Crossing the Line: protocol declaration

This protocol has regard for the HRA guidance

FULL/LONG TITLE OF THE STUDY

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

SHORT STUDY TITLE / ACRONYM

Crossing the Line

PROTOCOL VERSION NUMBER AND DATE

Protocol Version 3, 2nd April 2023

RESEARCH REFERENCE NUMBERS

IRAS Number:	322588
SPONSORS Number:	UW20-21 003
FUNDERS Number:	NIHR202970

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
....
Date:
03/04/2023

Name (please print): John-Paul Wilson
....

Position: Deputy Pro-Vice Chancellor Research
....

Chief Investigator:

Signature: Shirley B Evans
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Date:
03/04/2023

Name: (please print): Shirley Evans
....

LIST of CONTENTS

GENERAL INFORMATION	**Page No.**
HRA PROTOCOL COMPLIANCE DECLARATION	i
TITLE PAGE	i
RESEARCH REFERENCE NUMBERS	i
SIGNATURE PAGE	ii
LIST OF CONTENTS	iii
KEY STUDY CONTACTS	iv
STUDY SUMMARY	vii
FUNDING	viii
ROLE OF SPONSOR AND FUNDER	ix
ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS	ix
SECTION	
1. BACKGROUND	1
2. RATIONALE	2
3. THEORETICAL FRAMEWORK	3
4. RESEARCH QUESTION/OBJECTIVES	4
5. STUDY DESIGN/METHODS	5
6. STUDY SETTING	8
7. SAMPLE AND RECRUITMENT	8
8. ETHICAL AND REGULATORY CONSIDERATIONS	8
9. DISSEMINATION POLICY	11
10. REFERENCES	12
11. APPENDICES	18
12. AMENDMENTS	19

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STUDY SUMMARY

Study Title	Crossing the Line: Providing personal care in the context of families affected by dementia.
Internal ref. no. (or short title)	Crossing the Line
Study Design	Mixed methods
Study Participants	Adult family carers providing personal care to a person living with dementia.
Planned Size of Sample(if applicable)	500 survey respondents; 45-50 personal interviews.
Follow up duration (if applicable)	N/A
Planned Study Period	01/12/2022 – 31/05/2023
Brief Synopsis	Dementia family carers have reported that the issue of personal care (helping with going to the toilet, washing, bathing, dressing, mouth-care, shaving, haircare, foot and nail-care) is very important to them, but challenges around personal care are often a tipping point for the person living with dementia to move into a care home. Family carers face challenges adapting to the change in role that providing personal care brings, and this is worsened by lack of skills, know-how, shame and embarrassment. As dementia progresses, the person with dementia may be less aware that they require help, or of the impact it has on their family. This situation leads to high levels of distress, causing physical and emotional harm both to the person and their family carer. Past research shows little is known about this topic in the context of dementia and family care. We need first to understand the issues better, then develop materials that will help families better cope with these challenges. We will undertake a UK-wide survey of 500 family carers about the challenges they face and what they think would help, and would explore topics identified in the survey in 45-50 personal interviews to help us unpick the most relevant issues. We would use them to identify what could be put in place to better help carers, including advice and guidance materials for use by family carers directly, and resources for health and care professionals and staff. During three events with families and professionals we will develop a core set of pilot training materials for testing and evaluation with family carers. Training resources will be expanded post-study and evaluated in future research. At the end of the study we will have a comprehensive understanding of a wide range of dementia family carers' experiences of personal care giving and their strategies for managing these. We will have developed and piloted a core set of training resources, that can be also be used to inform others who develop dementia strategy or commission dementia education. Our study outputs and implementation plans will ensure significant numbers of dementia family carers are better supported around personal care giving.

Research Question/Aim(s)	**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 on 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 practice of staff and services who support and educate family carers of those with dementia?

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB), Research for Social Care Programme (Grant Reference Number NIHR202970)	£254,141

ROLE OF STUDY SPONSOR AND FUNDER

The University of Worcester (UW) is the Sponsor for this study. UW takes responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. UW will ensure that all necessary approvals from a HRA research ethics committee are obtained before engaging participants in the study. Signed ethically approved consent and acknowledgement forms from any participants who will be involved in the project will be obtained.

The study is funded by the National Institute for Health Research – Research for Patient Benefit (Social Care) funding stream. The funder has not had any influence over the study design or analysis.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

The research team will be supported by an Expert Advisory Group, including 6 PPI representatives and a range of study partners.

There will be four Expert Advisory Group meetings during the project and members will also be asked for their input and guidance on various aspects of the research, for example on the content and design of the survey and the suggested interview topics. They will also participate in the co-production events to give their perspectives on the development, testing, evaluation and dissemination of resources for family carers.

