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**Title: Shared decision making for people living with dementia in extended care settings:
protocol for a systematic review.**

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Tables – 2

References – 35 (inc. statute)

Supplementary files – PRISMA checklist

ABSTRACT

Introduction - Approximately 450,000 people in the United Kingdom are living in care homes, 70% of whom are thought to have dementia or significant memory problems. This means that they may need support with day-to-day decisions about their health and care. Shared decision-making interventions can have a positive impact on patient outcomes. They recognise an individual's rights to make decisions about their care or treatment and support person-centred approaches to care delivery.

Method – A systematic review of studies designed to assess, implement, measure and/or explore shared decision making with cognitively impaired adults in (or transferrable to) an extended care setting; with a view to answering the research question: How can people living with dementia and cognitive impairment be included in day-to-day decisions about their health and care in extended care settings? The systematic review will be commenced in May 2016. Studies are excluded that focus on advanced decision making. The search strategy is limited to a 20 year timeframe and English language and includes electronic databases; CINAHL, PubMed, the Cochrane Library, NICE Evidence, OpenGrey, Autism Data, Google Scholar, Scopus and MedicinesComplete.

Ethics and dissemination – ethical approval not required. Planned dissemination routes for protocol and systematic review through conference presentations, peer reviewed journals and research networks including the East of England CLAHRC, INTERDEM, and the National Care Homes Research and Development Forum.

Discussion – The review will explore the characterisation and constructs of shared decision making for people living with dementia and their staff and family carers in relation to the roles people play; facilitators and barriers and risk and benefits. The findings will inform an intervention study facilitating Shared Decision Making for people living with dementia and diabetes in care homes and have the potential to inform future policy and practice.

Strengths and limitations of this study – This review will provide a contemporary synthesis of evidence about the risks and benefits of Shared Decision Making for carers and people with a cognitive impairment in extended care environments. It is recognised that there are potential limitations in relation to reporting bias at both study and outcome level, for example, unsuccessful implementation studies are less likely to be

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3 published; and at review-level, the ability to retrieve all relevant research may be affected by the search
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5 strategy design, or bias related to data extraction, analysis or reporting methodologies.
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7 **Registration** - this protocol is registered with PROSPERO international prospective register of systematic
8
9 reviews registration number CRD42016035919.
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11 **Keywords** - Shared decision making, cognitive impairment, dementia, care homes, extended care, everyday
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13 care, day-to-day care
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15 **Word Count - 2,723**
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18 19 20 21 22 **BACKGROUND** 23

24
25 Despite increasing international recognition of the need for shared decision making in health and social care ,
26
27 and its potential impact on the global health economy [1] there is limited evidence of how it is used to support
28
29 people living with dementia in care homes [2].
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31 32 **Dementia** 33

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35 Dementia describes a collection of symptoms that present when the brain is affected by disease processes that
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37 include, for example, Alzheimer's, Lewy Body or vascular dementia. Symptoms are degenerative and individual
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39 but typically may include memory loss, personality changes and difficulties with word finding or problem-
40
41 solving. For people over 55 years of age dementia is more feared than any other health condition including
42
43 cancer and diabetes[3].
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45
46 There are estimated to be 850,000 people living with dementia in the UK, rising to over 1 million in 2025 and 2
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48 million by 2051 [4]. A psycho-social theory of dementia frames how the involvement of people living with
49
50 dementia is viewed, recognising the importance of personhood, and that social and relational losses (not only
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52 progressive cognitive impairment) can strip personhood and self-worth from those living with dementia [5, 6].
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54 Person centred care is an ethical and legal requirement throughout Europe, Australia and North America [1, 7,
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56 8] and is embedded in UK policy and health and care regulations (MCA, 2005; DH, 2010; Care Act, 2014). To
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58 abide by the law and fulfil the moral obligation to provide person centred care it is important to have an
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3 understanding of each person's needs and desires and, where possible, to include them in all the decisions
4
5 that shape their care.

6 7 8 **Extended Care Settings**

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10 For the purposes of this review the term 'extended care setting' is used to include all types of residential
11
12 housing with onsite care provision. In addition to care homes, extended care settings include supported living,
13
14 care villages and extra care housing. Approximately 450,000 people live in care homes in the UK [9] and Prince
15
16 et al. (2014) estimate that around 70% of care home residents in the UK have dementia or significant memory
17
18 problems; as a result this population may need support and assistance with decisions about their day-to-day
19
20 health and care.

21 22 23 **Shared Decision Making**

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25 Shared decision making is a partnership which enables clinicians and patients to make treatment,
26
27 management or support decisions based on best available clinical evidence and the patient's values and
28
29 preferences. It involves eliciting the patients ideas, concerns and expectations [1] and the provision of
30
31 evidence-based information about options, outcomes and uncertainties. [10].

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34 This review will explore the role of shared decision making in day-to-day health and care decisions between
35
36 (staff and family) carers and people living with dementia in extended care settings. For example, this might
37
38 include decision making about personal care preferences, medication regimes, or the timing and approach to
39
40 changing a wound dressing. Although some of these decisions might appear trivial, a person living with
41
42 dementia is often dependent on the help and support of others to fulfil their needs and desires. It is therefore,
43
44 *how* decision making is negotiated between the care receiver and the carers that can be indicative of how
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46 personhood and the risks and benefits of care choices are understood.

