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Case management for integrated care of frail older people in community settings (Protocol)

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[Intervention Protocol]

Case management for integrated care of frail older people in community settings

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness of case management for integrated care of frail older people compared to usual care.

BACKGROUND

Demographic changes and advances in medical care and technology have led to an ageing population. Despite gains in life expectancy, compression of morbidity in later life has not been achieved, meaning that although growing numbers of older people are living longer, they are doing so with one or more long-term conditions (Beard 2016). A key driving force for international policy agendas worldwide is to improve the quality, efficiency and safety of health and care services through the delivery of effective integrated care systems (World Health Organization 2016). Integrated care can be broadly defined as "an organising principle for care delivery that aims to improve patient care and experience through improved coordination" (Shaw 2011), and such approaches are being increasingly implemented as a key policy in many countries. This review will focus on case management as one service model for delivering integrated care, among others. Case management has gained traction with policy makers recently as a method of improving quality of care and related outcomes for populations at high risk of declines in health and wellbeing and emergency and hospital admission (Ross 2011), with the most vulnerable people in this group classified as frail (Goodwin 2014).

Description of the condition

This Cochrane Review focuses on frail older people. Frailty is defined as an age-related reduction in reserve capacity of multiple

physiological systems resulting in an increased risk of a sudden decline in health status, usually triggered by minor stress such as a fall or infection (Campbell 1997; Clegg 2013). The prevalence of frailty is higher among women than men, and gradually increases with age: 4% among older people aged 65 to 69 years; 7% between 70 and74 years; 9% between 75 and 79 years; 16% between 80 and 84 years; and 26% for those aged 85 years and over (Collard 2012; Clegg 2013). Frailty has also been found to be associated with lower socioeconomic status (Gu 2016). Older people with frailty commonly experience complex health and psychosocial needs (Manthorpe 2015), and multimorbidity (Hewitt 2016). They are often high users of health and social care services, with associated high costs (Bock 2016), but are also a population group at risk of experiencing reduced co-ordination and quality of care due to fragmented service provision (Ament 2014; Oliver 2014; Andreasen 2015).

Description of the intervention

The intervention to be evaluated is case management as a strategy for integrated care. In this review we define case management as a community-based intervention which focuses on the planning, provision and co-ordination of health and social care to meet the needs of the older person with frailty (Oeseburg 2009; Reilly 2015). Case management interventions are multi-faceted and comprise multiple components, including case-finding, comprehensive assessment, care provision, planning and care giving, care co-ordination, monitoring and evaluation (Gagnon 1999; Ross 2011; Sandberg 2014). Such interventions are typically led by a nurse, social worker or allied healthcare professional (e.g. physiotherapist), with the support of a multidisciplinary team, and are delivered in community care settings, i.e. the individual's own home environment and not an acute or residential care setting (Reilly 2015).

How the intervention might work

Frail older people commonly have health and social care needs (Manthorpe 2015), but experience reduced co-ordination of care due to fragmented service provision (Ament 2014; Oliver 2014; Andreasen 2015). Case management approaches as a strategy for improving health and social care integration aim to improve co-ordination of care to meet the holistic needs (physical, psychological and social) of individuals, thus reducing the fragmentation of health and social care services, and resulting in better patient and service outcomes.

A number of randomised trials of case management approaches to support frail older people have been conducted, but evidence from these studies has not been systematically synthesised. Some studies have found that case management for frail older people improves independence in activities of daily living (Eklund 2013), increases patient satisfaction (Berglund 2015), reduces mobility-related disability (Fairhall 2012), delays admission to hospital or a nursing home (Bernabei 1998; Oeseburg 2009), reduces healthcare service use (Bernabei 1998; Oeseburg 2009; Sandberg 2015), and lowers costs (Bernabei 1998; Oeseburg 2009). Other studies have found no effects on improving levels of disability (Metzelthin 2013), quality of life and functional status, reducing admission to hospital or length of hospital stay (Gagnon 1999), or preventing adverse outcomes (Ruikes 2016). One study reported an increase in readmission rates to an Emergency Department (Gagnon 1999). Evidence from a recent Cochrane Review has found that case management interventions delivered to people with dementia and their carers improves some outcomes, including reducing rates of care home admission and healthcare costs in the medium term, and improving psychosocial outcomes for carers (Reilly 2015). Given emerging positive benefits of delivering some services closer to the frail older person's home environment, and the older person's preference for this (Oliver 2014), it is important to examine the benefits of case management interventions for integrated care of frail older people.

