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PrAISED
Promoting Activity, Independence and Stability in Early Dementia

The Promoting Activity, Independence and Stability in Early Dementia (PrAISED) research programme is a NIHR funded project that has been designed to help people with mild cognitive impairment or early stage dementia to remain healthier and more independent for longer. We have designed an activity and exercise programme consisting of a combination of exercises, activities of daily living and memory strategies to help improve and maintain individual physical and mental health.

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The PrAISED2 Trial Implementation Sub-Study Protocol

Adams EJ[1]; Vickers R[2]; Goldberg SE [1], Cowley A[3,7], Booth V[3,7], Howe L[3], Bajwa RK[3], Smith H[4], Orton E[5], Timmins S[6], Gladman J[3,7], Masud T[3,7], Harwood RH[1,7].

Author Affiliations:

1. School of Health Sciences, University of Nottingham.
2. NIHR East Midlands Applied Research Centre (ARC).
3. Centre for Rehabilitation & Ageing Research, Unit 3 - Injury, Inflammation and Recovery Sciences, School of Medicine, University of Nottingham.
4. Nottinghamshire Healthcare NHS Foundation Trust, Nottingham
5. Division of Primary Care, School of Medicine, University of Nottingham.
6. Business School, University of Nottingham.
7. Nottingham University Hospitals NHS Trust, Nottingham.

Address for Correspondence:
Dr Emma Adams, School of Health Sciences, University of Nottingham, Queen's Medical Centre, Nottingham, NG7 2HA. Email: emma.adams@nottingham.ac.uk

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1. INTRODUCTION

1.1 THE PRAISED INTERVENTION

Our NIHR PGfAR Promoting Activity, Independence and Stability in Dementia (PrAISED) research aims to help people with early dementia stay well. Over seven years, we have theoretically and practically developed and refined a 12-month intervention to support people with dementia and their carers to remain active and independent. We have shown it to be feasible and early evidence (a return-on-investment analysis of the feasibility randomised controlled trial (RCT)) indicates that it is likely to be good value for money. Our stakeholder engagement and preliminary results from the process evaluation indicate that this intervention is well-received by patients and staff, and fills a gap in the provision of post-diagnostic support for patients diagnosed with dementia. The results of our RCT are not yet available, but we anticipate that it will be justified to adopt the PrAISED intervention, or a variant of it, in practice after the RCT.

The PrAISED research programme has anticipated post-trial adoption throughout, by co-producing the intervention with NHS staff, patients and their families, using NHS staff rather than research staff to deliver the intervention, creating training and support resources, and by studying fidelity, adaptation and reach in a process evaluation. However, we recognise the challenges of the "implementation gap" and the need to ensure that the benefits of our research for patients and healthcare services are realised widely and quickly after completion of the RCT.

1.2 THE OPPORTUNITY TO EXAMINE IMPLEMENTATION

A one-year time window (2022) is available within which there is a limited funding source (£94k) to support the implementation of the PrAISED intervention as a pilot service in one NHS Trust. Funding has been provided by NIHR (£97k) to evaluate this pilot service, evaluate related aspects of implementation (diversity in participation and long-term participation post-intervention) and prepare for dissemination and scale-up of the intervention. This protocol describes the research activities that will be undertaken to evaluate the implementation of the PrAISED intervention as a pilot service and assess aspects related to reach, adherence, sustainability and adoption. The implementation sub-study protocol is a supplement to the PrAISED2 trial, referred to in the main protocol version 2.8, 30th March 2022. This supplementary protocol for the implementation sub-study is version 4.3, 25th April 2022.

1.3 THEORETICAL FRAMEWORK

In recent decades, there has been increasing awareness of the "implementation gap" – the delay between the production of the evidence base for a new intervention and its

widespread adoption, and the failure to put research evidence into practice effectively. Alongside this growing awareness has been the development of a branch of research referred to as implementation science which is defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and hence, to improve the quality of effectiveness of health services"[1]. Implementation science research, which includes the study of implementation determinants, strategies and outcomes[2], has led to the development of many theoretical frameworks which aim to elaborate on the various elements of implementation. Such frameworks can be used to provide a comprehensive view of the factors affecting the implementation of a given intervention so that implementation failure does not result from overlooking one or more vital factors. A commonly used implementation framework is the "Consolidated Framework for Implementation Research" (CFIR)[3,4]. We have applied the CFIR to this implementation study to consider the range of implementation questions that face the PrAISED intervention as the RCT of its effectiveness draws to completion.

