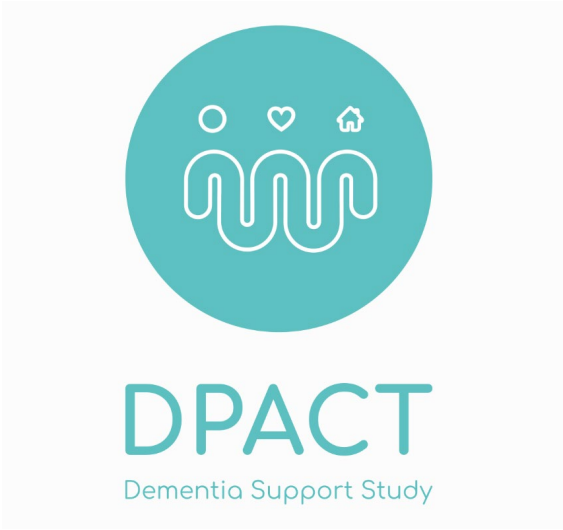
Health Research Authority



FULL/LONG TITLE OF THE STUDY
Dementia Person Aligned Care Team – Dementia Support Study

SHORT STUDY TITLE / ACRONYM

DPACT Dementia Support Study

PROTOCOL VERSION NUMBER AND DATE

Version 2.1 05 June 2019

RESEARCH REFERENCE NUMBERS

IRAS Number:	264596
SPONSORS Number:	Devon NHS Partnership Trust
FUNDERS Number:	RP-PG-0217-20004

This protocol has regard for the HRA guidance.

DPACT

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 publically 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:
23/04/2019

Name (please print):

Tobit Emmens

Position:

Managing Partner, Research & Development, Devon Partnership NHS Trust (DPT)

Chief Investigator:

Date:
23/04/2019

Name: (please print):

Richard Byng

DPACT

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KEY STUDY CONTACTS

Chief Investigator	Professor Richard Byng Professor in Primary Care Research/PenCLAHRC Deputy Director Community and Primary Care Research Group NIHR CLAHRC South West Peninsula (PenCLAHRC) Faculty of Medicine and Dentistry University of Plymouth Room N14, ITTC Building, Plymouth Science Park, Derriford, Plymouth, Devon, PL6 8BX
Study Co-ordinator	Dr Val Mann Community and Primary Care Research Group NIHR CLAHRC South West Peninsula (PenCLAHRC) Faculty of Medicine and Dentistry University of Plymouth Room N14, ITTC Building, Plymouth Science Park, Derriford, Plymouth, Devon, PL6 8BX
Sponsor Sponsor Main Contact	Ms Sarah Brampton on behalf of Devon NHS Partnership Trust (DPT) Tobit Emmens Managing Partner, Research & Development, Devon Partnership NHS Trust (DPT) Wonford House Dryden Road Exeter EX2 5AF
Sub-contractor	University of Plymouth A higher education corporation of Drake Circus, Plymouth, Devon PL4 8AA.
Funder(s)	NIHR PGfAR
Key Protocol Contributors	N/A
Committees	See Appendix 1 Programme Steering Committee

DPACT

STUDY SUMMARY

The Dementia Person Aligned Care Team Programme (DPACT) is a National Institute of Health Research (NIHR) Programme Grant for Applied Research (PGfAR) funded programme that aims to determine the most effective deployment of dementia support personnel in primary care in order to:

- Maintain the health and wellbeing of **people with dementia and their carers/families** through a person centred approach to care delivery.
- Facilitate proactive anticipatory care and therefore shift costs from acute unplanned admissions to community-based provision in an overall affordable model of care.

This five year programme consists of two main phases of work across two UK sites, South West (Devon Partnership Trust) and North West (Cheshire and Wirral Partnership Trust). Phase 1 (years 1 and 2) consists of the developmental work which includes a feasibility study which will go on to inform a cluster randomised control trial (cRCT) in Phase 2 (years 3-5). The initial developmental Phase 1 will test the uncertainties around the optimal components of a primary care based dementia support intervention, and the uncertainties of trial science methodology in relation to recruitment and appropriateness of outcome measures for people with dementia and their carers. Patient and Public Involvement (PPI) will meaningfully inform and critique the research process through a Peer Research Group (PRG) formed of people with dementia and their carers, from a diverse range of community groups that include dyads - partner and sandwich carers. The Peer Research Group will work in collaboration with the research team on intervention development, research materials, documentation and dissemination throughout the programme.

This HRA application applies to the Phase 1 developmental work and feasibility study. The protocol for a full cRCT (Phase 2) will be the subject of a second application, which will incorporate the learning from the developmental work and the feasibility study.

Developmental Phase 1 (Nov 2018 – Nov 2020)

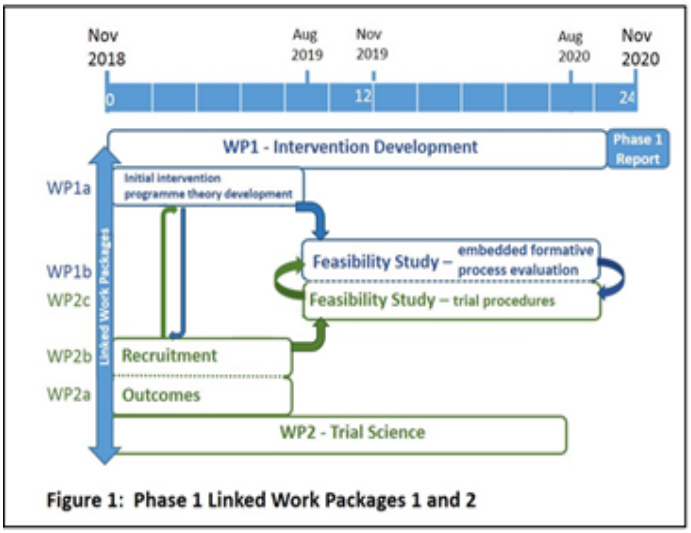


Figure 1: Phase 1 Linked Work Packages 1 and 2

The developmental phase will involve an iterative process to intervention delivery and trial science, exploring what works for whom, where, why, when and how with co-production with the Peer Research Group. Phase 1 consists of two parallel linked work packages (WPs) as shown in Figure 1. While theoretically separate, WP1 and WP2 involve the same practices and patients and carers in a single feasibility study with data collection which will inform analyses in each work package.

Work Package 1 (WP1) Intervention Development: development of a theoretically sound and practically feasible multidisciplinary complex intervention based in primary care for improving wellbeing and health-related quality of life for people with dementia and their carers/families.

Work Package 2 (WP2) Trial Science Development: this work package will focus on key interrelated issues of **a)** outcomes to be measured **b)** inclusion exclusion criteria and **c)** recruitment procedures for primary care based studies for people with dementia and their carers. We will test some of the uncertainties around these parameters in the Feasibility Study.

These two theoretical work packages will be operationalised as one feasibility study with individuals recruited from each contributing to both intervention development (WP1) and trial science (WP2).

The Feasibility Study will therefore contribute to WP1 supporting theoretical development of the intervention and specifically aims to assess:

a) the extent to which the intervention can be put into practice

b) what is required to support delivery

c) how the intervention and its delivery can be optimised.

The Feasibility Study will also contribute to WP2 and will test the recruitment and retention strategies along with other trial procedures and outcome measure collection.

The Feasibility Study will occur at eight **GP practices** (n=4 in the South West and n=4 in the North West sites). The aim is to recruit approximately 55 participants per site (n=110 participants in total). Up to 500 individuals may need to be approached in order to recruit these participants.

A report based on the findings will inform whether the programme should proceed to a full trial.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
NIHR PGfAR	£2,744,820.00
Alzheimer's Society	In kind support via Partnership Agreement

ROLE OF STUDY SPONSOR AND FUNDER

DPT has entered into a Contract with the funder NIHR in relation to the Project. DPT has decided to sub-contract some of its obligations under the Contract to the University of Plymouth. The University of Plymouth has agreed to perform such obligations in accordance with the terms and conditions of a sub-contract agreement (Appendix 1).

The Sponsor (DPT) and Sub-contractor (University of Plymouth) and Collaborating Partners (University of Manchester; University of Exeter; City, University of London; Newcastle University; London School of Economics and Political Science; Peninsula Clinical Trials Unit) will work collaboratively in the delivery of the programme in accordance with the terms and conditions of the partners' collaboration agreement (Appendix 2).

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Committees and groups involved in study coordination and conduct

Independent Programme Steering Group

Function: to strengthen and assure research governance arrangements.

Membership:

Independent Chair: Professor Steve Iliffe, Emeritus Professor of Primary Care for Older People, University College London.

Independent Member: Professor Jill Manthorpe, Director, Social Care Workforce Unit, Kings College London.

Independent Member (Statistician): Dr Kimberley Goldsmith, Senior Lecturer in Medical Statistics, Kings College London.

Independent Member (PPI Representative): Mrs Hilary Doxford.

Project Board (also known as the Study Group)

Function: All significant operational matters relating to the Project will be decided upon by the Board which shall also put in place any structure to manage the Project that it agrees.

