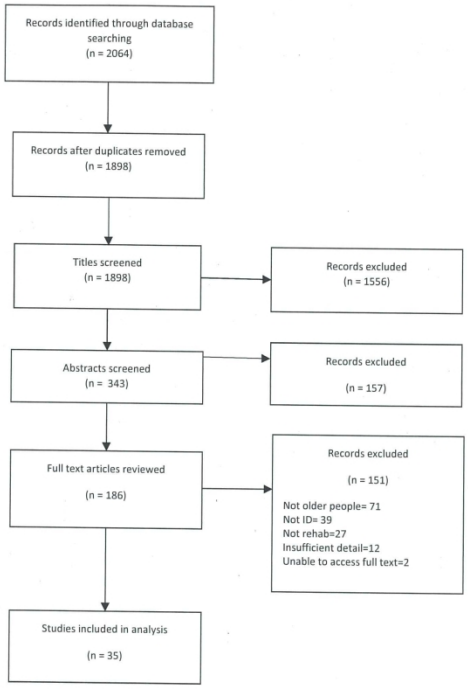

Figure 1: Flow diagram depicting the number of studies identified and excluded at each stage (each stage of the review process is depicted by a box in a sequential design as suggested by PRISMA (12)).

209x298mm (300 x 300 DPI)

Supplementary Material 1: Example of search strategy

Search strategy for MEDLINE (1996+)

a)	"developing and evaluating complex interventions" (all fields)
b)	"development" OR "develop*" (title)
c)	"intervention" (title)
d)	B) and C)
e)	A or D
f)	"older" OR "old*" OR "elderly" (all fields)
g)	E and F

Supplementary Material 2: Reporting standards for the included studies against the CReDECI2 criteria.

Reference		CReDECI 2 Checklist Item													Total
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	
14	Avery 2015	1	1	0	1	1	0	0	0	0	0	0	0	0	**4**
15	Barley 2012	1	1	0	1	0	0	0	0	0	0	0	0	0	**3**
16	Beaudet 2015	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
17	Blamey 2013	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
18	Brody 2016	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
19	Bruce 2017	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
20	Burgess 2008	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
21	Claflin 2005	0	1	0	0	1	0	0	0	0	0	0	0	0	**2**
22	Cunningham 2016	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
23	Dias 2017	1	1	0	1	0	0	0	0	0	0	0	0	0	**3**
24	Dougherty 2012	1	1	0	1	1	0	0	0	0	0	0	0	0	**4**
25	Duffy 2005	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
26	Ettema 2014	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
27	Faes 2010	1	0	1	1	1	0	0	0	0	1	0	0	0	**5**
28	Gildengers 2016	0	1	1	0	1	0	0	0	0	0	0	0	0	**3**
29	Hinrichs 2013	0	0	0	1	1	0	0	0	0	0	0	0	0	**2**
30	Kerkhof 2016	1	0	0	0	0	0	0	0	0	0	0	0	0	**1**
31	Kingstone 2017	1	0	0	1	0	0	0	0	0	0	0	0	0	**2**
32	Lai 2016	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
33	Menichetti 2016	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
34	O'Sullivan 2015	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
35	Parry 2016	1	1	1	1	1	1	1	1	1	1	1	1	1	**13**
36	Patel 2016	0	1	1	0	1	0	1	1	0	1	1	1	0	**8**
37	Price 2006	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
38	Redfern 2008	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
39	Roberts 2017	0	1	1	0	0	0	0	0	0	0	0	0	0	**2**
40	Sadler 2017	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
41	Sturt 2006	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
42	Troughton 2016	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
43	Van Hecke 2011	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
44	van Stralen 2008	1	1	1	1	1	1	1	1	0	1	0	0	0	**9**
45	Walters 2015	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
46	Wiedemann 2008	0	1	0	1	1	0	0	0	0	0	0	0	0	**3**
47	Wylie 2017	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
48	Zijlstra 2006	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**

Supplementary Material 3: Descriptions of the intervention development frameworks included in the review.

Name of framework	Description	Key reference(s) or website
Medical Research Council Guidance	The Medical Research Council guidance is a published framework for evaluating complex interventions. Its original 2000 guidance was updated in 2008 and suggests a non-linear phased sequence.	Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008, 337:a1655.
Intervention Mapping	Intervention Mapping is a six-stepped method going from identifying the problem through to solving the problem and is focused on behaviour change interventions. It is a self-described protocol which can aid the development of these types of interventions.	Bartholomew LK, Parcel GS, Kok G, Gottlieb NH, Fernández ME. Planning Health Promotion Programs - An Intervention Mapping Approach. 3rd ed. San Francisco: CA: Jossey-Bass; 2011. https://interventionmapping.com/
Conceptual Modelling	Conceptual modelling is a term used in multiple fields (e.g., business, computing, social sciences and health research). A conceptual model is a model or diagrammatic representation of the rationale, process and/or outcomes. It has been used in health research previously and examples are given.	E.g., Wagner E, Austin B, Von Korff M: Organizing care for patients with chronic illness. *Milbank Q* 1996, 74:511–543. Gask et al., Improving access to psychosocial interventions for common mental health problems in the United Kingdom: narrative review and development of a conceptual model for complex interventions. BMC Health Serv Res. 2012;12(1):249.
Programme Theory	Programme theory is a term that has been used by evaluators to describe the theory underpinning a programme, such as a social or health intervention. Programme theory also refers to a specific concept used within realistic evaluation.	Weiss CH (1998) Evaluation: Methods for Studying Programs and Policies. Upper Saddle River, NJ: Prentice Hall. Pawson R and Tilley N (1997) Realistic Evaluation. London: SAGE.
Van Meijel Model	The Van Meijel model was first reported in 2004 and was established in response to the development of a nursing-based intervention. The model uses four stages from defining the problem through to validating the intervention.	Van Meijel B., Gamel C., van Swieten-Duijfjes B. & Grypdonck M.H. (2004) The development of evidence-based nursing interventions: methodological considerations. *Journal of Advanced Nursing* 48, 84–92.