There is currently limited understanding of how case management approaches as a strategy for integrated care for frail older people might work. A number of factors are likely to influence this. Frail older people's health and social care needs will depend on the degree of frailty, disability and level of social support available. It is likely that individuals with different degrees of frailty will require different formulations and levels of intensity of case management, which will likely have different impacts on the frail older person, carer, providers and services (e.g. level and nature of carer and provider support required, with implications for health and social care utilisation and costs). As the available health and social care service provision, support and integration will vary between countries, this will likely influence how case management for frail older people might work. Finally, as frailty is more prevalent among particular subgroups - namely those of lower socioeconomic status (Gu 2016),older age and women (Collard 2012) - these characteristics are also likely to influence how case management for this population might work.

Why it is important to do this review

As integrated care is being implemented as a key policy internationally, providing the evidence of impact from randomised trials of case management interventions to improve integrated care for frail older people would be valuable for health care decision makers. Thus the primary aim of this Cochrane Review is to evaluate the effectiveness of case management for integrated care of frail older people compared to usual care. This review will evaluate effectiveness by examining the impact of case management on patient, carer, provider and service outcomes, as well as any adverse effects. Another reason for conducting this review is to identify which elements of these interventions drive the desired effect, and

also which patient cohorts might experience most benefit from such interventions. Using a systematic approach to establish the effects of this intervention would be useful for a range of stakeholders, including health and social care providers, service users and carers, commissioners of services, policy makers and academic researchers working in this field. Testing this in a systematic review and providing a synthesis of what (if anything) we know works about case management for integrated care of frail older people is essential to ensure that policy makers, commissioners of services, and practitioners deliver clinically improved interventions and achieve better value outcomes.

OBJECTIVES

To assess the effectiveness of case management for integrated care of frail older people compared to usual care.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised trials (RTs), of both individual and cluster design, that compare case management for integrated care of frail older people with usual care. An initial scoping of the literature indicates sufficient numbers of RTs to include in a meta-analysis in this review. We will include all trials, however old, conducted in high-, middle- and low-income countries.

We will include full-text, peer-reviewed publications, conference abstracts (with a view to identifying full studies), and unpublished data. We will include studies irrespective of their publication status and language of publication.

We will exclude the following types of study designs.

- Studies involving non-randomised designs (e.g. non-RT, interrupted time series designs).
- Studies involving observational methods only.

Types of participants

We will include men and women aged 65 years and over, who meet the following criteria.

- Identified as frail using criteria defined by trial authors.
- Living in a community setting, i.e. individuals living in their own home, retirement housing or sheltered accommodation, but excluding those living in a nursing or residential care setting.
- Not medically unwell, i.e. not receiving acute medical care.

Two dominant models of frailty are the phenotypical (Fried 2001), or accumulative deficit (Searle 2008), models of frailty. The former categorises frailty as a clinical syndrome, specifically meeting three or more of the following five criteria: weight loss, exhaustion, weak grip strength, slow walking speed, low physical activity (Fried 2001). The accumulative deficit model conceptualises frailty as a multidimensional state, including physical, psychological and social domains of function, using a proportion of health deficits from the number of problems assessed (Searle 2008). We will use criteria to define frailty as defined by trial authors of included studies, which may include validated measures to identify frailty based on one of the models mentioned above.

Types of interventions

We will include all trials comparing case management for integrated care of frail older people with usual care. To be included, the intervention should meet the following criteria,

- Led by a single health or social care professional who has a role in care delivery for older people with complex needs, supported by a multidisciplinary team (MDT). This can include a nurse, social worker or allied healthcare professional.
- Focused on the planning, provision and co-ordination of health and social care to meet the needs of the older person with frailty.
- Delivered in community care settings, and not acute care settings, with no minimum or maximum follow-up period to assess outcomes.

