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The Effectiveness of Integrated Care Interventions for Older People with different Frailty levels: A systematic review Protocol

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The Effectiveness of Integrated Care Interventions for Older People with different Frailty levels: A systematic review Protocol

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Abstract

Introduction

Frailty poses huge burden to individuals, their families and health system. Several interventions have been evaluated for improvement of outcomes for older people with frailty including integrated care interventions. Reviews synthesising evidence on the effectiveness of integrated care for older people with frailty have treated them as a single population without considering the heterogeneity between different frailty levels such non-frail, mild frailty, moderate frailty and severe frailty. Findings from these studies have shown inconsistent results on the various outcomes assessed. Furthermore, the focus has been on community dwelling older people, while residents of nursing homes or with medical conditions have been excluded. Since people with different frailty status have different care needs, therefore they should be treated as separate populations. The aim of this study is to synthesise evidence on the effectiveness of integrated care interventions on older people with different frailty status who are in different settings.

Methods and analysis

This is a protocol for a systematic review assessing effectiveness of integrated care interventions on older people with different frailty status. A literature search will be conducted on the databases CENTRAL, PubMed, Embase, Web of Science, CINAHL EBSCO and trial registers. Two authors will independently conduct search and screening for eligible studies. Full text screening will be done to include studies which fulfil the inclusion criteria. Data extraction will be done on a data extraction form and methodological quality of studies will be assessed using the EPOC risk of bias tool.

Ethics and dissemination

The ethical approval for this study was obtained from the Institute for Health Research Ethics Committee of the University of Bedfordshire (IHREC934). The results of the review will be disseminated through a peer reviewed journal article, conferences and also with the stakeholders involved in service provision or frail older people at the local level.

Prospero registration number: CRD42020166908

Keywords: Frailty, integrated care service, mild frailty, moderate frailty, severe frailty

Strengths and Limitations of this study

- This systematic review will synthesise evidence on the effectiveness of integrated care services for older people with different frailty levels and from different settings.
- Primary screening of the articles, data extraction and quality assessment will be performed independently by two researchers, to minimise the chance of personal biases.
- In this study, there is a possibility to have language bias as databases in languages other than English will not be searched or included.

Background

Frailty is a state characterised by decreased physiological reserves due to an age-related accumulation of deficits, which makes an individual vulnerable to minor stressors. [1-3] It is associated with adverse outcomes such as falls, fractures, emergency hospital admissions, institutionalisation and mortality. Frailty is more common among women than men, higher among older age groups, higher among some ethnic groups, as well as in people from low socioeconomic background, having less education and higher poverty. [2 4]

There is some evidence that frailty can be reversed by interventions that can be broadly categorised into single component, multi-domain and integrated care. Single component interventions are those that include only one component, such as exercise. A scoping review by Puts, et al. [5] and systematic reviews by Apóstolo, et al. [6] and Daniels, et al. [7] found that interventions with exercise were effective in preventing or reducing frailty in frail and pre-frail individuals. However, these studies did not provide pooled estimates or effect sizes. Some recently conducted randomised controlled trials (RCTs) [8-10] have also reported exercise interventions to be effective in reducing frailty. However, evidence on the effect of other single component interventions such as nutrition is inconsistent. [11] [12] Multi-domain interventions refer to those interventions that have two or more components. The most commonly reported multi-domain interventions are based on a combination of nutrition and exercise, with systematic reviews summarising evidence on these combinations reporting them to be effective. [13-15] A number of RCTs [16-18] that assessed multi-domain interventions in which physical activity and nutrition has been complemented by cognitive training, have shown a reduced risk of developing frailty as well as improvement in frailty status among older people and increases in functional status.

There are a growing number of systematic reviews that have evaluated integrated care interventions for frailty. [19-23] Integrated care can been defined as an organisational approach of coordinating continuous care based on a patient's needs and viewing the patient in a holistic manner. [24] All of the systematic reviews on integrated care have considered older people with different levels of frailty as a single population and did not distinguish by frailty status. However, there is evidence that older people with different frailty status have different care needs, require different types of interventions and respond differently to interventions. [25] Therefore, treating them as a single population may be one reason for the heterogeneity in the outcomes reported in systematic reviews of integrated care interventions. There is a Cochrane systematic review protocol that has proposed to assess the effectiveness of case management for frail older people including a sub-group analysis by frailty status, but this protocol has only included community dwelling elderly with no other medical conditions requiring care. [26] There is evidence that people in nursing home settings have complex needs and higher frailty status. For instance a systematic review reported the pooled estimates of pre-frailty and frailty to be 40.2% (95% CI: 28.9%,52.1%) and 52.3% (95% CI: 37.9%, 66.5%), respectively. [27] Accordingly, many systematic reviews have excluded studies of older people with frailty and complex care needs who are in nursing home settings.

The aim of this systematic review is to synthesise evidence on the effectiveness of integrated care interventions on older people with different frailty status, including those living in both the community and in residential care settings. This work programme has been informed by the Luton Clinical Commissioning Patient and Public Involvement Group. To this end, the proposed systematic review will answer the following questions:

Are integrated care interventions effective in preventing or managing frailty among older people with different frailty levels as compared to the usual care?

Are integrated care interventions effective for older people with different frailty levels living in different settings such as community or residential care settings as compared to usual care?

Methods and analysis

Eligibility criteria

Types of studies

Study designs considered will be quantitative empirical studies with a control group including randomised controlled trials of any design such as those with individual or cluster randomisation and quasi-experimental designs.

Types of participants

People aged 65 years old and above classified as frail using either an accumulation of deficits model or the frailty phenotype model. Participants must be classified according to their frailty level by the assessment tool used.

Types of interventions

Integrated care interventions that proactively seek to organise and coordinate care. Typical elements could include case finding, assessment, development of care plans, monitoring, referral to other services such as preventive components for health promotion, active lifestyle and health education; involvement of different professionals and involvement of different organisations.

Types of comparator

Interventions must be compared with usual care.

Types of outcome measures

Primary outcome: Frailty level on the tool (accumulation of deficits model or the frailty phenotype model) used to determine frailty status.