Membership: Each collaborator will appoint one individual to the Board. In addition each collaborator shall be entitled, but not bound, to appoint an additional individual to the Board to act as an observer. An observer appointed in such a manner shall be entitled to attend, but not vote, at meetings of the Board.

Professor Richard Byng will be the Chairman (also known as Chief Investigator) or such other individual as agreed by the sponsor and the project team. The Project Leader (also known as Programme Manager) (Dr Val Mann) will attend Board meetings at the request of the Chairman; be the primary contact for and with the Funder; be accountable to the Steering Group for the day-to-day management of the Project; be responsible for implementing decisions taken by the Board; and monitor the progress of the Project with respect to milestones and deliverables.

Expert Review Group

Function: The Expert Review Group (ERG) will be updated by the research team as to progress in relation to the programme. They will be updated as to the work of the Peer Research Group (PRG see below) and representatives from the PRG will attend ERG meetings and be given protected time within those meetings to discuss key issues.

The ERG will discuss and critique the prototype intervention before its delivery in the feasibility study trial. They will reflect on the analysis of the intervention and discuss issues in relation to trial science (inclusion, exclusion, outcomes). The ERG will discuss the formative process evaluation and suggest changes prior to Phase 2.

Membership: representatives from stakeholder organisations and/or people involved in dementia care (Appendix 3 for invited members).

PPI- Peer Research Group

Function: PPI will meaningfully inform and critique the research process through a Peer Research Group (PRG). The co-research with PRG will assist to shape intervention development and comment on material for trial science. The PRG input is interwoven throughout Phase 1 and Phase 2 of the programme.

Membership: people with a diagnosis of dementia with and/or without a care partner: people who are carers for or former carers of a person with a diagnosis of dementia.

Study Management

Professor Richard Byng will take overall lead and responsibility for managing the programme. Dr Paul Clarkson North West site lead and the programme manager Dr Val Mann will support both. Day to day running of the project will involve these three along with a Research Fellow at each site (South West and North West). The research team are working in Partnership with the Peninsula Clinical Trials Unit (PenCTU) who will provide Trial Management.

PROTOCOL CONTRIBUTORS

The following individuals have contributed to the Protocol being named as co-applicants in the application to the NIHR and contribute to the collaborative programme team. PPI have had and will continue to have input.

Name	Host Institution	
Professor Richard Byng	University of Plymouth	Principal Investigator who will lead research, and work with leads for each component to ensure delivery and coherence.
Dr Antonieta Medina-Lara	University of Exeter	Lead Health Economics.
Dr Cath Quinn	University of Plymouth	Co-lead qualitative analysis and lead theory development. Advise on PPI.
Dr Iain Lang	University of Exeter	Co-lead implementation work package and provide Dementia expertise.
Dr Michael Clark	London School of Economics	Provide social care dementia expertise lead, and support the North West site.
Dr Obioha Ukoumunne	University of Exeter	Support statistics, providing expertise on cluster trials.
Dr Val Mann	University of Plymouth	Project manage programme.
Mr Ian Kenneth Grant Sherriff	University of Plymouth	Provide expertise on dementia care, advocacy for individuals with dementia and carers, support dissemination.
Dr Paul Clarkson	University of Manchester	Lead Manchester site, provide dementia trials and dementia care expertise.
Mrs Siobhan Creanor	University of Plymouth	Lead statistics, provide trials expertise, oversee main trial via CTU role.
Mrs Dorothy Tudor	Independent	Carer for partner with Dementia – inform intervention actively involved in Expert Review Group and Peer Research Group.
Professor William Rodney Sheaff	University of Plymouth	Provide dementia expertise from psychiatric perspective and support implementation.
Dr James Fullam	University of Exeter	Intervention and trial science development.
Professor Louise Robinson	Newcastle University	Provide expertise in dementia and primary care. Support intervention development.
Professor Rose McCabe	City, University of London	Provide qualitative methodological expertise in interactional analyses and intervention design.

Mr Tobit Emmens	Managing Partner, Research & Development, Devon Partnership NHS Trust	
Ms Ashley Wilkie	Research and Development Manager, Occupational Therapist, Research and Development Team	
Nicola Walker	Clinical Lead for Research Research & Development, Devon Partnership NHS Trust	

KEY WORDS: Dementia; primary and community care; carers; person centred care; anticipatory care.

Dementia Person Aligned Care Team - DPACT

BACKGROUND AND RATIONALE

The term Dementia describes a progressive set of symptoms that includes loss of short-term memory and problem solving ability, communication problems and loss of visuospatial skills. In most cases dementia syndrome is the result of an underlying neurodegenerative condition such as Alzheimer's Disease. Currently, over 850,000 people in the UK live with dementia and if the prevalence of dementia remains the same this number is predicted to increase to 1,142,677 by 2025[1]. The overall economic impact of dementia in the UK is £26.3 billion with two thirds of this cost being borne by people living with dementia and their families[2]. With the risk of developing dementia increasing with age, rising from 1 in 14 individuals age 65 to 1 in 6 individuals age 85[2] and with 72% of individuals who have dementia also living with another medical condition or disability, our growing elderly population will have a significant impact on NHS services.

The Department of Health policy paper sets out the need to "deliver integrated and effective services that meet the needs of people with dementia and their families and carers"[3]. With an ambition to ensure that appropriate evidence is available across health and social care on best practice in post-diagnostic care"[3]. Feedback from people with dementia and carers suggests that current access to post-diagnostic dementia support and the model of support provided is extremely variable. People with dementia and their carers often find access to support services stressful and challenging, and describe the "maze" like services landscape, the limited remits of individual services and the need to fight to make headway[4]. People with dementia and carers themselves have identified that access to a single person, to aid in coordination of care, throughout the dementia trajectory is strongly desired[5,6].

There are currently a number of dementia support worker type roles for individuals with dementia and their carers that have been developed to achieve a variety of aims from signposting to services, emotional support through to admission prevention. These support worker roles include dementia advisors, case managers, care workers, dementia support workers (DSW), memory nurses, admiral nurses, dementia navigators and dementia practitioners. The distinction between the various types of dementia support roles is often unclear and while some provide active liaison between primary, secondary and social care, this function is not universal.

A recent extensive systematic review of 36 studies investigating the effectiveness of the range of support worker roles concluded that there is still a need for high quality studies that identify which components of support produce the most valuable outcomes for people with dementia and their carers along with a need for a cost effectiveness evaluation[7].

Proactive medical care, especially for those who are house bound, is often suboptimal and individuals with dementia can end up being admitted in crisis, often out of hours. Current policy calls for GPs to play a leading role in coordination and continuity of care for people with dementia[8] and guidelines call for coordinated delivery of health and social care that is dynamic, responsive and endorsed by people with dementia and their carers[9]. However, GP services are under strain and it is unlikely that they have the capacity to fulfil these functions without further additional support.

The primary care setting is familiar for people with dementia resulting in less anxiety for attendance and is often more accessible for hard to reach and rural communities. As well as requiring emotional and practical support, people with dementia and their carers require support to engage in anticipatory care planning, improve the management of comorbid medical conditions and to plan for and appropriately manage medical

admissions in the final stages of their dementia and end of life care. General practices incorporated in extended primary care teams have the potential to be central to delivery of integrated care and ensure that physical care is optimised, including anticipatory care with emotional and social care. There are a number of issues that need to be addressed in order to ensure services are equally accessible to and supportive of people with dementia and their carers.
Specific questions therefore include:

- What does good post-diagnostic dementia care look like and how best does it effectively support a person with dementia and their carer?

- Would a post-diagnostic dementia support role embedded within GP practices or in the community promote “living well with dementia”?

Primary care, being a trusted source of continuity across an individual’s lifespan, would seem to be an obvious setting for health research however there are uncertainties as to how individuals with dementia and their carers can be recruited to primary care based trials. Previous primary care based trials have struggled to recruit individuals with dementia who may benefit, with trials failing or being less generalizable due to small proportions of those in need being recruited. There is no established recruitment method and no systematic studies testing strategies to overcome the problems of frailty, cognitive deficit, lack of motivation, anxiety and social exclusion experienced by people with dementia with or without carers. All of which are likely to mean that individuals with dementia normally do not respond to written offers of involvement in research.
The key overarching question is therefore:

- What is the optimal model of engagement of participants from underserved populations with primary care research?

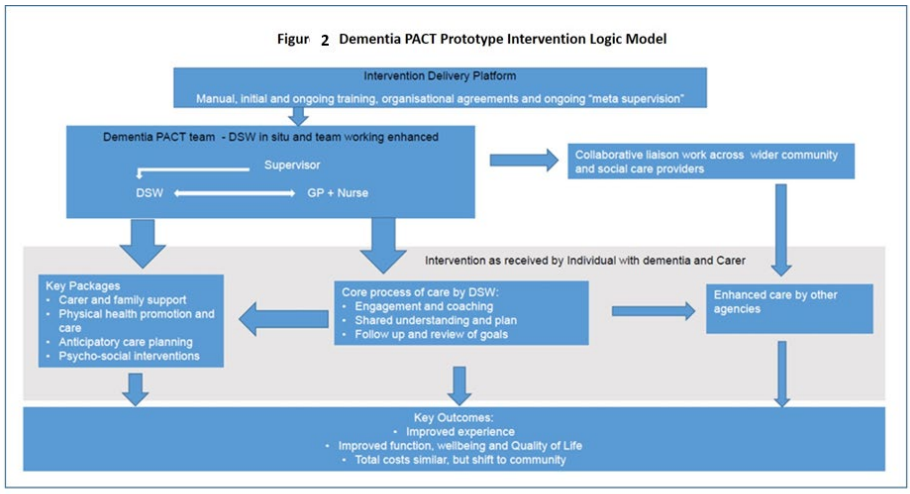
Outcome measures used in any evaluation need to reflect both the needs of participants and the potential for the intervention to reduce these needs (improve outcomes). While we propose support for a person with dementia and their carers is potentially justified on the basis of benefit to them, the cost per person also has the potential to be recouped through reduction in admissions due to the anticipatory care function of the proposed intervention.

