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Interventions for involving older patients with multimorbidity in decision-making during primary care consultations (Protocol)

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[Intervention Protocol]

Interventions for involving older patients with multimorbidity in decision-making during primary care consultations

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ABSTRACT

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

To explore the effectiveness of interventions delivered with the aim of involving older patients with multimorbidity in decision-making about their health care during primary care consultations.

BACKGROUND

Description of the condition

Life expectancy is predicted to continue to rise globally (Oeppen 2002), and the prevalence of long-term conditions also increases with age (Melzer 2015). The presence of more than one long-term health problem is termed multimorbidity. Quality of care for older patients with multimorbidity may be worsening when compared to the management of patients with long-term conditions in general (Higashi 2007; Steel 2014). The consequences of multimorbidity include functional decline with poor quality of life, high healthcare utilisation and costs, reduced life expectancy, and a negative impact on the health of carers (Academy of Medical Sciences 2018; Marengoni 2011).

Our previous work identified that older patients value being involved in decision-making about their health care (Butterworth 2014). However, they are less frequently involved in decision-making when compared with younger patients (van den Brink-Muinen 2006). There is some evidence of associated health inequalities, including discrepancies in rates of referral and requests for investigation (Drennan 2007; McBride 2010; Tate 2010).

The importance of involving older patients with multimorbidity in decision-making about their care when seeking to identify unmet healthcare needs, has been acknowledged (Couët 2015; Department of Health and Social Care (UK) 2001; Homa 2015; Iliffe 2004; Noël 2007). Older patients need support in prioritising and rationalising treatment options to maximise quality of life and day-to-day function (Kiesler 2006; Peters 1994). Recent research suggests that supporting older patients with multimor-

bidity in communicating their needs and concerns to healthcare providers could reduce risks to patient safety (Hays 2017).
'Old age' refers to somebody nearing the end of the natural human life cycle. Whilst the widely accepted definition of an older person in westernised countries encompasses individuals aged 65 years and above, with the rise in life expectancy, this age category is becoming increasingly vast (Dong 2016; Oeppen 2002). Therefore, there may be differing healthcare requirements across the widening older age group that must be considered by future research, and in particular by intervention studies designed to support the needs of this patient group. Many currently available interventions appear outdated in their assessments of this population with regard to their wish for involvement in decision-making about their health care.

Description of the intervention

This Cochrane Review will assess the effects of interventions for older patients with multimorbidity with the aim of involving them in decision-making about their health care during primary care consultations. We searched the literature for systematic reviews of similar interventions to inform the description of interventions to be included in this review (Kinnersley 2008; Légaré 2018; Smith 2016; Wetzels 2007). Our description of the components of patient involvement in decision-making is also influenced by the components of patient-centred care as suggested by Wensing 2003.
Interventions may be delivered either prior or during a single consultation, or they may span multiple consultations. Studies may encompass one of three types of intervention centred around a consultation with a primary healthcare practitioner or they may include elements of all three:

- patient-focused e.g. written or online decision-support tools such as 'option grids', that can either be completed with a practitioner during a consultation or completed by the patient outside of, and prior, to the consultation;
- practitioner-focused e.g. communication skills training for use during a consultation;
- relate to organisational change e.g. increased length of the consultation.

Interventions may be delivered, as well as received, by primary care practitioners, or they may be delivered by external clinicians/researchers, or by administration staff. They may also be facilitated by a patient's carer (a family member or paid helper who regularly looks after the patient), who may or may not be present during a consultation.
We will consider all interventions designed to facilitate the involvement of patients with multimorbidity in decision-making about their health care during primary care consultations.

How the intervention might work

Within the patient-practitioner consultation, patient involvement in decision-making refers to activities carried out by:

- a practitioner, seeking to facilitate a patient's active engagement in decision-making within the consultation (including the use of 'shared decision-making' related communication skills, and/or encouraging patient autonomy and empowering self-management, and/or changing the way that information is delivered to meet patient preferences); and
- patients. to increase their own involvement in decision-making during the consultation (including expressing a preference for involvement, the use of written decision-making support tools, and taking ownership of patient-held records).

In addition, changes can be made to the organisation of care, so that healthcare services more comprehensively address patients' needs and preferences, to enable patient involvement in decision-making about their health care. Therefore a third approach to patient involvement in decision-making is directed towards improving the quality of healthcare delivery within the consultation, and might include longer consultations (to allow time for patient involvement in decision-making to take place, for example), or system improvements to enable continuity of care with an individual practitioner (Wensing 2003).
Shared decision-making has been defined as "an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences" (Elwyn 2010). Shared decision-making during healthcare consultations has previously been identified as a priority feature of high quality patient-centred care (WHO 1994). Delivering such care is associated with improved outcomes for patients, doctors, and healthcare teams. These include patient adherence with treatment advice, satisfaction with health care, and trust in the doctor (Croker 2013; Flocke 2013; Loh 2007; Ommen 2011).
The primary care practitioner's role in shared decision-making involves seeking the patient's implicit or explicit involvement in the decision-making process; exploring the patient's ideas, fears, and expectations about the problem and possible treatments; providing a balanced view in the discussion of healthcare options; identifying the patient's preferred data format to provide tailor-made healthcare information; checking the patient's understanding of the information and their reactions to it; asking for the patient's decision-making role preference; making, discussing, or deferring decisions with the patient; and arranging for appropriate follow-up (Elwyn 2000).
Whilst many studies have reported patients' positive views of the processes of involvement in decision-making about their health care, some have suggested that older patients may not value feeling involved in this way (Levinson 2005). Our previous work used qualitative methods to examine these apparent conflicts (Butterworth 2014). We found that, in general, older patients do