Secondary outcomes: Falls; emergency hospital admissions including length of stay; institutionalisation for those people who were community dwelling; quality of life; mortality. The primary and secondary outcomes have been considered appropriate because frailty is associated with these outcomes and they pose a huge individual and health system level burden.

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Search Strategy

Electronic Databases:

- MEDLINE
- Embase
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature)
- Web of Science

Clinical Trials Registers:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- ClinicalTrials.gov
- WHO (World Health Organization) International Clinical Trials Registry Platform (ICTRP)

Other sources

- Reference lists of the included studies
- Systematic reviews on similar topics and their reference lists

Key word searches

The search strategy will use free words as well as MeSH terms for MEDLINE and CINAHL. Two authors (NK and DH) will independently carry out the search. An example of the search strategy for MEDLINE is shown in Appendix 1.

Inclusion and exclusion criteria

Articles will be limited to 2001-2020, which was chosen due to the date of the first article on the frailty phenotype. Articles will be limited to English, but no geographic locations will be specified. Furthermore, there will be no restriction on the setting such as older people with any frailty status receiving integrated care service in community or institutional setting except hospital, since hospital admission is one of the secondary outcome measures. Studies evaluating interventions other than integrated care will be excluded. Qualitative studies will be excluded. Studies that have used frailty assessment tools, which do not distinguish the severity of frailty will be excluded.

Data Extraction

Studies identified will be imported into reference management software EndNote for deduplication and filtering. Two reviewers (NK and DH) will independently screen the titles and abstracts of the studies fulfilling eligibility criteria. The articles will be categorised into three groups: relevant, irrelevant and unsure. Articles categorised as irrelevant by both reviewers will be eliminated from the study. Then, each reviewer will review the full text of the remaining articles and make a list of articles to be included. Any disagreements will be resolved by involving a third reviewer (GR). Full-text versions of the remaining articles will be assessed by using the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) standard data collection checklist, which will be adapted for data extraction. [28] For instance, data will be extracted on variables such as study design, participant characteristics (age,

gender and level of education), intervention characteristics, location of care (community or residential setting), country, primary and secondary outcomes, source of funding etc. Two review authors (NK and DH) will independently extract the study characteristics from the primary studies included in the review using a customised Microsoft Excel table, with article selection based on PICOS elements. Two review authors (NK and DH) will extract outcomes data from the included studies, with any disagreements on the outcomes data decided by a third reviewer (GR), in accordance with the Cochrane Handbook for Systematic Reviews of Interventions. [29]

Risk of bias assessment

Risk of bias will be evaluated using the EPOC risk of bias tool [28], which is suitable for this review because the method also includes non-randomised trials. This tool has nine criteria, including random sequence generation, allocation concealment, baseline characteristics, outcome measures at baseline, incomplete outcome data, knowledge of allocated intervention, protection against contamination and selective reporting of outcomes. For each of the nine domains, the procedures undertaken by individual studies will be described, including verbatim quotes. Two review authors (NK and DH) will independently assess the risk of bias and categorise the studies as having low risk, high risk or unclear risk of bias. Any disagreements will be resolved by involving a third reviewer (GR). Graphic representations of potential bias within and across studies will be computed using RevMan5.1 (Review Manager5.1). Each item in the risk of bias assessment will be considered independently, without an attempt to collate and assign an overall score.

Data synthesis

Quantitative data will, where possible, be pooled in statistical meta-analysis. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard χ^2 and also explored using subgroup analyses based on the different quantitative study designs included in this review. Subgroup analysis will be done by the frailty level of older people and the setting they live in for example, their own home or nursing home. Quality of evidence will be assessed using Grades of Recommendation, Assessment, Development, and Evaluation (GRADE).[30] Sensitivity analysis will be performed by removing studies with higher risk of bias. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate. These results will be combined to arrive at a conclusion from the research. After performing data synthesis, the final report will be prepared following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Furthermore, in case of any deviations from the protocol the authors will mention them in the final published report and update in the PROSPERO publication.

Discussion

Despite a plethora of systematic reviews conducted on synthesising evidence on the effectiveness of integrated care interventions for older people, they have treated older people with different levels of frailty as a single population. This could be one reason for the heterogeneity in findings from the existing reviews. Furthermore, existing reviews have restricted their inclusion criteria to studies having community dwelling older people and with no medical conditions. Therefore, the findings cannot be applied to frail older people living in care home settings and who have other medical conditions. This review will fill this gap by synthesising evidence on the effectiveness of integrated care interventions for older people with different frailty levels and who live in different residential settings.

Dissemination

The findings of this review will be shared through a peer reviewed journal article, conferences and with the local commissioners and stakeholders involved in providing integrated care services for the older population.

Ethical issues

The ethical approval for this study was obtained from the Institute for Health Research Ethics Committee of the University of Bedfordshire (IHREC934). The results of the review will be disseminated through a peer reviewed journal article, conferences and also with the stakeholders involved in service provision or frail older people at the local level. This is a systematic review that will only use data from existing studies, all of which will have obtained ethical approval. As such, there are no ethical considerations for the project, however, data collected from the studies included in the review will be treated with due consideration.

Contributors: NK conceived the idea, planned and wrote the first draft of the study protocol. DH developed the search strategy. The first draft was reviewed by DH and GR. DH and GR provided critical insights. All authors have approved and contributed to the final written manuscript. The guarantor of the review will be DH.

Funding: Luton Clinical Commissioning Group and University of Bedfordshire supported this study. The funding body had no role in developing the protocol. NK is recipient of a PhD scholarship from the Luton Clinical Commissioning Group and the Institute for Health Research of the University of Bedfordshire. The funders of this study have no role in development of the protocol.

Provenance and peer review: Not commissioned; externally peer reviewed.