The focus on cognitive performance in dementia trials in the last decades has been at the expense of research into outcome measures which are more likely to be important to a person with dementia and carer such as health related quality of life and functionality. A range of outcomes have been included in previous trials of models of support for people with dementia: (i) carer specific outcomes including: carer burden, health-related quality of life, social support, access to community services, depressive symptoms, general health and personal wellbeing. (ii) person with dementia outcomes including: symptom severity, institutionalisation rates, health-related quality of life, depressive symptoms and personal wellbeing[10]. Participant admission to homes[11], medicine optimisation[12], comprehensive cost-effectiveness evaluation[13,14], and cost utility analysis with a societal perspective[15,16] have been advocated.
Specific questions therefore include:

- Which aspects of support worker roles produce beneficial outcomes for a person with dementia, carers and health services?
- What are the methodological and practical difficulties concerning outcome measurement?

THEORETICAL FRAMEWORK

Figure 2 shows the overarching logic model for the intervention. It shows both how the intervention will be put in place by the research team in collaboration with providers, as well as how the DSW will deliver person centred and coordinated care. It also includes the key anticipated outcomes which will be measured in the trial.



RESEARCH QUESTION/AIM(S)

The main aim of the five year programme is to determine the most effective deployment of dementia support personnel in primary care in order to:

- Maintain the health and wellbeing of people with dementia and their carers/families through a person centred approach to care delivery.
- Facilitate proactive anticipatory care and therefore shift costs from acute unplanned admissions to community-based provision in an overall affordable model of care.

Overarching Research Question: What is the effectiveness and cost-effectiveness of the addition of a supervised dementia support personnel role to the primary care team for improving physical healthcare, mental wellbeing and health-related quality of life, compared to treatment as usual for a person with dementia (PwD) and their carers/families following diagnosis?

This application will address the key uncertainties for Phase 1 developmental work, which will prepare for the cRCT.

Phase 1 Research Questions

In order to prepare for a cluster randomised control trial in Phase 2 of the programme, the initial developmental work in Phase 1 will focus on the following specific research questions in addition to the more general questions detailed in the background section above:

- How should people with dementia be identified, approached and consented for trial?
- What proportion of people with dementia identified are consented?
- Are any harms observed from the recruitment approach procedure?
- What outcome measures and inclusion criteria should be used in the trial?
- How many practices would be needed for a full trial?

Objectives of Phase 1

- To develop a theoretically sound and practically feasible multidisciplinary complex intervention based in primary care for improving wellbeing and health-related quality of life for people with dementia and their carers/families.
- To develop the trial science for this and other primary/community dementia care trials and to develop a cost-effectiveness framework for evaluating the intervention.

Outcomes

Key outcomes from developmental Phase 1 of study will include:

- A theoretically sound practical intervention.
- Optimal recruitment methodology.
- Outcome measures and trial protocol.

STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

Research Overview

A Feasibility Study will occur in Phase 1 where we will recruit up to 110 people with dementia (PwD) with/without carers from eight practices whose data will contribute to WP1 and WP2. This will require approaching all those whose records suggest they may or are likely to have dementia in the eight practices (with the exception of those whose lack of capacity is formally recorded in the records).

The recruitment process of practice patients is described in detail in Recruitment Section. Briefly, we will take a person centred approach to recruitment with ongoing assessment at contact points to determine: the ability of a person with dementia to participate; person with dementia carer/wider support network relationship and carer participation. The aim is to recruit those individuals most likely to benefit from the intervention in order to collect data to contribute to WP1 and WP2. This group will include those with moderate dementia related problems who may live alone and are likely to respond least well to written material.

The recruitment of practices, PwD and carers, and data collected, contribute to ongoing work for both work packages, detailed rationales and analysis plans are described in the appropriate sections below. The following section provides a detailed description of the rationale and analysis.

WP1: Intervention Development

The research programme is based on the overarching assumption that a proactive team based approach to deliver health care and address social needs is best located in general practice, but also, in keeping with recent policy, that the team work required will involve all relevant community practitioners, social care and

the third sector. Currently the proposed intervention is a prototype. It is described here in terms of generic processes of care and key components specifically relevant to dementia. The aim of WP1 is to establish a more detailed practical theory in order to ensure it is robust enough to be submitted to a trial.

Proposed intervention:
The intervention is based around innovative primary care based models for dementia (Gnosall[17], Bristol Dementia Wellbeing Service[18] and CAREDEM[5]) and the evidence informed principles for how flexible person centred and coordinated care is best delivered to individuals with complex needs which have been developed through three projects that the research team are currently undertaking. These projects are: ENGAGER 2, (collaborative care for offenders with mental health problems, near to and after prison release); PARTNERS 2 (primary care based care for psychosis); and a programme of Person-Centred Coordinated Care for multimorbidity[19,20,21]. In turn these have been influenced by models of care, such as the Chronic Disease Model[22] and its derivative Collaborative Care[23].

These general principles underpinning the process of care are:

- Engagement (between DSWs and PwD and carers). DSWs will be trained to respond to the range of cognitive abilities and emotions, simultaneously allowing use of their own prior skills to ensure engagement, trust and good communication between the three parties. Skills within the coaching approach will be taught (i.e. elicitation of individuals' goals in order to build trust and ensure that PwD, and/or carers, are motivated to engage collaboratively within the intervention).
- Development of an individual 'shared understanding' bringing together biological, social and psychological needs is core to ensuring that the intervention supports the PwD and the carer in their particular situations. This personalised approach to assessment will respond to the heterogeneity of both carers' and individuals' dementia related needs. This shared understanding and plan incorporates a simple analytic logic. The first step addresses the most important issues from the perspective of both PwD and carer, and practitioner, with the explicit potential for both parties to change their views through the interaction. The second part ensures any causal links between these issues are explored and agreed together by PwD, carers and the support workers.
- Mobilisation of resources (personal and carer strengths; practitioners; third sector and community; and health and social care) to address specific needs in a coherent individual plan. The shared plan, based on mobilisation of resources, involves an examination of the shared understanding and decisions about how to improve the current situation with specific intervention components addressing biological, social or psychological needs, and also contributing to proactive anticipatory planning of future needs.
- Proactive ongoing support is critical; this is where the specific components of collaborative care and the chronic disease model are incorporated to ensure ongoing active care with support workers and allowing for individuals to have periods where care is reduced without discharging them from the service. The coordination across services also involved with the individual is another important component of this 'delivery' function.

Organisational support to deliver the model is also critical to the success of such a collaborative approach. This includes setting up of new organisational support and a freeing up of other existing organisational protocols. For example, the DSW will be empowered to engage and make decisions with the individual and do this with support from the supervisor. This is distinct from many current support worker roles, where support workers are asked to carry out specific tasks as decided by a more senior member of staff (although DSWs are often more autonomous than other support worker roles). Other organisational support will

include agreements for the support worker to use practice records as their primary record keeping and to work as part of the general practice team, rather than following all the procedures and protocols within community mental health teams. Organisational support includes ongoing supervision by an experienced mental health professional and support from members of the general practice team. Practice nurses and GPs will receive brief education and explanation of the DSW role; integration into the practice team will involve ongoing engagement of the support worker role based on practice meetings, where the support worker is a member, and also 1-1 reviews in the practice to ensure the support worker is embedded, overcoming inevitable minor issues as they arise.

This intervention delivery will be based around the work of DSWs who will work alongside GPs and Practice Nurses, and be supervised by a secondary care professional with experience in dementia care.

The intensity of input will vary according to individual need and changes over time with a case load of 50-60 (the maximum case load associated with improvements in previous research). Initial input will create the biopsychosocial 'shared understanding' (formulation) and individualised plan for ongoing care. Based on our previous evaluation of alternative psycho-social approaches[20] coaching will be used to clarify and support goal attainment for key areas based on individual need (selected for its flexibility and informality, compared to more formal psychological approaches such as CBT or motivational interviewing). The DSWs will also signpost to and actively liaise with services responsible for additional components. They will also link people with community organisations that can play a supportive role.

While the DSW role will stop short of having control of resources (as in Case Management) there will be a strong anticipatory care function. Planning will take place with the primary care team and secondary specialists, for foreseeable problems such as carer illness and care requirements for an individual with dementia during physical illness, in order to prevent harmful admissions and to reduce the burden of unnecessary care. In addition to this overarching delivery model, components of care will be based on the needs of individuals with dementia.