Reporting checklist for systematic review and meta-analysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA reporting guidelines, and cite them as:

Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

		Reporting Item	Page Number
	#1	Identify the report as a systematic review, meta-analysis, or both.	1
Structured summary	#2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	1-2
Rationale	#3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	#4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
Protocol and registration	#5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	n/a

Eligibility criteria	#6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	3
Information sources	#7	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	4
Search	#8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	See note 1
Study selection	#9	State the process for selecting studies (i.e., for screening, for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta-analysis).	4
Data collection process	#10	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	4
Data items	#11	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	4
Risk of bias in individual studies	#12	Describe methods used for assessing risk of bias in individual studies (including specification of whether this was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	4
Summary measures	#13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Planned methods of analyis	#14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	4
Risk of bias across studies	#15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	#16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
Study selection	#17	Give numbers of studies screened, assessed for eligibility, and	Figure 1

		included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	#18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	5
Risk of bias within studies	#19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	n/a
Results of individual studies	#20	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	5-11
Synthesis of results	#21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	5-11
Risk of bias across studies	#22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	#23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
Summary of Evidence	#24	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	12
Limitations	#25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	12-13
Conclusions	#26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14
Funding	#27	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	14

Author notes

1. Supplementary Material 1

BMJ Open

A systematic scoping review of frameworks used to develop rehabilitation interventions for older adults.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-024185.R3
Article Type:	Research
Date Submitted by the Author:	18-Dec-2018
Complete List of Authors:	Booth, Vicky; University of Nottingham School of Medicine, Division of Rehabilitation and Ageing Hood-Moore, Victoria; University of Nottingham School of Medicine, Division of Rehabilitation and Ageing Hancox, Jennie; University of Nottingham School of Medicine, Division of Rehabilitation and Ageing Logan, Phillipa; University of Nottingham School of Medicine, Division of Rehabilitation and Ageing Robinson, Katie; University of Nottingham School of Medicine, Division of Rehabilitation and Ageing
Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	Evidence based practice, Research methods
Keywords:	older adults, rehabilitation, intervention development, REHABILITATION MEDICINE

A systematic scoping review of frameworks used to develop rehabilitation interventions for older adults.

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Word Count: 3094

Abstract

Objectives

Rehabilitation interventions for older adults are complex as they involve a number of interacting components, have multiple outcomes of interest and are influenced by a number of contextual factors. The importance of rigorous intervention development prior to formal evaluation has been acknowledged and a number of frameworks have been developed. This review explored which frameworks have been used to guide the development of rehabilitation interventions for older adults.

Design

Systematic scoping review.

Setting

Studies were not limited for inclusion based on setting.

Participants

Studies were included that featured older adults (>65 years of age).

Interventions

Studies were included that reported the development of a rehabilitation intervention.

Primary and secondary outcome measures

Data was extracted on study population, setting, type of intervention developed and frameworks used. The primary outcome of interest was the type of intervention development framework.

Results

Thirty-five studies were included. There was a range of underlying medical conditions including mild cognitive impairment and dementia (n=5), cardiac (n=4), stroke (n=3), falls (n=3), hip fracture (n=2), diabetes (n=2), breast cancer (n=1), Parkinson's disease (n=1), depression (n=1), chronic health problems (n=1), osteoarthritis (n=1), leg ulcer (n=1), neck pain (n=1) and foot problems (n=1). The intervention types being developed included multicomponent, support-based, cognitive, physical activities, nursing-led, falls prevention and occupational therapy-led. Twelve studies (34%) did not report using a framework. Five frameworks were reported with the Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions being the most frequently cited (77%, n=17).

Conclusion

At present the MRC Framework is the most popular for developing rehabilitation interventions for older adults. Many studies do not report using a framework. Further, specific guidance to assist this complex field of rehabilitation research is required.

Key Words

Older adults, rehabilitation, intervention development

Article summary

- Rigorous intervention development prior to formal evaluation is important
- A number of frameworks have been developed but are inconsistently used or inconsistently reported
- PRISMA-ScR guidelines were followed for this systematic scoping review
- An electronic database search aimed to capture all studies reporting intervention development
- Studies involving older people and specifically reporting the development of a rehabilitation intervention were included

Introduction

"*Rehabilitation is concerned with lessening the impact of disabling conditions*" (p677 (1) and is a complex process requiring a holistic approach that considers physical, social and psychological function. Rehabilitation interventions for older adults are complex as they involve a number of interacting components, are often tailored to individual needs, have multiple outcomes of interest and are influenced by a number of environmental and contextual factors (2).

The need to develop a robust evidence base for complex rehabilitation interventions has led to an increased focus on developing and evaluating these interventions. Interventions initially showing promise in small scale testing are often ineffective when scaled into large multicentre randomised-trials (RCT). For example, an in-patient falls prevention programme that was effective during an observational study (3), failed to prevent falls to a significant degree compared to a control in a multisite RCT (4). A review including this example, explored the reasons for the difference in outcomes, citing different contextual factors (staffing, length of stay) (5). However, whilst

intervention development was reported by this example, a framework was not used and may have resulted in a lack of sound theoretical underpinning and understanding of the intervention mechanisms of action. The importance of rigorous intervention development prior to formal evaluation has been acknowledged by healthcare researchers in other fields (6) and a number of frameworks have been developed. These frameworks include the Medical Research Council (MRC) guidance for developing and evaluating complex interventions (7), Criteria for Reporting the Development and Evaluation of Complex Interventions (CReDECI) (8), intervention mapping (9) and the 6 Steps in Quality Intervention Development (6SQuID) (10). Although there are a number of intervention development frameworks, the lack of methodological detail and specificity to rehabilitation interventions may mean that researchers are using the frameworks in different ways or not using the frameworks at all.

Therefore the aims of this review were to a) to ascertain if intervention development frameworks are being used in older people rehabilitation research, b) to document which frameworks have been used and c) to explore how those frameworks are being used, what methods are employed, and how much detail is provided. This review will help researchers and clinicians to consider a range of frameworks for their studies and is the first step towards establishing more detailed guidance.

Methods

Review design

Systematic scoping review. This study was initially designed as a systematic review but was adapted at a late stage due to advice from reviewers and the editors.

Inclusion criteria

Target population of intervention

Studies were included if their participants were older people who were >65 years (either through study inclusion criteria, mean sample age of study population, or are described as older or elderly).

Intervention

The interventions being developed or described focused on rehabilitation. The definition of rehabilitation used was "*the process of returning to a healthy or good way of life, or the process of helping someone to do this after they have been in prison, been very ill, etc. or the process of returning something to a good condition*" (11). To be a rehabilitation intervention the paper had to report that the intervention: involved the individual(s) being rehabilitated; consisted of more than one session to indicate a process; aimed to create a change in the individual(s)' state or ability from doing the intervention; took place either after something or to prevent something (e.g., an incident/illness); and was described or labelled as "rehabilitation" by the authors.

Types of studies

Studies were included if they stated an aim or intent to either report the intervention that had been developed or to document the process or synthesis as justification or background for the next stage of intervention testing. This included mixed method studies, randomised control trials (RCT), controlled clinical trials, experimental studies, qualitative based analysis studies, cohort, cross-sectional and case control studies. Systematic reviews (all types) were considered for inclusion so reference lists could be explored for further studies that may not have been identified in the search strategy. Types of publications were also considered. Study protocols were considered for inclusion,

however, abstracts, thesis, dissertations, and conference proceedings were excluded due to the level of detail characteristic of these manuscripts (e.g., limited word counts with abstracts and significant word counts with thesis). Where possible if studies were part of a series of publications the other material available was sought and the most prominent paper detailing the intervention development process included.