value feeling involved in the decision-making process, but it is important to recognise that patient perceptions vary regarding what it means to be involved (Berkelmans 2010; Kiesler 2006). For example, some participants did not report valuing every element of a shared decision-making approach, identified as being of importance in the literature (Elwyn 2000). We therefore plan to consider studies evaluating all interventions designed to facilitate the involvement of patients with multimorbidity in decision-making about their care, in order to understand the effects of these interventions for the older patient population with multimorbidity, without solely focusing on a shared decision-making approach. We will also evaluate studies of interventions designed to facilitate patient involvement in decision-making that were not designed for, but were investigated with our population of interest.

Patients' perceptions of involvement in decision-making about their health care are considered important in predicting outcomes (Saba 2006). For example, there are positive associations between patients' trust in a general practitioner (GP) and their perceptions of having been involved in decision-making. The strength of this association increases with patient age (Croker 2013). A brief review of the current literature suggests it is difficult to draw firm conclusions regarding which types of interventions might most effectively facilitate the adoption of patient involvement in decision-making by primary care practitioners (Légaré 2018).

A 2007 Cochrane Review considered interventions to improve older patients' involvement in primary care consultations, including their involvement in decision-making about their health care (Wetzels 2007); however it did not address the issue of multimorbidity. At that time, the review authors reported on three relevant intervention studies, and concluded that the available evidence was sparse. However, that review is now dated, and we believe that new research is available. A systematic review of this evidence will provide greater clarity regarding the best use of interventions to support the involvement of older patients with multimorbidity in decision-making about their care, in order to achieve positive outcomes for patients, doctors, and healthcare teams as outlined above.

Why it is important to do this review

There are concerns that current delivery of good quality care is not meeting the needs of older patients who often experience multimorbidity (Salisbury 2012; Steel 2014). Older patients account for a large percentage of spending in primary care; 37% in the UK (RCGP 2013). Such patients consult more frequently (Hobbs 2016), creating a substantial component of the primary care workload. The burden on primary care from this vulnerable patient group can be expected to increase as the prevalence of multimorbidity in the older age groups is predicted to rise (from 45.7% in 2015, to 52.8% in 2035 for people aged 65 to 74 years) (Kingston 2018). It is only recently that the needs and benefits to older patients with multimorbidity of participating in decision-making about their health care have been acknowledged.

The National Institute for Clinical Excellence (NICE) in the UK has recently published guidelines for the clinical assessment and management of patients with multimorbidity (NICE 2016). The guidelines recommend that patients with multimorbidity should be involved in decision-making about their health care. However, the authors provide little instruction on how to achieve this. Our review is warranted to provide evidence-based guidance to policy makers, researchers, and commissioners about how to direct funding towards good quality interventions targeting the involvement of older patients in decision-making about their health care, and to provide practical guidance to clinicians when adopting these interventions.

We acknowledge six reviews, identified by a brief literature search and by seeking the advice of content experts, and we discuss the similarities and differences between these reviews and our proposed review by using the Donabedian structure/process/outcomes model (McDonald 2007). We discuss why our proposed review is needed to fill an important gap in the current literature (see Table 1).

There are other reviews of shared decision-making interventions. However, we feel it is important to carry out a review of all interventions developed with the aim of facilitating the involvement of patients with multimorbidity in decision-making about their care, specifically older patients with multimorbidity. Therefore our review will have a wider scope than those specifically focused on the evaluation of shared decision-making tools and instruments.

We are not aware of any significant overlap with other Cochrane or non-Cochrane Reviews, either published or in progress.

Our review will inform the development of a new intervention to facilitate the involvement of older patients with multimorbidity in decision-making about their health care when visiting a primary care physician. Feasibility testing will then inform the planning and design of a future definitive randomised controlled trial of the intervention. We hope that other researchers will use this review to similarly inform their work to support this growing and vulnerable patient population.

OBJECTIVES

To explore the effectiveness of interventions delivered with the aim of involving older patients with multimorbidity in decision-making about their health care during primary care consultations.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster-RCTs, and quasi-RCTs (a trial in which randomisation is attempted but subject to potential manipulation, such as allocating participants by day of the week, date of birth, or sequence of entry into a trial). We anticipate that few properly RCTs will have been conducted on the subject as many studies specifically exclude older patients or those with more than one health problem.