These six PPI representatives will all be lay advisers on the Expert Advisory Group alongside the research team members, study partners and other advisers. This is because everyone's skills and experiences are of equal value which fits with our authentic co-production approach throughout the study and not simply in Work Package 3. The PPI representatives' input will be at the four Expert Advisory Group meetings having been fully prepared for their role prior to the first of these and concluding their input at an extra debrief-session at the end of the study (totalling six meetings). The Expert Advisory Group will seek the PPI representatives' views across all three Work Packages about such things as recruitment, wording of public-facing materials such as recruitment documents and within- project event planning to ensure that these appeal to family carers. They will be involved in determining survey and interview questions also. They will also have their needs and preferences sought and met with regards to data analysis and dissemination involvement.

The study partners will support recruitment and uptake of study findings. The study partners are Alzheimer's Society; Dementia Carers Count; Dementia UK; Douglas MacMillan Hospice; Home Instead and TiDE.

KEY WORDS: Dementia; Family Carers; Home carers; UK carers; Personal care giving; Caring strategies; Caring challenges; Qualitative analysis; Co-production; Carer training materials; Carer support guides;

Study timeline

Appendix 1: Crossing the Line Gantt Chart

STUDY PROTOCOL

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

1 BACKGROUND

There are significant numbers of people living with dementia in the UK and this population is growing.[10] The known numbers of unpaid, informal family carers of people with dementia in the UK has surpassed 700,000.[11] There are challenges associated with being a family carer of someone living with dementia. A priority issue identified through extensive Patient and Public Involvement (PPI) activity relates to personal care (helping with going to the toilet, washing, bathing, dressing, mouth-care, shaving, hair-care, foot and nail-care), which can be stressful and significantly affect carer wellbeing, resilience, identity and relationships. The experiences and impact of undertaking personal care for family carers is not well understood although some research has been done with paid/professional carers. We are aware the current HOPES study which focuses on formal carers may identify relevant evidence in its soon-to-be completed scoping review of older adults' engagement in community care (https://www.york.ac.uk/spru/projects/the-hopes-study/).[12]

Research into the experiences of family carers of people living with dementia has tended to focus broadly on education, support, stress management, counselling and similar interventions.[13] 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. Family carers report the struggle to keep a sense of their own identity, often being portrayed as being one half of a couple or child/parent dyad. Family carers report feeling 'bundled together' as a homogenous group with a lack of understanding as to their diversity in terms of personal characteristics, caring situation and support mechanisms, and in turn, their differing experiences and needs.[14]

2 RATIONALE

Our previous PPI activity repeatedly 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. We need to better understand these issues 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, which are not tailored to family carer needs.

Our recent scoping of the literature (April 2020 repeated March 2021) sought evidence relating to family carers of dementia in relation to personal care from the previous 10 years utilising Briggs levels of Evidence.[15] Fifty-six articles were identified for review related to 53 individual studies and three expert opinion pieces. Forty-one of the 56 articles were solely concerned with personal care in care homes, nursing homes and residential aged care facilities. Of the 15 remaining, only eight focused on the home setting of people with dementia, with seven studies concerned with either assisted living, palliative care, hospital/clinical settings or multiple settings.

The activities of personal care referred to in this review included dressing, washing, personal hygiene (including mouth care and hand-washing), and toileting (including continence and bowel care). Eighteen of the 56 reviewed articles were concerned with multiple activities and used terms such as 'personal care', 'personal hygiene', 'activities of daily living', 'routine care' and 'morning care'. Of the articles focused on a single activity of personal care or bathing, the majority were concerned with using the toilet.

The majority of articles (47), focused on the improvement of personal care and bathing practice, whether through trialling an intervention, seeking better understanding of a topic or offering guidance. Almost all papers focused on paid care staff not family carers. Four studies found utilising arts as interventions during personal care and bathing beneficial. One pilot study used positive images during dressing and toileting activities (16) but none related to family carers. Consultation with family/informal caregivers of people with dementia was conducted in three studies towards the development of assistive technology. Findings from these studies related to a need for practical assistance with dressing[17] that private activities such as using the bathroom are more difficult to support than other activities of daily living and that assistive technology needs to be autonomous, familiar, simple and unobtrusive.[18] Articles identify interventions for reducing resistance to care behaviours[19-21] and understanding[22]while four articles highlight the need for support with managing these behaviours.[17,23-25] Findings from a study by Williams and Herman[26] suggest that emotional tone could be an important factor in resistance to care responses. Andrews[27] offers guidance on continence for care home staff and for advising families on continence care. Also seeking to support family caregivers, Mahoney, LaRose, and Mahoney[28] conducted an exploratory study that gained the perspectives of Alzheimer's family caregivers on assisted dressing and created a 'Preservation of Self Model: Care Recipient to Care Giver' to represent the trajectory of caregiving. Results from the study suggest dressing, counselling and aids as interventions to potentially support family caregiving.

Nine of the 47 articles found on personal care focused on developing education and training. Of these, only one was concerned with training for family caregivers in the home setting. That study's training program was found to increase family knowledge in several areas of assistive activity including toileting, bathing and dressing[29] .