The comparison for this review will be:

- case management compared with usual care, as described by trial authors, defined as non-case-management standard care for frail older people delivered in community care settings. This usually involves identification of frailty and related management and care planning by a General Practitioner (GP) in primary care, but does not focus on health and social care integration for this population.

We will provide a description of care for the intervention and usual care in the 'Characteristics of included studies' table, using the template for intervention description and replication (TIDieR) checklist (Hoffmann 2014).

Types of outcome measures

Primary outcomes

- Death (all types of analysis, i.e. rates, time to death, risk, coherence of place of death with patient preference), as defined by trial authors. We justify including death as a primary outcome because frailty is the leading cause of death in older people (Clegg 2013).

- Living at home or change in place of residence (e.g. nursing or residential care) at follow-up.
- Quality of life, as defined by trial authors.
- Serious adverse events (e.g. hospitalisation from falls or fracture, permanent disability or death).

Secondary outcomes

- Change in function (increase or decrease in level of independence in instrumental activities of daily life), as defined by trial authors.
- Change (increase or decrease) in health and social care utilisation and costs (e.g. due to admission or readmission to an emergency department or hospital ward, increased hospital length of stay, admission to nursing or residential care).
- Patient, carer (e.g. carer strain or burden) and provider experience and acceptability, as defined by trial authors

Search methods for identification of studies

Electronic searches

We will develop the search terms with the Cochrane Effective Practice and Organisation of Care (EPOC) Group's Information Specialist. We will search the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews.
We will search the following databases for primary studies, from inception to the date of search.

- Cochrane Central Register of Controlled Trials (CENTRAL), in the Cochrane Library, which will also include the Cochrane EPOC Group Register.
- MEDLINE Ovid, 1946 to date of search.
- Embase Ovid, 1974 to date of search.
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature), 1980 to date of search.
- Health Systems Evidence (https://www.pdq-evidence.org/), to date of search.
- PDQ Evidence (https://www.pdq-evidence.org/), to date of search.

Search terms will be comprised of keywords and controlled vocabulary terms. We will not apply any limits on language and we will search all databases from inception to the date of search. See Appendix 1 for the proposed MEDLINE search strategy, which we will adapt for other databases.

Searching other resources

Trial registries

- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp), to date of search.
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov), to date of search.
- McMaster Ageing Portal (www.mcmasteroptimalaging.org/), to date of search.

Grey literature

We will conduct a grey literature search to identify studies not indexed in the databases listed above.

- King's Fund Library Database (https://www.pdq-evidence.org/), to date of search.
- British Geriatrics Society (https://www.pdq-evidence.org/), to date of search.
- American Geriatrics Society (https://www.pdq-evidence.org/), to date of search.

We will also review reference lists of all included studies and relevant systematic reviews for additional potentially eligible primary studies. We will contact researchers with expertise relevant to the review topic to identify further unpublished literature. We will conduct cited reference searches for all included studies in ISI Web of Science, if the number of included studies is a manageable number (i.e. below 10), and screen individual journals and conference proceedings (e.g. through handsearching). We will provide appendices for all strategies used, including a list of sources screened and relevant primary studies reviewed.

Data collection and analysis

Selection of studies

We will download all titles and abstracts retrieved by electronic searching to a reference management database and remove duplicates. Six review authors (ES, AZ, ZK, JW, KS, JS) will independently screen titles and abstracts for inclusion. This will involve one author (ES) independently screening all titles and abstracts for inclusion, and five authors independently screening a proportion of titles and abstracts for inclusion, namely AZ (30%), ZK (20%), JW (20%), KS (20%) and JS (10%). We will retrieve the full-text publications of relevant studies and five review authors (ES, AZ, ZK, JW, KS) will independently screen the full-text and identify studies for inclusion, as well as identify and record reasons for exclusion of the ineligible studies. This will involve one author (ES) independently screening the relevant full-text study publications, and four authors independently screening a proportion of these, namely AZ (25%), ZK (25%), JW (25%), KS (25%). We will resolve any disagreement through discussion and, if required, we will consult a third review author (JS). We will list studies that

initially appeared to meet the inclusion criteria, but which we later excluded, in the 'Characteristics of excluded studies' table. We will collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review. We will also provide any information we can obtain about ongoing studies. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009).