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49 The purpose of decision support tools or aids is to clarify available treatment options, including possible harm
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51 and benefits, and support people to work with professionals to choose a course of care that reflects their
52
53 personal values. Internationally a variety of tools have been developed to support Shared Decision Making [11-
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55 13] especially in relation to specific healthcare screening and interventions [14-16]. Shared decision making
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57 has been recognised as having a positive impact on a range of patient outcomes [10, 17, 18].

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3 In their review of international literature on patient and carer involvement in shared decision making for
4 people living with dementia, Miller, et al. (2014) discovered that research in this area of practice is relatively
5 new. The review focussed on shared decision-making within 'family care dyads' (comprised of a person with
6 dementia and a family carer) although care dyads might equally comprise a health or social care professional
7 and a person living with a cognitive impairment. Regardless of the other parties involved, the person living
8 with the cognitive impairment must, at least, be given an opportunity to choose to participate in the decision
9 making process [18]. Furthermore, they identified evidence which indicates that people with dementia can
10 reliably report on their ideals and preferences in relation to their care, well-being, and quality of life, even
11 through moderate to severe dementia. Therefore, whilst family carer involvement is essential it should be
12 sought as a partner and not to supersede the views of the person living with dementia. Many people living
13 with dementia maintain their ability to communicate their values and preferences long after their executive
14 decision-making abilities are affected by cognitive changes [18].

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27 Central to the topic of shared decision making for a person living with dementia is their ability to make their
28 own decision, either with or without support. Successful shared decision-making assumes that patients are
29 informed and empowered to participate in discussions about their health and care. It requires patients to have
30 developed the skills, knowledge and confidence required to discuss their options with experts, challenge
31 professional views, and influence their care and outcomes [17]. The appropriateness of shared decision making
32 for people with cognitive impairments has been researched within the field of acute mental health and there is
33 evidence of positive outcomes for all involved, including improved knowledge, wellbeing and medication
34 adherence in addition to reduced conflict [19-21]. Despite the assumption that people living with
35 dementia/cognitive impairment cannot participate in decision making is increasingly being challenged an
36 individual living with a cognitive impairment's ability to maintain active participation in decisions about their
37 health and care causes debate [22-24]; in practice, many settings rely upon family members to make care
38 decisions for people living with dementia, regardless of legal, medical, or ethical processes [18]. Extensive
39 work undertaken in the UK by the Dementia Action Alliance [25] has identified that people living with
40 dementia want personal choice and control in decisions that affect them, and to know that services are
41 designed to meet the needs of themselves and their carers. This is reflected in the drive for improved diagnosis
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3 and treatment of people living with dementia and their carers [4] and, in part, through greater involvement in
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5 the decisions central to their care [26].
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10 **Method**

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13 The review will be conducted utilising methods outlined in the Cochrane handbook of systematic reviews of
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15 interventions [27]. This protocol has been designed in accord with the Preferred Reporting Items for
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17 Systematic Reviews and Meta-Analyses (PRISMA) guidelines [28] and checklist. (Additional file 1). The protocol
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19 is registered with PROSPERO international prospective register of systematic reviews registration number
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21 CRD42016035919.
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24 The aim of the review is to understand how day-to-day decisions are negotiated between people with a
25
26 cognitive impairment and their (staff and family) carers in extended care settings, with a view to gaining
27
28 transferrable learning that can be applied to people living with dementia in care homes.
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30 The review objectives are to;
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- 32
33 • Explore how shared decision making is understood and/or characterised for people living
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35 with dementia and their (staff and family) carers.
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- 38 • Explore the role of (staff and family) carers of people living with dementia in shared decision
39
40 making care dyads.
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- 43 • Analyse identified risks and benefits associated with shared decision making for people with
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45 cognitive impairment
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- 48 • Ascertain empirical evidence for the effectiveness of available shared decision making
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50 resources for people living with dementia
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- 53 • Seek to understand the barriers and facilitators to effective shared decision making for
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55 people living with dementia and their (staff and family) carers
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- Explore the extent to which shared decision making has been researched in extended care settings
- Identify implications for shared decision making in dementia care practice, policy and future research

Inclusion criteria

Participants

The focus of the review is adults, over 18 years, living with any type of dementia in an extended care setting. Studies relating to adults with other cognitive impairment (for example; learning disability or brain injury) will be included where the model, tools or intervention are transferable to people living with dementia in an extended care setting.

Setting

The term 'extended care setting' or is used to include all types of residential housing with onsite care provision. The UK Care Quality Commission define care homes as offering 'accommodation and personal care for people who may not be able to live independently' and register care homes 'with' and 'without' nursing[29]. Studies in other settings, e.g. people's own homes, will be included if they involve people with dementia or cognitive impairment and are transferable to an extended care setting.

Interventions

Studies will be included if they report interventions designed to assess, implement, measure and/or explore shared decision making with cognitively impaired adults. With particular focus on interventions relating to day-to-day health and/or care decision-making (for example decisions relating to personal care or medication management).

Exclusion criteria

Papers specific to advance decisions or advance care planning will be excluded as these reflect the person making decisions about future care whilst they are still considered to have capacity and the focus of this

review is on current day-to-day care being delivered to the cognitively impaired person. Studies where the shared decisions are made primarily by health or social care staff and, or family carers and do not include the person living with the cognitive impairment will also be excluded.