Appendix 1

MEDLINE Search Strategy

1. TI/AB: Frail*
2. MeSH Heading: Frail Elderly
3. 1 OR 2
4. TI/AB: Elder*
5. TI/AB: Older*
6. TI/AB: Geriatr*
7. TI/AB: Senior
8. 4 OR 5 OR 6 OR 7
9. TI/AB: Randomised controlled trial
10. TI/AB: Randomized controlled trial
11. TI/AB: RCT
12. TI/AB: Controlled clinical trial
13. TI/AB: Cluster randomised controlled trial
14. 9 OR 10 OR 11 OR 12 OR 13
15. TI/AB: Integrated care
16. TI/AB: Case management
17. TI/AB: Patient centred care
18. TI/AB: Coordinated care
19. 15 OR 16 OR 17 OR 18
20. 3 AND 8 AND 14 AND 19

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Information Reported	Line numbers
ADMINISTRATIVE INFORMATION				
Title:				
Identification	1a	Identify the report as a protocol of a systematic review	Done	Page 1: Line 2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not Applicable	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	PROSPERO CRD42020166908	
Authors:				
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Done	Page 1: Lines 3 to 10
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Done	Page 12: Lines 3 to 5
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Done	Page 7: Lines 32 to 33
Support:				
Sources	5a	Indicate sources of financial or other support for the review	Done	Page 12: Lines 6 to 9
Sponsor	5b	Provide name for the review funder and/or sponsor	Not Applicable	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not Applicable	
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	Done	Page 4: Lines 22 to 36
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Done	Page 5: Lines 5 to 8

METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Done	Page 5: Lines 10 to 32 and Page 6: Lines 18 to 25
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Done	Page 6: Lines 1 to 13
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated		Page 6: Lines 14 to 17 and Page 9: Lines 2 to 23
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Done	Pages 6: Lines 27 to 28
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Done	Page 6: 28 to 32
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Done	Page 6: Lines 32 to 34 and Page 7: Lines 2 to 7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Done	Page 6: Line 35 and Page 7: Lines 1 to 2
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Done	Page 5: Lines 26 to 32
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Done	Page 7: Lines 8 to 19
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Done	Page 7: Lines 21 to 23
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Done	Page 7: Lines 24 to 27
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Done	Page 7: Line 28
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Done	Page 7: Lines 29 to 30
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Done	Page 7: Lines 27-28
Confidence in	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Done	Page 7: Lines 27-28

cumulative evidence

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Abstract

Introduction

Frailty poses a huge burden to individuals, their families and to healthcare systems. Several interventions have been evaluated for the improvement of outcomes for older people with frailty, including integrated care interventions. Reviews synthesising evidence on the effectiveness of integrated care for older people with frailty have treated them as a single population, without considering the heterogeneity between different frailty levels such as non-frail, mild frailty, moderate frailty and severe frailty. Findings from these studies have shown inconsistent results on the various outcomes assessed. People with different frailty status have different care needs, which should be addressed accordingly. The aim of this study is to synthesise evidence on the effectiveness of integrated care interventions on older people with different frailty status who are community dwelling or living in retirement housing or residential setting but not in care homes or in nursing homes.

Methods and analysis

This is a protocol for a systematic review assessing the effectiveness of integrated care interventions on older people with different frailty status. A literature search will be conducted on the databases CENTRAL, PubMed, Embase, Web of Science, CINAHL and clinical trial registers. Two authors will independently conduct search and screening for eligible studies. Full text screening will be used to include only studies that fulfil the inclusion criteria. Data extraction will be done on a data extraction form and methodological quality of studies will be assessed using the EPOC risk of bias tool. The interventions will be described following Wagner's Chronic Care Model (CCM).

Ethics and dissemination

Ethical approval for this study was obtained from the Institute for Health Research Ethics Committee of the University of Bedfordshire (IHREC934). The results of the review will be disseminated through a peer reviewed journal article, conferences and also with local stakeholders involved in service provision and frail older people.

Prospero registration number: CRD42020166908

Keywords: Frailty, integrated care service, mild frailty, moderate frailty, severe frailty

Strengths and Limitations of this study

- To our best knowledge this is the first systematic review which will stratify older people based on their frailty status.
- The study will map integrated care interventions on the chronic care model.
- The protocol is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol guidelines.
- Essential steps such as screening of studies, data extraction and quality assessment will be done in duplicate.
- Databases in languages other than English will not be searched or included, which may cause language bias.

Background

Frailty is a state characterised by decreased physiological reserves due to an age-related accumulation of deficits, which makes an individual vulnerable to minor stressors.[1-3] It is associated with adverse outcomes such as falls, fractures, emergency hospital admissions, institutionalisation and mortality. Frailty is more common among women than men, higher among older age groups, higher among some ethnic groups, as well as in people from low socioeconomic background, having less education and higher poverty. [4 5]

There is some evidence that frailty can be reversed by interventions that can be broadly categorised into single component, multi-domain and integrated care. Single component interventions are those that include only one component, such as exercise. A scoping review by Puts et al. (2017)[5] and systematic reviews by Apostolo et al. (2018)[6] and Daniels et al. (2008)[7] found that interventions with exercise were effective in preventing or reducing frailty in frail and pre-frail individuals. However, these studies did not provide pooled estimates or effect sizes. Some recently conducted randomised controlled trials (RCTs) [8-10] have also reported exercise interventions to be effective in reducing frailty. However, evidence on the effect of other single component interventions such as nutrition is inconsistent.[11 12] Multi-domain interventions refer to those interventions that have two or more components. The most commonly reported multi-domain interventions are based on a combination of nutrition and exercise, with systematic reviews summarising evidence on these combinations reporting them to be effective. [13-15] A number of RCTs [16-18] that assessed multi-domain interventions in which physical activity and nutrition has been complemented by cognitive training, have shown a reduced risk of developing frailty as well as improvement in frailty status among older people and increases in functional status.

There are a growing number of systematic reviews that have evaluated integrated care interventions for frailty. [19-23] Integrated care has been defined as an organisational approach of coordinating continuous care based on a patient's needs and viewing the patient in a holistic manner. [24]All of the systematic reviews on integrated care have considered older people with different levels of frailty as a single population and did not distinguish by frailty status. However, there is evidence that older people with different frailty status have different care needs, require different types of interventions, and respond differently to interventions. [25]Therefore, treating them as a single population may be one reason for the heterogeneity in the outcomes reported in systematic reviews of integrated care interventions.