The CFIR is complex and generic. It posits that the factors affecting implementation can be summarised as related to five domains including the "intervention characteristics", the "inner setting", the "outer setting", "individual characteristics" and "process". The "intervention characteristics" in part refers to the evidence of its effectiveness and cost effectiveness - this will be answered by the PrAISED2 RCT – but also its adaptability, complexity, attractiveness and cost. The CFIR proposes that interventions need to be adapted, whilst fidelity is maintained, to the outer and inner settings. An example of the "outer setting" is the need for publicly funded interventions to be commissioned by those who control the payment for them – for example, in the UK this includes NHS, and health and social care commissioners, themselves sensitive to national priorities, policies and cost constraints. The "inner setting" would include the clinical services in which the intervention is delivered - in the case of PrAISED this is mental health services for older people. Clinical services differ in how they are resourced, organised and in their culture (e.g., readiness for change). "Individual characteristics" here means the features of the people who use the intervention, where factors such as acceptability and access are essential, as well as characteristics of the staff delivering the intervention, where

[1] Eccles, M.P. & Mittman, B.S. (2006) Welcome to Implementation Science, Implementation Science 1:1, doi:10.1186/1748-5908-1-1

[2] Peters, D.H., Adam, T., Alonge, O. Aggyepong, I.A. & Tran, N. (2013) Implementation Research: what it is and how to do it, BMJ, 347:f6753 doi: 10.1136/bmj.f6753

[3] https://cfirguide.org/

[4] Damschroder, L.J., Aron, D.C., Keith, R.E. et al. (2009) Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation Science, 4, 50, https://doi.org/10.1186/1748-5908-4-50

acceptability of the intervention, self-efficacy, knowledge and beliefs about the intervention are important. The "process" refers to ways in which implementation is planned (including plans for sustaining it), the degree of consultation and engagement with stakeholders, the competence of those putting the service into practice, and the degree to which lessons are learnt along the way. Across the five CFIR domains, 39 constructs[5] have been associated with effective implementation.

1.4 APPLICATION OF THE CFIR TO PRAISED: RESEARCH QUESTIONS

As the PrAISED programme moves from trial to implementation phases, the CFIR provides a framework to consider key implementation research challenges. Given CFIR's broad scope and the short time frame for this study (12 months), we do not propose to study every construct of the CFIR, only those relevant to the first steps in the translation of a research intervention to a clinical service.

Four research questions will be addressed:

1. What adaptations are required to the PrAISED intervention to deliver it in routine clinical practice? (Intervention characteristics; Inner setting; Process)
2. What factors influence diversity in the PrAISED intervention and dementia research? (Intervention characteristics; Outer setting; Inner setting; Individual characteristics)
3. What services and support are available for participants to help them maintain their activity and health once they have completed the PrAISED intervention? (Outer setting; Inner setting; Individual characteristics)
4. What implementation (spread) strategies can be used to support dissemination and scale-up of the PrAISED intervention? (Outer setting; Inner setting; Process)

Research question 1: What adaptations are required to the PrAISED intervention to deliver it in routine clinical practice?