Types of data and outcomes

Studies were included if they reported or described "intervention development" or "developing an intervention". Studies without a framework were included but only if they met the predetermined criteria that sufficient information and detail on the intervention development process or methods was presented. Studies that claimed to have completed an intervention development process but did not include any information on the process or method were excluded due to lack of data. All studies were assessed for inclusion by two authors and any discrepancy on the decision of a paper was discussed by all authors to reach a group consensus.

Studies were not limited nor selected according to their outcomes.

Search methods for identification of studies

The search strategy aimed to find both published and unpublished studies. A phased search strategy included search terms: "developing and evaluating complex interventions" (all fields), "development" OR "develop*" (title), "intervention" (title), "older" OR "old*" OR "elderly" (all fields).

Electronic searches

Initially, a limited search of MEDLINE and CINAHL was undertaken to identify and refine index terms used to describe relevant articles. Index terms and keywords were taken from known studies that reported their intervention development process and the search strategy refined to ensure these papers were captured.

A second full search using all identified keywords and index terms was then undertaken across relevant databases, including: The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue), MEDLINE, EMBASE, AMED, CINAHL and PsychINFO. The search was completed in October 2017. A full search strategy is presented in Supplementary Material 1.

Searching other resources

The reference list of full text studies were searched for related material that could be included or were more relevant for data extraction.

Data collection and analysis

Selection of studies

Each study identified for inclusion was considered independently by two reviewers at all stages: title screening, abstract screening, and full paper review for inclusion. Discrepancies between reviewer's decisions were recorded and discussed between the other authors to achieve an outcome.

Data extraction and management

Data was extracted from the included papers using a bespoke data extraction tool, the main categories of which were; study population, setting, type of intervention developed and frameworks used. If a framework was cited then a more detailed review of the components used was completed. Microsoft Excel was used as the data management software and compiled into a single database once agreement of included studies and data extraction had been completed. The review has been reported according to PRISMA-ScR guidelines and a checklist completed (12).

Assessment of methodological quality in included studies

Included studies were not assessed for methodological quality. However, each study was critiqued according to the latest reporting standards for the development and evaluation of complex interventions in healthcare (CReDECI2) (13). Assessment of the reporting standard of the studies would not influence their inclusion in the review.

Data synthesis

Data was collated and narratively described using tables and text.

Patient and Public Involvement

Patients were not involved.

Results

Thirty-five studies were included in the review for data extraction (14-48). The flow diagram depicting the number of studies identified and excluded at each stage is provided in Figure 1.

Description of the included studies

The most common population descriptor was community-dwelling or older adults of a certain age (17, 19, 27, 29, 31, 44, 45). Underlying conditions included mild cognitive impairment and dementia (n=5) (18, 28, 30, 32, 34), cardiac conditions (n=4) (15, 24-26), stroke (n=3) (22, 38, 40), falls and fear of falling (n=3) (21, 35, 48), hip fracture (n=2) (37, 39), diabetes (n=2) (14, 41, 42), breast cancer (20), Parkinson's disease (16), depression (23), chronic health problems (33), osteoarthritis (36), leg ulcer (43), neck pain (46) and foot problems (47).

The types of interventions reported were varied and included multicomponent (n=12) (14, 19, 23, 24, 26-29, 36, 39, 42, 45), support-based (n=5) (15, 16, 18, 30, 41), cognitive interventions (n=5) (31, 33, 34, 40, 48), physical activities (n=3) (17, 32, 46), nursing (n=2) (25, 43), falls prevention (21), occupational therapy (22), post-stroke care (38), podiatry (47) and dietary advice (37).

The included studies were from the UK (n=17) (14, 15, 17, 19, 20, 22, 31, 34-42, 47), Netherlands (n=6) (26, 27, 30, 44, 45, 48), USA (n=4) (18, 24, 25, 28), Canada (16), India (23), Germany (29, 46), Hong Kong (32), Italy (33), and Belgium (43). Ten studies were linked to other publications reporting the same intervention or other aspects of the development process (22, 25, 26, 28, 29, 31, 35, 39, 42, 43).

The reporting standard of the included studies was mixed with an average score of 4.4 (range=1-13) out of 13. All reported elements of the development and pilot phase of the checklist with only four studies reporting the evaluation stage (27, 35-36, 44). A table of the reporting standards for all included studies are provided in Supplementary Material 2.

What frameworks were reported

Thirteen studies did not report using a framework to assist their intervention development (18, 21, 23-25, 28, 32, 34, 35, 37, 46, 48). In total five frameworks were reported. The Medical Research Council (MRC) guidance was the most frequently used (77%, n=17) (15, 19, 20, 22, 26, 27, 29, 30, 33, 36, 38-42, 47). The other frameworks were intervention mapping (n=3) (16, 44, 45), conceptual modelling (n=1) (31), intervention/programme theory (n=1) (17), and the Van Meijel model (n=1) (43). Descriptions and key references for the frameworks are provided in Supplementary Material 3.

What methods were used for the different framework sections

MRC guided studies

A variety of different methods were utilised in the different stages of the MRC guidance within the included studies (see Table 1). Most (15, 22, 27, 30, 38, 40-42) reported their intervention development process according to the three MRC framework stages. These are: 1) identifying the evidence base, 2) developing theory, and 3) modelling processes and outcomes. Some only referenced the guidance and did not report the stages as distinct phases (19, 20, 29, 36, 39, 47) or described their own stages (such as *evidence exploration*, *tune-up with experts*, and *fine tuning with patients*) (33). Three papers adapted and added a fourth stage their development process (14, 26, 40).

All except the study by Wylie (47) reported using a literature review in their development work. The literature review was most commonly used to identify relevant evidence or theories to underpin the intervention being developed (n=11). Other methods utilised included: expert consultation (n=2), qualitative interviews with either clinicians or patients (n=7), and observations or surveying patients (n=8).

A variety of terms were used to describe the second stage of their development process, with some categorising this as theoretical development, whereas others were focusing on modelling. There was a wide range of research methods reported in this second stage, including literature reviews (n=4), expert consultations (n=3), qualitative interviews and focus groups (n=4), observations (n=2), and pilot studies (n=5).

Nine studies then described a feasibility or modelling stage (14, 15, 22, 26, 27, 30, 33, 38, 40). This phase included pilot studies (n=3), qualitative focus groups and interviews (n=6), where data was collected. One study (27) reported eight different research methods at this stage including a Delphi consensus process.

