Managing diabetes in people with dementia (DiMonD): A realist review

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Background and rationale

Dementia and diabetes mellitus are common long-term conditions and may co-exist in a large number of older people (1-3). Worldwide there are an estimated 35.6 million people with dementia. By 2050 this number will rise to over 115 million (4). Although there are differences in the physical and cognitive effects of the different types of dementias all are progressive, involve increasing physical and mental deterioration, and lead to a person with dementia becoming increasingly dependent. Diabetes mellitus is seen in 10-25% of older people (5, 6) and in nursing homes up to 27% of residents may have diabetes (7-9). As with dementia the prevalence of type 2 diabetes is increasing globally (10, 11) and there is evidence to suggest there is a link between cognitive dysfunction and type 2 diabetes (1, 12, 13). A recent scoping review found data to suggest that rates of diabetes in people with dementia are between 13 and 20 percent (14).

Having dementia or cognitive impairment impacts on a person’s ability to understand their condition and undertake self-care management tasks such as managing medication, and monitoring blood glucose (3, 15-17) and is associated with an increased use of both health and social services (17). Moreover, people with dementia are at greater risk of hypoglycaemia than older people without dementia (18-21) and may be at risk of drug interactions and adverse reactions due to polypharmacy (22). There is also evidence that people with dementia may have poorer access to diabetes services and monitoring than those without dementia (23-26).

There is currently no systematic approach to the management of diabetes and dementia (27) and most care pathways for diabetes do not take into account the needs of people with dementia (28). Clinical guidance on the management of diabetes in older adults (22, 29-31) suggests that glycaemic targets should be individualized for older people and take into account factors such as age, dementia, frailty, co-morbidities and polypharmacy (32, 33). However, there is limited evidence on the outcomes of such approaches for people with dementia (34).

The main approach to the management of long-term conditions such as diabetes revolves around self-management strategies focusing on the attitudes and self-efficacy of the patient, for example using motivational interventions (35) or education programmes (36, 37). Whilst this may be appropriate in the earlier stages of dementia (38) capacity for self-management will diminish as the dementia progresses and interventions may instead have to target family carers. The situation is further complicated in that management may differ for those whose diabetes pre-dates a diagnosis of dementia, compared to patients who develop diabetes post-dementia. There are additional difficulties related to insulin management. Interviews conducted as part of a recent NIHR study
suggest that as people living with dementia become unable to manage their own medication they find injections distressing and painful (39). They may also forget to eat or take medication leading to episodes of hypoglycaemia and in some instances hospitalisation (39).

Physical frailty (33) or end-stage dementia compound the complexity of diabetes management, with decisions needing to be made about whether to maintain treatment or consider admission into nursing home care (40). The underlying assumption of this proposal is that the effectiveness of programmes to manage diabetes in people with dementia is contingent not only on specific diabetes focused interventions but also on contextually situated decision making. Interventions designed to improve the management of diabetes in people with dementia are likely to be multi-component, specific to different stages of the dementia trajectory, and dependent on the behaviours and choices of those delivering and receiving the care.

To develop a theoretical understanding of the realities of working in and across complex, overlapping systems of care, and why and how different interventions may work, there is a need to synthesise the different strands of research evidence. Realist synthesis aims to make explicit the mechanism(s) of how and why complex interventions are effective (or not) in particular settings (41). It is a theory driven review process that recognises that the management of diabetes will always be a produce of intervention design, the different participants and settings, and how the stigmatised condition of dementia is acknowledged, understood and managed. Realist synthesis methodology will enable us to deconstruct the component theories underpinning different interventions aimed at people with dementia and/or diabetes and to consider relevant contextual data to test our understanding of the applicability of different approaches for this population and in different settings.

Aims and Objectives

The overall aim is to identify key features or mechanisms of programmes and approaches that aim to improve the management of diabetes in people with dementia, provide a context relevant understanding of the mechanisms by which interventions achieve different outcomes for this population, make explicit the barriers and facilitators to implementation and identify areas needing further research.
The objectives are:

1. Identify which interventions, or components of interventions, for managing diabetes in people with dementia could potentially work, for whom and in what circumstances.

2. Identify how interventions work, on what range of outcomes (i.e. organisational, resource use and patient care) and for whom they work (or why don’t they work) and in what contexts.

3. Identify the barriers and facilitators to the acceptability, uptake, and implementation of interventions designed to manage diabetes in people with dementia.

4. Establish what evidence there is on the feasibility and potential value of interventions to manage diabetes in people with dementia.

5. Establish what is known about the design of diabetes management technologies and identify the potential benefits of involving end users (people with dementia and their carers) in their development.

6. Identify key areas for future research, including promising interventions that merit further evaluation through a multicentre interdisciplinary approach.

