Project Title: Improving outcomes for people living at home with dementia and continence problems (DemCon)

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Plain Language Summary

Most people with dementia will develop problems with continence or toilet-use that can lead to major difficulties. Coping often places a heavy workload on caregivers, but there are no evidence-based strategies to help. We have identified five key ‘solutions’ (each tackling a different part of the problem) that can be combined into an intervention to be delivered into people’s homes to support them to self-manage continence issues.

We are developing a Research Programme to co-produce and test the intervention. In preparation, we used the Programme Development Grant (PDG) to address gaps in our knowledge by 1) gaining feedback on our plans from stakeholders 2) checking the translation into English of a questionnaire designed to measure continence-related impact for people with dementia and caregivers, 3) mapping current relevant literature to check our plans to use it in the Research Programme to help design the intervention are sensible.

To do this we:

- Held two online events to gain feedback on proposed Research Programme plans.
- Asked 13 unpaid caregivers whether a questionnaire developed to measure the impact of continence problems on people with dementia and their caregivers has been translated from German to English clearly. We found that the questionnaire did not fully meet the needs of unpaid caregivers and a different one for this caregiver group is needed.
- Searched the available literature on each ‘solution' to finalise the detail of the methods that we will use to design the intervention in the Research Programme.

Throughout the development of this work, we have talked to people with dementia and caregivers, health and social care workers and others. We will now use the findings from the PDG to finalise a Research Programme with the best chance of improving the lives of people living with dementia and continence problems.

Summary of Research Findings

Developmental work package 1: stakeholder engagement

The aim of DWP1 was to develop and expand stakeholder and PPI groups for the work in this PDG and for the planned PGfAR. We have built stakeholder and PPI networks that incorporate a diverse range of people, both in terms of characteristics and experience. We have explored our research with people with dementia, family and friend carers, healthcare professionals from a range of disciplines (including community nurses, specialist continence and dementia nurses, GPs, occupational therapists and psychologists) and social care professionals including home care workers. We have engaged with a range of local, regional and national organisations, for example the Home Care Association, Help & Care, and local carer groups.

We undertook two online workshops, one with professional stakeholders (n=5, a dementia nurse specialist, a bladder and bowel nurse specialist, an occupational therapist, a homecare manager and a GP) and the other with unpaid carers (n=6 - further detail of this group is provided in the PPI section of this report).

In each of the meetings we provided an overview of our proposed overarching study and Research Programme plans including the separate components and invited feedback, including identification of any gaps and barriers to likely acceptability and wide-scale implementation and effectiveness of the implementation and views on the trial, including outcomes. The key aim of these workshops was to discuss the planned content and development of the application.

We received overwhelming support for our plans, with some key lessons, including:

- Find ways to include people living by themselves with dementia who do not have the support of a local carer
- Implementation plans need to be considered from the outset, particularly for isolated people
- Avoid over-estimating the time (or other resources) that healthcare professionals have and should recognise/allow for competing priorities
- Be realistic. Don't under-estimate how little support is currently provided; a small but consistent improvement would be a big step forward
- No professional group has ownership of these problems - we need to bring groups together. This input has been used to iteratively revise and develop our plans for the PGfAR.

Developmental work package 2 (DWP2): Validate the ICIQ-Cog

Study methods

A cognitive debriefing semi-structured interview study was conducted to assess the interpretability and clarity of the English translation of the ICIQ(International Consultation on Incontinence Questionnaire)-Cog from German. The study was approved by the University Ethics Committee (ID 82101) and the UK Health Research Authority.

Participants were recruited via Join Dementia Research (JDR) between September 2023 and April 2024. Paid and unpaid carers, over 18 years old, able to read and communicate in

English (representing the target population for the ICIQ-Cog) were invited to take part in the study. Written informed consent was received prior to interview.