The four studies that added a fourth stage into their development processes varied in terms used to describe it, including "pilot study" (14), "face validity" (26) and "assessing feasibility of the intervention" (40). Two of the studies reported completing a pilot or feasibility study within this stage (14, 40) whereas the third included expert meetings (26).

Other framework guided studies

Six studies used a variety of intervention development frameworks (16, 17, 31, 43-45). Reporting of the research methods used in these studies were varied even when the same framework was used (Table 2). Intervention Mapping (9) was used in three studies, one of which provided no detail on the methods used in each section (16), whereas the other two reported very detailed processes and methods (44, 45). Table 2 describes the different intervention development frameworks and the research methods used within each framework.

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)
MRC Guidance				
Avery, et al. (2016)	*Exploratory work* 1. Interview with GPs 2. Interactive workshop (patients)	*Identification of active intervention ingredients* 1. Systematic review	*Assessing usability* 1. Use by adults with type 2 diabetes 2. Structured interview	*Pilot Study* 1. Acceptability and feasibility (semi-structured interviews)
Barley, et al. (2012)	*Studies to inform intervention* 1. Systematic review 2. Qualitative study (clinicians and patients)	*Integration of findings* 1. Findings from the informative studies 2. Iterative evidence review	*Modelling of the intervention* 1. Focus group 2. Evidence review	
Bruce, et al. (2012)	1. Systematic reviews 2. Clinical guidelines review 3. Expert views 4. Observations (clinicians) 5. Piloting of manual (patients)			
Burgess, et al. (2008)	*Phase 0 (Theoretical)* 1. Review of literature 2. Expert consultation	*Phase I (Piloting and Modelling)* 1. Pilot study 2. Qualitative interviews with participants to explore acceptability		
Cunningham, et al. (2016)	*Identify evidence* 1. Review of literature (clinical guidelines, systematic reviews)	*Model the intervention for delivery* 1. Piloting of manual (patients)	*Test feasibility* 1. Piloting of intervention	
Ettema, et al. (2014)	*Identified existing evidence* 1. Systematic review	*Identified and developed theory* 1. Systematic review 2. Derived the questionnaire 3. Analytical study (patient characteristics/outcomes)	*Modelled process and outcomes* 1. In-depth interviews (patients) 2. Survey (clinicians)	*Face validity* 1. Expert meetings (national experts) 2. Expert meetings (clinicians)
Faes, et al. (2010)	*Existing evidence* 1. Literature reviews 2. Project team meetings	*Theoretical understanding* 1. Literature review 2. Focus groups (experts) 3. Interviews (patients and caregivers) 4. Observations 5. Expert meetings	*Intervention modelling* 1. Focus groups 2. Delphi surveys 3. Interviews (patients and caregivers) 4. Literature review 5. Project team meeting 6. Observations 7. Interviews (experts) 8. Expert consultations	

Hinrichs, et al. (2013)	*Development* 1. Literature review 2. Cohort study (patients)			
Kerkhof, et al. (2016)	*Theoretical* 1. Literature reviews 2. Focus groups 3. Design of tool (users and stakeholders) 4. Mock-up and testing of app (patients) 5. Interviews 6. Development of theoretical framework and manual	*Modelling* 1. Pilot study 2. Interviews 3. Observational analysis 4. Case study (methods used) 5. Questionnaires 6. Inductive content analysis	*Exploratory trial* 1. Exploratory RCT 2. Literature search 3. Quantitative study 4. Qualitative evaluation	
Menichetti and Graffigna (2016)	*Evidences exploration* 1. Systematic review	*Tune-up with experts* 1. Expert group discussion	*Fine tuning with patients* 1. Semi-structured interviews	
Patel, et al. (2016)	1. Literature review 2. Pilot study 3. Process evaluation (observations of programme delivery, participant interviews)			
Redfern, et al. (2008)	*Pre-clinical phase* 1. Literature review 2. Analysis of current service 3. Interviews (patient representatives) 4. Observational study (patients) 5. Reviewing patient information leaflets	*Phase 1: Modelling* 1. Consensus meeting (researchers and experts) 2. Modification of data collection database 3. Developing computer algorithm 4. Development of patient intervention leaflets.	*Phase 2 Exploratory trial* 1. Pilot study (semi-structured interviews)	
Roberts, et al. (2017)	*Development of the intervention (phase 1 of MRC)* 1. Realist literature review 2. Surveys (patients and rehabilitation teams) 3. Focus groups (patients and rehabilitation teams)			
Sadler, et al. (2017)	*Identifying existing evidence and theory* 1. Literature search	*Developing the theoretical foundation of the intervention* 1. Qualitative literature review 2. Interviews (patients, spouse, carers and professionals)	*Modelling process and outcomes* 1. No formal method given " designed "	*Assessing feasibility of the intervention* 1. Feasibility study (questionnaires pre and post intervention, qualitative data from participants

		3. Stakeholder consultation (researchers, clinicians and service users) 4. Scoping of literature	and professionals delivering intervention).
Sturt, et al. (2006)	*Preclinical phase* 1. Literature search	*Phase I studies* 1. Iterative process between evidence and intervention components 2. Study (patients)	
Troughton, et al. (2016)	*Development "iterative process"* 1. Team and expert meetings 2. Literature review 3. Qualitative study (observation, telephone and face-to-face interviews and focus groups) 4. Pilot study (intervention)	*Feasibility and piloting* 1. Phased pilot study	
Wylie, et al. (2017)	1. Remodelling of intervention (feasible and acceptable in setting, refined recruitment processes and outcomes) 2. Pilot RCT (intervention)		