**Realist review approach**

Realist synthesis is a systematic, theory-driven approach designed to make sense of diverse evidence about complex interventions applied in different settings (42-45). Realism understands causation as working through mechanisms that operate, or not, according to context (46, 47), context being conceptualized as the conditions that bring about the firing or triggering of a particular mechanism. These mechanisms are the underlying, often implicit, processes or structures that generate or lead to particular diabetes related outcomes, for example the presence of specialist expertise.

Realist approaches are based on building plausible evidenced explanations of observed outcomes (48). It is particularly useful when dealing with a complex social intervention that has multiple components, operates across multiple sites, and involves multiple actors or agents (49). The underlying premise of realist review is that the observed “demi-regular patterns” of interactions between the components that make up complex interventions can be explained by mid-range theories. Programme theory is the idea behind the intervention, the reason it has been developed and the aims of what it is trying to achieve when implemented in practice (50). The iterative process
of the review tests those theories that are thought to work against the observations reported in evidence included in the review (51). The goal is to identify and explain the interaction between context, mechanism and outcome, to establish which interventions, or elements of interventions, are likely to work for whom and in what circumstances.

Realist synthesis takes account of a broad evidence base as well as the experiential and clinical knowledge that relates to the physiology and management of diabetes in older people and specifically older people with dementia. Evidence of interest would include evaluations of interventions relating to glycaemic control in older people, medication management, diabetes-related self-care, and those that address system wide issues about access to assessment and treatment. It would also include those that, by association, have the potential to improve diabetes care for people with dementia (for example studies on relationship-centred care, interventions to individualise or target care for people with dementia and the development and implementation of interventions).

Methods

An iterative four stage approach is proposed based on the stages set out by Pawson et al (52) and captured in the RAMESES publication standards (45), which optimises the knowledge and networks of the research team and is stakeholder driven. The assumption is that a review on interventions to manage diabetes in people with dementia has to consider complementary evidence, e.g. evidence on the effectiveness of interventions to improve diabetes management in older people without dementia, interventions to improve the health and well-being of people with dementia, and studies that rely on health care professionals in different settings working together, and with family carers, to improve diabetes management for people with dementia. It is likely that the review will be informed by theoretical work on:

- Management of diabetes in older adults and those with complex health needs (including issues such as individualising glycaemic targets for people with dementia and glycaemic targets that take into account the risk, and impacts of hypoglycaemia in this group) (29, 30, 53, 54)
- Patient-centered approaches to glycaemic management in people with diabetes that balance treatment targets against quality of life and patient and carer preferences (55, 56) and that involve patients and carers in the development of interventions
• Theories about the way services are designed, delivered or implemented for people with dementia; e.g. work that clinical staff do in tailoring or co-constructing interventions to individuals, including case management approaches and assistive technology (57)
• Theories around diagnostic or clinical overshadowing – for example if the dementia is associated with behaviours that are challenging (e.g. aggression, agitation, psychosis) then dementia may become clinically dominant and detract from the management of conditions such as diabetes mellitus (58, 59)
• Interventions that provide education or support for the family carers of people with dementia to help them cope with the behavioural, psychological and emotional consequences of dementia (60-65)
• Theories on the provision of person-centred/relationship-centred care for people with dementia (66-69)

Phase 1: Defining the scope of the review: concept mining and theory development

In Phase 1 we will develop initial programme theories about why diabetes management programmes for people with dementia do, or do not, work. These will provide provisional accounts of the potential impact of interventions by linking key areas of knowledge that inform how interventions are developed for this particular population.

We will undertake a preliminary scoping of a selection of key literature (e.g relevant evaluations of interventions for people with dementia, or interventions for frail older people with diabetes). References collated by the project team for recent work on diabetes and dementia (14, 27, 31) will be supplemented by key word searches, and via discussion with the wider project team and with stakeholder groups. Key stakeholder groups will include: clinicians with a special interest in the management of diabetes in older people, providers of care in primary and secondary care (e.g. diabetes specialist nurses, GPs and other clinicians), recipients of care and their family carers, and dementia specialists from primary, secondary and tertiary care and the voluntary sector (e.g. old age psychiatrists, dementia specialist nurses, and GPs with an interest in dementia).

This will be followed by a one-day workshop where the project team will begin to identify common concepts and map and prioritise the theory identified from the searches and consultation. The process will also draw on the existing research and clinical experience of the research team and project advisory group. To ensure transparency of approach, and an audit trail, we will transcribe recordings of group discussion and maintain structured field notes on suggestions and decision making processes about which sources of evidence were linked to which strands of theoretical
Phase 2: Retrieval, review and synthesis

First, we will target evidence relevant to the management of diabetes in people with dementia. This will include interventions that address the knowledge and skills required to promote effective diabetes care, and specific interventions to manage diabetes in people with dementia or cognitive impairment (including those that focus on family carers). However, previous and current work by the project team suggests that there are few studies that look specifically at the management of diabetes in people with dementia or that evaluate interventions designed specifically for this population. Realist synthesis enables the testing of the relevance and rigour of emerging findings from one body of literature to another and in line with the iterative nature of realist synthesis methodology (50) the inclusion criteria will be refined in light of emerging data and the theoretical development in Phase 1.