There is a distinct lack of research into ways of supporting families caring for people with dementia at home with personal care and bathing (or contributing to their care in care homes and hospices). Some related evidence from formal care giving is available relating to bathing associated aggression[30] and resistance to personal care.[31-32] The two main family carer focused studies focused on teaching carers how to "do" care such as how to dress people with dementia and training them to "assist" people with dementia in activities of daily living. No studies considered family carers experiences or effects of this kind of care on them. Providing the mechanics of assisting a person with dementia to bathe is an important issue. Nonetheless, unless the emotional, relationship and practical context is understood and utilised, then advice on the mechanics of bathing are likely to be wasted.

3 THEORETICAL FRAMEWORK

This research will focus on gaining a comprehensive understanding of the personal care giving experiences of dementia family carers, including their strategies for overcoming challenges. It will identify core content for development of general training resources on personal care giving for use by dementia family carers and those who support them.

We will utilise an Appreciative Inquiry methodology within an Implementation Science framework. In addition to statistical analysis of survey findings, we will use Interpretive Phenomenological Analysis to make sense of qualitative data. Survey findings will sequentially inform interviews yet all Work Packages (survey, interviews, coproduction) will be inter-connected and supported by 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 withinstudy piloting and evaluation.

Interpretive Phenomenological Analysis (IPA) is a particularly appropriate methodology in circumstances where relatively little is known about the situation and context[39] In this study we need to know not only what the issues are, but their meaning to family carers, how they affect them, how they respond to them and mitigate/manage them or not. We also need to know how these insights vary by family carers with differing characteristics, so that we can tailor personal care training materials accordingly. Gathering sufficient detail of family carer characteristics and the context in which care is given is crucial to aid to aid our understanding of their experiences and we need sufficient numbers of participants to capture this diversity.

4 RESEARCH QUESTION/OBJECTIVES

Our research aims and questions are :

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 on 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 practice of staff and services who support and educate family carers of those with dementia?

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study will be organised into three interlinked Work Packages (WPs):

WP1: Survey (months 1-5)

WP Lead: Bruce

Objective: To provide UK-wide survey data of the issues faced by dementia family carers relating to personal care, addressing Research Questions 1-5.

Rationale: The survey will facilitate a broad diversity of participation of UK family carers of those with dementia. It will scope out the parameters of key issues for different groups including the opportunity to understand carer's preferred terminology. This information will be important in its own right, to deepen understanding of this under-researched area. Furthermore, we have planned a sequential approach so the results will help inform the interview guide to be used in WP2 and the recruitment strategy for the interviews.

Methodology: This will involve a qualitative and quantitative survey using closed answer, Likert scale and free text responses using the secure online JISC platform. Methods A primarily online survey will be designed with the research team, study Expert Advisory Group (EAG) members (including PPI representatives), study partners and previous consultation with family carers and informed by literature review. The survey will be launched promptly and will be conducted by the Research Associates.

Sampling/Recruitment: A convenience sample (target 500) will be gained over a substantive survey period of 3 months utilising a range of distribution strategies via our study partners, extensive networks and social media etc. Participants will not be excluded on grounds of ethnicity and recruitment materials and participant information will be in different languages. MPFT and BCUHB NHS translators will be provided to support these processes and translate responses for analysis. We will record a range of characteristics pertaining to each participant to aid analysis and identify any gaps in need of targeted recruitment to ensure sufficient diversity. Participants will be sought across the UK which may also identify carer training provision differences in the four countries.

We will employ strategies to target participant groups if needed using creative methods and local radio as well as use of the NIHR Join Dementia Research registry.

Inclusion Criteria: • An existing or previous family carer of a person who has dementia. • Direct experience of personal/intimate care and bathing with a cared for person who has dementia • Adult carers.

Exclusion Criteria: • No experience of the topic under investigation in the last ten years to ensure relevance of their experiences to current practice. • Carers under age 18 years.

Data Collection: Whilst primarily an online survey, options will be given for it be administered by telephone/Zoom/Teams or post to be accessible if needed for some participants.

Analysis: Descriptive statistics will be created by the survey platform and interpreted by the Research Associates, with further inferential analysis (e.g. Chi Square) carried out to explore differences based on demographic information (e.g. age, gender, relation to person with dementia, length of time as carer, ethnicity). Free-text responses will be analysed thematically using NVivo. Final analyses will be in Month 5 and fed into WP2 planning.

WP2: Qualitative data inquiry (Months 5-12)

WP Lead: Evans

Objective: To provide UK-wide in-depth understanding of the issues faced by dementia family carers relating to personal care addressing Research Questions 1-5.

Rationale: Individual interviews will enable participant's lived experiences of personal care and bathing to be explored and examined to gain a deep insight into the issues they face, concerning personal care giving. The rich data and indepth understanding gained will go beyond what is possible through the survey alone.

Methods: Commensurate with an interpretative approach, in-depth individual interviews (40-60 mins) with family carers will be conducted, some face-to-face and some online/telephone enabling a UK-wide sample to be achieved. Interviews will be conducted by the Research Associates who will keep audio recordings and make notes. The interview guide will be designed with the team and study EAG members (including PPI representatives) and informed by our literature review and survey findings.