Types of participants

The patient participant population will be older patients (aged 65 years and over) with multimorbidity (more than one long-term health problem), and will include their carers. However, we anticipate that searching for studies with such specific participant inclusion criteria may limit our findings, therefore we will include studies of multimorbidity where we can differentiate the study findings by patient age, or obtain this information from the study authors, with stratification where possible. We will also include studies if 75% or more of the patient population are aged 65 years or over.

We, like most researchers conducting studies in developed world countries, have accepted the chronological age of 65 years and above as a definition of an older person. However we recognise that, like many westernised concepts, this does not adapt well to the situation in developing countries.

We will include any study where the study authors' definition of multimorbidity is encompassed by our own. Our definition of 'more than one long-term health problem' therefore encompasses studies where multimorbidity is defined as 'three or more chronic conditions', for example.

We will not specify a minimum length of time for long-term conditions, examples of which include: angina or heart problem; arthritis or joint problem; asthma or chest problem; blindness or severe visual impairment; cancer in the last five years; deafness or severe hearing impairment; diabetes; epilepsy; high blood pressure; kidney or liver disease; back problem; mental health problem; and neurological problem. We adapted this list from the English National General Practice Patient Survey. Where dyads of conditions occur within the same category, e.g. anxiety and depression, we will only count these as one condition e.g. mental health problem.

We define primary care as "first-contact, continuous, comprehensive, and coordinated care provided to populations undifferentiated by gender, disease, or organ system" (Starfield 1994). We will include all interventions involving patients, their carers, primary care practitioners, and primary care administration staff (including receptionists) that are delivered within primary care with the aim of improving patient involvement within a primary care consultation. This will include interventions delivered in the patient's home but initiated by the primary healthcare team. We will include patients in care or nursing homes. We will include carer participation because this is likely to be of relevance to consultations involving vulnerable older patients with multimorbidity. We recognise that interventions may have multiple components that will be important to capture, and that using administration staff, to ensure organisational change within the practice, may be one of these elements. We will not exclude patient participants based on whether they have public or private insurance.

We will include studies involving interventions delivered by all types of practitioner working within primary care, e.g. doctors, nurses, physiotherapists, occupational therapists, mental health workers, and pharmacists. We will exclude dentists because the focus will be around general medical practice. We will include interventions delivered by non-clinical researchers or teachers/trainers to patients or practitioners, for example, training in communication skills.

Interventions may be directed at patients, primary care practitioners, or both. Interventions may also be delivered to patients by primary care practitioners, and in some situations practitioners may receive one element of an intervention (e.g. training in communication skills) and deliver another element (e.g. written support tool used during a consultation).

Alternatively, or additionally, interventions may involve organisational change, for example longer consultation times, within the practice.

We will exclude interventions delivered by secondary care practitioners to their patients because we consider the primary care setting to include healthcare practitioners and administrative staff working within the patient's general practice surgery, in the wider community, for example community pharmacies and community support groups, and in the patient's home. We will exclude consultations in acute care settings (e.g. accident and emergency department settings and out of hours services) because we are interested in first-contact, continuous, comprehensive, and co-ordinated care with a primary care practitioner as described by Starfield 1994. We will exclude studies where only part of the intervention was delivered or facilitated via primary care, unless it is possible to differentiate findings according to intervention setting.

Types of interventions

There may be different types of interventions with the common aim of involving patients in decision-making about their health care. We expect to find face-to-face interventions for patients and/or practitioners, written or online information sheets and prompts for use before or during consultations, and some elements of organisational change within the primary care environment.

As we are interested in all interventions that facilitate patient involvement in decision-making about their health care, this is not limited to a shared decision-making approach. Therefore, we will not specify that the intervention meets a certain number of shared decision-making elements (Elwyn 2000). Equally, whilst we recognise that shared decision-making usually requires shared equipoise informed by the preferences and values of the patient and prac-

titioner, we will not exclude interventions whereby the goal has already been set by the heath practitioner, e.g. motivational interviewing approaches, or by the patient.

We will include interventions if they only address a decision-making process surrounding a single long-term condition in a patient with multimorbidity, as long as the aims of the study are to facilitate patient involvement in decision-making about their care.

We will include both patient-focused and practitioner-focused interventions taking place either before or during consultations. These may relate to single patient encounters with a practitioner or may relate more broadly to patients' use of primary health care. Interventions may focus on the use of healthcare information resources, on preparing patients for patient-practitioner contacts, or on training practitioners in consultation skills.

Patient-focused interventions might include patient decision-aids: mailouts pre-consultation, advising patients how to actively seek involvement in decision-making about their care during a consultation; 'option grids' and 'risk diagrams' delivered by practitioners to aid involvement in decision-making regarding medications or regarding investigations during consultations; handheld patient care plans with documentation of shared decisions made between patient and practitioner to aid in subsequent follow-up discussions about these decisions; conversation aids "designed to encourage and directly support the conversations that patients and clinicians have when making decisions together" (Montori 2017); and patient agenda cards (Hamilton 2006).