The cognitive debriefing interviews were conducted either by telephone or Microsoft teams, using an unprobed self- administration method followed by debriefing session. All participants were asked to complete the questionnaire at the start of the interview. They were then asked open-ended questions about their understanding of the title, instructions, questions and response options. The interviews lasted 30-60 minutes and were recorded and transcribed verbatim; notes were taken.

The interviews were conducted across 3 rounds. Following the first round of interviews, the interviewer summarised the field notes and consulted with the study team and the ICIQ and questionnaire development teams to identify necessary modifications to improve the translation. The modified questionnaire was used for the round 2 interviews. Further modifications were made and the final interviews took place in round 3.

The data analysis was completed using Microsoft Excel and included analysis of field notes and interview recordings. The field notes were tabulated by questionnaire section (title, instructions, questions and missing items); the data was then combined and aggregated across interviews to check for clarity and consistent interpretation of questions, confirm comprehension or highlight areas of misinterpretation, lack of clarity or possible improvements. The interview recordings were transcribed verbatim and analysed thematically on a per question basis; the coding process was based on Braun and Clark six-phase process. The analysis focused on the clarity of the English translation, problems with questions and suggested solutions.

Study findings

There were 13 participants recruited across three rounds of interviews: round one (n=5), round two (n=5) and round three (n=3). After 13 interviews, and an initial review of the findings, the decision was made by the study team that the needs of unpaid carers could not be fully addressed by the questionnaire, so there was no further recruitment.

There were 11 females and 2 male participants, mean age 63.5 years. All participants were White British, Irish or European and had experience as unpaid carers. All had experience of caring for someone with dementia and urinary and/or faecal incontinence. The mean time taken for the participants to complete the ICIQ-Cog questionnaire was 2 minutes 42 seconds (range: 50 seconds - 9 minutes 54 seconds).

Participants emphasised the need for and importance of the questionnaire. One participant described how they hadn’t seen anything like it before and others were keen that the impact on the person with dementia and carer were being considered. Overall, most participants found the majority of the questionnaire easy to complete. It was described as ‘really succinct’ and ‘quite straightforward’ with nothing ‘scary’ in the language used.

Some modifications were made to the questionnaire after interview rounds 1 and 2. These included changes to the title; the phrase ‘cognitively impaired elderly’ was changed to ‘cognitively impaired adult’. Modifications were made to the wording of 5 of the 12 questions and 10 of the 12 sets of response options. ‘Never’ was added to the response options for all the questions in ICIQ-Cog-P and the response option ‘seldom’ was changed to ‘rarely’.

Other issues were raised where modifications were not made. These mainly related to the need to simplify the English, but also the phraseology and type of questions included which target a formal caring relationship by comparison with the roles undertaken by unpaid carers.

For example, there was uncertainty about the phrase ‘caregiving responsibilities.’ One participant described the difference between a paid, professional carer who had a ‘duty of care’ to the person to often that of an unpaid spousal caregiver who loves the person and wants the best for them. Another participant raised the difference between unpaid caregivers and paid carers more generally. They described the shock and worry of caring for the person for the unpaid caregiver compared with that of a paid carer for whom it was part of their job and a ‘completely different scenario’. Many of the participants had difficulty answering the question about the difference in managing incontinence in a person with or without dementia due to only experience with one person.

The participants highlighted some new emerging question areas they considered important for inclusion; most were more relevant to unpaid carers. They related to the financial burden of managing incontinence for the person with dementia and their carer (such as cost of continence aids and extra washing) as well as difficulty in sourcing suitable absorbent products and the embarrassment of having to collect and dispose of products.