Table 1: Presentation of the methods used for each element of the MRC framework

Study Reference	Methods used in IDF element (a)	Methods used in IDF element (b)	Methods used in IDF element (c)	Methods used in IDF element (d)	Methods used in IDF element (e)	Methods used in IDF element (f)
Intervention Mapping						
Beaudet, et al. (2015)	*Assessing needs and preferences* 1. Interviews (patients)	*Developing intervention* 1. Theory and model selection 2. Intervention proposal validation (patients and stakeholders)	*Formalising*	*Testing and evaluating* 1. Pilot testing (intervention)		
Stralen, et al. (2008)	*A needs assessment of the study population and the definition of programme objectives* 1. Literature search 2. Focus-group interviews (patients) 3. Interviews (stakeholders)	*Defining the performance objectives, specifying what changes are needed* 1. Literature review 2. Delphi study (experts) 3. Theoretical models review	*Selecting theory-based intervention methods and practical strategies to change health behaviour and its determinants* 1. Literature search 2. Search of existing interventions 3. Focus-group interviews (patients)	*Developing an intervention programme in which all strategies are integrated, as well as selecting, testing and producing intervention materials* 1. Brainstorming sessions (experts and patients)	*Developing a programme adoption and implementation plan* 1. Pilot study (implementation and recruitment)	*Anticipating a process and effect evaluation of the programme* 1. Process and effect evaluation
Walters, et al. (2015).	*Needs assessment* 1. Literature search 2. Survey 3. Project management group consultations 4. Interviews (experts)	*Programme objectives* 1. Survey 2. Literature search 3. Project management group consultations 4. Interviews (experts and workers)	*Theory-based methods and practical applications* 1. Literature search 2. Project management group consultations 3. Interviews (experts and workers)	*Programme plan* 1. Project management group consultations 2. Interviews (experts and workers) 3. Pilot study (training)	*Programme implementation* 1. Literature search 2. Consultation with stakeholders 3. Idea collection (workers and instructors)	*Evaluation plan* 1. Evaluation (questionnaire and discussion of workers and training)
Conceptual modelling						
Kingstone, et al. (2017)	*PPIE involvement*	*Development of conceptual model* 1. Interviews (patients and clinicians	*Agreement of conceptual model* 1. Consensus process (researchers)			
Intervention/programme theory						

Blamey, et al. (2013)	1. Logic model of intervention theory		
Van Meijel model			
Van Hecke, et al. (2011).	*Collection of building blocks needed for the design of the intervention* 1. Literature review 2. Interviews (problem and needs analysis) 3. Focus groups (clinicians)	*Intervention design* 1. Expert commentary	*Validation of the nursing intervention* 1. Qualitative study (patients) 2. Evaluation

Table 2: Presentation of the methods used for each element of the other intervention development frameworks

Discussion

Principle findings

Thirty-five studies were included in the review for data extraction. Twelve studies did not cite a framework to assist their intervention development. Five frameworks were reported by the 23 studies who did use one. The MRC guidance was the most frequently used with 77% (n=17). The other four frameworks were intervention mapping, conceptual modelling, intervention/programme theory, and the Van Meijel model but these were only used in a small number of studies. Of the numerous potential frameworks researchers could be using this study highlights that most researchers felt that the MRC, is at present, the most appropriate for their use. Although the quality of the studies in this review was not measured against any standardised measure, the studies that used the MRC guidance provided considerably more details about the components of intervention development than the studies using other frameworks providing a greater degree of confidence that the results had been rigorously collected and not biased. This may indicate that the MRC is written in a way that helps researchers follow a process more easily. However, three studies also adapted and added to the MRC process, indicating that there are further aspects to consider that are not addressed in that guidance.

Strengths and weaknesses of this study

This review was conducted in line with PRISMA-ScR guidelines following a systematic process, using pre-defined eligibility criteria and independent assessment by two reviewers at each stage. As with all reviews, there may have been studies that were missed due to the parameters of the review, such as, the definition of rehabilitation that was used. Data extraction was completed using a standardised spreadsheet by all authors and despite regular review meetings there was discrepancy in the interpretation of research methods and the level of detail extracted. For example, what is counted as a "literature review" could for one study be a Cochrane review whilst for another it is a non-systematised narrative description of the field of research.

The findings of this review are limited by the information available about intervention development within the identified literature. It is acknowledged that many journals prefer to publish detail on the intervention content with little focus on the development process and this was evident in this review. Intervention development frameworks are a relatively recent development and studies conducted before the MRC guidance was introduced in 2000 may have had limited methodological literature to guide their intervention development. This review searched all literature from the date of inception of the electronic database and this search strategy may have biased the number of studies not reporting the use of a framework. It is anticipated that over the coming years there will be many more studies reporting the use of a framework and providing more details on that process. Details on the intervention development may not be through journal publications, but through online supplementary material, discussion series, study or institution websites, or online data repositories.

This review did not report on the quality of the studies. Whilst quality assessments are standard practice in systematic reviews (49), there is not yet a quality assessment tool for intervention development studies. The intention of this review was to make comment on the current state of the literature relating to intervention development. Studies were not included or excluded based on their quality, but on their detail of the intervention development process and methods. A critique against the reporting standards was included as a compromise and to compare the included studies to the recognised publishing standards.

Strengths and weaknesses in relation to other studies

To our knowledge this is the first review of intervention development frameworks used in developing rehabilitation interventions for older people.

The MRC guidance (7) from the UK provides a structure to the development and evaluation process for complex interventions. However, the MRC guidance is brief and has been criticised for not dealing well with the complexity of complex interventions (50-52). Although the MRC framework was the most commonly cited framework, the included papers provided varying levels of detail over how the framework was used, and a lack of clarity over whether all three stages of development were explored. The lack of consistency and detail may be a result of the limited practical guidance offered by the MRC framework. There were however common approaches used in the papers citing the MRC framework which included; literature reviews, consultation with stakeholders, interviews with patients and clinicians, consensus methodologies and pilot work. It is clear from this review that there is not a consistent approach to developing rehabilitation interventions for older adults and further work is needed to establish how, and which, research methods should be used within the different stages of intervention development.

Other frameworks to support intervention development include the 6SQUID which was based on the experiences of Wight and colleagues (10) in developing public health interventions. Although this framework provides more detail there is still a lack of methodological detail on how to undertake each element. It also has a public health focus which may not consider all aspects needed in the development of a complex rehabilitation intervention. In providing a rationale for the development of the 6SQUID framework, Wight and colleagues provided a summary and appraisal of existing intervention development frameworks in public health and included both the MRC framework and Intervention Mapping which were identified in this review. Intervention Mapping is an involved and detailed process (9) which may account for it being referred to in only three papers in this review. Mohler and colleagues (8) published criteria for reporting the development and evaluation of complex interventions (CREDECI) through a three-stage consensus process. This aimed to improve quality of the reporting on the underlying theory of an intervention, the components and interactions of an intervention as well as any contextual factors. Whilst its merits are acknowledged, the primary focus was on the evaluation phase and the criteria provide little detail on how to undertake the process of intervention development. The COM-B model and theoretical domains framework (53) is another intervention development framework that is becoming increasingly popular in the behaviour change literature but has not widely been used in rehabilitation research as yet.

Meaning and implications

Many studies did not use an intervention framework and in those that did there was a lack of consistent detail regarding the intervention development process. Rigorous intervention development is necessary to avoid costly trials of underdeveloped interventions that have no theoretical basis, however there is a distinct lack of practical guidance to help researchers determine when an intervention is sufficiently developed. It is acknowledged that each rehabilitation intervention is by its very nature complex and therefore reliant on the experience of the individuals developing it, as well as the context and circumstances it is to be delivered in. A rigid framework that dictates exactly how an intervention should be developed may therefore not be appropriate as it would not allow for the nuances of each individual intervention and the different approaches that may be more pertinent to their circumstances. Nevertheless there does appear a need to provide researchers with further detail on the indicators of good practice and what to consider when undertaking quality intervention development.