Types of studies

All empirical study types that meet all other inclusion criteria will be included; randomised controlled trials (RCTs), controlled studies, observational studies and qualitative studies using any recognisable qualitative methodology.

Outcomes

- Involvement in care planning (e.g. as stated within care plans)
- Care delivery congruent with decision made/expressed choice (e.g. as stated in daily care records)
- Quality of life for people living with dementia
- Carer satisfaction (staff and/or family carers)
- Wellbeing for people living with dementia
- Behavioural changes (e.g. reduction in behaviours that challenge services)
- Adverse effects (e.g. falls, weight loss, adverse outcomes related to medication management)

Search strategy

The predefined search strategy is cross discipline. Limitations have been set with regard to;

- Time - 20 years (start date 1996) due to the fast paced nature of treatment and intervention development in this area of care, but to still include the seminal works of Tom Kitwood.
- Language – only studies published in English language will be included
- Free text search terms will be limited to Title and Abstract to promote relevance of search results

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3 Electronic searches will be performed on the following databases; CINAHL Plus, PubMed, the Cochrane Library,
4 NICE Evidence, OpenGrey, Autism Data, Google Scholar, Scopus and MedicinesComplete. In addition the
5 reference list of all relevant primary and review articles will be searched manually to identify studies which
6 have not been picked-up by the electronic search. A citation search will also be performed using the 'cited by'
7 option on Google Scholar and Scopus, and the 'related articles' option in PubMed.
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12 Medical Subject Heading (MeSH) search terms will be combined with Boolean operators AND, and NOT
13 (between columns) to create a search strategy for PubMed and other electronic databases which recognise
14 MeSH terms. See *table 1* columns for MeSH headings and alternative MeSH terms combined with OR for an
15 inclusive search strategy. See *table 2* for alternative but equivalent free text terms operated with 'wildcards'
16 and truncations will be used to search CINAHL and other databases which do not recognise MeSH headings.
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30 **Study screening and Data extraction**

31 Electronic search results will be downloaded into EndNote bibliographic software and duplicates removed
32 where possible. Initially all titles and abstracts retrieved by electronic searches will be screened by one
33 reviewer (RD) against the predefined inclusion criteria and a second reviewer (FB) will independently screen
34 10% of records to check for consensus. Full-text manuscripts of all potentially relevant citations will be
35 obtained. Hard copies will then be screened independently by RD and either FB or CG. Any disagreements will
36 be resolved by discussion and consensus.
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40 Data will be extracted on the following 1) the author(s), 2) publication year, 3) country, 4) type of study design,
41 5) aim(s) and research questions, 6) type of participants and sample size, 7) data collection method (i.e.
42 measure of Shared Decision-making/patient activation/patient involvement), 8) response rate, 9) method(s) of
43 analysis, 10) outcomes.
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52 Additional information will be collected relating to the accessibility and characteristics of interventions,
53 duration of follow-up and any unexpected supplementary findings/outcomes identified by the researcher.
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57 **Quality Assessment**

Quality assessment will be undertaken by one reviewer (RD), with 10% checked by a second reviewer (FB/CG). RCTs and controlled studies will be assessed using the Cochrane risk of bias tool [27], observational studies using the Centre for Evidence Based Management assessment tool and qualitative studies using JBI System for the Unified Management of the Assessment and Review of Information (JBI SUMARI) - Qualitative Assessment and Review Instrument (Qari) framework, which has been identified as one of the most coherent critical appraisal tools to facilitate an assessment of qualitative research validity [30].

Analysis

Quantitative studies

Results from all studies will be reported in a narrative format. In addition if there is sufficient homogeneity, and if relevant studies are available, RCTs will be pooled in a meta-analysis with dichotomous outcomes presented as relative risks (RR) and continuous data as mean differences (MD), both with 95% confidence intervals. Heterogeneity will be assessed using the Chi-Square test and I^2 test [27]. However, in the likely event of heterogeneity (or few RCTs being found) studies will not be pooled but data will be presented in a narrative format with an indication of whether the effect of the intervention was positive, negative or not statistically significant.

Qualitative studies

Review findings will be compiled and evaluated using thematic analysis. This is a widely recognised process [30-32], which involves using recurrent themes in primary studies to synthesise new qualitative evidence [33]. All relevant 'data' will be considered for synthesis including those data labelled as quotes, 'findings' and 'results' as per guidance [34].

Amendments:

If any amendments to the protocol are required they will be individually described, dated and rationalised to ensure transparency and enable the reader to identify potential bias and to replicate the searches if required.