There are two types of adaptations that may take place in transitioning the PrAISED intervention from research into practice. Firstly, there are several research processes that will need to be consciously adapted for delivery of the intervention as a service in routine clinical practice. Adaptations might include, a change from study recruitment to patient referral, changes in the way patients are informed about the intervention (the patient information sheet and consent form replaced by a patient leaflet and usual clinical practice for consent to treatment), changes in screening processes, changes in

[5] https://cfirguide.org/wp-content/uploads/2019/08/cfirconstructs.pdf

the way patient involvement and intervention delivery are documented in patient records, changes in patient communication (e.g. the timing and content of patient letters) and changes in clinical assessments. For example, in the PrAISED RCT, clinical measurements of clinical process and outcomes were gathered as part of the research process, and the tools used to do so were those justifiable on research grounds. These tools may not be used in the clinical practice in which the intervention will become embedded. Secondly, less conscious adaptations may be made to the intervention because there is less research oversight (e.g., changes in the number of therapy sessions or content), because real world pressures mean that the implemented PrAISED service will be subject to resource constraints that did not apply during the research phase, or because changes are made to fit with normal practice/service delivery or therapist preferences.

This research question aims to observe the adaptations that are made as the intervention changes from a research study to delivery in routine clinical practice. The adaptations will be explored in one NHS Trust recruited to deliver a pilot service. We will examine the changes that are made to implement the intervention in practice and consider the extent to which any adaptations might affect the reach or fidelity of the intervention tested in the RCT. Additionally, the barriers and facilitators of translating the intervention into practice experienced by the NHS team and the research team will be explored, and the opinions of clinicians/therapists based at other study sites who are not involved in the pilot service delivery will be sought.

Research question 2: What factors influence diversity in the PrAISED intervention and dementia research?

A systematic review conducted by Public Health England (2015) identified that dementia is more common in female, African-American, black-Caribbean or Hispanic individuals. There is an increased prevalence among those from lower socio-economic positions and those with learning disabilities. Little evidence was found relating to the prevalence in people with a South East Asian background. There is also little evidence available about the influence of religion and sexual orientation on the prevalence of dementia. Improving equality, diversity and inclusion within research, and consequentially healthcare, is a core principle of the NIHR and a feature of the NHS Long Term Plan[6].

The PrAISED intervention was carefully co-designed with people with dementia and therapists to ensure it was acceptable and feasible and this was tested in a feasibility

[6] https://www.longtermplan.nhs.uk/

study. Anecdotal information from the PrAISED therapists, researchers and Patient and Public Involvement and Engagement (PPIE) members identified that, although there are five intervention sites for PrAISED encompassing wide geographical areas, recruitment to the trial did not appear to be representative of the diversity that is known to be present in the areas where the sites were based. Across the study, only 2% of participants were from ethnic minority groups (3 Black, 2 South Asian and 2 Asian out of 365 participants), this compares to a population prevalence of these groups in those >60 of 8%. The participants were also likely to have less socio-economic disadvantage than the population in general: PrAISED RCT participants had a mean of 12.5 (SD 3.4) years in full time education compared to the UK mean of 9.1 years (years in education is closely correlated with socio-economic status). Thus, as the PrAISED intervention moves from trial to practice, and hence from "recruitment to a study" to "referral to a service", it is important to understand who is referred and who agrees to participate in the programme as well as the factors that influence this. This might include, but is not limited to, the recruitment/referral processes and whether the intervention design meets participants' needs and is acceptable to diverse populations.

This research question aims to explore diversity in recruitment to, and participation in, interventions such as PrAISED and in dementia research. It will use the PrAISED trial as an exemplar of a large dementia research study, to determine what may prevent engagement with more diverse groups (such as referral routes, the research process, or the intervention design). This could lead to a better understanding of how to widen participation in PrAISED and how to adapt the PrAISED intervention to suit the needs of different groups in practice, as well as how a diverse population can be better represented within similar research studies in the future.

Research question 3: What services and support are available for participants to help them maintain their activity and health once they have completed the PrAISED intervention?

The nature of the RCT design used to assess the effectiveness of interventions is that studies have a trial end point and they do not consider or control what happens after that end point. In the case of the PrAISED intervention, we hope that participants take actions to maintain their activity levels once the intervention phase is over. However, this has not yet been investigated. For the PrAISED intervention to be successfully implemented and the impact sustained, we need to explore what dementia-friendly services are available to support these activities, the exit strategy used by therapists to support long-term participation and whether patients are aware of and access opportunities to sustain their activity levels.