Practitioner-focused interventions might involve training in patient-centred communication skills and interventions that raise practitioner awareness of the potential benefits of involvement in decision-making for this patient group.

Studies of interventions encompassing organisational change might include longer consultations for older patients with multimorbidity in order to allow time for effective involvement in decision-making, or allowing for a third person, e.g. a carer, to be present within the consultation to act as a facilitator of the patient's involvement. We will include interventions solely focused on improving appointment availability, waiting lists, and consultation duration only where the intervention is explicitly aiming to facilitate the involvement of older patients with multimorbidity in decision-making about their health care.

Interventions delivered by clinician-researchers could include leaflets for patients or training for practitioners. Interventions delivered by practitioners to patients during consultations could be based on the use of patient-centred communication skills. Interventions delivered by administration staff to patients could include mailouts of information sheets and decision-aids, or distribution of consultation prompts in the waiting room.

We will include studies that compare the intervention with usual care or with no intervention. We will include studies with multiple arms, evaluating the effectiveness of one form of intervention versus another, or evaluating the effectiveness of more than one intervention by comparing each with usual care.

We will exclude studies where decision-making about hypothetical issues has taken place.

We will include studies where interventions have been investigated with older patients with multimorbidity, even if the intervention was not originally designed for this patient population.

We expect to identify studies assessing outcomes from patient and/or practitioner and/or observer perspectives.

We will use the TIDieR checklist (Hoffmann 2014), to describe the intervention components.

Types of outcome measures

The outcomes likely to be main outcomes for the 'Summary of findings' table are: evidence of patient involvement in decision-making; physical health status; psychological and psychosocial health status; patient evaluation of care; practitioners' knowledge and skills; resource use and cost; and adverse outcomes (patient, practitioner, or observer perceptions of less patient involvement in decision-making than prior to the intervention).

We will use the Institute for Healthcare Improvement Triple Aim (improving the patient experience of care, improving the health of populations, and reducing the per capita cost of health care) to guide our selection of secondary outcomes (Berwick 2008).

Primary outcomes

Evidence of patient involvement in decision-making during the consultation from patient and/or practitioner and/or observer perspectives

Elwyn 2000 proposed that a sequence of skills should be demonstrated by the practitioner in order to involve the patient in the decision-making process. These skills can be measured by a variety of scales, including by an observer using the OPTION scale (Elwyn 2005):

- implicit or explicit involvement of patients in the decision-making process;
- explore ideas, fears, and expectations of the problem and possible treatments;
- portrayal of equipoise and options;
- identify preferred data format and provide tailor-made information;
- checking process: understanding of information and reactions (e.g. ideas, fears, and expectations of possible options);
- acceptance of process and decision making role preference;
- make, discuss, or defer decisions; and
- arrange follow-up.

Simple rating scales, such as those used in the General Practice Patient Survey in England (Croker 2013), can be used to measure patient and practitioner perceptions, including whether patient

involvement in decision-making about their health care took place during a primary care consultation.

Secondary outcomes

Patient and carer outcomes

- Physical health status: clinical outcomes (physiological measures), other patient-reported physical health outcomes (from patient-reported outcome measures and the Charlson index of comorbidity (Charlson 1987);.
- psychological and psychosocial health status: including patient quality of life, social behaviour, life satisfaction (from short-form health surveys such as the World Health Organization (WHO) quality of life instrument (WHO 2012));
- treatment burden: medication burden (polypharmacy, co-ordinating medication, obtaining prescriptions, using devices), prescribed lifestyle changes (diet, exercise, smoking, alcohol), self-monitoring, impact on relationships (family/friends/carers);
- health behaviours: adherence to treatment plans (from practice databases and patient survey data), patient-initiated lifestyle changes (diet, exercise, smoking, alcohol);
- knowledge and skills acquisition for patients: information access; knowledge about diseases/conditions; knowledge about treatments and risks, health beliefs; patient enablement for self-care (Howie 1998); symptom control skills; health enhancing lifestyle measures;
- patient evaluation of care: patient satisfaction with practitioners and care procedures; trust in the practitioner; perceptions of practitioner behaviours (knowledge, skills, empathy, attitudes regarding patient involvement); complaints. Tools could include the Patient Perceptions of Patient-Centredness (PPPC) instrument (Stewart 2000), and the General Practice Patient Survey (Croker 2013);
- carer support: patient perceptions or ratings of carer support;
- carer evaluation of care: ratings of satisfaction with the encounter.

Practitioner outcomes

- Knowledge and skills: knowledge of the potential benefits of patient involvement in the decision-making process; competence in patient-centred communication skills e.g. shared decision-making skills (as assessed by the OPTION scale Elwyn 2005 or similar);
- attitudes (towards the intervention and compliance with it);
- practitioner satisfaction with the intervention.

Health service outcomes

- Resource use and cost: length of consultation, frequency of attendance, types of appointment, cost implications of rates of referral and investigation, accident and emergency department attendance, hospital admissions;
- organisational change as a result of evaluation of the intervention: patient feedback (satisfaction with care procedures); practice administrative evaluation (feasibility of intervention); economic evaluation.