The aim of this systematic review is to synthesise evidence on the effectiveness of integrated care interventions on older people with different frailty status, including those living in both the community and in residential care settings. To this end, the proposed systematic review will answer the following question:

Are integrated care interventions effective in preventing or managing frailty among older people with different frailty levels as compared to the usual care?

Methods and analysis

Eligibility criteria

Studies will be included in the review if they meet the following inclusion criteria:

Participants

People aged 65 years old and above classified as frail using a valid frailty assessment instrument such as accumulation of deficits model or the frailty phenotype model as described by the trial authors. Participants must be classified according to their frailty level by the assessment tool used.

Interventions

We will include studies in which a population health management model has been used ,for example the Kaiser Permanente model, to stratify community-dwelling older people into risk profiles based on their levels of frailty, with care and support offered using multidisciplinary teams with the intensity determined by the individual risk profile. For example, those identified as robust or having mild frailty could be offered self-management support, healthy lifestyle advice and participation in physical activity programmes. Those with moderate frailty could be provided with case management support from various healthcare professionals such as GPs and district nurses, with social care workers as case managers and coordinating follow-up. Older people who are severely frail or have high complexity could receive intensive case management. Several frameworks have been developed to improve the understanding of the key elements of a successful integrated care programme. One of the most influential among them is the chronic care model (CCM), which is an evidence-based conceptual framework that provides guidance on the organisation of healthcare for people with chronic conditions to improve their outcomes.[26 27] The CCM, which has been acknowledged by the World Health Organisation (WHO), includes six elements: i) Provide support to patients for self- management; ii) Decision making support to providers; iii) Case management; iv) Establishing a clinical information system; v) Community resources for healthy living, and vi) Leadership within the health system. [28]

The interventions in included studies will be described using the taxonomy of the CCM, whereby elements of each intervention will be mapped on the elements of CCM, as described by Wagner (1998), [26] since frailty shares many features with a chronic condition. For example, frailty is a dynamic syndrome that cannot be cured, but can be prevented and better managed through the action of an interdisciplinary approach that proactively organises and coordinates care to prevent the associated adverse outcomes .[28] The CCM provides a comprehensive framework to manage long term conditions such as frailty by covering all essential elements of integrated care.[29] Therefore, by mapping the interventions on the six elements of the CCM we will be able to examine whether interventions contain the essential components of integrated care services and also their association with outcomes.

Comparator (s)

Interventions must be compared with usual care.

Outcomes

Primary outcome:

- Falls: The WHO has defined falls as an involuntary event bringing the body to the ground or other surfaces.[30]
- Emergency hospital admission is when a person is admitted to hospital urgently and unexpectedly, i.e. the admission is unplanned.[31]
- Quality of life (QoL) is a complex concept and its precise definition is debated. The WHO has described QoL as "an individual's perceptions of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns".[32] Due to diverse definitions of quality of life, we will include studies that have used valid instruments such as the Older People's Quality of Life (OPQOL) questionnaire[33], the Short Form-36 health-related quality of life tool[34], the WHO Quality of Life (WHOQOL) assessment instrument [35] to measure and report on outcomes such as "quality of life", "well-being" or "life satisfaction".
- Institutionalisation is defined as when individuals who are no longer capable of living independently in their own home, are provided with accommodation and care support in institutional settings.[36]
- Mortality.
- Transitioning in frailty status such as shift from robust to pre-frailty, from pre-frailty to frailty or vice versa.[25 37] We justify inclusion of these outcomes based on existing studies, which have stated that frailty is associated with adverse outcomes such as falls, emergency hospital admission, poor quality of life, institutionalisation and mortality. [3 13 23 25 38-48] Furthermore, studies have shown that frailty is a condition, which can transition from better to worst or vice versa.[49]

Secondary outcomes:

- Physical disability measured by screening for ability to perform self-care tasks such as activities of daily living (ADL) and tasks of household management like instrumental activities of daily living (IADL), or any other valid measurement as stated by the trial authors. It has been included because frailty is identified as a risk factor for physical disability.[38]
- Carer burden measured using valid instruments such as the Zarit Burden Interview [50] will be included.
- Healthcare utilisation and cost effectiveness [23] as stated by trial authors.

Studies

Study designs considered will be quantitative empirical studies with a control group including randomised controlled trials of any design such as those with individual or cluster randomisation and quasi-experimental designs.

Search Strategy

Electronic Databases:

- MEDLINE
- Embase
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- Web of Science

Clinical Trials Registers:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- ClinicalTrials.gov
- WHO (World Health Organization) International Clinical Trials Registry Platform (ICTRP)

Other sources

- Reference lists of the included studies
- Systematic reviews on similar topics and their reference lists

Key word searches

The search strategy will use free words as well as MeSH terms for MEDLINE and CINAHL. Two authors (NK and DH) will independently carry out the search during June-July 2020. An example of the search strategy for MEDLINE is shown in supplementary material.

Inclusion and exclusion criteria

There will no time limitation. Articles will be limited to English, but no geographic locations will be specified. Furthermore, studies having older people with different levels of frailty who are either community dwelling or living in retirement housing or residential setting but not care home or nursing home will be included.

Studies evaluating interventions other than integrated care will be excluded. Qualitative studies will be excluded. Studies that have used frailty assessment tools that do not distinguish the severity of frailty will be excluded.