The components of care include:

- communication with others and relationships
- accommodation; the home and other important places
- carer support
- physical healthcare; management of comorbid long term conditions
- anticipatory care planning: advance directives and care plans
- maintaining physical ability through healthy behaviours; exercise, nutrition
- creative activities; cognitive stimulation.

All of the potential components have an evidence base, but the evidence for the need, acceptability and practical deliverability of these components is varied. For example, the evidence for the need for anticipatory care planning is strong, but the evidence on how it should be delivered is weak. The evidence for cognitive stimulation is less strong and it is unclear as to whether it is possible to deliver it in a practical and acceptable manner. These uncertainties will be tested (WP1a) and a Programme Logic Model will be produced. Programme Logic Models support understanding causal connections, between inputs and outputs, and facilitate the testing of feasibility[24].

Key uncertainties to be addressed in Phase 1 include: a) whether to operate in care homes; b) what range of specific roles should be taken on by DSWs; c) how to ensure advocacy is balanced with integration into NHS and proactive anticipatory care; d) how to involve dementia champions; e) how to optimise the coaching approach with individual with dementia-carer dyads; f) how to link with primary and secondary care and third sector colleagues (including when care needs stepping up); g) how to ensure suitability for rural and urban context.

Phase 1 Initial Intervention Programme Theory Development (WP1a)

The intervention Theory of Change Logic Model, which will represent how change will occur, is being constructed from multiple sources of evidence. Firstly, primary care based models for dementia: Gnosall[17], Bristol Dementia Wellbeing Service[18] and CAREDEM[11]; secondly it incorporates overarching principles of person centred complex care for complex needs, that we have developed in three projects[27,28,29]; thirdly, it will incorporate the dementia specific components. The Model will be used to inform data collection and analysis. The model is being developed via analysis of reviews and key evidence, including grey literature, in relation to person centred or primary care based dementia care. We are not carrying out a full systematic review but anticipate extracting key knowledge from reviews and sometimes primary articles for the dementia specific components.

A complementary Programme Logic Model, detailing resources, planned activities and outcomes over time will also be constructed using realist approaches[26] to bring together micro theories from these sources into a coherent and deliverable whole in which causal links are made explicit[32,33,34]. The emergent findings, conflicts and questions will be explored at the PRG meetings and the deeper findings will be reflected on and challenged. Known unknowns, and gaps or conflicts in the data, will be identified to inform further data collection and analysis.

The Programme Logic Model will detail both what should happen (care to be provided) and an implementation delivery platform. The latter will ensure and support delivery of this complex intervention and will include organisational agreements, training of DSWs, GPs and Nurses and Supervisors, and training materials/manuals developed to accompany these. Training for DSWs will be provided including coaching skills to support DSWs to work together and plan based on the goals of PwD and their carers. Training will also include review of recordings of practitioner interactions. The education and acquisition of skills by support workers is key to this programme. We see education as being an ongoing process for the DSWs, with training reinforced by ongoing supervision in which supervisors will employ reflective practice and revisit the manual.

While the overall theory will be consistent, the emphasis in the manual will be on components that are likely to be acceptable to the DSW (fit with current beliefs and skills) but need to be detailed explicitly, with examples of when they are likely to be useful. We have found in previous projects that having a longer detailed manual allows reflective re-reading key parts of the education and training process: alone, with the support of peers, and with supervisors.

Contrastingly the formal training will focus on skills that may not have been previously acquired by support workers, in particular coaching, with about two-thirds of the training focused on coaching skills using role play. It will also emphasise any key changes in values that have been shown to be less easily accepted by some workers (e.g. positive risk management). This approach to skills and values development will be continued following the training, with recorded sessions reflected on individually and with peers and supervisors to ensure that these difficult skills components can be fully taken on and practised to a high degree of fidelity (albeit in a flexible coaching model).

Phase 1 Feasibility Study

The Feasibility Study will collectively assess formative process evaluation[35] (WP1) and trial procedures (WP2). The Feasibility Study will occur at eight **GP practices** (n=4 in the South West and n=4 in the North West sites).

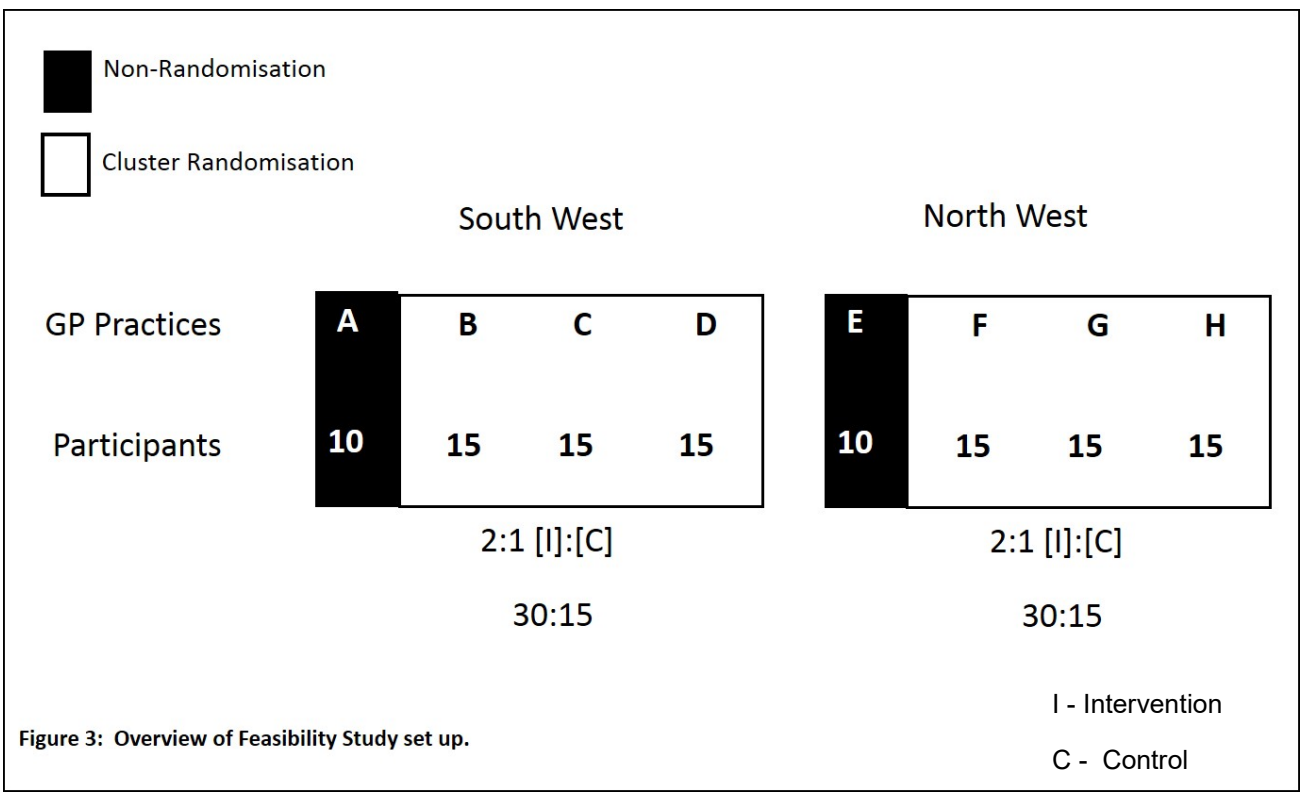


Figure 3: Overview of Feasibility Study set up.

The aim is to recruit approximately 55 participants per site (n=110 participants in total). Participants recruited from the first practice at each site will receive the DSW intervention (to allow early learning to feed into revisions to the intervention for the other practices). Cluster randomisation process will be applied to the remaining three GP practices at each site (to test acceptability of randomisation) (Fig 3).

WP1) Feasibility Study: embedded formative process evaluation (linked with trial science procedures WP2) August 2019 – August 2020.

Aim: To assess the extent to which the intervention can be put into practice, what is required to support delivery and how the intervention and its delivery can be optimised.

Participants and Setting: Non-Randomisation: 10 PwD from the first practice at each site (total 20) will be recruited and will receive the DSW intervention [non-randomisation applied] (Fig 3). This will allow early learning from the process of both training and support, as well as interactions with the practice teams and with PwD and their carers, and will be fed back into the theory of the intervention programme logic model being developed and ongoing feasibility work.

Participants and Setting: Cluster Randomisation: 30 PwD from two out of three practices at each site (total 60) will receive the intervention if randomised (2:1 ratio). This will provide sufficient experience and data to assess implementation and understand barriers and facilitators to delivery. By examining implementation over time, and carrying out ongoing analysis with rapid feedback, the intervention and our understanding of how it is working should be improved sufficiently (or be proved to be unfeasible).