Sampling/Recruitment: A purposive, diverse sample of 45-50 maximum family carers will be sought from across the UK through our partners, networks and study publicity. We have costed for 25 face-to-face interviews and 25 online/telephone interviews. By way of justification for this sample size, we wish to stress this number of participants is the upper limit likely to be needed to answer our research questions and this may well be achieved in the region of 30 participants with an IPA approach, however we have costed for the upper limit to be prudent. We also know from experience that some participants may prefer to be interviewed over two occasions and so we have allowed for a large number of interviews although the actual number of participants (voices) could be less. We already know from consultation with family carers, the literature review and our own experience that there will be a large number of factors affecting family carer's experience of giving personal care. A larger number of interviews will enable us to explore these differences as well as target participants known to have characteristics of interest to us (according to our sampling framework which we will develop to ensure diversity of participants is achieved). For example characteristics may include participant's living arrangements in relation to the person they care for (e.g. living together, living separately but local, separately at a distance, living in a care home), ethnicity, gender, relationship to the cared for person, work and family commitments, type of dementia of the cared for person and the stage of their dementia, carers who are coping well with personal care, carers who are not coping well with personal care and less engaged carers etc. Any unanticipated new insights or characteristics that come to light as being relevant, can also be explored further with subsequent interviewees. Finally, having scope for a larger number of participants will also mitigate against interviewees who provide less than rich data or who simply may not engage well at interview, requiring us to seek more participants.

Participants will not be excluded on grounds of ethnicity and recruitment materials and participant information will be in different languages. Betsi Cadwalldr University Health Board and Midlands Partnership Foundation Trust NHS translators will be provided to support these processes and translate responses for analysis.

Dementia UK and Alzheimer's Society partners have a key role in helping with recruitment because of their extensive networks and communication channels within the UK dementia carers community. Their input will be invaluable if we need to target carers with certain characteristics to achieve the maximum diversity we seek within interview sampling. Furthermore, they are trusted and respected organisations which may help us to recruit less engaged participants or those newly known to them. We will actively seek less engaged participants as a means of widening engagement in research and not solely focusing on 'easier to reach' participants. It is important that we gain participation from those who may be managing personal care for someone with dementia, whilst not well connected with community and statutory support mechanisms or peers. We will agree the characteristics of interest with the EAG and in light of insights from the survey. We will stop recruiting once sufficient number and quality of participants have been achieved and data saturation has been arrived at. The proposed number of interviews should be sufficient to answer the study research questions.

Inclusion Criteria: • An existing or previous family carer of a person who has dementia. • Direct experience of personal/intimate care and bathing with a cared for person who has dementia • Adult carers

Exclusion Criteria: • No experience of the topic under investigation in the last ten years to ensure relevance of their experiences to current practice. • Carers under age 18 years.

Data Collection Over a six-month data collection period we will conduct interviews (average 6-8 per month in Months 5-10) with ongoing analyses then final analyses in Months 11-12. Using our various study promotion channels, we will distribute a study information flier. Survey participants will have had the option of volunteering for an interview also. Following answering of initial queries and checking of eligibility, an interview will be arranged once the participant information pack has been sent and the family carer has had time to review it and make an informed decision about participation. Interviews will be at a time and place to suit participants at home, community group venues, online or by telephone.

Sometimes a person being cared for who has dementia may be present during interviews, if this best suits the needs of them and the family carer. Whilst the person with dementia may unavoidably contribute, their data will not be used as part of the research. Carers who want to be interviewed alone usually make arrangements for this, such as when they and the cared for person are attending a community support group. We will find a suitable way to ensure no carers are excluded due to caring responsibilities and we have included funding for paid carers to cover.

Analysis: Interviews will be transcribed by a trusted provider/translators and analysed thematically using NVivo qualitative data analysis software. IPA will lead to a set of super-ordinate themes and smaller sub-ordinate themes enabling us to make interpretations across the data whilst also capturing the unique experiences of individual carers. As well as asking about views and experiences we will also ask how carers manage and can best be supported to address the issues they raise, including how training needs may best be met, which will inform our work to maximise the study's pathway to family carer benefit during WP3.

Diversity: This will be considered in its widest sense such as nature of relationship (spouse, daughter), living situation, accommodation type, ethnicity, age, disability, location and those with paid, peer or other family member support, and stage of dementia of cared for person (mild, moderate, end of life). Rather than statistical representation, sampling in phenomenology is about gaining a deep understanding into the complexity of the issue under study.

Findings will be generalisable at a theoretical level and sufficient to inform development of a core set of training resources in WP3. We will take a staged approach to recruitment. A sampling frame will be devised to assist with recruitment to ensure diversity is achieved. More targeted recruitment can then address any gaps identified. To ensure we address diversity issues fully, we have dedicated advisers for LGBGTQ+ and BAME communities. Their input will enable us to reflect diversity comprehensively in our recruitment, data collection tool design, interpretation of data, co-production event planning and training materials. Translation services including BSL will be used as needed. These advisers will also help us address diversity in planning future research priorities during the co-production events and at the EAG meetings.