Data Extraction

Studies identified will be imported into reference management software EndNote (Version X9.3 Clarivate, Philadelphia, PA, USA) for deduplication and filtering. Two reviewers (NK and DH) will independently screen the titles and abstracts of the studies fulfilling eligibility criteria. The articles will be categorised into three groups: relevant, irrelevant and unsure. Articles categorised as irrelevant by both reviewers will be rejected. Each reviewer will assess the full text of the remaining articles and make a list of articles to be included. Any disagreements will be resolved by involving a third reviewer (GR). Full-text versions of the remaining articles will be assessed by using the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) standard data collection checklist, which will be adapted for data extraction. Data will be extracted on study design, participant characteristics (age,

gender and level of education), intervention characteristics, location of care (community or residential setting), country, primary and secondary outcomes, source of funding etc. Furthermore, information on intervention fidelity such as adherence, frequency, duration, coverage and other elements mentioned by trial authors will be extracted. Two review authors (NK and DH) will independently extract the study characteristics from the primary studies included in the review using a customised Microsoft Excel table, with article selection based on PICOS elements. Two review authors (NK and DH) will extract outcomes data from the included studies, with any disagreements on the outcomes data decided by a third reviewer (GR), in accordance with the Cochrane Handbook for Systematic Reviews of Interventions.[51]

Risk of bias assessment

Risk of bias will be evaluated using the EPOC risk of bias tool[52], which is suitable for this review because the method also includes non-randomised trials. This tool has nine criteria, including random sequence generation, allocation concealment, baseline characteristics, outcome measures at baseline, incomplete outcome data, knowledge of allocated intervention, protection against contamination and selective reporting of outcomes. For each of the nine domains, the procedures undertaken by individual studies will be described, including verbatim quotes. Two review authors (NK and DH) will independently assess the risk of bias and categorise the studies as having low risk, high risk or unclear risk of bias. Any disagreements will be resolved by involving a third reviewer (GR). Graphic representations of potential bias within and across studies will be computed using Review Manager (RevMan) (Version 5.4, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2020). Each item in the risk of bias assessment will be considered independently, without an attempt to collate and assign an overall score.

Data synthesis

Quantitative data will, where possible, be pooled in statistical meta-analysis. All results will be subject to double data entry. Effect sizes expressed as odds ratio or relative risk (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard χ^2 and also explored using subgroup analyses based on the different quantitative study designs included in this review. Furthermore, we will use L'Abbé plot to explore heterogeneity and identify outlying trials in a meta-analysis.[53]

Quality of evidence will be assessed using Grades of Recommendation, Assessment, Development, and Evaluation (GRADE).[54] Sensitivity analysis will be performed by removing studies with higher risk of bias. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate. These results will be combined to arrive at a conclusion from the research. After performing data synthesis, the final report will be prepared

following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Furthermore, in case of any deviations from the protocol the authors will mention them in the final published report and update in the PROSPERO record.

Discussion

Despite a plethora of systematic reviews conducted on synthesising evidence on the effectiveness of integrated care interventions for older people, all such reviews have treated older people with different levels of frailty as a single population. This could be one reason for the heterogeneity in findings from the existing reviews. This review will fill this gap by synthesising evidence on the effectiveness of integrated care interventions for older people with different frailty levels.

Dissemination

The findings of this review will be shared through a peer reviewed journal article, conferences, and with local commissioners and stakeholders involved in providing integrated care services for the older population.

Ethical issues

This is a systematic review that will only use data from existing studies, all of which will have obtained ethical approval. As such, there are no ethical considerations for the project, however, data collected from the studies included in the review will be treated with due consideration.

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Footnotes

Contributors: NK conceived the idea, planned and wrote the first draft of the study protocol. DH developed the search strategy. The first draft was reviewed by DH and GR. DH and GR provided critical insights. All authors have approved and contributed to the final written manuscript. The guarantor of the review will be DH.

Funding: Luton Clinical Commissioning Group and University of Bedfordshire supported this study. The funding body had no role in developing the protocol. NK is recipient of a PhD scholarship from the Luton Clinical Commissioning Group and the Institute for Health Research of the University of Bedfordshire. The funders of this study have no role in development of the protocol.

Competing Statement: None declared

Patient and Public involvement: No patient involved

1 **Provenance and peer review:** Not commissioned; externally peer reviewed.

Appendix 1

MEDLINE Search Strategy

1. TI/AB: Frail*
2. MeSH Heading: Frail Elderly
3. 1 OR 2 OR
4. TI/AB: Elder*
5. TI/AB: Older*
6. TI/AB: Geriatr*
7. TI/AB: Senior
8. MeSH Heading: Aged
9. MeSH Heading: Aged, 80 and over
10. 4 OR 5 OR 6 OR 7 OR 8 OR 9
11. TI/AB: “Randomised Controlled Trial”
12. MeSH Heading: Randomized Controlled Trial
13. TI/AB: RCT
14. MeSH Heading: “Controlled Clinical Trial“
15. 11 OR 12 OR 13 OR 14
16. TI/AB: “Integrated care”
17. MeSH Heading: Delivery of Health Care, Integrated
18. TI/AB: “Integrated Delivery Systems”
19. TI/AB: “Integrated Health Care Systems”
20. TI/AB: “Integrated Healthcare Systems”
21. MeSH Heading: Patient Care Bundles
22. TI/AB: “Care Bundles”
23. MeSH Heading: Continuity of Patient Care
24. TI/AB: “Continuity of Care”
25. TI/AB: “Continuum of Care”
26. MeSH Heading: Case Management
27. TI/AB: “Patient centred care”
28. TI/AB: “Coordinated care”
29. MeSH Heading: Health Services for the Aged
30. MeSH Heading: Nurses Improving Care for Health System Elders
31. 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30
32. 3 AND 10 AND 15 AND 31

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Information Reported	Line numbers
ADMINISTRATIVE INFORMATION				
Title:				
Identification	1a	Identify the report as a protocol of a systematic review	Done	Page 1: Line 2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not Applicable	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	PROSPERO CRD42020166908	
Authors:				
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Done	Page 1: Lines 3 to 10
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Done	Page 12: Lines 3 to 5
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Done	Page 7: Lines 32 to 33
Support:				
Sources	5a	Indicate sources of financial or other support for the review	Done	Page 12: Lines 6 to 9
Sponsor	5b	Provide name for the review funder and/or sponsor	Not Applicable	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not Applicable	
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	Done	Page 4: Lines 22 to 36
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Done	Page 5: Lines 5 to 8

METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Done	Page 5: Lines 10 to 32 and Page 6: Lines 18 to 25
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Done	Page 6: Lines 1 to 13
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated		Page 6: Lines 14 to 17 and Page 9: Lines 2 to 23
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Done	Pages 6: Lines 27 to 28
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Done	Page 6: 28 to 32
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Done	Page 6: Lines 32 to 34 and Page 7: Lines 2 to 7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Done	Page 6: Line 35 and Page 7: Lines 1 to 2
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Done	Page 5: Lines 26 to 32
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Done	Page 7: Lines 8 to 19
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Done	Page 7: Lines 21 to 23
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Done	Page 7: Lines 24 to 27
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Done	Page 7: Line 28
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Done	Page 7: Lines 29 to 30
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Done	Page 7: Lines 27-28
Confidence in	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Done	Page 7: Lines 27-28

cumulative evidence

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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The Effectiveness of Integrated Chronic Care Interventions for Older People with Different Frailty Levels: A Systematic Review Protocol

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The Effectiveness of Integrated Chronic Care Interventions for Older People with Different Frailty Levels: A Systematic Review Protocol

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Abstract

Introduction

Frailty poses a huge burden to individuals, their families and to healthcare systems. Several interventions have been evaluated for the improvement of outcomes for older people with frailty, including integrated care interventions. Reviews synthesising evidence on the effectiveness of integrated care for older people with frailty have treated them as a single population, without considering the heterogeneity between different frailty levels such as non-frail, mild frailty, moderate frailty and severe frailty. Findings from these studies have shown inconsistent results on the various outcomes assessed. People with different frailty status have different care needs, which should be addressed accordingly. The aim of this study is to synthesise evidence on the effectiveness of integrated care interventions on older people with different frailty status who are community dwelling or living in retirement housing or residential setting but not in care homes or in nursing homes.

Methods and analysis

This is a protocol for a systematic review assessing the effectiveness of integrated chronic care interventions on older people with different frailty status. A literature search will be conducted on the databases CENTRAL, PubMed, Embase, Web of Science, CINAHL and clinical trial registers. Two authors will independently conduct search and screening for eligible studies. Full text screening will be used to include only studies that fulfil the inclusion criteria. Data extraction will be done on a data extraction form and methodological quality of studies will be assessed using the EPOC risk of bias tool. The interventions will be described following Wagner's Chronic Care Model (CCM).

Ethics and dissemination

Ethical approval for this study was obtained from the Institute for Health Research Ethics Committee of the University of Bedfordshire (IHREC934). The results of the review will be disseminated through a peer reviewed journal article, conferences and also with local provider and user stakeholders.

Prospero registration number: CRD42020166908

Keywords: Frailty, integrated care service, mild frailty, moderate frailty, severe frailty

Strengths and Limitations of this study

- To our best knowledge this is the first systematic review which will stratify older people based on their frailty status.
- The study will map integrated care interventions on the chronic care model.
- The protocol is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol guidelines.
- Essential steps such as screening of studies, data extraction and quality assessment will be done in duplicate.
- Databases in languages other than English will not be searched or included, which may cause language bias.

Background

Frailty is a state characterised by decreased physiological reserves due to an age-related accumulation of deficits, which makes an individual vulnerable to minor stressors.[1-3] It is associated with adverse outcomes such as falls, fractures, emergency hospital admissions, institutionalisation and mortality. Frailty is more common among women than men, higher among older age groups, higher among some ethnic groups, as well as in people from low socioeconomic background, having less education and higher poverty. [4 5]

There is some evidence that frailty can be reversed if identified at an earlier stage of the process.[6-7] Several interventions that can be broadly categorised into single component, multi-domain and integrated care have been evaluated to improve outcomes for older people with frailty. Single component interventions are those that include only one component, such as exercise. A scoping review by Puts et al. (2017)[5] and systematic reviews by Apostolo et al. (2018)[8] and Daniels et al. (2008)[9] found that interventions with exercise were effective in preventing or reducing frailty in frail and pre-frail individuals. However, these studies did not provide pooled estimates or effect sizes. Some recently conducted randomised controlled trials (RCTs) [10-12] have also reported exercise interventions to be effective in reducing frailty. However, evidence on the effect of other single component interventions such as nutrition is inconsistent.[13 14] Multi-domain interventions refer to those interventions that have two or more components. The most commonly reported multi-domain interventions are based on a combination of nutrition and exercise, with systematic reviews summarising evidence on these combinations reporting them to be effective. [15-17] A number of RCTs [18-20] that assessed multi-domain interventions in which physical activity and nutrition has been complemented by cognitive training, have shown a reduced risk of developing frailty as well as improvement in frailty status among older people and increases in functional status.

There are a growing number of systematic reviews that have evaluated integrated care interventions for frailty. [21-25] Integrated care has been defined as an organisational approach of coordinating continuous care based on a patient's needs and viewing the patient in a holistic manner. [26]All of the systematic reviews on integrated care have considered older people with different levels of frailty as a single population and did not distinguish by frailty status. However, there is evidence that older people with different frailty status have different care needs, require different types of interventions, and respond differently to interventions. [27] Therefore, treating them as a single population may be one reason for the heterogeneity in the outcomes reported in systematic reviews of integrated care interventions.

The aim of this systematic review is to synthesise evidence on the effectiveness of integrated care interventions on older people with different frailty status, including those living in both the community and in residential care settings. To this end, the proposed systematic review will answer the following question:

Are integrated care interventions effective in preventing or managing frailty among older people with different frailty levels as compared to the usual care?

Methods and analysis

Eligibility criteria

Studies will be included in the review if they meet the following inclusion criteria:

Participants

People aged 65 years old and above classified as frail using a valid frailty assessment instrument such as accumulation of deficits model or the frailty phenotype model as described by the trial authors. Participants must be classified according to their frailty level by the assessment tool used.