Discussion

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3 In the UK there are estimated to be 850,000 people living with dementia and approximately 450,000 people
4 living in care homes, the majority of whom have significant memory problems [4]. An understanding of each
5 person's needs and desires is important to include them in the decisions that shape the decisions about their
6 health and care[5, 6] which is a moral imperative.
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11 The systematic review will provide a contemporary synthesis of evidence in relation to the current
12 understanding of Shared Decision Making policy and practice for people living with a cognitive impairment in
13 extended care settings. It is designed to explore the characterisation and constructs of shared decision making
14 for people living with dementia and their carers in relation to the roles people play; facilitators and barriers
15 and risk and benefits. The findings will inform the design of an intervention study facilitating Shared Decision
16 Making for people living with dementia and diabetes in care homes and have the potential to inform future
17 policy and practice.
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32 **Authors Contributions:**

33
34 All authors contributed to the selection, bias assessment and data extraction criteria. Statistical expertise will
35 be provided by FB. RD created the protocol with supervision by FB and CG as part of a wider PhD project. RD
36 prepared the search strategy with support from FB and the University of Hertfordshire health information
37 manager. FB and CG critically appraised all drafts and will independently review 10% of all search results to
38 promote consistency with inclusion criteria. All authors agreed the final manuscript.
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46
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49 Leadership in Applied Health Research & Care (CLAHRC) East of England.
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55 Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England, at Cambridgeshire
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3 and Peterborough NHS Foundation Trust. The views expressed are those of the author(s) and not necessarily
4 those of the NHS, the NIHR or the Department of Health.
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8 **Competing Interests**
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10 Authors declare that they have no competing interests.
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For peer review only

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The Mental Capacity Act, UK (2005) [online] Available at
http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf

Abbreviations

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|--------|--|
| CINHAL | Cumulative Index to Nursing and Allied Health Literature |
| CLAHRC | Collaboration for Leadership in Applied Health Research & Care |
| DH | Department of Health |

| | | |
|----|----------|---|
| 1 | | |
| 2 | | |
| 3 | INTERDEM | Early detection and timely INTERvention in DEMentia |
| 4 | | |
| 5 | JBI | Joanna Briggs Institute |
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| 7 | MCA | Mental Capacity Act |
| 8 | | |
| 9 | MeSH | Medical Subject Heading |
| 10 | | |
| 11 | PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
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| 13 | Qari | Qualitative Assessment and Review Instrument |
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| 15 | SUMARI | System for the Unified Management of the Assessment and Review of Information |
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| 17 | UK | United Kingdom |
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| Cognition Disorders | AND | (Shared Decision Making) | NOT | Paediatrics | NOT | Advance Directives |
|--------------------------|-----|--------------------------|-----|-------------|-----|-----------------------|
| Dementia | | Decision Making | | Children | | Advance care planning |
| Neurocognitive Disorders | | Patient Participation | | | | |
| Brain Injuries | | Consumer Participation | | | | |
| Autistic Disorder | | Cooperative Behaviour | | | | |
| Learning Disorders | | Decision Support | | | | |
| Stroke | | | | | | |

Table 1

| Cogniti* Disorder* | AND | Shared Decision Making | NOT | Paed* | NOT | Advance Directives |
|--------------------|-----|------------------------|-----|--------|-----|------------------------|
| Dementia* | | Deci* Mak* | | Child* | | Advance* care planning |
| Alzheimer* | | Patient Participat* | | | | Advance* deci* |
| Neurocogniti* Dis* | | Consumer Participat* | | | | |
| Brain Injur* | | Cooperat* | | | | |
| Autis* | | Decision Support | | | | |
| Learning Dis* | | | | | | |
| Stroke | | | | | | |

Table 2



PRISMA 2009 Checklist

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| Section/topic | # | Checklist item | Reported on page # |
|------------------------------------|----|---|--------------------|
| TITLE | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | Title - 1 |
| ABSTRACT | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 2 |
| INTRODUCTION | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 3 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 6-8 |
| METHODS | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. PROSPERO number CRD42016035919 | 2 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | 6-7 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 8 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | Tables page 14 |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | 9 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 9 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 9 |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 9 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 9-10 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2 for each meta-analysis) | 9-10 |

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PRISMA 2009 Checklist

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| Section/topic | # | Checklist item | Reported on page # |
|-------------------------------|----|--|--------------------|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | 9-10 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | 9-10 |
| RESULTS | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | n/a |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | n/a |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | n/a |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | n/a |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | n/a |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | n/a |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | n/a |
| DISCUSSION | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 10 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 10 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 10 |
| FUNDING | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 11 |

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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BMJ Open

Shared decision making for people living with dementia in extended care settings: protocol for a systematic review.

| | |
|---------------------------------|--|
| Journal: | <i>BMJ Open</i> |
| Manuscript ID | bmjopen-2016-012955.R1 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 21-Sep-2016 |
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| Primary Subject Heading: | Geriatric medicine |
| Secondary Subject Heading: | Nursing, Mental health, Health services research, Research methods |
| Keywords: | Dementia < NEUROLOGY, Delirium & cognitive disorders < PSYCHIATRY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PRIMARY CARE |
| | |

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Manuscripts

**Title: Shared decision making for people living with dementia in extended care settings:
protocol for a systematic review.**

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Keywords: Dementia, Shared Decision Making, Care Homes, Extended Care

Tables – 2

References – 41 (inc. statute)

Supplementary files – PRISMA-P checklist

ABSTRACT

Introduction - Approximately 450,000 people in the United Kingdom are living in care homes, 70% of whom are thought to have dementia or significant memory problems. This means that they may need support with day-to-day decisions about their health and care. Shared decision-making interventions can have a positive impact on patient outcomes. They recognise an individual's rights to make decisions about their care or treatment and support person-centred approaches to care delivery.