WP3: Co-production: Making sense of findings, Piloting, Consensus and Dissemination (Months 12-18)

WP3 Lead: Brooker
Objective To use a process of co-production to help make sense of study findings, develop initial pilot personal care resources for informal testing and feedback, arrive at consensus about research priorities, next steps, study recommendations, and plan dissemination/pathways to carer benefit (addresses Research Questions 5 and 6). Rationale The parameters for this study include that it will end with a better understanding of carer experiences and needs relating to personal care including what needs to change and how those changes may best be brought about. Our approach to co-production is a fitting one to develop some initial family carer training resources (such as accessible self-help booklets for carers and general guidance on personal care for carers and those who support them) for within-study informal testing and feedback. A Work Package focused on co-production and translation of study findings into training resources for testing, will require us to have placed sufficient emphasis on synthesis of findings from WPs 1 and 2.

This WP is the vehicle for utilising the synthesized findings to develop our training materials (intervention). Co-production will also enable us to explore and agree the plans for our next study which would seek to refine and expand the core training materials (intervention) developed in this study and to undertake a feasibility study that would inform a subsequent trial for formal evaluation of our intervention.

Co-production will further enable wide dissemination to a variety of audiences using a range of accessible media to maximise carer benefit.

Methodology: We propose a co-production approach that will be facilitated robustly by team members with extensive experience of co-production and participatory, multi-stakeholder approaches.

Methods Our co-production[40] mechanism will be channelled cyclically through three multi-stakeholder events over a suitable timeframe for each cycle to inform the next.

Process:
Event 1 – Sharing of findings (from both data sets and literature) and verification of findings with event participants; exploration of what needs to change and how; ideas for initial pilot personal care resources e.g. generic training or educational interventions, guidance materials, information leaflets for carers and those who support them; initial consideration of future research priorities; preparation for Event 2.

Participants will include EAG members (the PPI advisers, study staff, partners), some study participants and family carers drawn from the wider public (approx. 10), as well as staff representatives from across health, social care, charity sector etc. Between cycles 1 & 2 the study team will capture and distil views and research ideas/priorities from Event 1, draft pilot personal care resources and firm up plans for Event 2, jointly with all EAG members.

Event 2 – Review and agree final changes needed to draft personal care resources developed from Event 1; finalise plan for informal testing and feedback; refinement of ideas and priorities for follow-on research; exploration of a community of practice approach to keep study stakeholders connected post-study to take research ideas forward. Participants will include EAG members (PPI representatives, study staff and partners), some study participants and family carers drawn from the wider public, (approx. 10), as well as staff representatives from across health, social care, charity sector etc (some participants may be different to Event 1).

Between cycles 2 & 3 the study team will make final changes needed to draft resources and implement the plan for informal testing; collate and analyse feedback (descriptive statistics and thematically); create a format for proposing final priorities for follow-on research; firm up a community of practice approach or similar to take research ideas forward. Decisions will be made jointly with all EAG members.

Event 3 – Consider feedback from pilot testing; agree steps needed to finalise personal care resources; reach consensus of ideas and priorities for follow-on research and plans to take these forward; final feedback on penultimate drafts of traditional yet creative study dissemination materials; agree study recommendations; agree dissemination plan/responsibilities. Research prioritisation activities will draw on good practice principles.[41] Participants will include the PPI advisers, EAG members, study staff and partners, some study participants and family carers drawn from the wider public, (approx. 10), as well as staff representatives from across health, social care, charity sector; hospice sector, social enterprises etc (some participants may be different to Events 1 & 2). After Cycle 3 the study team will make final changes to personal care resources; disseminate the resources and other standard study dissemination outputs; prepare to take forward follow-on research plans post-study which we anticipate may include further educational intervention tool development to especially meet the needs of diverse carers, drawing on complex intervention development, evaluation and implementation guidance.[42] Decisions will be made jointly with all EAG members.

Linkages across Work Packages 1-3: To ensure each WP is well executed, we have allocated a dedicated lead to each as well as the joint Co-PIs having a helicopter view over all WPs. We will employ regular inter-WP meetings to communicate effectively within and between WPs and make full use of the EAG in overseeing the approaches we take. In this way we expect a cohesive approach whereby WPs operate separately but are not dis-connected in a negative way. It is essential that we avoid the potential pitfalls of not having robust plans to manage the inter-relatedness of the WPs.

We also recognise the need to synthesize the findings from WPs 1 and 2 and present these in such a way as to be useful in WP3. Indeed, WP3 is itself part of the synthesis as the evaluation findings from the pilot testing in WP3 form part of our overall study findings. Our sequential analysis approach will be helpful as one method informs the other (e.g. survey first and then this informs our topic guides for interviews). Following this 'development' aspect of the mixed methods, the findings from the survey and interviews will be triangulated to inform WP3.