Recommendations

Following this review a number of recommendations can be made, including:

- Researchers should carefully plan and clearly detail the process of developing rehabilitation interventions for older people using a recognised framework such as MRC
- Rehabilitation journals need to welcome further detail on the intervention development process utilising online supplementary material
- A consensus process is needed to depict best practice and provide guidance on developing a rehabilitation intervention for older adults

Conclusion

The MRC guidance is the most popular framework being used by researchers developing rehabilitation interventions for older adults. However, many studies do not report using a framework to guide their development. Further, specific guidance to help researchers chose and use the best framework for their intervention are needed.

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Competing interests statement

The authors declare no competing interests.

Author contributions

The original idea for the review was provided by KRR and VB. VB and KRR completed the electronic searches. VB, KRR, VHM and JEH completed data extraction. KRR and VB drafted the paper. PAL, JEH and VHM edited the paper. All authors contributed to the final paper in intellectual content, design and writing.

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Data Statement

Data can be accessed through correspondence with the lead author.

References

1. Young J. Rehabilitation and older people. BMJ: British Medical Journal. 1996;313(7058):677.
2. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ: British Medical Journal. 2007;334(7591):455.
3. Barker AL, Morello RT, Ayton DR, Hill KD, Landgren FS, Brand CA. Development of an implementation plan for the 6-PACK falls prevention programme as part of a randomised controlled trial: protocol for a series of preimplementation studies. Injury prevention. 2016;22(6):446-52.
4. Barker AL, Morello RT, Wolfe R, Brand CA, Haines TP, Hill KD, et al. 6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial. Bmj. 2016;352:h6781.
5. Slade SC, Carey DL, Hill A-M, Morris ME. Effects of falls prevention interventions on falls outcomes for hospitalised adults: protocol for a systematic review with meta-analysis. BMJ Open. 2017;7(11).
6. Walker MF, Hoffmann TC, Brady MC, Dean CM, Eng JJ, Farrin AJ, et al. Improving the development, monitoring and reporting of stroke rehabilitation research: Consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable. International Journal of Stroke. 2017;12(5):472-9.
7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337:979-83.
8. Mohler R, Bartoszek G, Kopke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): Guideline development. International Journal of Nursing Studies. 2012;49(1):40-6.
9. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory and evidence-based health education programs. Health Education & Behavior. 1998;25(5):545-63.
10. Wight D, Wimbush E, Jepson R, Doi L. Six Steps In Quality Intervention Development (6SQuID). J Epidemiol Community Health. 2015;0:1-6.
11. Cambridge Dictionary. Definition of "rehabilitation" - English Dictionary https://dictionary.cambridge.org/us/dictionary/english/rehabilitation: Cambridge University Press; 2018 [
12. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. Annals of Internal Medicine. 2018;169(7):467-73.
13. Möhler R, Köpke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2). Trials. 2015;16(1):204.
14. Avery L, Charman SJ, Taylor L, Flynn D, Mosely K, Speight J, et al. Systematic development of a theory-informed multifaceted behavioural intervention to increase physical activity of adults with type 2 diabetes in routine primary care: Movement as Medicine for Type 2 Diabetes. Implementation Science. 2015;11(1):99.
15. Barley EA, Haddad M, Simmonds R, Fortune Z, Walters P, Murray J, et al. The UPBEAT depression and coronary heart disease programme: using the UK Medical Research Council framework to design a nurse-led complex intervention for use in primary care. BMC family practice. 2012;13(1):119.
16. Beaudet L, Ducharme F, L'Écuyer N, Chouinard S, Jodoin N, Panisset M. Development and evaluation of a dyadic intervention for elderly couples living with moderate-stage Parkinson disease. Applied Nursing Research. 2015;28(4):e21-e7.
17. Blamey AA, MacMillan F, Fitzsimons CF, Shaw R, Mutrie N. Using programme theory to strengthen research protocol and intervention design within an RCT of a walking intervention. Evaluation. 2013;19(1):5-23.
18. Brody AA, Guan C, Cortes T, Galvin JE. Development and testing of the Dementia Symptom Management at Home (DSM-H) program: An interprofessional home health care intervention to

improve the quality of life for persons with dementia and their caregivers. Geriatr Nurs. 2016;37(3):200-6.
19. Bruce J, Ralhan S, Sheridan R, Westacott K, Withers E, Finnegan S, et al. The design and development of a complex multifactorial falls assessment intervention for falls prevention: The Prevention of Falls Injury Trial (PreFIT). BMC Geriatr. 2017;17(1):116.
20. Burgess C, Bish A, Hunter H, Salkovskis P, Michell M, Whelehan P, et al. Promoting early presentation of breast cancer: development of a psycho-educational intervention. Chronic Illn. 2008;4(1):13-27.
21. Claflin S. Development of a home care falls prevention and intervention program. J Clin Outcomes Manage. 2005;12(12):637-42.
22. Cunningham P, Turton AJ, Van Wijck F, Van Vliet P. Task-specific reach-to-grasp training after stroke: development and description of a home-based intervention. Clin Rehabil. 2016;30(8):731-40.
23. Dias A, Azariah F, Cohen A, Anderson S, Morse J, Cuijpers P, et al. Intervention development for the indicated prevention of depression in later life: The "DIL" protocol in Goa, India. Contemporary clinical trials communications. 2017;6:131-9.
24. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and Testing of an Intervention to Improve Outcomes for Partners Following Receipt of an Implantable Cardioverter Defibrillator in the Patient. Advances in Nursing Science. 2012;35(4):359-77.
25. Duffy JR, Hoskins LM, Dudley-Brown S. Development and Testing of a Caring-based Intervention for Older Adults With Heart Failure. J Cardiovasc Nurs. 2005;20(5):325-33.
26. Ettema RG, Hoogendoorn ME, Kalkman CJ, Schuurmans MJ. Development of a nursing intervention to prepare frail older patients for cardiac surgery (the PREDOCS programme), following phase one of the guidelines of the Medical Research Council. Eur J Cardiovasc Nurs. 2014;13(6):494-505.
27. Faes MC, Reelick MF, Esselink RA, Rikkert MGO. Developing and evaluating complex healthcare interventions in geriatrics: the use of the medical research council framework exemplified on a complex fall prevention intervention. J Am Geriatr Soc. 2010;58(11):2212-21.
28. Gildengers AG, Butters MA, Albert SM, Anderson SJ, Dew MA, Erickson K, et al. Design and implementation of an intervention development study: Retaining Cognition while Avoiding Late-Life Depression (ReCALL). The American Journal of Geriatric Psychiatry. 2016;24(6):444-54.
29. Hinrichs T, Brach M, Bucchi C, Moschny A, Wilm S, Thiem U, et al. An exercise programme for community-dwelling, mobility-restricted and chronically ill older adults with structured support by the general practitioner's practice (HOMEfit). Z Gerontol Geriatr. 2013;46(1):56-63.
30. Kerkhof YJ, Graff MJ, Bergsma A, de Vocht HH, Dröes R-M. Better self-management and meaningful activities thanks to tablets? Development of a person-centered program to support people with mild dementia and their carers through use of hand-held touch screen devices. International psychogeriatrics. 2016;28(11):1917-29.
31. Kingstone T, Burroughs H, Bartlam B, Ray M, Proctor J, Shepherd T, et al. Developing a community-based psycho-social intervention with older people and third sector workers for anxiety and depression: a qualitative study. BMC family practice. 2017;18(1):77.
32. Lai CK, Lai DL, Ho JS, Wong KK, Cheung DS. Interdisciplinary collaboration in the use of a music-with-movement intervention to promote the wellbeing of people with dementia and their families: Development of an evidence-based intervention protocol. Nursing & health sciences. 2016;18(1):79-84.
33. Menichetti J, Graffigna G. "PHE in Action": Development and Modeling of an Intervention to Improve Patient Engagement among Older Adults. Frontiers in psychology. 2016;7:1405.
34. O'Sullivan M, Coen R, O'Hora D, Shiel A. Cognitive rehabilitation for mild cognitive impairment: developing and piloting an intervention. Aging, Neuropsychology, and Cognition. 2015;22(3):280-300.
35. Parry S, Bamford C, Deary V, Finch T, Gray J, MacDonald C, et al. Cognitive–behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and