Adverse outcomes

- Patient, practitioner, or observer perceptions of less patient involvement in decision-making than prior to the intervention; adverse effects of medications; inappropriate frequency of appointment attendance (in excess or did not attend); unwarranted treatments/procedures; increase in hospital admissions and accident and emergency department attendances; increased anxiety in patient due to the intervention process; stress of the patient due to receiving information; increased practitioner anxiety/stress from the intervention; complaints.

At the protocol stage we may not be able to predict every secondary outcome reported by included studies. However, we have selected a primary outcome, a main adverse outcome, and pre-specified secondary outcome categories for use at the review stage. We will apply the categorisation process to meta-analysis or narrative synthesis of outcomes and to the selection of outcomes for reporting in the 'Summary of findings' table.

Two review authors will independently assign the outcomes reported in each included study to the review's outcome categories and will resolve any differences in categorisation, if they occur, by involving a third review author. This may mean that we assign more than one outcome to each outcome category per study at review stage. In this scenario, we will:

- select the primary outcome identified by the publication authors;
- where no primary outcome has been identified, select the one specified in the sample size calculation;
- if there are no sample size calculations, rank the effect estimates (i.e. list them in order from largest to smallest) and select the median effect estimate. Where there is an even number of outcomes the outcome whose effect estimate is ranked n/2, where n is the number of outcomes, can be selected;
- if this approach is not feasible, we will list the outcomes for each trial (without considering either the size of the effect or its statistical significance) and will decide which is most 'clinically' important. Two review authors will independently decide before mutual discussion of the decision and will consult a third review author if disagreements occur.

It will not be appropriate to define, in advance, the timing of outcome assessment.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL, the Cochrane Library, latest issue);
- MEDLINE (OvidSP) (1966 to present);
- Embase (OvidSP) (1988 to present);
- PsycINFO (OvidSP) (1806 to present);
- CINAHL (Ovid) (1982 to September 2008) then in Ebsco when no longer indexed by Ovid (2009 to present);
- Centre for Reviews and Dissemination Databases (Database of Abstracts and Reviews of Effects (DARE));
- Health Technology Assessment (HTA) Database;
- Ongoing Reviews Database; and
- Dissertation Abstracts International (1861 to present).

The MEDLINE (OvidSP) search strategy is in Appendix 1.
We will tailor strategies to other databases and report them in the review. There will be no language or date restrictions.

Searching other resources

We will seek additional studies by searching the reference lists of relevant trials and reviews identified. In addition, we will examine our personal literature collections to identify relevant studies. We will contact experts in the field and authors of included studies for advice as to other relevant studies. We will also search online trial registers (WHO International Clinical Trials Registry Platform, National Institutes of Health, ClinicalTrials.gov) for ongoing and recently completed studies.
As an intervention review, we will run the resulting Endnote Library of all references through the Cochrane RCT Classifier.
We will also consider searching sources of grey literature.

Data collection and analysis

Selection of studies

Two review authors will independently screen all titles and abstracts identified from searches to determine which meet the inclusion criteria. We will retrieve the full-text articles identified as potentially relevant by at least one review author. Two review authors will independently screen full-text articles for inclusion or exclusion, and will resolve discrepancies by discussion and by consulting a third review author if necessary to reach consensus. We will list all potentially relevant papers excluded from the review at this stage as excluded studies, with reasons provided in the 'Characteristics of excluded studies' table. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart (Liberati 2009).

Data extraction and management

Two review authors will extract data independently from included studies. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third review author where necessary. We will develop and pilot a data extraction form using the Cochrane Consumers and Communication data extraction template.
We will extract data on: study details (aim of intervention, study design including type of intervention (practitioner/patient-focused), description of comparison group, recruitment and retention, randomisation, blinding), description of participants (country, setting, age, gender, ethnicity, socio-economic status, frailty, mobility, receipt of carer support and whether the carer was present during the consultation, communication vulnerability (e.g. health literacy, sensory impairment, cognitive impairment, local language proficiency), exclusions), definition of multimorbidity used in the study (whether numbers of long-term health problems were listed and counted, and the types and numbers recorded), types of intervention (written support tools versus communication skills training; timing of intervention delivery, either before or during a consultation; whether the intervention was a single episode of care versus multiple episodes), outcomes (timing of outcome assessment, primary and secondary outcomes). We will use the TIDieR checklist (Hoffmann 2014), to describe the intervention components.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the *Cochrane Handbook of Systematic Reviews of Interventions* (Higgins 2011), and the Cochrane Consumers and Communication guidelines (Ryan 2013), which recommends the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; and selective outcome reporting. We will consider blinding separately for different outcomes where appropriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures). We will judge each item as being at high, low, or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the 'Risk of bias' table.
We will deems studies to be at the highest risk of bias if they are scored as at high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing

empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011). We will assess and report quasi-RCTs as being at a high risk of bias on the random sequence generation item of the 'Risk of bias' tool. For cluster-RCTs we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants. Two review authors will assess studies to identify if an alternative design, using individual randomisation, could have been employed. We will extract data on the randomisation procedure and the likelihood of this introducing bias to the selection of participants into the study.