Data collection and analyses

i) Up to 26 qualitative interviews[30] with practitioners and managers to collaboratively test and build the Programme Logic Model and supporting theory. Interviewees will include two DSW at each site interviewed three times each; the supervisors interviewed twice; GPs, practice nurses and managers interviewed once. Interviewees will include DSWs, supervisors, GPs, practice nurses and practice managers. Participants will also be asked about their experiences of delivering the intervention: the perceived benefits, challenges and suggested adaptations. These interviews will last around one hour. Interviews will take place at the end of the intervention testing stage for the GPs, practice nurses and practice managers. The DSWs will be interviewed at three points: after training, mid-way through the intervention delivery and at the end of the feasibility study. Interviews will be audio recorded and audio data will be orthographically transcribed and analysed using a Framework Analysis approach. NVivo software will be used to support the data organisation and analysis. All data will be stored on password protected and encrypted computers.

ii) Semi-structured, face to face interviews with 23 PwD and if relevant, their carers in each site (n=46). regarding their experiences of recruitment and the intervention (intervention participants) or their motivations for taking part (treatment as usual participants). PwD and carer participants will be interviewed separately or as dyads depending on preferences. [31] These interviews will combine use of a realist interviewing approach, to explore the emergent Programme Logic Model, and more open qualitative questions to explore previously unsurfaced salient issues (unknown unknowns). Particular attention will be paid to issues concerning PwD-carer relationships and the experiences of PwD without carers. Interviews will take place face-to-face towards the end of the intervention testing phase and will last around 45-90 minutes depending on individuals' need for breaks and levels of fatigue. A question guide will be refined prior to the interviews through analysis of the literature and consultation with the PRG and ERG. Participants will be sent a guide to the kinds of questions that will be asked prior to the interview to allow

time for reflection. Data will be orthographically transcribed, with every effort made to ensure that individuals are not identifiable in the transcript. Data will be analysed using a Framework Analysis approach. NVivo software will be used to support the data organisation and analysis. All data will be stored on password protected and encrypted computers.

iii) Audio and video interactions (n=20) between DSW and PwD/carer dyad. These will be taken earlier and later in the feasibility. Audio recordings will be used as a backup if video is not possible in some settings. Tape assisted recall (TAR) will be used to replay excerpts to DSWs and interview them to elicit their thoughts about what was happening at key points of the interaction[36].

Purposive sampling, driven by the priorities highlighted by ongoing development of the Programme Logic Model (WP1a), will direct data collection. Data from i-v) above will be analysed using framework analysis[37] to assess how different components of the intervention are working for different participants in different places. The framework columns will be constructed from the components of the intervention specified in the Programme Logic Model. Additional inductive columns and cross cutting themes will also be allowed to emerge in the analytical process. Case study analyses will also be undertaken, bringing together the various pieces of data relating to theoretically sampled individuals, to examine how the different components of the intervention interact for a range of individuals[38].

Two researchers will undertake the analyses and differences will be resolved by discussion. We will also deepen our understanding of the ongoing findings through discussions with the PRG. We know from other studies[8, 9] and from qualitative feedback from interviews that how practitioners communicate is critical to success[36]. Practitioners' communication skills are central to the delivery of this intervention and so the audio/video recordings of interactions (v) will also be micro analysed, using a low intensity method of conversation analysis[39] to examine how the DSW engages and involves the PwD and carer in setting priorities and decision making. We will analyse verbal and non-verbal communication as non-verbal communication is central in optimising participation of people with communication difficulties in interaction.

These three analyses will then be interpreted together to refine the intervention theory and Programme Logic Model (practitioner and team work actions and implementation platform) by articulating how the intervention components can generate key intermediate and more distal outcomes. The results of the analyses will be fed back in the following three stages, which we found to be effective in fine tuning the intervention and maximising the fidelity of the intervention delivery in the Engager formative evaluation[40]:

1. Iterative feedback of emergent findings at three top up training sessions with practitioners and supervisors.

2. Discussion and validation of formative evaluation data and findings at the expert review group meeting (month 18), outstanding uncertainties or conflicts will be discussed and final decisions will be made about which key components will be included in the intervention to be delivered in the main trial.

3. Further depth analysis to understand nuances in relation to communication and to understand for whom particular interventions are likely to be effective and how these should be enacted. This analysis will feed into final versions of the manual, training and supervision for the main trial.

Phase 1 Trial Science (WP2)

Phase 1 Trial Science will enable us to finalise trial design through working on key interrelated issues of a) outcomes to be measured, b) inclusion and exclusion criteria, and c) recruitment procedures. The PRG sessions will include discussions of these issues and the recruitment materials will be jointly critiqued and edited.

Key methodological aspects of large RCTs of complex interventions are still being developed and while there is general guidance[35], there is not yet consensus with regard to how outcome measures, inclusion criteria and recruitment strategies should be agreed in a logical and coherent way. The study population is highly heterogeneous in terms of both individual characteristics and carer-patient dyad characteristics, which further compounds these issues. The focus on cognitive performance in dementia trials in the last decades has been at the expense of research into outcome measures which are likely to be more important to patients and carers, e.g. health related quality of life and functionality[41]. Additionally, while issues with recruitment for dementia trials are well documented, most of the difficulties identified and amelioration strategies offered, relate to pharmacological trials rather than non-pharmacological community based trials[42].

Exploration of the literature, taking into account the experience of other national community based trials, along with primary data collection (see below) and analysis, will be used, in conjunction with the intervention logic developed, to develop inclusion and recruitment strategies. Feasibility of the study procedures will be tested. Methods for collecting resource use data for the economic evaluation will also be developed and tested in Phase 1. The timeframes for associated Phase 1 Trial Science are intended to allow for sufficient adjustment, refinement, and evaluation of study procedures and protocols prior to the full cRCT.

Trial Science Outcomes (WP2a):

Aim: To determine outcome measures for the trial.

There are a range of outcomes pertinent in a complex intervention. The choice of primary and secondary outcomes is compounded by a highly heterogeneous population. A “one size fits all” approach is unlikely to be suitable, for example, some evidence suggests that there may be differential effects of interventions based on the severity of dementia symptoms in trial participants[43]. Additionally we will need to consider the ability of the PwD, and carer if present, to complete outcome measures reliably. Methodological and practical difficulties concerning outcome measurement will be addressed by the strategy outlined below:

i) *Literature*. We will build on ongoing studies developing core outcome sets[32,44] and make decisions about outcome domains and then outcome measures. These decisions will be informed by the need to match outcome selection to the range of outcomes which could be affected by the intervention, taking into account the psychometric properties of potential measures. The existing literature will be investigated, focussing on the potential for existing measures to be used with PwD with variable capacity for self-reporting, or variable relationships with potential proxies, e.g. friends, family members or nursing home staff that do not fit the traditional characterisation of an PwD-carer dyad. We will aim to identify a primary outcome measure that maximises the range of individuals that will be eligible for inclusion. Selection of the primary outcome

measure will be important, as is the need for robust secondary measures which reflect the potential (but not yet fixed) range of pathways to improved health and wellbeing the intervention might generate.

ii) Decisions will be made in stakeholder meetings involving individuals with dementia, carers (from the PRG), practitioners and researchers. The former will be included if they have capacity to be involved in complex decisions. Individuals with dementia and carers will attend a pre-meeting and have support during the process.

Presentation of data will be made with accompanying education about trial outcomes for non researchers participating in this decision making process. Decisions will be made through a system of discussion and interrogation, with subsequent voting, as carried out in previous programmes[19,20].

- Stakeholder meeting 1 (Month 2). Potential domains to be selected will include: function, mental and physical wellbeing, health-related quality of life (HRQoL), carer HRQoL, carer mental wellbeing, experience of care, adverse events, service use (both to assess costs and to examine changes in patterns of care brought about by the intervention).
- Criteria for selection of domains: a) demonstrable need according to the literature, b) potential for intervention to make a change in the domain.
- Stakeholder meeting 2 (Month 8). Measures to represent domains selected in meeting 1 will be identified from the literature and psychometric and other properties tabulated, and a scientific assessment of suitability to be a primary measure made. The measures will be discussed, in advance by the PRG (Month 7), and representatives from the PRG will attend the stakeholder meeting to share their discussions and insights; they will be given protected time and the chair will ensure that they are able to contribute at other points. Agreement of a primary measure and key secondaries will be made.
- Criteria for selection of measures: **a)** face validity of measure; **b)** validity of measure; **c)** sensitivity to change; **d)** feasibility and burden (determined by literature and in PPI groups) **e)** the potential for completion of the measure by PwD without full-time/cohabitating carers, but who have sufficient capacity to provide meaningful data to a researcher with or without the input of a third party. The following outcome measures are potential candidates for key domains and will be collected during recruitment: functional impairment - Bristol Activities of Daily Living Scale (BADLS); behavioural and psychological symptoms – Neuro Psychiatric Inventory (NPI); dementia-related quality of life - Dementia Quality of Life scale (DEMQOL). (Our team is involved in a trial with procedures to allow proxy completion of DEMQOL (normally completed by individual) and a trial using a researcher to support PwD to complete BADLS (normally proxy completed) and we will incorporate this experience into the process).
- Measures of carer mood/wellbeing and quality of life are critical and will also be determined, with a separate similar process.

Recruitment procedure and inclusion criteria studies (WP2b):

Aim: To develop recruitment procedures and inclusion criteria.