Data synthesis will be further enhanced by use of 'Data Displays' as an aid to analysis. Williamson has published about her use of them during her Department of Health PHD fellowship.[9] Data displays commonly comprise matrices that permit individual and cross-case comparison of whatever phenomena is of interest (individual participants, processes, characteristics etc) and relationships between them. Use of meta-matrices can deepen analysis and matrices can include quantitative data such as frequency or subjective indicators of the strength of something (such as the degree of importance placed on a view made by a participant). Data displays may facilitate the identification of possible relationships between categories which would aid the formulation of tentative propositions and interpretation of the data. These could then guide further data gathering and will likely be refined in the light of this or be discarded.

WP leads will regularly agree displays to develop and compare their contents as a means of collaborative inquiry across WPs 1 and 2. IN WP3, data displays will be very useful for sharing as summaries of data with others such as co-production event participants, as well as being beneficial at EAG meetings.

6. STUDY SETTING

N/A

(Surveys will be primarily remote with an option for it to be administered by telephone/Zoom/Teams; interviews will be administered in a location that is convenient for the participant or by telephone/Zoom/Teams)

7. SAMPLE AND RECRUITMENT

This is described under WPs 1 and 2 above.

With regards to the survey (WP1), information for potential participants will be included at the start of the survey, and an individual's subsequent completion of the survey taken as their consent for their (anonymous) survey data to be included for use in this research.

With regards to interviews (WP2), individuals who express interest in taking part will be shown or read the Participant Information Sheet and then given the opportunity to ask questions or take time to consider whether to participate, without pressure. If they do then decide to participate, they will be asked to sign a consent form, again with the opportunity to ask questions or decline at any time, before proceeding to interview. Participants will also be made aware that they may stop the interview and/or withdraw from participation at any time in the process.

8. ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Some survey and interview questions may be of a sensitive nature. This is flagged up in the Participant Information Sheets and will be repeated at the start of the interviews. Participants will be supported and encouraged to take a break or cease interviews if they become upset. We will offer to check in on participants post-interview by phone or email (according to their preferences) and a written list of places to contact for support if needed. Researchers will adhere to the University's Lone Researcher policy.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

HRA and HCRW approval is necessary as recruitment of some participants to the study will include two different NHS sites, Betsi Cadwaladr University Health Board and Midlands Partnership NHS Foundation Trust. The University of Worcester's own ethic panels are not empowered to provide ethical approval for this. In addition, the *Research for Patient Benefit Programme Welcome pack and overview of the grant holders' project monitoring responsibilities* states that:

"NIHR requires, where appropriate, evidence that an approval has been granted by the HRA... Favourable ethical approval does not need to be provided before the project starts, but will need to be in place before any patient recruitment commences."

Of significant relevance are the Mental Capacity Act (2005)[44] equalities legislation the Race Relations Amendment Act (2000)[45] the Data Protection Act (1998)[46] and the Freedom of Information Act (2000)[47]. The research team are familiar with issues around capacity to give informed consent and safeguarding and related University policy.

8.2.1 Regulatory Review & Compliance

The Association for Dementia Studies is designated as a Research Centre within the University of Worcester. Its overall governance and quality assurance systems are rigorous and set in place by the University of Worcester. We work within the legislative framework of English Law. Of particular pertinence to our work are the Mental Capacity Act (2005); equalities legislation the Race Relations Amendment Act (2000); the Data Protection Act (1998) and the Freedom of Information Act (2000). We work as professionals within the codes of conduct from the General Social Care Council, British Psychology Society and the Nursing and Midwifery Council.

8.2.2 Amendments

Amendments will be decided amongst the project management team. For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.3 Peer review

This study has undergone high quality peer review as part of the bidding process for funding. It was submitted to the NIHR RfSC (RfPB) programme, which is in two stages (outline proposal and full proposal). At both stages the study proposal was internally peer reviewed by two reviewers within the University of Worcester, as well as independent reviewers on the RfSC (RfPB) committee panel, with amendments made in line with reviewer feedback.

8.4 Patient &Public Involvement

A range of stakeholder perspectives have been sought in development of our research idea and this funding application, including partners from the hospice sector, local authority and home care, community and acute NHS and carer advocacy organisations and those that deliver dementia family carer training.

Williamson held a research prioritising event with seven family carers of people living with dementia in 2018 and a research prioritising full-day event with 14 family carers of people living with dementia in June 2019. Further 40-60 minute discussions have been held with four family carers by telephone in 2020 to inform our bid along with scoping of twitter and online forums discussing family care issues to identify discussions relating to bathing and personal care (e.g. Dementia Diaries, Carers UK Discussion Forum). One of these PPI informants, Briggs, has agreed to be a co-applicant and work with the other five Patient and Public Involvement (PPI) advisers.

Originally there was consensus that a family carer co-applicant was appropriate and that three other advisers was sufficient for a study of this size and one of these should ideally be a person living with dementia. However, we have since reflected and added an LGBTQ+ and ethnicity and cultural diversity adviser totalling six PPI advisers (5 with a family carer perspective and one with a cared for person with dementia perspective). However, there was a very strong view that study participants should only be family carers and not people living with dementia in this first exploratory study. This is to give family carers opportunity to have their unique voices heard rather than being combined with those they care for which is very common.