The review is likely to include evidence sources that cover the following:

- People with mild, moderate or advanced dementia (of any type e.g. Alzheimer’s disease, vascular dementia, Lewy body dementia, Parkinson’s disease dementia, fronto-temporal dementia and alcohol-related dementia) and type 1 or type 2 diabetes, resident in the community or a care home or other long-term setting, or who are being treated in hospital.
- Studies of any intervention designed to promote the management of diabetes in people with dementia and the prevention of potential adverse effects associated with poorly managed diabetes such as falls, blindness, vascular complications or renal failure.
- Studies that provide evidence on barriers and facilitators to the implementation and uptake of interventions designed to improve the physical health of people with dementia (e.g. dementia-friendly initiatives, the impact of the cognitive versus behavioural and psychological symptoms of dementia and the progression of dementia on family carers and service providers).
- Studies that offer opportunities for transferable learning such as those that evaluate interventions for people with dementia and other clinical conditions, or those that look at the way services are delivered and implemented for people with dementia (for example interventions to: improve access or continuity, tailor care to the needs of individuals with dementia, or support family carers).
Outcomes

Outcomes will be informed by emerging context and mechanism relationships (i.e. programme theories). They will be established by the project team in an iterative process but are likely to include the following:

- Health and well-being of older people with diabetes and dementia and their family carers: e.g.
  - Glycaemic management and the prevention of hypoglycaemia and hyperglycaemia
  - Management of cardiovascular risk factors such as hypertension and hyperlipidemia
  - Identification, management and prevention of long-term complications such as depression, visual problems, neuropathic complications (28)
  - Medication adherence
  - Knowledge and quality of life for older people with dementia and their family carers.
- Outcomes related to service use: e.g. unplanned hospital admissions.
- Process related outcomes: e.g. quality of care, ‘what works’ in terms of designing and tailoring diabetes management technologies.

Types of studies

A diversity of evidence provides an opportunity for richer data mining and theory development. Therefore, we will include studies of any design including randomised controlled trials, controlled studies, uncontrolled studies, interrupted time series studies (ITS), cost effectiveness studies, process evaluations, surveys and qualitative studies of participants’ views and experiences of interventions. We will also include unpublished and grey literature, policy documents, and information about locally implemented programmes in the UK. For example, initiatives or interventions that have been reported in specialist conferences (e.g. Dementia Congress, British Geriatrics Society, Royal College of Psychiatry Old Age Section) and/or that could provide a model for future practice or merit future evaluation. Relevant evidence may also exist in unpublished form, e.g. care pathways and policy documents. We will seek to maximise opportunities for identifying this literature, through our consultations with different groups in phase one and through our project steering committee.
Searching for relevant studies

We will develop search strategies in the following areas: 1) dementia and diabetes (focusing on issues relating to management), 2) diabetes management in older adults and those with multimorbidity, 3) interventions to support people with dementia and comorbid health conditions (all conditions not just diabetes) and 4) interventions that involve the family carers of people with dementia. The search will be iterative and search areas will be revised as the review progresses.

In conjunction with an Information Scientist the project team will develop a list of relevant search terms to use in the following electronic databases: Medline (PubMed), CINAHL (Cumulative Index to Nursing & Allied Health Literature), SCOPUS, Cochrane Library (incl. the Cochrane Database of Systematic Reviews, DARE (Database of Abstracts of Reviews of Effects), the HTA Database, NHS EED (NHS Economic Evaluation Database)), AgelInfo (Centre for policy on Ageing – UK), Sirius, OpenGrey, Social Care Online, the National Research Register Archive, the National Institute of Health Research portfolio database, NHS Evidence, Google and Google Scholar.

Dementia reviews undertaken by members of the project team (70, 71) have highlighted the importance of lateral searching for identifying studies in this area. Therefore, in addition to the above electronic database searches we will undertake the following:

- Check reference lists from primary studies and systematic reviews (72)
- Perform citation searches using the ‘Cited by’ option on Google Scholar and Scopus, and the ‘Related articles’ option on PubMed and WoS (73)
- Contact experts and those with an interest in dementia to uncover grey literature (e.g. DeNDRoN, National Library for Health Later Life Specialist Library, Alzheimer’s Society and For Dementia)
- Contact diabetes specific charities and user groups (Diabetes UK, TREND)

Search results will be downloaded into bibliographic software and, where possible, duplicates deleted. Two reviewers will independently screen titles and abstracts for relevance.