This research question aims to assess the exit strategy from the intervention including, for example, therapists' awareness of where patients could be signposted or referred to, the advice given to patients by therapists and suggestions for how to maintain their activity, information provided to patients about where they could go to do activity or referral to other services. In addition, this research question will seek to identify key stakeholders and organisations which support or provide existing services and initiatives for dementia patients at local, regional and national levels to help identify opportunities to promote awareness of the PrAISED intervention, and to develop strategies to support long-term participation in activities following completion of the intervention.

Research question 4: What implementation (spread) strategies can be used to support dissemination and scale-up of the PrAISED intervention?

Evidence for the effectiveness of the PrAISED intervention and value for money will be available in December 2022. The next stage of the intervention development process is to identify and develop implementation (spread) strategies which will facilitate the adoption and scale-up of the intervention in routine clinical practice or in other relevant settings, and facilitate future dissemination research.

There are several factors which need to be considered in the translation of the intervention into routine clinical practice to support implementation. These include:

- Provision of accessible intervention guidance materials – in order to support implementation and scale-up of the intervention, evidence-based intervention manuals and training will need to be provided and made available to clinical services or other relevant settings where the intervention might be delivered.
- Developing a skilled workforce - clinical services will need to develop and maintain the skills of the workforce once the research team is no longer available to provide training.
- Quality assurance and quality improvement – clinical services will need to adopt their own quality assurance and improvement mechanisms to ensure the effectiveness and efficiency of the service they provide as well as fidelity to the original evidence-based intervention.
- Funding, resources and staff capacity - The PrAISED intervention is a new intervention for people with dementia with significant resource implications and it cannot be put into widespread practice in the UK NHS without a successful commissioning process; this is likely to be similar in other countries. It is important to determine what information would be required to develop a business

case to promote future adoption of the PrAISED intervention, taking into account the needs, interests and agendas of different commissioners and stakeholders to understand the data and evidence they need to make decisions.

- Partnering with key organisations and stakeholders – healthcare services are often commissioned or delivered in partnership with other local organisations; identifying potential organisations and stakeholders who might facilitate adoption and implementation of the PrAISED intervention at a larger scale or provide services following completion of the intervention is therefore important.

This research question aims to explore these factors and develop implementation (spread) strategies for the PrAISED intervention.

1.5 FURTHER DEVELOPMENT OF THE PRAISED INTERVENTION

Drawing on the findings across all research questions, we will begin to:

- Identify factors that affect or predict implementation success
- Tailor implementation (spread) strategies and develop guidance on how the PrAISED intervention can be adapted for implementation in routine clinical or non-clinical practice
- Provide a basis for developing models and theories related to the implementation of PrAISED.

Future research opportunities will be identified which might investigate these areas in more detail and may include evaluation of the translated intervention (Research Question 1) using a hybrid type 3 effectiveness-implementation study[7], testing a variety of implementation (spread) strategies or investigating replication and adoption of the intervention in different settings or populations.

2. METHODS

We will evaluate the adaptations of the intervention required for routine clinical practice (Work package A), explore factors influencing diversity in recruitment and participation in PrAISED and dementia research (Work package B), investigate long-term engagement and participation in activity following completion of the intervention (Work package C) and assess what is needed to disseminate and scale up the PrAISED intervention (Work package D). Findings from work package (WP) A, WPB and WPC will also inform the outputs from WPD. A summary of the timelines for data collection, analysis and reporting are outlined in Table 1.

[7] Curran, G.M., Bauer, M., Mittman, B., Pyne, J.M., & Stetler, C. (2012) Effectiveness-implementation hybrid designs: combing elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care,* 50 (3), 217-226

