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Crossing the Line: Providing personal care in the context of families affected by dementia

Submission date 11/04/2023	**Recruitment status** No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 26/04/2023	**Overall study status** Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/07/2025	**Condition category** Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims
There are significant numbers of people living with dementia in the UK and this population is growing, and the known number of unpaid, informal family carers of people with dementia in the UK has surpassed 700,000. The experiences and impact of undertaking personal care for family carers are not well understood, although some research has been done on paid /professional carers. Psycho-social intervention research focuses primarily on the person diagnosed with dementia rather than on the family carer. Carer perspectives in relation to personal care interventions are under-researched and this is reflected in service development. The team's previous patient and public involvement (PPI) activity highlighted personal care as a top priority for a wide range of family carers of people living with dementia. Whilst this aspect of caring can be considered potentially challenging for any family carer, regardless of the condition experienced by the person they care for, for those with dementia the challenges faced can be especially complex. A better understanding of these issues is required through focused research before identifying and developing interventions that may help carers. Without this research family carers and those supporting them only have access to resources aimed at training paid /professional carers to deliver this kind of care, and with a lack of resources tailored to the needs of family carers. The aim of this study is to obtain a deep understanding of their experiences in relation to providing personal care to a family member living with dementia, and the impact on carer burden and stress. Deepening the understanding of these issues will help address the gap in family carer education and support, and to develop resources that will help families to cope better with the challenges of their situation.

Who can participate?
Family carers of those living with dementia

What does the study involve?
The overarching aim of the research is to gain a deep understanding of the experiences of family carers relating to their provision of personal care to people living with dementia. This includes the experience of assisting with going to the toilet, continence care, washing, bathing, dressing, mouth care, shaving, hair care, and foot and nail care. Having gained an understanding of the salient issues, the limited number of existing interventions will be appraised and the team will consider whether new ones need adapting and/or development to better meet carer needs.

Through a co-production approach with family carers and the study partners, who are mostly leading UK providers of dementia carer training and support, the team anticipates the development of some initial pilot materials (e.g. generic training or self-help leaflets). Evidence-based personal care guidance will also be provided for family carers and those who support them. The research is based on the fact that family carers are not a homogenous group. The answers to the research questions will focus on the differences as well as commonalities between subgroups such as spouse/partner and adult child carers, gender, ethnicities, sexuality and age cohort. Our follow-on research will focus on substantive intervention development and testing in response to this study's findings.

An in-depth 18-month mixed-methods study will be undertaken with a diverse sample of family carers of those living with dementia delivered in three Work Packages. The information that participants provide about their experiences of giving personal care will be used to guide the development of resources providing advice and guidance for family carers. Further analyses will be used to explore the lived experience of family carers in their particular context and situation. The study will include three interlinked Work Packages (WPs) carried out in sequence. This sequential approach will enable the survey results to inform the topic guides for the interviews, and the findings from the survey and interviews will subsequently be triangulated to inform the co-production.

The aim of WP1 is to obtain UK-wide survey data on issues that dementia family carers face in providing personal care. The survey will primarily be online, though it will also be accessible by telephone, Zoom, Teams or post if needed, to make it widely accessible for participants. The survey will be designed collaboratively by the research team, the Expert Advisory Group (EAG), PPI representatives and study partners, and will be informed by previous consultation with family carers and the literature review.

Survey data on participants' experiences will be used to inform the questions to be explored via more in-depth interviews with family carers during WP2. The interview guide will be designed by the research team and EAG members and will be informed by our literature review and survey findings. Individual interviews will allow us to explore each participant's experiences of providing personal care more fully, giving us a deeper insight into the issues they face than gained from the survey alone.

Participants in the WP3 co-production process will include the research team, EAG members, PPI advisers, study partners and representatives from the health, social care and charity sectors, as well as around 10 study participants and family carers drawn from the wider public. The process will focus on synthesizing the findings of WP1 and WP2 to develop initial pilot personal care resources for informal testing and feedback, arrive at a consensus about research priorities, next steps, study recommendations, and plan dissemination/pathways to carer benefit. It will also enable us to explore and agree on the plans for our next study, which would aim to refine and expand the core training materials developed in this current study and to undertake a feasibility study that would inform a subsequent trial for formal evaluation.

What are the possible benefits and risks of participating?
By taking part in this study participants will be providing valuable information to help develop resources that give guidance and advice for family carers.