randomised controlled trial–the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study. Health Technol Assess. 2016;20(56):1-206.
36. Patel S, Heine PJ, Ellard DR, Underwood M. Group exercise and self-management for older adults with osteoarthritis: a feasibility study. Primary health care research & development. 2016;17(3):252-64.
37. Price RJ, McMurdo ME, Anderson AS. A personalized snack-based intervention for hip fracture patients: development, feasibility and acceptability. Journal of human nutrition and dietetics. 2006;19(2):139-45.
38. Redfern J, Rudd AD, Wolfe CD, McKevitt C. Stop Stroke: development of an innovative intervention to improve risk factor management after stroke. Patient education and counseling. 2008;72(2):201-9.
39. Roberts JL, Din NU, Williams M, Hawkes CA, Charles JM, Hoare Z, et al. Development of an evidence-based complex intervention for community rehabilitation of patients with hip fracture using realist review, survey and focus groups. BMJ open. 2017;7(10):e014362.
40. Sadler E, Sarre S, Tinker A, Bhalla A, McKevitt C. Developing a novel peer support intervention to promote resilience after stroke. Health & social care in the community. 2017;25(5):1590-600.
41. Sturt J, Whitlock S, Hearnshaw H. Complex intervention development for diabetes self-management. J Adv Nurs. 2006;54(3):293-303.
42. Troughton J, Chatterjee S, Hill SE, Daly H, Martin Stacey L, Stone MA, et al. Development of a lifestyle intervention using the MRC framework for diabetes prevention in people with impaired glucose regulation. Journal of Public Health. 2016;38(3):493-501.
43. Van Hecke A, Verhaeghe S, Grypdonck M, Beele H, Flour M, Defloor T. Systematic development and validation of a nursing intervention: the case of lifestyle adherence promotion in patients with leg ulcers. J Adv Nurs. 2011;67(3):662-76.
44. van Stralen MM, Kok G, de Vries H, Mudde AN, Bolman C, Lechner L. The Active plus protocol: systematic development of two theory-and evidence-based tailored physical activity interventions for the over-fifties. BMC Public Health. 2008;8(1):399.
45. Walters ME, Dijkstra A, de Winter AF, Reijneveld SA. Development of a training programme for home health care workers to promote preventive activities focused on a healthy lifestyle: an intervention mapping approach. BMC health services research. 2015;15(1):263.
46. Wiedemann AM, von Trott P, Luedtke R, Reisshauer A, Willich SN, Witt CM. Developing a qigong intervention and an exercise therapy for elderly patients with chronic neck pain and the study protocol. Complementary Medicine Research. 2008;15(4):195-202.
47. Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, et al. Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study). BMC Geriatr. 2017;17(1):143.
48. Zijlstra GR, Tennstedt SL, van Haastregt JC, van Eijk JTM, Kempen GI. Reducing fear of falling and avoidance of activity in elderly persons: The development of a Dutch version of an American intervention. Patient Education and Counseling. 2006;62(2):220-7.
49. Grant MJ, Booth A. A typology of reviews: an analysis of 14 review types and associated methodologies. Health Information & Libraries Journal. 2009;26(2):91-108.
50. Anderson R. New MRC guidance on evaluating complex interventions. BMJ: British Medical Journal (Online). 2008;337.
51. Kernick D. Guidelines perpetuate inappropriate methods. BMJ: British Medical Journal (Online). 2008;337.
52. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. International Journal of Nursing Studies. 2013;50(5):587-92.
53. Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. Needed: physician leaders. 2014;26:146.

Figure Legend

Figure 1:

Flow diagram depicting the number of studies identified and excluded at each stage (each stage of the review process is depicted by a box in a sequential design as suggested by PRISMA-ScR (12)).

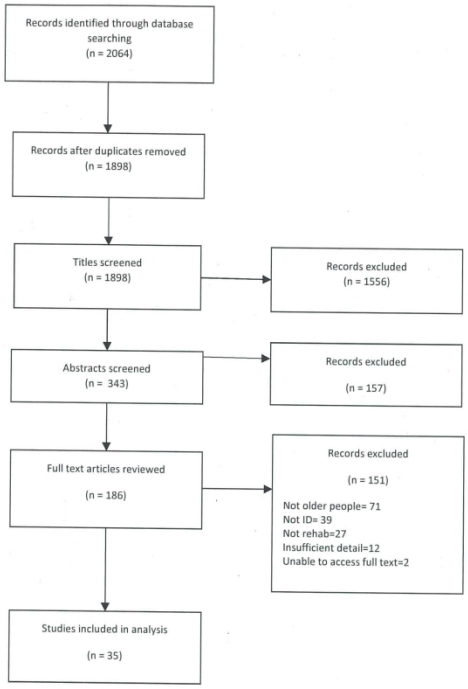

Figure 1: Flow diagram depicting the number of studies identified and excluded at each stage (each stage of the review process is depicted by a box in a sequential design as suggested by PRISMA (12)).