Conclusions:

The importance of a questionnaire in English that purposefully explores the impact of managing incontinence for unpaid caregivers of a person with dementia was highlighted. However, the linguistic validation process in the study was stopped before the intended recruitment target as it became clear through the rounds of interviews that the ICIQ-Cog did not fully meet the needs of unpaid caregivers. A questionnaire to assess the impact of managing incontinence designed purposefully for unpaid caregivers of a person with dementia is still needed in order to be able to evaluate the quality of care and to measure the health benefits of assistive technology or new interventions for this carer group. Following discussion with the ICIQ advisor, we have established that our existing qualitative data from this and other studies will be sufficient to form the basis of an adaptation of the questionnaire. We intend to incorporate the additional development and evaluation work into the planned PGfAR.

Work package 3 – scoping reviews (n=5)

Scoping reviews were undertaken for literature relevant to the five components of the planned intervention. We aimed to understand the nature and extent of the literature available to support plans for a realist review (*focussed on intervention planning and prototype development using a realist approach*) in the first stage of the Research Programme.

The scoping reviews helped to clarify working definitions, key concepts and boundaries of the topics and the scale and nature of the literature. Each of the scoping reviews followed a five-stage process - identify the research question, identify relevant studies and literature, select studies, chart the data and summarise the results.

For each scoping review, the database searches were finalised by the team with support from a University of Southampton information scientist. The search strategy included consulting MEDLINE and CINAHL, Google Scholar and Proquest Dissertations & Theses Global. The reference lists of included articles were hand-searched for potentially eligible studies. A grey search was conducted using guidance from the University of Leeds, including a manual review of websites, documents and guidelines (google, NICE, NIHR, WHO IRIS, Kings Fund). All designs of study, policy documents and information about locally implemented UK-based programmes were included. The review findings for each component are summarised below:

SR1 – Stigma reduction

Question: What 'Stigma Reduction Intervention' strategies could help people cope with stigma associated with both incontinence and dementia and avoid associated social isolation?

The aim was to explore what we know about stigma reduction interventions for people with dementia and incontinence and what we can learn from stigma reduction interventions for other health conditions.

Inclusion/exclusion criteria (boundary setting)

We included studies in any setting or age group, any stigma reduction intervention studies applicable to people with dementia and/or carers focused on self/felt/internalised/personal stigma (not public stigma) that would be feasible for the person and/or carer living at home, intervention development studies and relevant systematic reviews. High-cost, high-intensity (requiring several sessions/contacts), group or peer support-based interventions, therapies, staff- focussed or public stigma focussed interventions or descriptions of personal experiences (not part of intervention development) were excluded.

Selected papers

There were 24 relevant papers selected; 8 different (relevant) stigma reduction interventions (n=9). Five papers focused on the theoretical basis of stigma reduction; there were 10 relevant systematic reviews. Interventions focused on women living with HIV or AIDS, youth living with HIV, people with depression or suicide ideation, refuges with post-traumatic stress disorder and military personnel. There were no intervention studies for self-stigma for dementia or incontinence or both.

Stigma reduction interventions

The interventions were developed through literature review, consultation with target group/relevant stakeholders and identification of relevant validated tools. They included contact (in person, online or video) and education interventions; cognitive reappraisal, communication approaches and direction to services and sources of help. Most were multi-modal. Most were online or web-based; one was delivered face to face and 3 included a print brochure.

Types of outcomes measured

The feasibility, acceptability and utility of the intervention; levels of internalised stigma (questionnaire), help-seeking, disclosure and knowledge were types of outcomes measured.

SR2 – Assistive technology

Question: *What Assistive Technologies (AT) for Continence could help people with dementia and their caregivers manage incontinence or toilet use issues (aiming for independent or dependent continence or containment)?*

The aim was to explore what AT interventions (that could be used by an informal carer in the home setting) for incontinence, have been evaluated for people with dementia (or have been tested with people with other relevant/comparable health conditions or older people in general and could be used for people with dementia)?

Inclusion/exclusion criteria (boundary setting)

We included studies in any setting or age group, any AT for incontinence or toilet use applicable to people with dementia and/or carers (even if focus is not dementia) that would be feasible for the person and/or carer living at home, intervention development studies and relevant systematic reviews. High-cost, high-intensity (requiring several sessions/contacts), those only applicable to a nursing home or hospital and telehealth interventions were excluded.