In all cases, two review authors will independently assess the risk of bias of included studies, and will resolve any disagreements by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the 'Risk of bias' assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgment about the internal validity of the review's results.

We will not restrict our meta-analysis to only low risk of bias studies but will instead explore the effects of risk of bias through sensitivity analysis.

Measures of treatment effect

For dichotomous outcomes, we will analyse data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we will analyse data based on the mean, standard deviation (SD), and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the inverse variance method in Review Manager 5 (Review Manager 2014).

Unit of analysis issues

If cluster-RCTs meet the inclusion criteria, we will check for unit-of-analysis errors. If we identify errors and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis by taking account of the intra-cluster correlation (ICC). We will obtain estimates of the ICC by imputing them using estimates from external sources. If we are unable to obtain sufficient information to re-analyse the data, we will report effect estimates and annotate unit-of-analysis error.

Dealing with missing data

We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, we will, where possible, conduct analysis on an intention-to-treat basis; otherwise we will analyse data as reported. We will report on the levels of loss to follow-up and assess this as a source of potential bias.

For missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

Assessment of heterogeneity

Where we consider studies similar enough (based on consideration of populations or interventions) to allow pooling of data using meta-analysis, we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. Heterogeneity will be quantified using the I^2 statistic. We will consider an I^2 statistic value of 50% or more to represent substantial levels of heterogeneity, but we will interpret this value in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi^2 test (Higgins 2011).

Where we detect substantial clinical, methodological, or statistical heterogeneity across included studies, we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event, we will attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of populations, intervention features, or methodological features to explore differences in intervention effects.

Assessment of reporting biases

We will assess reporting bias based on the characteristics of the included studies. If only small studies indicating positive findings are identified for inclusion, we will use qualitative methods to report bias. Similarly, we will report bias qualitatively if information that we obtain from contacting experts and study authors suggests that there are unpublished studies of relevance to the review.

If we identify sufficient studies (at least 10) for inclusion in the review we will construct a funnel plot to investigate small study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice in Higgins 2011, and bearing in mind that there may be several reasons for funnel plot asymmetry when interpreting the results.

Data synthesis

We will decide whether to meta-analyse data based on whether the interventions in the included trials are similar enough in terms

of participants, settings, intervention, comparison, and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in the populations and interventions of included studies, we will use a random-effects model for meta-analysis.

If we are unable to pool the data statistically using meta-analysis we will conduct a narrative synthesis of results. We will present the major outcomes and results, organised by intervention categories according to the major types and/or aims of the identified interventions. Depending on the assembled research, we may also explore the possibility of organising the data by population. Within the data categories we will explore the main comparisons of the review:

- intervention versus control (no intervention, wait list, placebo);
- intervention versus usual care;
- one form of intervention versus another.

Where studies compare more than one intervention, we will compare each separately to no intervention/control.

If we are unable to pool the data statistically using meta-analysis, we will group the data based on the category that best explores the heterogeneity of studies and makes most sense to the reader (i.e. by interventions, populations, or outcomes). Within each category we will present the data in tables and narratively summarise the results. We will consider the Foundations Framework for Developing and Reporting New Models of Care for Multimorbidity, Stokes 2017, when we report our findings.

Subgroup analysis and investigation of heterogeneity

The potential subgroups for analysis will include: the type of intervention e.g. written support tools versus communication skills training; timing of intervention delivery, either before or during a consultation; whether the intervention was a single episode of care versus multiple episodes (and whether these were with the same practitioner). Subgroup analyses investigating intervention type and delivery will be important for practitioners and policy makers looking to implement these types of interventions into practice, in order to inform them regarding the most effective approach.

To reduce the chance of observing spurious results by undertaking too many subgroup analyses, we have limited the number to those of most relevance to this review.

It may not be possible to pool data statistically to carry out subgroup analysis or there may be too few included studies to warrant statistical subgroup analyses, by intervention components for instance. Therefore we will present a narrative form of subgroup analyses where it is not possible to do so statistically.

Sensitivity analysis

We will use sensitivity analysis to assess the robustness of results, such as the impact of notable assumptions, imputed data, choice of meta-analysis method, and inclusion of studies at high risk of bias. We plan to base the sensitivity analysis on the 'Risk of bias' assessment, comparing the results of studies at higher and lower risk of bias. We will remove lower quality studies from the analysis and see how robust the results are when based only on higher quality studies.

We will consider formally comparing 'Risk of bias' assessments using meta-regression; however, a minimum of 10 studies is recommended for meta-regression for each variable included in the model (Thompson 2002). This may not be feasible if only a small number of studies meet the inclusion criteria of the review.