Inclusion criteria and approach methods need to be constructed that do not exclude participants that are representative of the target population and stand to benefit from the intervention. We need to avoid waste

of resources and unnecessary burden on patients by not including those at a disease stage so mild that it precludes benefit. Inclusion criteria will require careful consideration from practical perspectives. Roughly one third of people with dementia live alone and while some may still have an active and engaged carer, it is likely that assistance received is more variable than in dyads where the carer is cohabitating. This may also influence engagement with a DSW. There is also a higher trial dropout rate associated with people with dementia with non-spousal carers. While our intention is to include such individuals in the trial, it will be necessary to explore the mechanisms of the intervention in the context of variable carer capacity and care-delivery; also the proxy reporting capacity of the carer will need to be considered with regard to valid outcome completion. This is one of the key aspects of the intervention that the PRG will be engaged with.

The second issue relates to those individuals with dementia in care homes. We have agreed with the steering group not to recruit individuals in care homes. A previous UK based trial which did not meet recruitment targets in the developmental stage attributes this failing, in part, to overly narrow inclusion criteria. Including patients attending specialist clinics and living in care homes could have both benefitted the patients and increased recruitment[5]. However the current consensus is that separate interventions are being developed which will be more suitable for those in care homes.

A third issue relates to capacity. Our previous submission was turned down in large part due to our plan to include those without capacity following Mental Capacity Act 2005 guidance. It is clear this is a contested issue nationally and we propose revisiting the possibility of involving those without capacity in a future amendment.

Fieldwork and a targeted review of the literature in relation to inclusion criteria for community based dementia trials will aid in the initial development of criteria. This work will be complementary to elements of WP1a.

Recruitment: There is a dearth of evidence to inform the design of effective recruitment strategies in this area. Existing guidance is rarely based on evidence from controlled comparison of strategies and unlikely to factor in cost-effectiveness[45]. Much of the present guidance emanates from the US, the appropriateness of which needs further exploration in the UK context. Population heterogeneity will require a recruitment strategy that is tailored and flexible, and draws strongly from the programme theory (related to engagement) developed in WP1. From the patient perspective, if the tangible components of the intervention do not reflect their needs, recruitment will suffer. The PRG will discuss potential problems and solutions as to how to engage and retain potential participants, and how the intervention and research will be presented to potential participants and participating GP practices including editing of the recruitment materials (months 1 and 2).

We will also draw on our experience of iteratively developing recruitment procedures for other vulnerable populations[20]. There is a need to ensure that individuals are provided with sufficient opportunities to make decisions about involvement. Trials recruiting those who respond most quickly will be systematically biased in their recruitment, potentially excluding by default those most likely to benefit (individuals living alone with moderate severity dementia).

In order to optimise the recruitment strategy and include individuals with dementia and carers that stand to benefit from this intervention, particularly those PwD living alone at risk of not responding to letters or attending appointments, a structured and iterative development process is proposed:

1. We will develop flexible procedures (legal, feasible and ethical) with the aim of recruiting 30-50% of individuals with dementia (identified as likely to have dementia according to registers and coding in each practice). We will test combinations of letters, telephone calls (to individuals with dementia and carers), and invitation letters building on our knowledge of recruiting vulnerable populations from primary care[20], visits (as in Care 75 plus study[46]), as well as other procedures identified in the literature and during the expert interviews. Given the lack of evidence, we will operate a test and learn approach with researchers, and participants, reflecting on every contact, revealing helpful and unhelpful strategies. Recruitment of a conservative 30% of the 0.75% of practice populations estimated to be on registers, would give 55x2=110 PwD from eight practices with lists of 6,000 (0.3 x 0.0075 x 6,000 x 8). We will assess actual proportion recruited, to inform calculation of recruitment rates anticipated for the trial.

2. We will explore ethical issues, and recruitment of individuals with dementia with and without carers (normally relied on for consent and outcomes). Consent and procedures for 10-15 PwD being recruited will be observed by supervising researchers to identify good and less good practice and to optimise procedures. We will pay attention to: ensuring a balanced involvement of carers and PwD; ensuring capacity for all decisions; helping PwD and carers understand the implications of being involved.

3. The capacity of the PwD, the carer (if present) and researcher to complete the outcome measures will need to be investigated in the target population. Guidance on the use of measures in ongoing programmes, e.g. the use of the BADLS in Effective Home Support in Dementia Care: Components, Impacts and Costs of Tertiary Prevention at The University of Manchester, will be sought and integrated into this research.

4. To determine objective cut off points for inclusion, we will investigate the use of a system combining cognitive and functional levels to categorise potentially eligible participants. We will use the MMSE and ACE III[47] for assessing level of dementia related cognitive function. An assessment of function and needs (those specified as needs to be addressed by the intervention) will also be carried out, the
BADLS will be the most likely candidate measure for this process. Each individual will have a Neuropsychiatric Inventory (NPI) and DEMQOL (Dementia Quality of Life), or DEMQOL-proxy, completed with and without the carer, if present.
Analyses of initial findings will inform decisions regarding both inclusion criteria (including level of functional and cognitive deficit) and recruitment strategy within the feasibility study (WP2c). Further refinements may be made for the full trial.

Feasibility Study: Trial procedures

Aim: To test the recruitment strategies, along with other trial procedures and outcome measure collection at baseline, in order to ensure smooth running of the main RCT. Follow up procedures will be assessed for the first half of the participants randomised. The embedded formative evaluation for the intervention is embedded within the overarching feasibility study. Eight practices will be recruited (in Aug – Sept 2019)

across the two geographical settings. Our current cluster randomised trial for psychosis care in general practice has shown willingness of practices to engage in research with the potential to provide support for a complex group of patients so we anticipate 30-50% take up if flexible approach procedures are used.

For the first practice in each site we will offer all those approached the intervention allowing us to start delivery of the intervention earlier so as to feed back learning. We will use 2:1 (Intervention: Control) randomisation of six practices (Fig 3). This will allow a higher number to receive the intervention than 1:1 ratio, ensuring adequate material to carry out the formative evaluation (WP1b). We do not believe that the 2:1 ratio will significantly affect our testing of consent and randomisation. We will aim to recruit 40% of those approached from QOF registers and to have 60 individuals from the 4 practices from the intervention arm (one DSW in each area supporting 2 practices each) and 30 from the control arm (or adjust based on WP2b). The embedded formative evaluation described above will also concurrently investigate and refine strategies of engagement with researchers to enhance retention in both arms of the cRCT through interviews with participants. Recruitment strategies may be further optimised during this phase.

We will test the feasibility of asking patients or whether someone else (the caregiver -'proxy') needs to provide the response on behalf of the patient. We will compare the responses of the patients and their proxies in order to estimate the inter-rater gap, which is the difference observed between self-report and the proxy-patient responses. A recently published systematic review found that only 19.5% (8/41) of the clinical trials in dementia or cognitive impairment interventions have collected resource use data [48]. These studies have mostly used an adapted version of the Client Service Receipt Inventory (CSRI) (http://www.pssru.ac.uk/csri/client-service-receipt-inventory/) which is what we are proposing to use. However, we are aware that the Resource Utilisation in Dementia (RUD) tool is also available [49]. We will review carefully the RUD questionnaire and assess if there are items that the CSRI have missed that are specifically intended for recording resource use with patients with dementia and carers. We have used this in PPI with patients, carers and researchers participating in clinical trials as a way of testing whether the questions are clearly presented and whether we are including redundant items or if there are important missing items.

Outputs will include analyses of: proportions of practices approached and enrolled; proportions of patients approached and enrolled; rates of recruitment per researcher time; data completion rates; patient burden; DSW burden; logistical challenges encountered by DSW; ceiling effects on the outcomes.

The statistical team will use these analyses to help inform the subsequent sample size calculation for the definitive trial along with the number of practices (clusters) and sites (areas) needed for the full cRCT. Adjustments to inclusion criteria cut offs may be made after the feasibility study. Data from piloting and formative evaluation will inform the framework for health economics analysis in the main trial.

OUTCOME MEASURES

The following outcome measures are potential candidates for key domains to be measured in the main trial: physical well-being, psychological well-being and social functioning. We will employ those as listed below both to test feasibility of collection for individuals with and without carers and to use in analyses to make decisions on inclusion criteria.

Any changes as a result of ongoing work within WP1 and WP2 will be the subject of protocol and ethics amendment.

- functional impairment - Bristol Activities of Daily Living Scale (BADLS);
- behavioural and psychological symptoms – Neuro Psychiatric Inventory (NPI);
- dementia-related quality of life - Dementia Quality of Life scale (DEMQOL and DEMQOL-Proxy).
- cognition Addenbrooke's Cognitive Examination (ACE) Mobile
- Mini-Mental State Examination (MMSE)
- Carer well-being and support questionnaire (CWS)

STUDY SETTING

The setting will be primary care (community care setting as research sites) within South West (Devon Partnership Trust) and North West (Cheshire and Wirral Partnership Trust).

SAMPLE AND RECRUITMENT

This section covers sample, recruitment and consent for the following:

1. **PwD and their carers for Phase 1**
2. **Practitioners – DSW; Supervisor; GPs, Practice Nurse; Practice Manager**

1. Person/People with Dementia (PwD) and their carer(s)

Identification and approach of potentially vulnerable individuals in the community is fraught with problems and the need to balance ethical and legal requirements. General practices, as part of extended primary care teams are currently experiencing unprecedented workloads and finding involvement in research increasingly difficult, while at the same time involving additional practitioners to care for individuals with complex needs.