Selected papers

There were 12 relevant papers selected, with 8 different (relevant) assistive technologies, 2 intervention development papers and 2 mixed intervention development and evaluation. The interventions focused on the elderly and/or those with dementia diagnosis and related to 'morning care routine', ADLs generally and urinary incontinence.

AT interventions

One intervention specified the theoretical basis – included the chronic illness trajectory theory, social cognitive theory, adult learning theory and primary styles of adult learning theory. The interventions were developed through literature review, piloting, qualitative interviews with target group, previously developed interventions and expert panel review. The AT's included sensor technology, ultrasound, visual colour assessment, pad design, prompting and visual mapping technology, education and skills training. Some were multi-modal.

Types of outcomes measured

The number of changes/leakages of pads, comfort, amount of prompting needed from carers, burden, acceptability and quality of life.

SR3 – Conservative strategies

Question: What common conservative strategies to manage incontinence (or toilet use issues) have been or could be adapted for use by people living at home with dementia?

The aim was to identify papers exploring common conservative strategies used to manage incontinence in people with dementia and learn from conservative strategies for incontinence used by people with other health conditions (that could be adapted for use for people with dementia).

Inclusion/exclusion criteria (boundary setting)

We included any conservative strategies (non-pharmacological/non-surgical) for incontinence (or for behavioural symptoms if link to incontinence) in people with dementia and other health conditions such as learning disability, head injury and frailty. We included studies In the home setting (only in other setting if directly focussing on incontinence), studies that focus on ADLs, dementia symptoms or studies focused on lifestyles changes. We excluded PFMT or electrical stimulation studies, complementary therapies and biofeedback and nursing home/secondary care setting studies (unless directly about incontinence/conservative strategies).

Selected papers

There were 58 relevant papers selected and an additional 14 systematic review papers. There were 20 experimental papers, 6 descriptive, 13 review papers, 5 case studies, 6 qualitative, 6 opinion papers, a framework description, a product evaluation and a thesis. 33

focused on urinary incontinence, 2 on faecal incontinence, 20 on both and 3 not stated. There were 39 reports/websites/guidelines included from the grey search.

Conservative strategies

The conservative strategies were bladder training regimes (n=48) which was most commonly 'prompted voiding', environment-related considerations (n=22) such as lighting, colour, wayfinding and signage, lifestyle factors (n=29) such as diet and exercise, communication (n=19), use of AT (adaptive clothing etc) (n=29), strategies outside house (n=2), physical assistance (n=12) and multi-component (n=2).

SR4 – Caregiver coping

Question: *What caregiver coping strategies to help carers manage practically, physically and emotionally with continence problems have been or could be adapted for those caring for people living with dementia?*

The aim was to identify interventions to help dementia caregivers cope specifically with problems related to incontinence and toilet use but including dementia caregiver interventions related to activities of daily living (ADL) or symptoms or situations that arise through the clinical trajectory of dementia, which could be applied to incontinence care.

Inclusion/exclusion criteria (boundary setting)

We included studies in the home setting only, unpaid carers of a person with dementia, intervention or development of intervention studies, focus on continence management or other ADLs or specific symptoms or situations such as pain management or medications management. We did not include interventions for paid carers, high-intensity, high- cost strategies, rehabilitation, therapy or respite care or psychosocial or peer-support interventions.

Selected papers

There were 32 relevant papers selected; 19 different (relevant) carer coping interventions. Within the 32 papers, there was 6 review papers, 1 protocol paper, 7 pilot or feasibility studies, 7 descriptive studies, 7 intervention papers, 2 qualitative focus groups and 2 mixed methods studies. The interventions focussed on supporting independence, activities of daily living, medications management, oral hygiene, driving cessation, falls prevention, communication, pain assessment, handwashing, sleep, memory and wandering.