Data extraction and management

We will use the EPOC standard data collection form and adapt it for study characteristics and outcome data (EPOC 2013a). We will pilot the form on at least one study in the review. Two review authors (ES and AZ) will independently extract the following study characteristics from the included studies and enter the data into Review Manager 5 (Review Manager 2014).

- Methods: study design, number of study centres and location, study setting, withdrawals, date of study, follow-up.
- Participants: number, mean age, age range, gender, socio-economic status, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria, baseline mobility/function, presence of cognitive impairment, and other relevant characteristics.
- Interventions: intervention components, comparison, fidelity assessment, and acceptability of intervention.
- Outcomes: main and other outcomes specified and collected, time points reported.
- Notes: funding for trial, notable conflicts of interest of trial authors, ethical approval.

Three review authors (ES, AZ, JW) will independently extract outcome data from the included studies. This will involve one review author (ES) independently extracting outcome data from all included studies, and two authors independently extracting outcome data for a proportion of these, namely AZ (50%) and JW (50%). We will note in the 'Characteristics of included studies' table if outcome data from any included studies were reported in an unusable way. We will resolve disagreements by consensus or by involving a third review author (JS).

Assessment of risk of bias in included studies

Two review authors (ES and ZK) will independently assess risk of bias for each included study using the criteria outlined in Section 8.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and the guidance from the EPOC group (EPOC 2013b). We will resolve any disagreements by discussion or by involving a third review author (JS). We will assess the risk of bias according to the following domains.

- Random sequence generation
- Allocation concealment
- Blinding of outcome assessment
- Blinding of participants and personnel
- Incomplete outcome data
- Selective outcome reporting
- Baseline outcomes measurement
- Baseline characteristics
- Other bias, such as recruitment bias

We will judge each potential source of bias as high, low, or unclear and provide a quote from the study report, together with a justification for our judgement in 'Risk of bias' tables. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will assign an overall 'Risk of bias' assessment (high, moderate or low) to each of the included studies using the approach suggested in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Specifically, we will consider studies with low risk of bias for all key domains, or where it seems unlikely for bias to seriously alter the results, to have a low risk of bias. We will consider studies to have an unclear risk of bias where risk of bias in at least one domain was unclear or judged to have some bias that could plausibly raise doubts about the conclusions. We will consider studies with a high risk of bias in at least one domain, or judged to have serious bias that decreases the certainty of the conclusions, to have a high risk of bias.

We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient reported quality-of-life scale). Where information on risk of bias relates to unpublished data or correspondence with a trial author, we will note this in the 'Risk of bias' tables. We will not exclude studies on the grounds of their risk of bias, but will report the risk of bias when presenting the results of the studies.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

As we will be including cluster-randomised trials, we will also consider the following additional biases, as proposed in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

- Recruitment bias
- Baseline imbalance
- Loss of clusters
- Incorrect analysis
- Compatibility with individual RTs
- Contamination

We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will estimate the overall effect of the intervention using four primary outcomes. For dichotomous outcomes (death; living at home or change in place of residence and adverse events) we will

use relative risks, and for continuous scores (quality of life) we will use mean differences or standardised mean differences, with the corresponding 95% confidence intervals (Higgins 2011). We will ensure that an increase in scores for all the outcomes can be interpreted in the same way for each outcome. We will also explain the direction to the reader, and report where the directions were reversed, if this is necessary. As there is likely to be heterogeneity in included studies, we will conduct a random-effects meta-analysis.

Unit of analysis issues

We will include cluster-RTs in this review. As proposed in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), we will obtain a direct estimate of the required effect measure, for example, an odds ratio with its corresponding confidence interval, should the analysis properly account for the cluster design.