209x298mm (300 x 300 DPI)

Supplementary Material 1: Example of search strategy

Search strategy for MEDLINE (1996+)

a)	“developing and evaluating complex interventions” (all fields)
b)	“development” OR “develop*” (title)
c)	“intervention” (title)
d)	B) and C)
e)	A or D
f)	“older” OR “old*” OR “elderly” (all fields)
g)	E and F

Supplementary Material 2: Reporting standards for the included studies against the CReDECI2 criteria.

Reference		CReDECI 2 Checklist Item													Total
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	
14	Avery 2015	1	1	0	1	1	0	0	0	0	0	0	0	0	**4**
15	Barley 2012	1	1	0	1	0	0	0	0	0	0	0	0	0	**3**
16	Beaudet 2015	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
17	Blamey 2013	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
18	Brody 2016	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
19	Bruce 2017	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
20	Burgess 2008	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
21	Claflin 2005	0	1	0	0	1	0	0	0	0	0	0	0	0	**2**
22	Cunningham 2016	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
23	Dias 2017	1	1	0	1	0	0	0	0	0	0	0	0	0	**3**
24	Dougherty 2012	1	1	0	1	1	0	0	0	0	0	0	0	0	**4**
25	Duffy 2005	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
26	Ettema 2014	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
27	Faes 2010	1	0	1	1	1	0	0	0	0	1	0	0	0	**5**
28	Gildengers 2016	0	1	1	0	1	0	0	0	0	0	0	0	0	**3**
29	Hinrichs 2013	0	0	0	1	1	0	0	0	0	0	0	0	0	**2**
30	Kerkhof 2016	1	0	0	0	0	0	0	0	0	0	0	0	0	**1**
31	Kingstone 2017	1	0	0	1	0	0	0	0	0	0	0	0	0	**2**
32	Lai 2016	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
33	Menichetti 2016	1	1	1	1	0	0	0	0	0	0	0	0	0	**4**
34	O'Sullivan 2015	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
35	Parry 2016	1	1	1	1	1	1	1	1	1	1	1	1	1	**13**
36	Patel 2016	0	1	1	0	1	0	1	1	0	1	1	1	0	**8**
37	Price 2006	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
38	Redfern 2008	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
39	Roberts 2017	0	1	1	0	0	0	0	0	0	0	0	0	0	**2**
40	Sadler 2017	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
41	Sturt 2006	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
42	Troughton 2016	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
43	Van Hecke 2011	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
44	van Stralen 2008	1	1	1	1	1	1	1	1	0	1	0	0	0	**9**
45	Walters 2015	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**
46	Wiedemann 2008	0	1	0	1	1	0	0	0	0	0	0	0	0	**3**
47	Wylie 2017	0	1	1	1	1	0	0	0	0	0	0	0	0	**4**
48	Zijlstra 2006	1	1	1	1	1	0	0	0	0	0	0	0	0	**5**

Supplementary Material 3: Descriptions of the intervention development frameworks included in the review.

Name of framework	Description	Key reference(s) or website
Medical Research Council Guidance	The Medical Research Council guidance is a published framework for evaluating complex interventions. Its original 2000 guidance was updated in 2008 and suggests a non-linear phased sequence.	Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008, 337:a1655.
Intervention Mapping	Intervention Mapping is a six-stepped method going from identifying the problem through to solving the problem and is focused on behaviour change interventions. It is a self-described protocol which can aid the development of these types of interventions.	Bartholomew LK, Parcel GS, Kok G, Gottlieb NH, Fernández ME. Planning Health Promotion Programs - An Intervention Mapping Approach. 3rd ed. San Francisco: CA: Jossey-Bass; 2011. https://interventionmapping.com/
Conceptual Modelling	Conceptual modelling is a term used in multiple fields (e.g., business, computing, social sciences and health research). A conceptual model is a model or diagrammatic representation of the rationale, process and/or outcomes. It has been used in health research previously and examples are given.	E.g., Wagner E, Austin B, Von Korff M: Organizing care for patients with chronic illness. *Milbank Q* 1996, 74:511–543. Gask et al., Improving access to psychosocial interventions for common mental health problems in the United Kingdom: narrative review and development of a conceptual model for complex interventions. BMC Health Serv Res. 2012;12(1):249.
Programme Theory	Programme theory is a term that has been used by evaluators to describe the theory underpinning a programme, such as a social or health intervention. Programme theory also refers to a specific concept used within realistic evaluation.	Weiss CH (1998) Evaluation: Methods for Studying Programs and Policies. Upper Saddle River, NJ: Prentice Hall. Pawson R and Tilley N (1997) Realistic Evaluation. London: SAGE.
Van Meijel Model	The Van Meijel model was first reported in 2004 and was established in response to the development of a nursing-based intervention. The model uses four stages from defining the problem through to validating the intervention.	Van Meijel B., Gamel C., van Swieten-Duijfjes B. & Grypdonck M.H. (2004) The development of evidence-based nursing interventions: methodological considerations. *Journal of Advanced Nursing* 48, 84–92.

Reporting checklist for systematic scoping reviews (PRISMA-ScR).

Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Annals of Internal Medicine*. 2018;169(7):467-73.

PRISMA-ScR Checklist			
Section	Item	PRISMA-ScR Checklist Item	Page
TITLE	1	Identify the report as a scoping review.	1
ABSTRACT	2	Provide a structured summary that includes (as applicable) background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	2-3
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	3
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	n/a
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	3
Information sources	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	4
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supplementary material 1
Selection of sources of evidence	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	4
Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	4

Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	4
Critical appraisal of individual sources of evidence	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	5
Summary measures	13	Not applicable for scoping reviews.	n/a
Synthesis of results	14	Describe the methods of handling and summarizing the data that were charted.	5
Risk of bias across studies	15	Not applicable for scoping reviews.	n/a
Additional analysis	16	Not applicable for scoping reviews.	n/a
RESULTS			
Selection of sources of evidence	17	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Figure 1
Characteristics of sources of evidence	18	For each source of evidence, present characteristics for which data were charted and provide the citations.	6
Critical appraisal within sources of evidence	19	If done, present data on critical appraisal of included sources of evidence (see item 12).	6 & supplementary material 2
Results of individual sources of evidence	20	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	6-12
Synthesis of results	21	Summarize and/or present the charting results as they relate to the review questions and objectives	6-12
Risk of bias across studies	22	Not applicable for scoping reviews.	n/a
Additional analysis	23	Not applicable for scoping reviews.	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	13
Limitations	25	Discuss the limitations of the scoping review process.	13-14
Conclusions	26	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	14-15
FUNDING	27	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	15