Where is the study run from?
The University of Worcester (UK)

When is the study starting and how long is it expected to run for?
December 2022 to June 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Shirley Evans, shirley.evans@worc.ac.uk

Study website
https://www.worcester.ac.uk/about/academic-schools/school-of-allied-health-and-community/allied-health-research/association-for-dementia-studies/ads-research/current-projects.aspx

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322588

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR202970, IRAS 322588, 20/21 003

Study information

Scientific Title
Crossing the Line: Providing personal care in the context of families affected by dementia

Acronym
Crossing the Line

Study objectives
Research aim: To gain a deep understanding of the experiences of family carers relating to their provision of personal care to people living with dementia.
Research Question 1: How have family carers been prepared for the range of personal care activities they undertake as part of their carer role?
Research Question 2: What barriers and facilitators to providing personal care do family carers experience and what strategies do they commonly use in response?
Research Question 3: What are the effects of providing personal care on family carers e.g. financial, physical health and wellbeing, mental health, social, interpersonal relationships etc?
Research question 4a: How does providing help with personal care impact the relationship with the person with dementia and how does this change over time? 4b: What strategies do family carers utilise to help them cope with the emotional impact of providing personal care over time?
Research Question 5: What are the views of family carers about their education and support needs around personal care and how these could be best met?
Research Question 6: What findings are most relevant to the practice of staff and services who support and educate family carers of those with dementia?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2023, Liverpool Central REC (3rd Floor, Barlow House, HRA NRES Centre - Manchester, M1 3DZ, UK; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), ref: 23/NW/0098

Study design
Mixed methods survey and interview study

Primary study design
Other

Secondary study design

Study setting(s)
Charity/Voluntary sector, Community, Home, Hospital

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Carers of people living with dementia

Interventions

Review of existing evidence

A recent scoping of the literature (March 2021) found 56 articles relating to family carers of dementia in relation to personal care, with only eight focusing on the home setting of people with dementia. Consultations with family carers that support people with dementia have highlighted the importance of personal care (helping with going to the toilet, washing, bathing, dressing, mouth care, shaving, hair care, and foot and nail care). However, adapting to the change in the role that providing personal care brings is worsened by a lack of skills, know-how, shame and embarrassment, and the person with dementia may be increasingly unaware of their needs or the impact on their family. This leads to high levels of distress, causing physical and emotional harm both to the person and their family carer, and is often a tipping point for the person living with dementia to move into a care home, though existing research shows a lack of knowledge about the impact on family carers.

Research aims and questions

The overarching aim of the research is to gain a deep understanding of the experiences of family carers relating to their provision of personal care to people living with dementia.

The study will focus on the following questions:
Research Question 1: How have family carers been prepared for the range of personal care activities they undertake as part of their carer role?
Research Question 2: What barriers and facilitators to providing personal care do family carers experience and what strategies do they commonly use in response?
Research Question 3: What are the effects of providing personal care on family carers e.g. financial, physical health and wellbeing, mental health, social, interpersonal relationships etc?
Research question 4a: How does providing help with personal care impact the relationship with the person with dementia and how does this change over time? 4b: What strategies do family carers utilise to help them cope with the emotional impact of providing personal care over time?
Research Question 5: What are the views of family carers about their education and support needs around personal care and how these could be best met?
Research Question 6: What findings are most relevant to the practice of staff and services who support and educate family carers of those with dementia?

Having gained an understanding of the salient issues, we will appraise the limited number of existing interventions and consider whether new ones need adapting/developing to better meet carer needs. Through our co-production approach with family carers and our study partners, who are mostly leading UK providers of dementia carer training and support, we anticipate the development of some initial pilot materials (e.g. generic training or self-help leaflets). We also plan evidence-based personal care guidance for family carers and those who support them, which our team believes will be impactful study outputs with significant utility. Our research is based on the fact that family carers are not a homogenous group. The answers to the research questions will focus on differences as well as commonalities between subgroups such as spouse /partner and adult child carers, gender, ethnicities, sexuality and age cohort. Our follow-on research will focus on substantive intervention development and testing in response to this study's findings.

Project Plan

We will undertake an in-depth 18-month mixed-methods study with a diverse sample of family carers of those living with dementia delivered through three Work Packages (WPs). This sequential approach will enable the survey results to inform the topic guides for the interviews, and the findings from the survey and interviews will subsequently be triangulated to inform the co-production.

Methodology
The research will use an Appreciative Inquiry (AI) methodology within an Implementation Science framework. This means that the information that participants provide about their experiences of giving personal care will be used to guide the development of resources providing advice and guidance for family carers. We will also use Interpretative Phenomenological Analysis to explore the lived experience of family carers in their particular context and situation.

Participants
Study participants will be adult carers from across the UK who have direct experience in providing personal care to a family member with dementia. Potential participants will be identified utilising our research team's networks and social media, with the option of also registering the survey on the UK-wide NIHR Join Dementia Research (JDR) database if needed. The team will also recruit more locally through Admiral Nursing Services, a hospice, a social care provider and Midlands Partnership NHS Foundation Trust, as well as promoting the survey at community venues such as dementia cafes.