It was agreed that two-hour pre-project and post-project meetings of PPI advisers was a good idea to prepare then and debrief them for their roles. There was agreement that seven further PPI engagements were needed. Four of these will be at the two-hour EAG meetings alongside all of the team, collaborators and other advisers. The remaining three full-day attendances of the PPI advisers will be in the latter six months of the study to help co- create personal care resources and dissemination materials for family carers and those who work with them at three co-production events.

Views were also sought about the importance of the study, its design, focus, recruitment approaches, factors likely to affect participation, payment and other reward for PPI, dissemination, support needs (e.g. PPI training/development) and interest in further involvement if the study was funded. All preferences have been included in our PPI approach including INVOLVE rates for meeting attendance, travel reimbursement and funding for paid carers to care for a person living with dementia so the PPI advisers can attend meetings. We also costed for paid carers to care for a person living with dementia to enable co-production event attendees to attend the events.

There was overwhelming support for the study as everyone we spoke to recognised personal care as a multi- faceted and challenging aspect of caring that was little understood. It was suggested that findings would be far reaching and beneficial to huge numbers of family carers, with dementia family carers facing especial challenges unique to them. A number of interview topics were suggested for inclusion such as continence, and these will be included. PPI representatives were confident carers would be very willing to be interviewed. Their suggestion of attention to diversity during sampling has been incorporated (e.g. ensuring inclusion of ethnic and cultural diversity and LGBGTQ+ participants). There will also be an end-of-study celebration lunch as part of reward and recognition for PPI contribution.

PPI activity will be coordinated by Evans but overseen by Williamson who has contributed to development of much NIHR INVOLVE guidance on payments and PPI practices.

8.5 Protocol compliance

Protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

8.6 Data management, protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

Participants will be provided with a data privacy notice which outlines how we intend to use and store their data and that their data will be used for the stated purposes of the study. Only members of the research team will have access to the data. Data minimisation will be achieved by collecting minimal personal data.

Any face-to-face meetings (interviews) will be recorded digitally on an encrypted recording device, with recordings transferred to secure cloud-based storage on the University One Drive at the first opportunity, ready for transcription using a trusted external transcription service. Interviews conducted online meetings using Microsoft Teams will be recorded using the facilities provided on Teams, which includes an automatic transcription option. These recordings are saved to Microsoft Stream (a secure cloud-based service).

Transcripts will be checked for accuracy and anonymised through the removal of people’s names and other personal information. Where necessary, non-identifiable terms or pseudonyms will be used instead, with unique participant identification codes used in data storage. All study participants will have a code identifier known only to the research team. A key to codes will be securely stored separately. Following checking, the audio recordings will be deleted.

The transcripts will be stored electronically on computers and access will be controlled via passwords and permissions to dedicated study folders. Where it is necessary to create hard copies of transcripts or other data, then these will be securely stored in locked filing cabinets that are accessible only to research staff. Participants’ personal details (including their names and addresses) will only be used to maintain contact with participants. This will be stored separately from transcriptions and will be kept in a separate file on a password protected computer at the relevant study site. Access to data will be limited to quality control, audit, and analyses. Data shared between sponsor and co-investigators will be de-identified to minimise breach of confidentiality.

8.6.1 Home working.

We anticipate that members of the research team will work from their University offices or remotely and store electronic data on either secure One Drives, or on a hard drive on their office computer following the relevant university guidelines for home working during the pandemic~~.~~ Electronic data will not be stored using home computers. Hard (paper) copies of personal data will not be kept at home.

8.6.2 Sharing of data.

As part of the checking of transcripts, it may be necessary to share recordings between researchers or between the research team and translators. Recordings will be cloud based and can only be accessed using a secure, password-based process. Recordings will not be downloaded and will be deleted once the checking and transcribing process has been completed.

8.6.3 Reporting of data.

In reports of the work, where excerpts are quoted from interviews, any information that might lead to the identity of participants, other people or organisations being inferred will be fully anonymised.

8.6.5 Data disposal.

Recordings of online interviews will be deleted once a transcription of the meeting has been checked and agreed. Records of personal details will be securely deleted at the end of the study. All written records data will be kept for 10 years in line with University of Worcester (2013) Guidelines and Procedures for Good Research Practice. Stored information will be subject to the usual controls under the Data Protection Act 1998 and University of Worcester (2016) Policy for the effective management of research data.

8.7 Indemnity

Indemnity/insurance arrangements will be covered by the University of Worcester's Employer's Liability, Public Liability and Professional Indemnity insurance. More information and letters with policy details can be found on the University's finance pages at: https://www2.worc.ac.uk/finance/758.htm

8.8 Access to the final study dataset

The co-applicants of this project detailed at the outset of the protocol will have access to the full dataset. Any secondary analysis of the data will be permitted with consent from participants.