Not all decisions regarding sensitivity analyses will be possible before the review is conducted; we will need to make some decisions based on the assembled data and included studies. To minimise bias we will identify the relevant sensitivity analyses a priori, i.e. once we have ascertained the scope of the data set, but before we undertake statistical analysis.

'Summary of findings' table

We will prepare a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We will present the results of meta-analysis for the major comparisons of the review, including the major primary outcome, as outlined in the 'Types of outcome measures' section. We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE system to assess the quality of the evidence using GRADEpro GDT software (GRADEpro GDT 2015; Schünemann 2011). If meta-analysis is not possible, we will present results in a narrative 'Summary of findings' table format, such as used by Chan 2011.

Ensuring relevance to decisions in health care

At least one consumer peer reviewer and one health professional peer reviewer will provide feedback on the protocol and the review as part of Cochrane's standard editorial processes.

Using links with the patient involvement group from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care, South West Peninsula (PenCLAHRC), we have established a group of eight older members of the public who have varying degrees of morbidity and varying health service experiences. We will arrange workshops to enable these Patient and Public Involvement group members to advise on the direction of the review and to ensure end-user relevance of the presentation of our results.

The lead author is a GP and therefore has insight into the relevance of our review to primary health care. In addition, we will seek the opinions of content experts, including primary healthcare practitioners with a special interest in older patients and experts on shared decision-making, regarding relevant evidence and theory,

and ask for critical appraisal of our review methods and results. We will discuss methods of delivering our results that are acceptable, engaging, and sustainable in context, giving consideration to resource allocation, recruitment issues, and the format of future evaluation.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. A comparison of our proposed review with existing systematic reviews of similar interventions

Systematic review	Structure	Processes	Outcomes
Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. Smith 2016	Smith 2016 excluded interventions that included people with comorbid conditions where the intervention was targeted solely at one condition. We will include studies where older people with multimorbidity were exposed to an intervention to facilitate patient involvement in their healthcare, and where outcomes were reported in respect of this population, even if the intervention was not originally designed for older patients with multimorbidity	Smith 2016 did not design their search strategy to find studies of interventions to facilitate the involvement of older patients with multimorbidity in decision-making about their care, which is the aim of our review Smith 2016 was not specifically interested in the processes within, and supporting, a general practice consultation, which is the focus of our review	Our review will differ from Smith 2016 as our primary outcome, of whether or not patient involvement in the decision-making process occurred during a consultation, was not a primary outcome, or a specific focus of a secondary outcome, in Smith 2016. Smith 2016 excluded the outcomes of attitude and knowledge when reporting studies, both of which are highly relevant to the delivery of patient-centred care, and to patient involvement in decision-making about their healthcare during a primary care consultation. Our review will include these outcomes in order to inform clinicians and policy makers

Table 1. A comparison of our proposed review with existing systematic reviews of similar interventions (*Continued*)

			about interventions supporting improved patient knowledge of their conditions and treatments, improved patient enablement for self-care, positive changes in patients' health beliefs and lifestyle choices, patient satisfaction with healthcare and trust in the practitioner, and improved practitioner communication skills including shared-decision making. Attitudes towards the intervention and compliance with it will also be important in the development of future interventions to facilitate the involvement of older patients with multimorbidity in decision-making about their healthcare
Interventions for providers to promote a patient-centred approach in clinical consultations. Dawmena 2012	Dawmena 2012 included studies of interventions facilitating shared decision-making, however they focus only on studies of interventions directed at healthcare professionals, or at healthcare professionals and patients together. Our review would additionally include studies of interventions targeting only patients, and in particular the very important and vulnerable patient population of older patients with multimorbidity	-	-
Personalised care planning for adults with chronic or long-term health conditions. Coulter 2015	The type of care planning evaluated by Coulter 2015 does not routinely take place within a primary care consultation alone, being more likely to be initiated by a secondary care specialist liasing with the primary care team. Primary care will be the focus of our review	Coulter 2015 looked at personalised care planning and their inclusion criteria captures a subset of studies evaluating elements of patient involvement in decision-making. Our review criteria are much broader in terms of studies to facilitate patient involvement	-

Table 1. A comparison of our proposed review with existing systematic reviews of similar interventions (*Continued*)

Interventions before consultations for helping patients address their information needs. Kinnersley 2008	Kinnersley 2008 focused on interventions targeted only at patients, whereas we are interested in interventions aimed at patients, practitioners, or both, as well as any elements of organisational change	Kinnersley 2008 looked at studies of interventions to support patients in information gathering from a doctor or a nurse during a consultation. Whilst this is an important aspect of patient involvement, it is only one element of a complex process. We therefore feel that the inclusion criteria used in this review will have missed many studies that are of relevance to our review	-
Interventions for improving the adoption of shared decision making by healthcare professionals. Légaré 2018	This review covers an important topic in the research area of shared decision-making. However, it focuses only on studies of interventions designed to improve the healthcare professional's adoption of shared decision-making and excludes many studies focusing on patient-mediated involvement in decision-making	-	-
Interventions for improving patients' trust in doctors and groups of doctors. Rolfe 2014	-	We know from our own work that there are associations between patients' trust in the doctor and their involvement in decision-making about their care. Studies of interventions to promote patient involvement in decision-making would be included by Rolfe 2014. However the scope of this review is very broad and it does not address our aim; to systematically review studies of interventions that facilitate patient involvement, focusing on older people with multimorbidity	-