The Work Packages
The aim of WP1 is to obtain UK-wide survey data on issues that dementia family carers face in providing personal care. The survey will primarily be online, though it will also be accessible by telephone, Zoom, Teams or post if needed, to make it widely accessible for participants. The survey will be designed collaboratively by the research team, the Expert Advisory Group (EAG), patient and public involvement (PPI) representatives and study partners, and will be informed by our previous consultation with family carers and the literature review. Calculations indicated a minimum survey sample of 300 family carers of people with dementia across the UK, though the study aims to recruit 500 respondents to allow further exploratory analysis that will help to indicate areas of further research and offer information to develop tailored interventions.

The survey data on participants' experiences will be used to inform the questions to be explored via more in-depth interviews with family carers during WP2. The interview guide will be designed by the research team and EAG members and will be informed by our literature review and survey findings. A purposive, diverse sample of 45-50 family carers will be sought, based on characteristics of interest agreed with the EAG, including those that reflect the diversity of caring situations, and in light of insights from the survey. Individual interviews will allow us to explore each participant's experiences of providing personal care more fully, giving us a deeper insight into the issues they face than gained from the survey alone.

Participants in the co-production process (WP3) will include the research team, EAG members, PPI advisers, study partners and representatives from the health, social care and charity sectors, as well as around 10 study participants and family carers drawn from the wider public. The process will focus on synthesizing the findings of WP1 and WP2 to develop initial pilot personal care resources for informal testing and feedback, arrive at a consensus about research priorities, next steps, study recommendations, and plan dissemination/pathways to carer benefit. It will also enable us to explore and agree on the plans for our next study, which would aim to refine and expand the core training materials developed in this current study and to undertake a feasibility study that would inform a subsequent trial for formal evaluation.

Intervention Type
Other

Primary outcome measure

Understanding of the experiences of family carers relating to their provision of personal care to people living with dementia measured using a survey and interviews with an Appreciative Inquiry methodology within an Implementation Science framework by the end of the project.

Survey findings will sequentially inform interviews yet all Work Packages (survey, interviews, coproduction) will be inter-connected and supported by the use of Data Displays developed to link the different elements of the study and integrate analyses. A co-production Work Package will produce core training resources for within-study piloting and evaluation.

Secondary outcome measures

There are no secondary outcome measures.

Overall study start date

01/12/2022

Completion date

02/06/2024

Eligibility

Key inclusion criteria

1. An existing or previous family carer of a person who has dementia
2. Direct experience of personal/intimate care and bathing with a cared-for person who has dementia
3. Adult carers

Participant type(s)

Carer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

550

Total final enrolment

318

Key exclusion criteria

1. No experience of the topic under investigation in the last ten years to ensure the relevance of their experiences to current practice
2. Carers under the age of 18 years old

Date of first enrolment

16/04/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Worcester
Henwick Grove
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/00v6s9648

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Dissemination and impact planning will commence early in the study but will necessarily be focused on the last 6 months during authentic co-production activities. All study outputs will be cascaded through our wider networks using their websites, social media platforms, academic platforms etc including INTERDEM, Young Dementia UK, Innovations in Dementia, UK Dementia Meeting Centres Programme implementation team, 3 Nations Working Group Dementia and Higher Education Dementia Research Network, to reach academic (research and education) providers, workers who support family carers and policy advisers, along with family carers etc.

Use of social media (blogs and vlogs; Facebook and Twitter posts, Twitter chats), online seminars /dissemination events and partner organisations' newsletters will be optimised. A plain language publication and website materials for download that summarises the study findings and any learning from the process of doing the research will be published. Articles will be published in Open Access peer-reviewed journals.

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
Data will be available to share upon request to the Association for Dementia Studies at the University of Worcester, after the completion of the study (31/05/2024). It will include anonymised transcripts of interviews. This data will be retained for 10 years. Personal data from participants will not be shared and will be securely destroyed 3 months after the end of the study. Participants will give consent for the use of their anonymised data, for the purposes of

research, at the point of collection. For access to datasets following the completion of this study, contact shirley.evans@worc.ac.uk in the first instance, or the Association for Dementia Studies generally at dementia@worc.ac.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	14/12/2022	17/04/2023	No	Yes
Participant information sheet	version 1	14/12/2022	17/04/2023	No	Yes
Protocol file	version 3	02/04/2023	17/04/2023	No	No
HRA research summary			20/09/2023	No	No
Basic results			24/07/2025	No	No