Eligibility Criteria

We shall recruit people living with dementia (people with a formal diagnosis of dementia regardless of specific type) and significant cognitive problems which could indicate dementia and their carer, resident within the local authority boundary to be served. The programme also aims to investigate ways in which people with dementia without a carer can be included.

Inclusion criteria

People with a diagnosis of dementia† and/or significant memory problems and their carers‡.

†Dementia is a broad term used to describe a range of neurodegenerative disorders which may include but will not be limited to: Alzheimer's disease (AD); Late Onset Alzheimer's disease (LOAD); Early Onset Alzheimer's disease (EOAD); Vascular dementia (VAD); Mixed dementia (AD with VAD); Dementia with Lewy bodies (LBD); Frontotemporal dementia (FTD); Parkinson's disease dementia (PDD).

‡Carers in this context are defined as "the primary person who feels responsible for, and supports, the person with dementia". Inclusion criteria need to be constructed that do not exclude participants that are representative of the target population and stand to benefit most from the intervention. We need to avoid

waste of resources and unnecessary burden on patients by not including those at a disease stage so mild that it precludes benefit. Inclusion criteria will require careful consideration from practical perspectives. Roughly one third of people with dementia live alone and while some may still have an active and engaged carer, it is likely that assistance received is more variable than in dyads where the carer is cohabitating. This may also influence engagement with a Dementia Support Worker intervention. There is also a higher trial dropout rate associated with people with dementia with non-spousal carers.

While our intention is to include such individuals in the trial, it will be necessary to explore the mechanisms of the intervention in the context of variable carer capacity and care-delivery; the proxy reporting capacity of the carer will need to be considered with regard to valid outcome completion. This is one of the key aspects of the intervention that the Peer Research Group will be engaged with.

Exclusion criteria

- Those who are resident outside the local authority boundary to be served.
- Those currently undergoing emergency treatment or care.
- Those within care home setting.

Sample Numbers

Feasibility Study

We will recruit from eight practices (four in each site - South West DPT and North West CWPT) (Fig 3)

Purposive sampling approach will be used to recruit 55 people with dementia (PwD) from 4 x GP practices at each site South West and North West (n=110 PwD in total from n=8 GP practices).

- Up to 500 individuals approached.
- Up to 110 individuals recruited and completing measures (up to 80 receiving intervention)

At 1 x GP Practice per site we aim to recruit 10 people with dementia (n=20 PwD in total) all of whom will receive the intervention.

Cluster Randomisation

At 3 x GP Practices per site we aim to recruit 45 people with dementia (n=90 PwD in total). A 2:1 (Intervention [I]:Control [C]) cluster randomisation will be applied resulting in a 60:30 PwD [I]:[C]. Therefore at each site (South West and North West) 2 x GP practices with n=15 PwD per practice will receive the intervention and 1 x GP Practice with n=15 PwD will be in the control group and will receive treatment as usual.

Sample Identification

Search Process*:* Staff engaged as part of the primary care team (including embedded clinical workers employed by mental health trusts) at participating GP practices will generate a list of patients with read codes for Dementia along with symptom and problem read codes. The resultant list will be cross checked with the list of service users currently being seen in secondary care. Staff considered part of the primary care team at participating GP practices will screen list for eligibility.

Flexible approach: All eligible patients (primary and secondary) will be sent an Approach Pack (DPACT Dementia Support Study Letter; Expression of Interest Form; User Friendly Study Leaflet [with photographs of the research team]; Return Envelope).

Recruitment (Figure 4 Recruitment Flow)

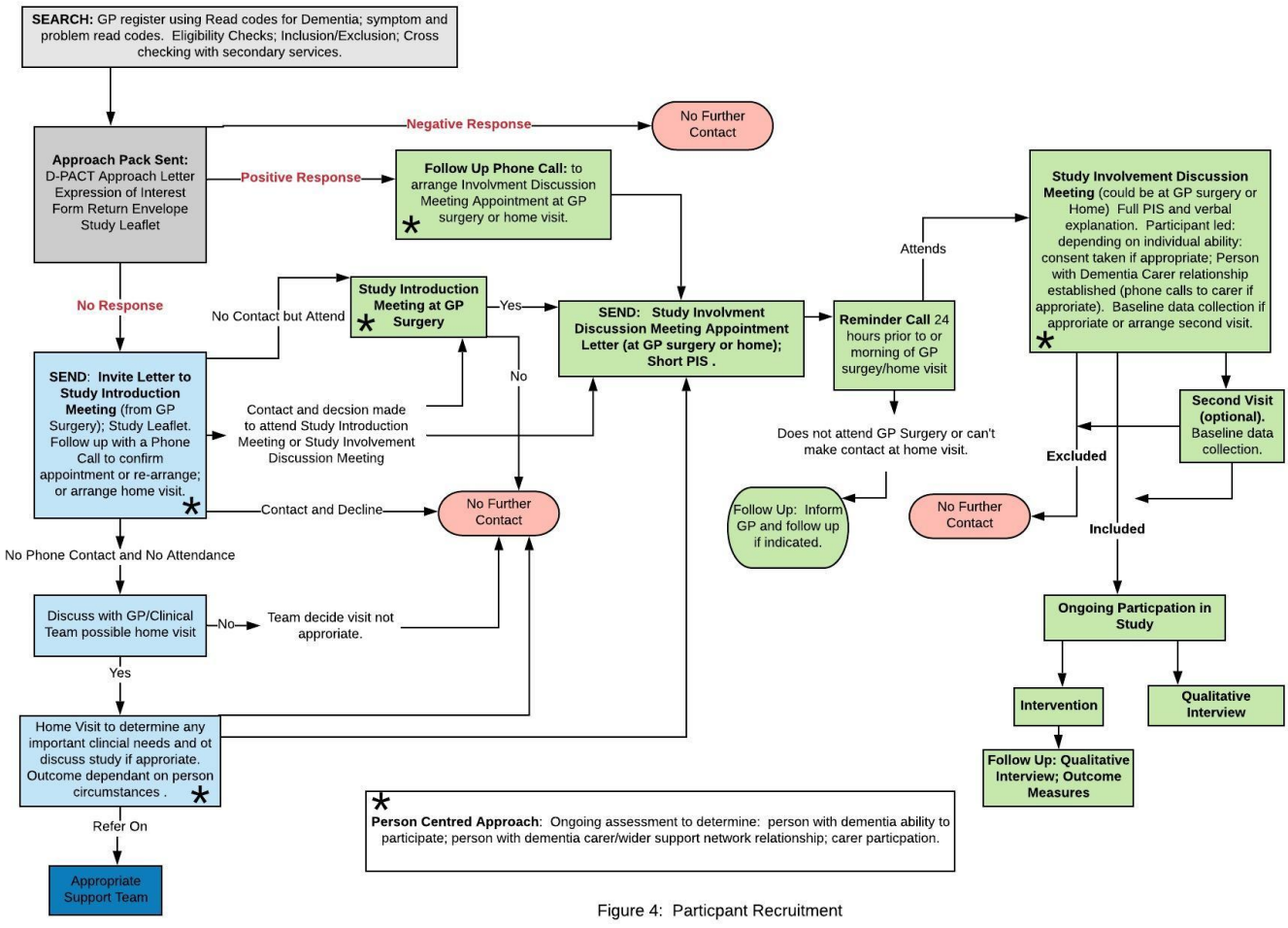


Figure 4: Particpant Recruitment

Patients will have the opportunity to respond positively or negatively to the EOI in the approach pack. The Research Team want to understand the barriers for this population in participating in the dementia support study and negative responders will receive a follow up call to determine the reason for decline. Patients who respond positively to the EOI will receive a follow up phone call in order to arrange a meeting to discuss involvement in the study. This meeting could be arranged at the GP surgery or at home depending on individual circumstances. Reminder calls will be made either 24 hours before or on the day of meeting appointment (based on individual requirements).

Individuals not responding to the approach pack will be invited to an Introduction Meeting at the practice with a set time. A follow up phone call will be made from the practice both to help engage individuals and to allow individuals to decline involvement or set up a different appointment at home or in the practice. The meeting is an introduction and would lead to a more depth meeting or no further contact.

Individuals not attending and with no contact will be discussed with the practice GPs to decide if the individual should receive a visit by staff considered part of the primary care team to assess clinical need (and also if appropriate discuss the research).

Consent

In order to minimise anxiety for an individual and to avoid multiple visits the nature of consent taking will take into account an individual's preference.

A face to face meeting with the researcher will be arranged (Study Involvement Discussion Meeting) where a full explanation of the study covering all of the essential elements: the aim, the intervention, anticipated benefits and potential disadvantages of taking part, will be explained. Researchers will stress that participation is voluntary and that the participant is free to refuse to take part and may withdraw from the study at any time. The potential participant may take the opportunity to reflect on the decision and/or discuss their participation with others outside of the site research team. If the participant agrees to take part, written consent will be obtained and depending on individual circumstances baseline measurements made or a follow up appointment arranged for the baseline data collection. The length of these meetings will be based on individuals' ability and incorporate comfort breaks where necessary for example if on consent the participant wants to go on to have baseline measurements.