APPENDICES

Appendix 1. MEDLINE search strategy

1. exp aged/
2. Aging/
3. (Late life or elder* or aged or old age or geriatric or seniors).ti,ab,kw.
4. ((old or older or aging or aged or senior or elder*) adj3 (person or persons or people or adult* or subject* or patient* or consumer* or male or males or female* or men or women)).ti,ab,kw.
5. or/1-4
6. "Physician-Patient Relations"/
7. "Professional-Patient Relations"/
8. exp Decision Making/
9. Decision Support Techniques/
10. Decision Support Systems, Clinical/
11. Cooperative Behavior/
12. exp Communication/
13. partnership*.ti,ab,kf.
14. ((share or shared or sharing or support* or inform* or making or behavior* or aid*) adj2 (decision* or deciding or choice*)).ti,ab,kw.
15. "Group Processes"/
16. or/6-15
17. exp Patients/
18. caregivers/
19. exp Family/
20. Friends/
21. or/17-20
22. and/16,21
23. exp Community Participation/
24. Stakeholder Participation/
25. exp Patient-Centered Care/
26. ((patient* or consumer* or user* or carer* or caregiver* or client* or famil* or lay*) adj3 (partner* or participat* or centre* or center* or communicat* or consult* or decision* or deliberation* or co#design* or involv* or contribut* or role* or empower* or engag* or collab* or advoca* or organi#ation* or respons* or question* or educat* or inform* or train* or shar* or joint or choice* or preference*)).tw.
27. or/22-26
28. exp Comorbidity/
29. exp polypharmacy/
30. (multidisease* or multi-disease* or multimorbidit* or comorbid* or multi-morbidit* or co-morbid*).ti,ab,kw.
31. ((concomit* or concurren* or multi* or multiple) adj3 (ill* or condition* or morbidit* or syndrom* or disorder* or disease*)).ti,ab,kw.
32. exp Chronic Disease/
33. (chronic* adj3 (disease* or ill* or care or condition? or disorder* or health* or medication* or syndrom* or symptom* or chronic*)).ti,ab,kw.
34. ((coocur$ or co-ocur$ or coexist$ or co-exist$ or multipl$) adj3 (disease? or ill$ or care or condition? or disorder$ or health$ or medication$ or symptom$ or syndrom$)).ti,ab,kw.
35. or/28-34
36. exp Primary Health Care/
37. General Practice/
38. General Practitioners/
39. exp Home Care Services/
40. physicians, family/
41. Physicians, primary care/
42. Private Practice/

43. "Family Practice"/
44. Community Health Services/
45. Community Health Nursing/
46. Community Pharmacy Services/
47. Community Health Workers/
48. Preventive Health Services/
49. Primary care nursing/
50. Community medicine/
51. Community health centres/
52. Health Promotion/
53. health promotion.ti,ab,kw.
54. ((home* or visit* or preventive* or general or family or primary or community) adj3 (health or practice* or medicine or physician* or nursing or pharmacy or program* or service* or care)).ti,ab,kw.
55. ((family or primary or general or community) adj2 (pharmacist* or physician* or doctor* or practitioner* or healthcare*)).ti,ab,kw.
56. ((nurse* or nursing) adj2 (practice* or practitioner* or prescriber*)).ti,ab,kw.
57. (GPs or GPSI or GPwSI).ti,ab,kw.
58. or/36-54
59. randomized controlled trial.pt.
60. controlled clinical trial.pt.
61. randomized.ab.
62. placebo.ab.
63. drug therapy.fs.
64. randomly.ab.
65. trial.ab.
66. groups.ab.
67. or/59-66
68. quasi experimental study/
69. pragmatic clinical trial/
70. or/67-69
71. (animals not (humans and animals)).sh.
72. 70 not 71
73. and/5,27,35,58,72

CONTRIBUTIONS OF AUTHORS

Joanne Butterworth is the first author and the review's guarantor. She is leading on the conception and design of the study and has given final approval for the protocol to be published.

Rebecca Hays has contributed heavily to the conception and design of the study. She has been involved in drafting the protocol, and commenting on it critically, before giving approval of the document to be published.

Suzanne Richards has been involved in the conception and design of the study. She has contributed to drafting the protocol, has commented on it critically for intellectual content, and provided approval of the document to be published.

Peter Bower and John Campbell have both commented critically on the protocol for intellectual content and have also given their approval of the document to be published.

DECLARATIONS OF INTEREST

JB: none known.

RH: none known.

SR: none known.

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JC: none known.

NOTES

This protocol is based on standard text and guidance provided by the Cochrane Consumers and Communication Group (CCCG 2013).