The co-applicants will work together to identify at what points study progress can be promoted e.g. through social media and the ADS website. It is a contractual requirement for a Chief Investigator to send a draft copy of a proposed publication (including articles, presentations and press releases) to comms@nihr.ac.uk at the same time as submission for publication or at least 28 days before the date intended for publication, whichever is earlier.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Dissemination, outputs and impact: Dissemination and Impact planning will commence early in the study but will necessarily be focused in the last six months during authentic co-production activities. Our research team is highly experienced in designing and delivering local, regional and national co-production, workshops and dissemination/consensus events. We will ensure participants are supported to attend the events and contribute during them, including people with dementia. We have costed for funding to support carers who need to pay for care at home for the person they care for so they can take part. We will have a balance of repeat or one-off event participants to meet their preferences, which will likely add balance between diverse contributions and consistency. In addition to the personal care resources we produce, accessible and creative standard study outputs will be cocreated and made available using common-place media, to best communicate findings. These materials will be freely available online along with some available in print and in printable versions for adaptation and use widely. If we identify relevant resources used in formal care settings that are relevant and of a good quality, we will raise awareness of those also, with permissions.

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. We will make good use of social media (blogs and vlogs; Facebook and twitter posts, twitter chats), online seminars/dissemination events and our partner organisations' newsletters. We will provide a plain language publication and website materials for download that summarise the study findings and any learning from the process of doing the research, including impact of PPI.43 We will publish in Open Access peer reviewed journals and professional practice journals and present at relevant conferences, along with PPI advisers. We will produce a high-quality dissemination video. We will build in evaluation mechanisms to capture who uses our study resources so we gain further feedback about their use, perceived utility and impact so we can use these insights to inform our follow on research and provide evidence of our pathways to benefit. Working closely with our study partners, we will facilitate ongoing use of the study findings and resources within Admiral Nurse training (Dementia UK), as well as within family carer education programmes provided by Tide, Alzheimer's Society and Dementia Carers Count. We will seek opportunities to embed findings within health and social care curricula through the Higher Education Dementia Network (HEDN). We will promote findings to Nursing audiences e.g. Royal College of Nursing and non-nursing audiences e.g. Royal College of OTs, the hospice sector and home care/social care sector, alongside national dementia organisations and policy makers. The study partners that we have assembled bring their wealth of knowledge from their roles and organisations they work in and understanding of how their sector works and the channels to communicate and engage people in those sectors. We have commitment from our partners to support WP3 especially and engage their wider networks through a range of mechanisms.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The final report will be written by the project team, in particular those at the Association for Dementia Studies, led by Dr Evans. Other members of the project team will contribute, revise and approve as appropriate. All authors who make a substantial contribution to the final study report will be named individually. By substantial contribution we mean (in line with guidance from the International Committee of Medical Journal Editors[64]) that they will have: *contributed to the conception or design of the work or the acquisition, analysis, or interpretation of data; helped draft or critically revise the report; had final approval of the version to be published; and agreed to be accountable for all aspects of the work.*

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Appendix 1: Crossing the Line Gantt chart

WP & TASKS ↓ PROJECT MONTH →	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Pre-project																			
Contracts and Collaboration Agreement prep	🟪																		
NHS and Social Care, University ethics applications and approval	🟪																		
Identify 6 additional PPI Advisers	🟪																		
Pre-meeting with PPI Advisers to build relationships and identify training/support needs prior to launch	🟪																		
Meetings																			
Expert Advisory Group (EAG) meetings (also at Co-pro events 1-3)		*				*					*				**		*	*	
Research team meetings monthly / weekly check-ins	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦
PPI adviser de-brief, evaluation, celebration																			🟦
WP1 - Survey																			
Survey design (with EAG /PPI input)		🟦																	
Survey distribution/data collection			🟦	🟦	🟦	🟦	🟦												
Targeted diversity recruitment/data analysis							🟦												
Transition WP 1 to 2								🟦											
WP2 - Interviews																			
Develop interview guide in light of survey findings / Produce and distribute recruitment materials									🟦										
Launch/ongoing recruitment and interviews									🟦	🟦	🟦	🟦	🟦	🟦					
Targeted diversity recruitment														🟦					
Interview transcriptions and ongoing analyses									🟦	🟦	🟦	🟦	🟦	🟦					
Overarching and final analyses															🟦				
Synthesis interview data with survey data / refresh literate review to compare findings															🟦				
WP3 - Co-production/dissemination																			
Event preparation															🟦			🟦	
Events 1& 2 – draft personal care resources and gain feedback															🟦				
Design pilot / pilot testing / analysis																🟦	🟦		
Event 3 – finalise penultimate resources, explore recommendations, future research																		🟦	
Finalise resources, recommendations, future research plans, final reporting prep																		🟦	
Design and complete dissemination materials, plan conference attendance, distribution of dissemination materials																		🟦	🟦
Evaluate study conduct – key learning and plan community of practice/learning, plan next steps																		🟦	🟦

Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.