Copies of the consent will be sent to the participants notes. Original signed informed consent form will be filed within the Investigator site file at the GP practice. Consent will be taken at the GP practice or other convenient location (home visit if appropriate).

Person (PwD and carers) consenting will then participate in the study as described above potentially completing baseline quantitative data, doing qualitative interviews, and receiving DSW help (and having qualitative interview about this experience).

2. Practitioners for qualitative interviews.

Once the participating GP practices have been identified, along with all key practitioners, these practitioners will be sent a letter inviting them to participate in interviews. These key practitioners are the DSWs, the supervising nurse, the GP and the practice manager. The letter will explain that for the DSWs the interviews will take place at three time points and for the other practitioners the interviews will take place once, at the end of the intervention phase. If practitioners are interested in taking part in the interviews, they will be asked to email the researchers. We will then arrange to phone them or meet in person to discuss their participation and answer any questions they have about the research. If they are then still happy to take part we will ask them to complete a consent form and return it to us in person, by post or email. We will then contact them to agree a convenient time for the interview/s.

ETHICAL AND REGULATORY CONSIDERATIONS

Potential risks and burdens for participants.

The proposed study is unlikely to present any major risks to participants involved. However, potential risks for respondents are: the additional demands placed on them in terms of completing research interviews, in giving their views and participating in discussions with researchers.

One of the key issues in this research is to ensure that the approach and consent process is practical and ethical, balancing the need to ensure individuals are both given full opportunity to be involved and also that they are not burdened or distressed by the process.

Taking part in the interviews will not impact or alter the routine care that participants may be receiving from local agencies or health care providers. The risk of harm to participants is therefore judged to be low or negligible. The intervention may result in some small changes to lifestyle expected in terms of responding to the advice given by support workers, however these will be fully discussed with the participants and any risks discussed.

The feasibility study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, 1964, amended by the 48th WMA General Assembly, Somerset West, Republic of South Africa, 1996 (website: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/).

The feasibility study will be conducted in accordance with the UK Policy framework for Health and Social Care Research 2016, the Data Protection Act 1998 and the Principles of Good Clinical Practice (GCP) The protocol will be submitted to and approved by the main Research Ethics Committee (REC) prior to circulation. Before any participants are enrolled into the trial, the Principal Investigator at each site is required to obtain local R&D approval/assurance. Sites will not be permitted to enrol participants until written confirmation of R&D approval/assurance is received by the PenCTU trials team.

It is the responsibility of the Principal Investigator to ensure that all subsequent amendments gain the necessary local approval. This does not affect the individual clinicians' responsibility to take immediate action if thought necessary to protect the health and interest of individual participants.
The study has been designed to minimise pain, discomfort, fear and any foreseeable risk in terms of the intervention. As such, we do not anticipate any major ethical issues arising during the conduct of this trial. The explicit wishes of the participant will be respected including the right to withdraw from the trial at any time and these wishes will prevail over those of science and society.
If a participant in the intervention arm withdraws from the trial they will be transferred back to usual care in accordance with Clinical Governance arrangements agreed with each site. A two month transition period back to normal care will be offered to ensure the participant and relevant practitioners decide together the nature of ongoing care after trial involvement.

Assessment and management of risk

Ongoing assessment will be made at each interview to determine person with dementia ability to participate. The research team will have a duty to inform the GP or Adult Safeguarding if they become

aware of information that indicates a risk of harm to the participant or others, or if there is evidence of abuse or malpractice by those providing care.

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

A favourable opinion will be sought from NHS REC. The application (IRAS: 264596 - May 2019) is currently under review.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

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 (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Due to the ongoing nature of the developmental phase it is likely that amendments will be required. Valid notice of amendment will be made to the REC for consideration by the research team and PenCTU.

Peer review

The programme and design were extensivly reviewed as part of the NIHR Programme Grants for Applied Reseach independent review panel.

Patient & Public Involvement

PPI were involved in the production of the application and will meaningfully inform and critique the research process through activities of the Peer Research Group (PRG) which consists of people with dementia with and without carers; carers and former carers of person with dementia working in collaboration with the research team. The Peer Research Group have had active input into the production of the research plan and research documentation and will continue to be involved in their refinement. The main focus of the PRG's work will be in Phase 1 in order to allow this contribution to have the greatest influence on and shape the intervention developed and its delivery.

The PRG will meet monthly in the early stages of development work and feedforward and feedback to the Expert Review Group (ERG). The PRG group will work closely with the research team on intervention development, research materials and documentation in preparation for cRCT. Small group and 1-1 work on key tasks will allow participation from the PRG for those who have particular needs-based knowledge

for example, recruitment issues for person with dementia who do not have carers. PRG members who still want and are able to, and other local groups, will be given the opportunity to review the findings, add additional insight where appropriate and consider how they might like to contribute to dissemination. We recognise that the trajectory of dementia, and other pressures at this time of life, might mean that those who are involved at the beginning of the research may not be able to continue their involvement throughout the Programme. In working with populations with equivalent challenges we have previously successfully used a 'top up' approach where new members are added to, and integrated into, the group at regular intervals, as required.

Protocol compliance

All trial procedures will be conducted in compliance with the protocol and according to the principles of Good Clinical Practice. Procedures specifically conducted by the CTU team (e.g. randomisation, data management, trial management and study monitoring) will be conducted in compliance with CTU standard operating procedures (SOPs). Prospective, planned deviations or waivers to the protocol will not be permitted, in accordance with UK regulations on Clinical Trials. Any protocol deviation will be documented as a Non-Compliance Report and will be monitored by the CTU and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action, and could potentially be classified as a serious breach. The PIs and the participating NHS Trusts will be required to permit the CTU trial manager or deputy to undertake trial-related monitoring to ensure compliance with the approved trial protocol and applicable SOPs, providing direct access to source data and documents as requested.

Data protection and patient confidentiality

The CTU data manager is the data custodian for the duration of the study.
Research teams at all study sites will ensure that participant confidentiality is maintained at all times. All investigators and study site staff must comply with the requirements of the Data Protection Act 1998/General Data Protection Regulation 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Acts' core principles.
Referral forms completed by clinic staff and interview questionnaires and case report forms completed by staff will be returned to research team through secure post or by hand. Any document linking participant study numbers with identifiable data, and consent forms, will be stored securely at the University of Plymouth and separate from the study data.
With the participant's consent, the participant's name and contact telephone number will be recorded by the local research team in order to carry out the qualitative interviews. This information will be stored securely at xx and be accessible only to the research staff for the purpose of conducting the follow-up. Once the study is completed, these contact details should be destroyed.
Within the CTU, pseudo-anonymised paper-based study data will be stored in locked filing cabinets within a locked office. Electronic records will be stored in a SQL Server database on a restricted access, secure server maintained by University of Plymouth. Data in the SQL Server database will be backed up as part of University of Plymouth's standard back-up process. Direct access to study data will be restricted to members of the research team and the CTU, with access granted to the Sponsor on request. Access to the database will be overseen by the CTU data manager and trial manager.
Any data transfer (e.g. from CTU to the study statistician for analysis purposes) will be done using a format and method suitable to the requirements of the data being transferred. As a minimum, data will be

secured in a password protected encrypted file and will be anonymised according to the requirements of the data transfer. All data will be transferred in accordance with the Data Protection Act/General Data Protection Regulation 2018 and PenCTU standard operating procedures (SOPs).

Indemnity

This is an NHS-sponsored research trial. If an individual suffers negligent harm as a result of participating in the trial, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an ex-gratia payment may be considered in the event of a claim.

Access to the final study dataset

Direct access to study site documentation and participants' clinical notes will be granted to authorised representatives from the Sponsor, the CTU and the regulatory authorities to permit trial-related monitoring, audits and inspections. Permission to access participants' clinical records will be explicitly requested in the Informed Consent Form for the study.

DPACT research team and collaborators will have access to the final dataset. Other interested parties (e.g. site investigators) may make a formal request to access the electronic dataset but this will be approved/declined by the CI in accordance with the Data Management Plan that will detail management of access, sharing and preservation of the data. Any use of the electronic data set must comply with the dissemination policy (see below) and be requested via Project Manager who will collaborate with the CI with regards to access. Non-digital data supporting this study are stored by the corresponding author at University of Plymouth. Only electronic data will be shared with bona fide researchers intending to use the data for non-commercial research purposes, after an embargo period of approximately 24 months.

DISSEMINATION POLICY

Results of this work will be submitted for publication in peer reviewed journals. Manuscripts will be prepared by the DPACT team and authorship will be determined by the publication policy.
Any secondary publications and presentations prepared by Investigators will be reviewed and approved by the Programme Management Group. Manuscripts will be submitted in a timely fashion and, in advance of being submitted for publication, manuscripts be reviewed and any outstanding issues resolved. Intellectual property rights will be addressed in the Clinical Trial Site Agreement between Sponsor and site.

Trial results will also be communicated to participants, healthcare professionals, the public, and other relevant groups using appropriate formats for the audience, for example, leaflets, short reports, and presentations. The protocol will be submitted for publication and will be accessible via the DPACT study website.

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