Method – A systematic review of studies designed to assess, implement, measure and/or explore shared decision making with cognitively impaired adults in (or transferrable to) an extended care setting; with a view to answering the research question: How can people living with dementia and cognitive impairment be included in day-to-day decisions about their health and care in extended care settings? The systematic review will be commenced in May 2016. Studies are excluded that focus on advance decision making. The search strategy is limited to a 20 year timeframe and English language and includes electronic databases; CINAHL, PubMed, the Cochrane Library, NICE Evidence, OpenGrey, Autism Data, Google Scholar, Scopus and MedicinesComplete.

Ethics and dissemination – ethical approval not required. Planned dissemination routes for protocol and systematic review through conference presentations, peer reviewed journals and research networks including the East of England CLAHRC, INTERDEM, and the National Care Homes Research and Development Forum.

Discussion – The review will explore how shared decision making is characterised and constructed in extended care settings for people living with cognitive impairment and their staff and family carers, in relation to their preferences and desires, the roles people play, facilitators, barriers, risk and benefits. The findings will inform an intervention study facilitating shared decision making for people living with dementia in care homes and have the potential to inform future policy and practice.

Article summary - Strengths and limitations of this study include;

- Provision of a contemporary synthesis of evidence relating to recognised risks and benefits of Shared Decision Making for people with a cognitive impairment and their carers in extended care environments.

- Creation of a robust interdisciplinary baseline outlining existing resources, tools and methods used to understand, facilitate and promote shared decision making for people living with a cognitive impairment in extended care settings.
- Reporting bias at study level, e.g. unsuccessful implementation studies are less likely to be published.
- Bias related to data extraction techniques, analysis or reporting methodologies at outcome level and potential inability to retrieve all relevant research due to the search strategy design.

Registration - this protocol is registered with PROSPERO international prospective register of systematic reviews registration number CRD42016035919.

Keywords - Shared decision making, cognitive impairment, dementia, care homes, extended care, everyday care, day-to-day care

Word Count – 3,169

BACKGROUND

Despite increasing international recognition of the need for shared decision making in health and social care, and its potential impact on quality of life and the global health economy [1] there is limited evidence of how it is used to support people living with dementia in care homes [2].

This protocol defines each element in turn; dementia, extended care and shared decision making before discussing the complex concept of shared decision making for people living with dementia in extended care environments, and the factors that are known to influence it. Gaps in current knowledge will be identified along with how the review proposes to address those gaps.

Dementia

Dementia describes a collection of symptoms that present when the brain is affected by disease processes that include, for example, Alzheimer's, Lewy Body or vascular dementia. Symptoms are degenerative and individual

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3 but typically may include memory loss, personality changes and difficulties with word finding or problem-
4 solving. For people over 55 years of age dementia is more feared than any other health condition including
5 cancer and diabetes[3]. There are estimated to be 850,000 people living with dementia in the UK, rising to
6 over 1 million in 2025 and 2 million by 2051 [4].
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11 A psycho-social theory of dementia frames how the involvement of people living with dementia is viewed,
12 recognising the importance of personhood, and that social and relational losses (not only progressive cognitive
13 impairment) can diminish the personhood and self-worth of those living with dementia [5, 6].
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17 18 **Extended Care Settings** 19

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21 For the purposes of this review the term 'extended care setting' is used to include all types of residential
22 housing with onsite care provision. In addition to care homes, extended care settings include supported living,
23 care villages and extra care housing. Approximately 450,000 people live in care homes in the UK [7] and Prince
24 et al. estimate that around 70% of care home residents in the UK have dementia or significant memory
25 problems; as a result this population may need support and assistance with decisions about their day-to-day
26 health and care.
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33 34 **Shared Decision Making** 35

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37 Shared decision making is a partnership which enables clinicians and patients to make health and care related
38 treatment, management or support decisions based on best available clinical evidence and the patient's own
39 values and preferences. It involves eliciting the patients ideas, concerns and expectations [1] and the provision
40 of evidence-based information about options, outcomes and uncertainties. [8].
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46 Decision support tools or aids clarify available treatment options, including possible harm and benefits, and
47 support people to work with professionals to choose a course of care that reflects their personal values.
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50 Internationally a variety of tools have been developed to support Shared Decision Making [9-11] especially in
51 relation to specific healthcare screening and interventions [12-14]. Shared decision making has been
52 recognised as having a positive impact on a range of patient outcomes [8, 15, 16].
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56 This review will explore the role of shared decision making in day-to-day health and care decisions between
57 (staff and family) carers and people living with dementia in extended care settings. For example, this might
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3 include decision making about personal care preferences, medication regimes, or the timing and approach to
4 changing a wound dressing. Some of these more seemingly trivial decisions need to be faced each day and for
5 a person living with dementia who may be dependent on help and support from others to fulfil their care
6 needs and desires, *how* decision making is approached, understood, and negotiated that can be indicative of
7 the impact on their personhood. The opportunities for choice and control and the perceived risks and benefits
8 of any given decision may be largely dependent upon the relationship between the person living with
9 dementia and their carers [1, 17].
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17 Central to the topic of shared decision making for a person living with dementia is their ability to make their
18 own decision, either with or without support. Successful shared decision-making assumes that care receivers
19 are informed, empowered and enabled to participate in discussions about their health and care. It requires
20 them to have developed the skills, knowledge and confidence required to discuss their options with experts,
21 challenge professional views, and influence their care and outcomes [15]. This may prove a significant
22 challenge for individuals living with dementia. The possibilities for, and appropriateness of, shared decision
23 making for people with cognitive impairments has been researched within the field of acute mental health and
24 there is evidence of positive outcomes for all involved, including improved knowledge, wellbeing and
25 medication adherence in addition to reduced conflict [18-20].
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36 The historical assumption that people living with a cognitive impairment cannot participate in decision making
37 is increasingly being challenged and an individual living with a cognitive impairment's ability to maintain active
38 participation in decisions about their health and care has caused considerable debate [21-23]. In practice,
39 many settings rely upon family members to make care decisions for people living with dementia, often
40 regardless of individual's currently stated preferences, legal, medical, or ethical processes [16]. In their review
41 of international literature on patient and carer involvement in shared decision making for people living with
42 dementia, Miller, et al. acknowledged that research in this area of practice is relatively new, however they
43 identified multiple sources of evidence which indicates that people with dementia can reliably report on their
44 ideals and preferences in relation to their care, well-being, and quality of life, even through moderate to
45 severe dementia. Therefore, whilst family carer involvement is essential it should be sought as a partner and
46 not to supersede the views of the person living with dementia. The review focussed on shared decision-making
47 within 'family care dyads' in the community (comprised of a person with dementia and a family carer)
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3 although care dyads might equally comprise a health or social care professional and a person living with a
4 cognitive impairment. Regardless of the other parties involved, the person living with the cognitive
5 impairment must, at least, be given an opportunity to choose to participate in the decision making process
6 [16]. Furthermore, many people living with dementia maintain their ability to communicate their values and
7 preferences albeit through verbal, non-verbal and tailored communication aids, long after their executive
8 decision-making ability is affected by cognitive decline [16].