Review

Screening and data extraction

Two reviewers will screen full manuscripts for inclusion based on the relevance and rigour of the evidence, with disagreements resolved by discussion with a third author. Relevance is defined as
the extent to which it can contribute to theory building and/or testing, and rigour the extent to which the methods used to generate that particular piece of data are credible and trustworthy (41, 45). For studies that meet the test of relevance data will be extracted onto bespoke data extraction forms which will enable us to populate the evidence on Context Mechanism and Outcomes (44). The data extraction form will be informed by programme theories that emerge from Phase 1 and will be pre-tested by the review team (74). Data will be extracted by one reviewer and checked by a second.

**Synthesis**

The analytical task is in synthesising, across the extracted information, the relationships between mechanisms (e.g. underlying processes and structures), contexts (e.g. conditions, types of setting, organisational configurations) and outcomes (i.e. intended and unintended consequences and impact). Rycroft-Malone et al (2012) have developed an approach to synthesis, incorporating the work of Pawson (2006) and principles of realist enquiry that includes:

1. Organisation of extracted information into evidence tables representing the different bodies of literature (e.g. diabetes management, dementia, health care, organisation of services, technology)

2. Theming across the evidence tables in relation to emerging patterns (demi-regularities in realist literature) amongst context, mechanism, and outcomes (C-M-Os), seeking confirming and disconfirming evidence.

3. Linking these demi-regularities (patterns) to refine hypotheses.

Data synthesis will involve individual reflection and team discussion and will;

1) Question the integrity of each theory, 2) Adjudicate between competing theories, 3) Consider the same theory in different settings and 4) Compare the stated theory with actual practice. Data from the studies will then be used to confirm, refute or refine the candidate theories. Where theories fail to explain the data, alternative theories will be sought.

Once the preliminary mapping of the evidence into tables is complete we will hold a second one day workshop with the research team. This day will be structured to include in-depth discussion of the findings and to develop and confirm the resultant hypotheses. These will act as synthesised statements of findings around which a narrative can be developed summarising the nature of the context, mechanism and outcome links, and the characteristics of the evidence underpinning them.
The synthesis process will reflect RAMESES publishing standards for realist reviews (45). The transparency of a realist review synthesis is reliant on careful documentation of the reasoning processes, how they are grounded in the evidence and justification of inferential shifts through engagement with different evidence sources (42). This aspect of the review process is resource intensive and reliant on discussion and deliberation, across and with particular members of the research team. Outputs from Phase 2 will include a comprehensive evidence base related to programmes designed to manage diabetes in people with dementia in community, hospital and long-term care settings, and a set of hypotheses supported by relevant evidence to be refined in Phase 3.

**Phase 3: Test and refine programme theory/ies (validation)**

To enhance the trustworthiness of the resultant hypotheses and develop a final review narrative that addresses what is necessary for the effective implementation of programmes to manage diabetes in people with dementia, we will review the hypotheses and supporting evidence through telephone interviews with up to 15 stakeholders (or until saturation is reached). These participants will be purposively sampled from participants in Phase 1 to obtain different perspectives relevant to the emerging outputs of the review including diabetes specialists, dementia specialists, academics, policy makers, PPI representatives and those commissioning and providing services. An interview schedule will be developed based on the findings that have emerged from the synthesis process and will aim to elicit stakeholder’s views on their resonance, both from a practice and a service user perspective. Outputs from Phase 3 will be a refined set of hypotheses with accompanying evidence-based narrative.

**Phase 4: Actionable recommendations**

We will work with the Project Advisory Group and commissioners and providers, e.g. CCG representatives and diabetes and dementia experts, to develop a set of actionable recommendations designed to inform practice and the development of future research studies. This will include the development of an evidence informed framework of what works for whom and in what context in relation to programmes to manage diabetes in people with dementia, and recommendations for promising interventions for future evaluation.
Patient and public involvement

A well-established Public Involvement in Research Group (PIRG) at the University of Hertfordshire trains and provides support to public members and has a broad membership of service users and carers. Two members of this group, who have experience of caring for a family member with dementia and diabetes, have been involved in the development of this proposal. They will be part of the Advisory Group, will be invited to attend PMG workshops, will collaborate with the researchers throughout the project, and be involved in interpreting and disseminating the review findings. In addition, we will recruit additional PPI representatives to the stakeholder groups where they will be involved in validation of findings. They will be recruited from the networks of project team members.
References


57. Bowes A, , Dawson A, , Greasley-Adams C, . Literature review; the cost effectiveness of assistive technology in supporting people with dementia. Report to the Dementia Services Development Trust. School of Applied Social Science, University of Stirling, 2013