Caregiver coping interventions

The theoretical frameworks underpinning the interventions included stress and coping theory, self-efficacy theory, communication model of pain and environment fit theory. Interventions developed through learning the needs of the person with dementia and their carer, literature review, clinician/researcher/stakeholder review and using existing interventions. They included education and skills training, goal setting, problem-solving approach, communication and assistive technology.

S54 – BPSD

Question: What management strategies could be used to reduce the behavioural and psychological symptoms of dementia (BPSD) associated with continence problems?

The aim was to explore what interventions have been developed (or are being developed) to reduce the BPSDs associated with continence problems. The review will include

interventions more broadly related to activities of daily living and BPSD in daily life, but which could be applied to continence and toileting problems.

Inclusion/exclusion criteria (boundary setting)

We included studies in any setting, any age, any intervention studies to reduce BPSD associated with continence problems or other relevant ADLs, symptoms or circumstances, focussing on people with dementia and/or their carers, Including development of interventions and relevant systematic review papers. We excluded studies with a 'staff approach' to manage BPSD and high-cost and high-intensity strategies and studies that were descriptive only.

Selected papers

There were 19 relevant papers selected; 9 different (relevant) interventions included in the 12 evaluation papers. The interventions focused on oral hygiene, mealtimes and feeding, 'morning care sessions', dressing and toileting and BPSD symptoms more generally. The interventions focussed mainly on memory and concentration, resistance and refusals of care and threat reduction.

BPSD focused interventions

There were many theoretical frameworks used in the development of the interventions including adaptive leadership framework applied to chronic illness, models of music therapy in dementia care, need-driven dementia-compromised behaviour model and person-centred strategies to name a few. Interventions developed through review of the literature, based on previously developed interventions and through pilot and feasibility studies. The interventions included music-based interventions, reading-based interventions, use of personal stories, communication strategies, goal setting, problem-solving, identifying verbal and visual cues, demonstration and practice and education and threat reduction or a mix of these.

Patient and Public Involvement

Our PPIE co-applicant contributed to the research during planned study team meetings through the course of the research. JW has broad expertise in dementia care, the research process, engaging with relevant groups and ensuring that the voices of people living with dementia are utilised throughout the research process; from protocol and stakeholder group development to impact activities.

PPIE activities were a key element of the project (DWP1). In the unpaid carers workshop group (DWP1), we considered the degree of diversity we had achieved within the group with success in some areas but not others. We achieved a degree of diversity with regards to ethnic background (two contributors who were British Asian) and a degree of diversity of socio-economic background (based on the contributors own descriptions). However, we had less success in including people with physical differences or disability (an area we think is particularly important for this work) and we are actively seeking to address this for the Programme Grant. For example, we hope that through our new relationship with Help & Care (an organisation whose work particularly focuses on supporting people who are isolated or house bound in Dorset), we will be able to support people who do not usually get involved with research to become involved. We hope this will include people who have both dementia and a physical disability.

As well as workshops, we undertook ad hoc engagement activities with carers and people living with dementia. For example, we visited carer groups and had discussions about different elements of the planned intervention with individuals as part of this engagement. We have identified and engaged with PPIE co-applicants for the planned Research Programme. A small patient/public advisory panel (n=3) has been formed and is supporting us with our on-going development work. However, as we go forward, we plan to expand this group to gain greater diversity of experience and achieve our inclusion goals (focusing particularly on people who are isolated/house bound as described above).

We additionally have an on-going stakeholder group currently comprising one dementia specialist nurse, one continence specialist nurse, one GP, two occupational therapists, a homecare manager, a homecare worker and a community nurse.

Data sharing statement - See link

[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

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This project was carried out between April 2023 and September 2024. This final report has not been peer-reviewed. The report was examined by the Programme at the time of submission to assess completeness against the stated aims. These reports do not undergo a peer review process.