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11 Extensive work undertaken in the UK by the Dementia Action Alliance [24] has identified that people living
12 with dementia want personal choice and control in decisions that affect them, and to know that services are
13 designed to meet the needs of themselves and their carers. Person centred care is now widely accepted as the
14 method for ensuring individuals are involved in planning and designing their own care and is an ethical and
15 legal requirement throughout Europe, Australia and North America [1, 25, 26]. It is also embedded in UK
16 national policy and health and care regulations (MCA, 2005; DH, 2010; Care Act, 2014) and international
17 guidance [27]. To abide by the law and fulfil the moral obligation to provide person centred care it is important
18 to have an understanding of each person's needs and desires and, where possible, to include them in all the
19 decisions that shape their care. This is reflected in the drive for improved treatment of people living with
20 dementia and their carers [4] and greater involvement in the decisions central to their care [28].

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Method

The review will be conducted utilising methods outlined in the Cochrane handbook of systematic reviews of interventions [29]. This protocol has been designed in accord with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) guidelines [30] and checklist (supplementary file 1). The protocol is registered with PROSPERO international prospective register of systematic reviews registration number CRD42016035919.

The aim of the review is to understand how day-to-day decisions are negotiated between people with a cognitive impairment and their (staff and family) carers in extended care settings, with a view to gaining transferrable learning that can be applied to people living with dementia in care homes.

The review objectives are to;

- Explore how shared decision making is understood and/or characterised for people living with dementia and their (staff and family) carers.
- Explore the role of (staff and family) carers of people living with dementia in shared decision making care dyads.
- Analyse identified risks and benefits associated with shared decision making for people with cognitive impairment
- Ascertain empirical evidence for the effectiveness of available shared decision making resources for people living with dementia
- Seek to understand the barriers and facilitators to effective shared decision making for people living with dementia and their (staff and family) carers
- Explore the extent to which shared decision making has been researched in extended care settings
- Identify implications for shared decision making in dementia care practice, policy and future research

Inclusion criteria

Participants

The focus of the review is adults, over 18 years, living with any type of dementia in an extended care setting. Studies relating to adults with other cognitive impairment (for example; learning disability or brain injury) will be included where the model, tools or intervention are transferable to people living with dementia in an extended care setting. To be considered transferrable the person living with a cognitive impairment must be in receipt of care in addition to their family carer and the intervention, measure, resource or method should be able to be practically implemented within an extended care setting. Authors will discuss and agree by consensus if there is any doubt regarding the inclusion of any paper.

Setting

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3 The term 'extended care setting' is used to include all types of residential housing with onsite care provision.
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5 The UK Care Quality Commission define care homes as offering 'accommodation and personal care for people
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7 who may not be able to live independently' and register care homes 'with' and 'without' nursing[31]. Studies
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9 in other settings, e.g. people's own homes, will be included if they meet all other inclusion criteria and are
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11 transferable to an extended care setting.
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13 **Interventions**

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15 Studies will be included if they report primary research designed to assess, implement, measure and/or
16
17 explore shared decision making with cognitively impaired adults. With particular focus on interventions
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19 relating to day-to-day health and/or care decision-making (for example decisions relating to personal care or
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21 medication management).
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24 **Exclusion criteria**

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26 Papers specific to advance decisions or advance care planning will be excluded as these reflect the person
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28 making decisions about future care whilst they are still considered to have capacity and the focus of this
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30 review is on current day-to-day care being delivered to the cognitively impaired person. Studies where the
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32 shared decisions are made primarily by health or social care staff and, or family carers and do not include the
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34 person living with the cognitive impairment will also be excluded. Studies pertaining to participants living with
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36 potentially relevant symptoms and/or conditions but without cognitive impairment will be excluded due to the
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38 primary focus being on the person living with dementia.
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42 **Types of studies**