Interventions

Integrated chronic care models are introduced to overcome the currant fragmentation in healthcare system. It aims to move away from disease-oriented approach to patient-centred care by offering services based on the needs, preferences and choices of individuals.[28] Since older people can be stratified based on their frailty levels. Those identified as robust or pre-frail include older adults without complex care needs. Whereas, those who are moderately frail have higher level of frailty and are at increased risk of developing complex care needs. The older adults who are severely frail have complex care needs.[29 30] Therefore, we will include studies in which a population health management model has been used, for example the Kaiser Permanente model, to stratify community-dwelling older people into risk profiles based on their levels of frailty, with care and support offered using multidisciplinary teams with the intensity determined by the individual risk profile and care needs. For example, those identified as robust or having mild frailty could be offered self-management support, healthy lifestyle advice and participation in physical activity programmes. Those with moderate frailty could be provided with case management support from various healthcare professionals such as GPs and district nurses, with social care workers as case managers and coordinating follow-up. Older people who are severely frail or have high complexity could receive intensive case management. Several frameworks have been developed to improve the understanding of the key elements of a successful integrated care programme. One of the most influential among them is the chronic care model (CCM), which is an evidence-based conceptual framework that provides guidance on the organisation of healthcare for people with chronic conditions to improve their outcomes.[31 32] The CCM, which has been acknowledged by the World Health Organisation (WHO), includes six elements: i) Provide support to patients for self- management; ii) Decision making support to providers; iii) Case management; iv) Establishing a clinical information system; v) Community resources for healthy living, and vi) Leadership within the health system. [33]

The interventions in included studies will be described using the taxonomy of the CCM, whereby elements of each intervention will be mapped on the elements of CCM, as described by Wagner (1998),

[31] since frailty shares many features with a chronic condition. For example, frailty is a dynamic syndrome. There is some evidence that suggests that frailty is reversible if identified and interventions provided at an earlier stage of the process. However, less is known about reversibility of frailty among those who are severely frail or have complex care need.[6 7] It can be prevented and better managed through the action of an interdisciplinary approach that proactively organises and coordinates care to prevent the associated adverse outcomes.[33] The CCM provides a comprehensive framework to manage long term conditions such as frailty by covering all essential elements of integrated care. [34] Therefore, by mapping the interventions on the six elements of the CCM we will be able to examine whether interventions contain the essential components of integrated care services and also their association with outcomes.

Comparator (s)

Interventions must be compared with usual care.

Outcomes

Primary outcome:

- Falls: The WHO has defined falls as an involuntary event bringing the body to the ground or other surfaces.[35]
- Emergency hospital admission is when a person is admitted to hospital urgently and unexpectedly, i.e. the admission is unplanned.[36]
- Quality of life (QoL) is a complex concept and its precise definition is debated. The WHO has described QoL as "an individual's perceptions of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns".[37] Due to diverse definitions of quality of life, we will include studies that have used valid instruments such as the Older People's Quality of Life (OPQOL) questionnaire[38], the Short Form-36 health-related quality of life tool[39], the WHO Quality of Life (WHOQOL) assessment instrument [40] to measure and report on outcomes such as "quality of life", "well-being" or "life satisfaction".
- Institutionalisation is defined as when individuals who are no longer capable of living independently in their own home, are provided with accommodation and care support in institutional settings.[41]
- Mortality.
- Transitioning in frailty status such as shift from robust to pre-frailty, from pre-frailty to frailty or vice versa.[27 42] We justify inclusion of these outcomes based on existing studies, which have stated that frailty is associated with adverse outcomes such as falls, emergency hospital admission, poor quality of life, institutionalisation and mortality. [3 15 25 27 43-53] Furthermore, studies have shown that frailty is a condition, which can transition from better to worst or vice versa.[54]

Secondary outcomes:

- Physical disability measured by screening for ability to perform self-care tasks such as activities of daily living (ADL) and tasks of household management like instrumental activities of daily living (IADL), or any other valid measurement as stated by the trial authors. It has been included because frailty is identified as a risk factor for physical disability.[43]
- Carer burden measured using valid instruments such as the Zarit Burden Interview [55] will be included.
- Healthcare utilisation and cost effectiveness [25] as stated by trial authors.

Studies

Study designs considered will be quantitative empirical studies with a control group including randomised controlled trials of any design such as those with individual or cluster randomisation and quasi-experimental designs.

Search Strategy

Electronic Databases:

- MEDLINE
- Embase
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- Web of Science

Clinical Trials Registers:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- ClinicalTrials.gov
- WHO (World Health Organization) International Clinical Trials Registry Platform (ICTRP)

Other sources

- Reference lists of the included studies
- Systematic reviews on similar topics and their reference lists

Key word searches

The search strategy will use free words as well as MeSH terms for MEDLINE and CINAHL. Two authors (NK and DH) will independently carry out the search during June-July 2020. An example of the search strategy for MEDLINE is shown in supplementary material.

Inclusion and exclusion criteria

There will no time limitation. Articles will be limited to English, but no geographic locations will be specified. Furthermore, studies having older people with different levels of frailty who are either community dwelling or living in retirement housing or residential setting but not care home or nursing home will be included.

Studies evaluating interventions other than integrated care will be excluded. Qualitative studies will be excluded. Studies that have used frailty assessment tools that do not distinguish the severity of frailty will be excluded.

Data Extraction

Studies identified will be imported into reference management software EndNote (Version X9.3 Clarivate, Philadelphia, PA, USA) for deduplication and filtering. Two reviewers (NK and DH) will independently screen the titles and abstracts of the studies fulfilling eligibility criteria. The articles will be categorised into three groups: relevant, irrelevant and unsure. Articles categorised as irrelevant by both reviewers will be rejected. Each reviewer will assess the full text of the remaining articles and make a list of articles to be included. Any disagreements will be resolved by involving a third reviewer (GR). Full-text versions of the remaining articles will be assessed by using the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) standard data collection checklist, which will be adapted for data extraction. Data will be extracted on study design, participant characteristics (age,

gender and level of education), intervention characteristics, location of care (community or residential setting), country, primary and secondary outcomes, source of funding etc. Furthermore, information on intervention fidelity such as adherence, frequency, duration, coverage and other elements mentioned by trial authors will be extracted. Two review authors (NK and DH) will independently extract the study characteristics from the primary studies included in the review using a customised Microsoft Excel table, with article selection based on PICOS elements. Two review authors (NK and DH) will extract outcomes data from the included studies, with any disagreements on the outcomes data decided by a third reviewer (GR), in accordance with the Cochrane Handbook for Systematic Reviews of Interventions.[56]