Dealing with missing data

We will contact study investigators to obtain any missing data (e.g. when a study is identified as abstract only), including to verify key study characteristics and missing outcome data where possible. Should it not be possible to obtain complete data, we will report this as a potential source of bias in the data analyses. We will assume that all missing data are missing at random, in line with guidance suggested in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of heterogeneity

We will use the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identify strong evidence for heterogeneity - namely, I^2 values greater than 75% - we will explore it by prespecified subgroup analysis (Higgins 2011).

Assessment of reporting biases

We will attempt to contact study authors, asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results**.** If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible publication biases, and interpret the results with caution (Sterne 2011).

Data synthesis

We will conduct a random-effects meta-analysis only where this is meaningful, i.e. if the treatments, participants, and the underlying clinical question are similar enough for pooling to make sense. If it is not possible to conduct a meta-analysis we will conduct a narrative synthesis to summarise the evidence and characteristics of included studies. Meta-analysis will be considered for feasibility prior to undertaking the analysis. A common way trial authors indicate that they have skewed data is by reporting medians and interquartile ranges. When we encounter this, we will note that the data are skewed and consider the implication of this. Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) must be entered into the same meta-analysis, we will halve the control group to avoid double-counting.

'Summary of findings' table and GRADE

In order to draw conclusions about the certainty of the evidence within the text of the review, we will create a 'Summary of findings' table for the main intervention comparisons and the following outcomes:

- death;
- living at home/change in place of residence;
- quality of life;
- serious adverse events;
- change in function;
- change in health and social care utilisation and costs. .

If during the review process, we become aware of an important outcome that we failed to list in our planned 'Summary of findings' table, we will include the relevant outcome and explain the reasons for this in the section 'Differences between protocol and review'. Two review authors (ES and ZK) will independently assess the certainty of the evidence (high, moderate, low, or very low) using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias) (Guyatt 2008). We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2011), and the EPOC worksheets (EPOC 2013c). We will use GRADEpro GDT software to do this (GRADEpro GDT 2014). We will resolve disagreements on certainty ratings by discussion and provide justifications for decisions to downgrade or upgrade the ratings using footnotes in the table, and make comments to aid readers' understanding of the review where necessary. We will use plain language statements to report these findings in the review (EPOC 2013c).
We will consider whether there is any additional outcome information that was not possible to incorporate into meta-analyses and will note this in the comments, stating if it supports or contradicts the information from the meta-analyses. If it is not possible to meta-analyse the data we will summarise the results in the text.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses.

- Case management which includes care provision versus models that do not and just consist of co-ordination. This is

important because different levels and formulations of case management (i.e. case-finding, comprehensive assessment, care provision, planning and care giving, care co-ordination, monitoring and evaluation components) are likely to have a dose response depending on level and combination of components of case management, which we would like to test. We will examine the dose related impact by level of case management (i.e. model of care or number of staff involved) to ascertain how strong the effect of case management was in each trial.

- Lower number of visits (i.e. initial assessment and follow-up) versus multiple visits (i.e. more than two) at different time points. This is important because our initial review of the literature showed that studies varied in the number of visits (face-to-face or telephone contact) provided to frail older people, indicating a likely dose response, with multiple visits likely to have better outcomes, which we would like to test. We will record actual number of visits for each trial in the 'Characterictics of included studies' table.
- Individuals with mild to moderate versus severe degrees of frailty. This is important because case management approaches will have different objectives for those with mild to moderate degrees of frailty (e.g. healthy living, chronic disease self-management or even reversal of frailty) compared to those with severe degrees of frailty (e.g. symptom control or palliation). In addition, we will consider a subgroup analysis for different models of frailty (i.e. phenotypical versus accumulative deficit models), if possible.
- Case management interventions to support frail older people conducted in high- to middle-income countries versus those conducted in low-income countries. This is important because the availability, nature, and scope of health and social care services, support and integration will vary between countries.

We will use the following outcomes in subgroup analysis.

- Death
- Living at home or change in place of residence
- Quality of life
- Serious adverse events

Furthermore, if data are available we will analyse socio-economic status, age and gender subgroups as covariates, and adjust analyses accordingly.