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44 All empirical study types that meet all other inclusion criteria will be included; randomised controlled trials
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46 (RCTs), controlled studies, observational studies and qualitative studies using any recognisable qualitative
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48 methodology.
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51 **Outcomes**

- 52 • Involvement in care planning (e.g. as stated within care plans)
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- Care delivery congruent with decision made/expressed choice (e.g. as stated in daily care records)
- Quality of life for people living with dementia
- Carer satisfaction (staff and/or family carers)
- Wellbeing for people living with dementia
- Behavioural changes (e.g. reduction in behaviours that challenge services)
- Adverse effects (e.g. falls, weight loss, adverse outcomes related to medication management)

Search strategy

The predefined search strategy is cross discipline. Limitations have been set with regard to;

- Time - 20 years (start date 1996) due to the fast paced nature of treatment and intervention development in this area of care, but to still include the seminal works of Tom Kitwood.
- Language – only studies published in English language will be included
- Free text search terms will be limited to Title and Abstract to promote relevance of search results

Electronic searches will be performed on the following databases; CINAHL Plus, PubMed, the Cochrane Library, NICE Evidence, OpenGrey, Autism Data, Google Scholar, Scopus and MedicinesComplete. In addition the reference list of all relevant primary and review articles will be searched manually to identify studies which have not been picked-up by the electronic search. A citation search will also be performed using the 'cited by' option on Google Scholar and Scopus, and the 'related articles' option in PubMed.

Medical Subject Heading (MeSH) search terms will be combined with Boolean operators AND, and NOT (between columns) to create a search strategy for PubMed and other electronic databases which recognise MeSH terms. See *table 1* columns for MeSH headings and alternative MeSH terms combined with OR for an inclusive search strategy. See *table 2* for alternative but equivalent free text terms operated with 'wildcards' and truncations will be used to search CINAHL and other databases which do not recognise MeSH headings.

Study screening and Data extraction

Electronic search results will be downloaded into EndNote bibliographic software and duplicates removed where possible. Initially all titles and abstracts retrieved by electronic searches will be screened by one reviewer (RD) against the predefined inclusion criteria and a second reviewer (FB) will independently screen 10% of records to check for consensus. Full-text manuscripts of all potentially relevant citations will be obtained. Hard copies will then be screened independently by RD and either FB or CG. Any disagreements will be resolved by discussion and consensus.

Data will be extracted on the following 1) the author(s), 2) publication year, 3) country, 4) type of study design, 5) aim(s) and research questions, 6) type of participants and sample size, 7) data collection method (i.e. measure of Shared Decision-making/patient activation/patient involvement), 8) response rate, 9) method(s) of analysis, 10) outcomes.

Additional information will be collected relating to the accessibility and characteristics of interventions, duration of follow-up and any unexpected supplementary findings/outcomes identified by the researcher.

Quality Assessment

Quality assessment will be undertaken by one reviewer (RD), with 10% checked by a second reviewer (FB/CG). RCTs and controlled studies will be assessed using the Cochrane risk of bias tool [32], observational studies using the Centre for Evidence Based Management assessment tool and qualitative studies using JBI System for the Unified Management of the Assessment and Review of Information (JBI SUMARI) - Qualitative Assessment and Review Instrument (Qari) framework, which has been identified as one of the most coherent critical appraisal tools to facilitate an assessment of qualitative research validity [33].

Analysis

Quantitative studies

Results from all studies will be reported in a narrative format. In addition if there is sufficient homogeneity, and if relevant studies are available, RCTs will be pooled in a meta-analysis with dichotomous outcomes presented as relative risks (RR) and continuous data as mean differences (MD), both with 95% confidence intervals. Heterogeneity will be assessed using the Chi-Square test and I^2 test [32]. However, in the likely

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3 event of heterogeneity (or few RCTs being found) studies will not be pooled but data will be presented in a
4 narrative format with an indication of whether the effect of the intervention was positive, negative or not
5 statistically significant.
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8 9 **Qualitative studies**

10 Review findings will be compiled and evaluated using thematic analysis. This is a widely recognised process
11 [33-35], which involves using recurrent themes in primary studies to synthesise new qualitative evidence [36].
12 All relevant 'data' will be considered for synthesis including those data labelled as quotes, 'findings' and
13 'results' as per guidance [37].
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20 21 **Amendments:**

22 If any amendments to the protocol are required they will be individually described, dated and rationalised to
23 ensure transparency and enable the reader to identify potential bias and to replicate the searches if required.
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28 29 **Discussion**

30 In the UK there are estimated to be 850,000 people living with dementia and approximately 450,000 people
31 living in care homes, the majority of whom have significant memory problems [4]. An understanding of each
32 person's needs and desires is important to include them in the decisions that shape the decisions about their
33 health and care[5, 6] which is a moral imperative.
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40 Little is known about how decision making between people living with dementia in extended care settings is
41 shared with their staff and family carers, and further research has been recommended e.g. [16, 38]. With a
42 view to adding to the body of knowledge, this review will build on the evidence about the measures, tools and
43 resources from different specialities and aims to bring together all relevant evidence rather than focussing on
44 any specific field of practice, thereby expediting an integrated and interdisciplinary approach to research into
45 dementia care centring around the individual reflecting the comparable drive in health and social care practice
46 (e.g. WHO global strategy on people-centred and integrated health services)[27].
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54 The systematic review will provide a contemporary synthesis of evidence in relation to the current
55 understanding of Shared Decision Making policy and practice for people living with a cognitive impairment in
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3 extended care settings. It is designed to explore the characterisation and constructs of shared decision making
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5 for people living with dementia and their carers recognising relationships in care and how those relationships
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7 impact on care choices and decisions. Facilitators and barriers and risk and benefits will be explored in the
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9 context of resources, methods and tools in an effort to identify a readily available and financially viable
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11 intervention that can be independently trialled with a view to comprehensive and equitable implementation
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13 throughout the care sector.