Risk of bias assessment

Risk of bias will be evaluated using the EPOC risk of bias tool[57], which is suitable for this review because the method also includes non-randomised trials. This tool has nine criteria, including random sequence generation, allocation concealment, baseline characteristics, outcome measures at baseline, incomplete outcome data, knowledge of allocated intervention, protection against contamination and selective reporting of outcomes. For each of the nine domains, the procedures undertaken by individual studies will be described, including verbatim quotes. Two review authors (NK and DH) will independently assess the risk of bias and categorise the studies as having low risk, high risk or unclear risk of bias. Any disagreements will be resolved by involving a third reviewer (GR). Graphic representations of potential bias within and across studies will be computed using Review Manager (RevMan) (Version 5.4, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2020). Each item in the risk of bias assessment will be considered independently, without an attempt to collate and assign an overall score.

Data synthesis

Quantitative data will, where possible, be pooled in statistical meta-analysis. All results will be subject to double data entry. Effect sizes expressed as odds ratio or relative risk (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard χ^2 and also explored using subgroup analyses based on the different quantitative study designs included in this review. Furthermore, we will use L'Abbé plot to explore heterogeneity and identify outlying trials in a meta-analysis.[58]

Quality of evidence will be assessed using Grades of Recommendation, Assessment, Development, and Evaluation (GRADE).[59] Sensitivity analysis will be performed by removing studies with higher risk of bias. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate. These results will be combined to arrive at a conclusion from the research. After performing data synthesis, the final report will be prepared

following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Furthermore, in case of any deviations from the protocol the authors will mention them in the final published report and update in the PROSPERO record.

Discussion

Despite a plethora of systematic reviews conducted on synthesising evidence on the effectiveness of integrated care interventions for older people, all such reviews have treated older people with different levels of frailty as a single population. This could be one reason for the heterogeneity in findings from the existing reviews. This review will fill this gap by synthesising evidence on the effectiveness of integrated care interventions for older people with different frailty levels.

Dissemination

The findings of this review will be shared through a peer reviewed journal article, conferences, and with local commissioners and stakeholders involved in providing integrated care services for the older population.

Ethical issues

This is a systematic review that will only use data from existing studies, all of which will have obtained ethical approval. As such, there are no ethical considerations for the project, however, data collected from the studies included in the review will be treated with due consideration.

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Footnotes

Contributors: NK conceived the idea, planned and wrote the first draft of the study protocol. DH developed the search strategy. The first draft was reviewed by DH and GR. DH and GR provided critical insights. All authors have approved and contributed to the final written manuscript. The guarantor of the review will be DH.

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Competing Interests Statement: None declared

Patient and Public involvement: No patient involved

Provenance and peer review: Not commissioned; externally peer reviewed.

Appendix 1

MEDLINE Search Strategy

1. TI/AB: Frail*
2. MeSH Heading: Frail Elderly
3. 1 OR 2 OR
4. TI/AB: Elder*
5. TI/AB: Older*
6. TI/AB: Geriatr*
7. TI/AB: Senior
8. MeSH Heading: Aged
9. MeSH Heading: Aged, 80 and over
10. 4 OR 5 OR 6 OR 7 OR 8 OR 9
11. TI/AB: “Randomised Controlled Trial”
12. MeSH Heading: Randomized Controlled Trial
13. TI/AB: RCT
14. MeSH Heading: “Controlled Clinical Trial“
15. 11 OR 12 OR 13 OR 14
16. TI/AB: “Integrated care”
17. MeSH Heading: Delivery of Health Care, Integrated
18. TI/AB: “Integrated Delivery Systems”
19. TI/AB: “Integrated Health Care Systems”
20. TI/AB: “Integrated Healthcare Systems”
21. MeSH Heading: Patient Care Bundles
22. TI/AB: “Care Bundles”
23. MeSH Heading: Continuity of Patient Care
24. TI/AB: “Continuity of Care”
25. TI/AB: “Continuum of Care”
26. MeSH Heading: Case Management
27. TI/AB: “Patient centred care”
28. TI/AB: “Coordinated care”
29. MeSH Heading: Health Services for the Aged
30. MeSH Heading: Nurses Improving Care for Health System Elders
31. 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30
32. 3 AND 10 AND 15 AND 31

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Information Reported	Line numbers
ADMINISTRATIVE INFORMATION				
Title:				
Identification	1a	Identify the report as a protocol of a systematic review	Done	Page 1: Line 2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not Applicable	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	PROSPERO CRD42020166908	
Authors:				
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Done	Page 1: Lines 3 to 10
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Done	Page 12: Lines 3 to 5
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Done	Page 7: Lines 32 to 33
Support:				
Sources	5a	Indicate sources of financial or other support for the review	Done	Page 12: Lines 6 to 9
Sponsor	5b	Provide name for the review funder and/or sponsor	Not Applicable	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not Applicable	
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	Done	Page 4: Lines 22 to 36
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Done	Page 5: Lines 5 to 8

METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Done	Page 5: Lines 10 to 32 and Page 6: Lines 18 to 25
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Done	Page 6: Lines 1 to 13
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated		Page 6: Lines 14 to 17 and Page 9: Lines 2 to 23
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Done	Pages 6: Lines 27 to 28
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Done	Page 6: 28 to 32
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Done	Page 6: Lines 32 to 34 and Page 7: Lines 2 to 7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Done	Page 6: Line 35 and Page 7: Lines 1 to 2
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Done	Page 5: Lines 26 to 32
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Done	Page 7: Lines 8 to 19
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Done	Page 7: Lines 21 to 23
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Done	Page 7: Lines 24 to 27
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Done	Page 7: Line 28
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Done	Page 7: Lines 29 to 30
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Done	Page 7: Lines 27-28
Confidence in	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Done	Page 7: Lines 27-28

cumulative evidence

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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