We will perform tests for interaction for subgroup analysis, and use meta-regression techniques to test for subgroup interactions providing that sufficient studies (i.e. five or more) are available.

Sensitivity analysis

We will perform sensitivity analyses defined a priori to assess the robustness of our conclusions and explore its impact on effect sizes. This will involve the following.

- Restricting the analysis to published studies.
- Restricting the analysis to studies with a low risk of bias, as specified in Section 13.2.1, Chapter 8 of the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2011).
- Imputing missing data.
- Analysis by ten-year publication band to account for likely changes over time.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE (OVID)
MEDLINE (including epub ahead of print, in-process & other non-indexed citations 1946 to present).

No.	Search terms
1	"aged, 80 and over"/
2	aged/
3	frail elderly/
4	geriatrics/
5	"health services for the aged"/
6	((geriatric? or senior? or elderly or old*) adj2 (person? or people or adult? or patient?)).ti,ab
7	(frail* adj2 (adult* or elder* or old or senior? or person? or people or patient?)).ti,ab
8	or/1-7
9	exp delivery of health care, integrated/
10	(integrat* adj1 (care or pathway* or service* or delivery or healthcare or program* or approach* or model*)).ti,ab
11	(deliver* adj1 (care or healthcare or service*)).ti,ab.
12	((system or systems) adj1 (care or healthcare or service*)).ti,ab
13	((organis* or organiz*) adj1 (care or healthcare or service*)).ti,ab
14	patient care planning/
15	((coordinat* or co-ordinat*) adj2 (care or healthcare or service* or program* or approach* or management or team care or team treatment* or team assessment* or team consultation*)).ti,ab
16	case management/
17	((case or care) adj manag*).ti,ab.
18	(comanag* or co-manag*).ti,ab.
19	comprehensive health care/

(*Continued*)

20	(comprehensive adj2 (healthcare or care)).ti,ab.
21	care navig*.ti,ab.
22	(collaborat* adj1 (care or manage* or healthcare or service* or program* or approach* or working)).ti,ab
23	shared care.ti,ab.
24	(holistic adj2 (care or healthcare)).ti,ab.
25	((partner* or joint) adj2 (care or working)).ti,ab.
26	("health* and social care" or "medical care and social care" or "care and social care").ti,ab
27	(team* adj2 (care or treatment* or assessment* or consultation* or healthcare or service* or program* or approach*)).ti,ab
28	((multidisciplinary or multi-disciplinary or interprofessional or inter-professional or interdisciplinary or inter-disciplinary or multispeciality or multi-speciality or multiagency or multi-agency or interagency or inter-agency or multi-professional or mulitprofessional or interorganisation* or interorganization* or inter-organisation* or inter-organization* or multiagenc* or multi-agenc* or interagenc* or inter-agenc*) adj2 (team* or care or working or collaboration or intervention* or management or provider? or consultation? or approach* or program* or treatment*)).ti,ab
29	kaiser permanente.ti,ab.
30	or/9-29
31	8 and 30
32	exp randomized controlled trial/
33	controlled clinical trial.pt.
34	randomi#ed.ti,ab.
35	placebo.ab.
36	randomly.ti,ab.
37	clinical trials as topic.sh.
38	trial.ti.
39	or/32-38
40	exp animals/ not humans/
41	39 not 40

(*Continued*)

42	31 and 41

CONTRIBUTIONS OF AUTHORS

ES and JS conceived the protocol.

ES, ZK and JS designed the protocol.

ES co-ordinated the protocol.

ES and ZK designed the search strategies.

ES, ZK and JS wrote the protocol.

ZK, AZ, IB, DW, JW, NS, KS, JS provided general advice on the protocol.

Secured funding for the protocol: not applicable.

DECLARATIONS OF INTEREST

ES: none known.

ZK: none known.

AZ: none known.

IB: none known.

DW: none known.

JW: none known.

KS: none known

NS: Nick Sevdalis is the Director of London Safety and Training Solution Ltd, which provides quality and safety training and advisory services on a consultancy basis to healthcare organisations globally.

JS: none known.

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