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15 It is recognised that there are potential limitations in relation to reporting bias at both study and outcome
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17 level, for example unsuccessful implementation studies are less likely to be published by authors; and at
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19 review-level, for example, the inability to retrieve all relevant research due to possible inadequacies in the
20
21 search strategy; or reporting bias related to data extraction or analysis. In an effort to overcome these
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23 limitations the search terms and strategy have been reviewed to facilitate a wider breadth of results (e.g.
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25 databases from a number of professional fields and have been searched to allow for publication bias). The
26
27 findings will inform the design of an intervention study facilitating Shared Decision Making for people living
28
29 with dementia in care homes and have the potential to inform future policy and practice.

30 31 32 **Authors Contributions:**

33
34 All authors contributed to the selection, bias assessment and data extraction criteria. Statistical expertise will
35
36 be provided by FB. RD created the protocol with supervision by FB and CG as part of a wider PhD project. RD
37
38 prepared the search strategy with support from FB and the University of Hertfordshire health information
39
40 manager. FB and CG critically appraised all drafts and will independently review 10% of all search results to
41
42 promote consistency with inclusion criteria. All authors agreed the final manuscript.

43 44 45 **Funding:**

46
47 The protocol and resulting review is undertaken as part of a wider doctoral study focusing on dementia care in
48
49 care homes which has been funded by the National Institute for Health Research (NIHR) Collaboration for
50
51 Leadership in Applied Health Research & Care (CLAHRC) East of England.

52
53 This report presents independent research funded by the National Institute for Health Research (NIHR)
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55 Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England, at Cambridgeshire
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and Peterborough NHS Foundation Trust. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing Interests

Authors declare that they have no competing interests.

For peer review only

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Abbreviations

| | |
|----------|---|
| CINHAL | Cumulative Index to Nursing and Allied Health Literature |
| CLAHRC | Collaboration for Leadership in Applied Health Research & Care |
| DH | Department of Health |
| INTERDEM | Early detection and timely INTERvention in DEMentia |
| JBI | Joanna Briggs Institute |
| MCA | Mental Capacity Act |
| MeSH | Medical Subject Heading |
| PRISMA-P | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| Qari | Qualitative Assessment and Review Instrument |
| SUMARI | System for the Unified Management of the Assessment and Review of Information |
| UK | United Kingdom |

| Cognition Disorders | AND | (Shared Decision Making) | NOT | Paediatrics | NOT | Advance Directives |
|--------------------------|-----|--------------------------|-----|-------------|-----|-----------------------|
| Dementia | | Decision Making | | Children | | Advance care planning |
| Neurocognitive Disorders | | Patient Participation | | | | |
| Brain Injuries | | Consumer Participation | | | | |
| Autistic Disorder | | Cooperative Behaviour | | | | |
| Learning Disorders | | Decision Support | | | | |
| Stroke | | | | | | |

Table 1

| Cogniti* | AND | Shared Decision | NOT | Paed* | NOT | Advance Directives |
|----------|-----|-----------------|-----|-------|-----|--------------------|
|----------|-----|-----------------|-----|-------|-----|--------------------|

| Disorder* | Making | | |
|-----------------------|----------------------|--------|------------------------|
| Dementia* | Deci* Mak* | Child* | Advance* care planning |
| Alzheimer* | Patient Participat* | | Advance* deci* |
| Neurocogniti* Dis* | Consumer Participat* | | |
| Brain Injur* | Cooperat* | | |
| Autis* | Decision Support | | |
| Learning Dis* | | | |
| Stroke | | | |

Table 2

For peer review only

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Research checklist – PRISMA-P 2016.09.13 RD protocol for publication

| PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol* | | | Page Number |
|---|----------------|---|--------------------|
| Section and topic | Item No | Checklist item | |
| ADMINISTRATIVE INFORMATION | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | Title -1 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | Page -3 |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | Page -1 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | Page – 11 |
| 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 | Page – 11 |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | Page – 12 |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | |
| INTRODUCTION | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | Page 4-6 |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | Page 6-8 |
| 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 | Page 7-9 |
| 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 | Page - 9 |
| 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 16 |
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | Page 10 |
| 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) | |

Research checklist – PRISMA-P 2016.09.13 RD protocol for publication

| | | | |
|---|-----|--|---------|
| 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 | Page 10 |
| 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 | Page 10 |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | Page 10 |
| 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 | Page 10 |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | Page 10 |
| | 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) | |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | Page 11 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | Page 12 |
| <p>* 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.</p> <p><i>From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.</i></p> | | | |