Table 1. Summary timelines for research activities

	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
REC amendment approval	X									
WPA: Intervention adaptation										
Observing service delivery meetings		X	X	X	X	X	X			
Review of minutes/outputs/email correspondence		X	X	X	X	X	X			
Secondary data analysis							X			
Staff interviews (non-pilot delivery sites) (n=6-8)		X	X							
Staff interviews (pilot delivery site) (n=6-8)						X	X			
Interviews with research staff (n=3-5)						X	X			
WPB: Participant diversity										
Stakeholder mapping and consultation		X	X	X	X					
Data exploration and comparisons					X	X	X			
Interviews with key stakeholders (n=8-12)					X	X	X			
WPC: Long-term participation										
Staff interviews (all sites) (See WPA)		X	X	X	X	X	X			
Interviews key stakeholders/organisations (See WPD)		X	X	X						
WPD: Implementation strategies										
Update of current clinical guidelines/policy		X								
Interviews key stakeholders/organisations (n=10-15)		X	X	X						
Develop draft business case		X	X	X	X					
Consultation on draft business case (n=10-15)					X	X	X			
Implementation toolkit and website development		X	X	X	X	X	X	X		
Data analysis						X	X	X	X	
Report writing									X	
Final study report										X

2.1 WORK PACKAGE A: ADAPTATION OF THE INTERVENTION FOR ROUTINE CLINICAL PRACTICE

The objectives of this work package are to:

- Assess changes that were made to research processes to facilitate implementation of the PrAISED intervention in practice. This includes, but is not limited to, any changes in the aims of the service, training of therapists, recruitment/referral, screening processes, eligibility criteria, clinical assessments (outcomes assessed, measurement tools used and frequency of assessment), intervention dose delivered (frequency, duration and content of sessions)
- Evaluate the adaptations which are made to deliver the PrAISED intervention in routine clinical practice, assessing what was planned in the delivery of the service versus what was implemented and comparing this to the original PrAISED intervention (fidelity)
- Undertake secondary analysis of anonymised data collected by Nottinghamshire Healthcare NHS Foundation Trust as part of a pilot service to:
  - Describe the number of patients who are referred to the pilot service and their key characteristics, including gender, age on referral, ethnicity, socio-economic status, level of education and postcode area (reach)
  - Describe the number of patients who agree to participate in the programme (acceptance), the number of patients who complete the programme and the number of patients who withdraw (adherence)
  - Describe the number and duration of therapy sessions delivered to each patient (dose)
- Explore how patients are encouraged to maintain their activity levels or are referred or signposted to other services on completion of the programme
- Identify how details of the patient's involvement in the intervention are recorded in the patient's medical notes and what is recorded
- Identify the barriers and facilitators for implementing the intervention in routine clinical practice
- Assess user/patient engagement and involvement in the adaptations made to the intervention to facilitate service delivery
- Explore therapists' self-efficacy to deliver the intervention and their acceptance and satisfaction with the adapted intervention and processes
- Determine what would be required to sustain delivery of the intervention
- Explore the perspectives of the research team in transitioning from the PrAISED RCT to the PrAISED service and the barriers and facilitators which were encountered during this transition.

The CFIR domains to be assessed include the intervention characteristics, the inner setting and the implementation process.

PILOT SERVICE

One NHS Trust which took part in the main RCT will be recruited to take part in the study (Nottinghamshire Healthcare NHS Foundation Trust). The therapy team within the Trust's Mental Health Services for Older People (MHSOP) service, which includes staff who were trained for the PrAISED2 RCT, will deliver a pilot service (April 2022-November 2022). Any new staff will be trained by the research team for this pilot service. The Trust PrAISED team will be encouraged to take ownership of the intervention and make changes as necessary to deliver it as a Trust service, but may seek advice from the research team or others where required. This includes adapting the trial recruitment and screening processes to identify eligible patients, adapting eligibility criteria if necessary, developing referral mechanisms, recording clinical information and contact details, undertaking necessary clinical assessments, and developing any patient or clinician resources for use in the service and determining the approaches for recording the patient's involvement in the service in their medical records. It is anticipated that it will be possible to provide the PrAISED intervention to 20-25 patients in this pilot service. The nature of the available funding will allow a 6-month programme to be delivered only (the duration of the PrAISED programme in the RCT was 12 months). This will be adapted as the clinical team deem necessary following the principles of the intervention schedule in the RCT and the changes will be evaluated in the study outlined below. This limited implementation exercise provides an opportunity to evaluate the implementation processes to generate information to support further, and wider, implementation and future research.

MIXED METHODS STUDY

A mixed methods evaluation will be conducted to assess the adaptations made by the NHS Trust to the intervention to enable it to be delivered as a service in routine practice. We will study clinical staff and their actions as they adapt the PrAISED intervention for implementation. Data collection methods will include:

- secondary analysis of anonymised data collected by Nottinghamshire Healthcare NHS Foundation Trust as part of the service to describe the number of patients referred/screened, number of patients eligible, number of patients who agree to participate, number of patients who complete or withdraw from the service (and reasons), patient characteristics and the number and duration of therapy visits which are conducted.

- staff interviews (NHS Trust pilot site) (including clinical managers, therapists (including those who were involved in the PrAISED RCT and those who joined to deliver PrAISED as a service) (n=6-8)
- staff interviews (non-pilot sites taking part in RCT) (including clinical/research managers and therapists (n=6-8)
- staff interviews (research team who were involved in the PrAISED RCT and the transition to the PrAISED service) (n=3-5)
- observation of planning meetings and examination of the minutes and/or outputs of meetings
- reviewing any new process documents or intervention materials developed as part of the service
- review of any e-mail correspondence on which the research team are copied which discuss or outline adaptations or changes to the service.

INTERVIEWS IN PILOT SERVICE SITE

Interviews will be conducted mid- to end of the pilot service delivery (September to October 2022) to allow time for adaptations to be made; observations will take place throughout the delivery period (April to October 2022). We will use these interviews and observations to describe what the Trust planned, why they did so and whether these processes were adopted in practice, identify any service user engagement in making the changes, identify the barriers and facilitators for translating the intervention for implementation in routine clinical practice, assess therapists' self-efficacy to deliver the intervention and their acceptance and satisfaction with the adapted intervention, explore the exit strategy from the intervention to support patient participation (see WPC) and determine what would be required to sustain delivery of the intervention (see WPD). We will investigate what has been delivered by examining the number and duration of the therapist visits with patients who participate in the PrAISED pilot delivery service. The findings from interviews, observations and secondary data analysis will be collated and will be used to compare and contrast with the PrAISED RCT intervention. We will use these findings to assess the degree to which the planned service resembled the delivered service, and the degree to which either or both resembled the PrAISED RCT intervention (adaptation and fidelity).

INTERVIEWS IN NON-PILOT SERVICE SITES

A series of interviews will be conducted between May and July 2022 with clinical/ research managers and/or therapists based in the four sites that participated in the RCT but who are not attempting to deliver a pilot service (Derby, Lincoln, Bath and Oxford). This will provide a broader view of the changes that might be required to translate the PrAISED intervention into routine clinical practice in a wider range of contexts, and

provide insights into the barriers and enablers to adoption. One clinical/research manager and/or therapist from each of the four sites will be interviewed (subject to availability) (total n=6-8).

2.2 WORK PACKAGE B: DIVERSITY OF PARTICIPANTS IN PRAISED AND DEMENTIA RESEARCH

The objectives of this work package are to:

- Identify key stakeholder groups within the East Midlands
- Explore data relating to diversity within the PrAISED participants, compared to data relating to diversity in their local area
- Explore the facilitators and barriers to engaging different groups within research studies, the PrAISED intervention and other rehabilitation/exercise services.

The CFIR domains to be assessed include the intervention characteristics, outer setting, inner setting and individual characteristics.

Whilst it is acknowledged that there are a wide range of characteristics that constitute diversity, due to the short timescales for this study the research will primarily focus on ethnicity. The study will be conducted using a sequential mixed methods design, with qualitative interviews being used to explore the quantitative data in further detail.

Stage 1 (May to September 2022)

Stakeholder mapping of existing groups within the East Midlands in terms of ethnicity and dementia, through liaison with the Clinical Lead for Shared Governance and Inclusive Leadership (Aquiline Chivinge, Institute of Care Excellence, NUH), and to hold a stakeholder consultation to develop these links and explore the barriers and facilitators for accessing rehabilitation/exercise and participation in research.

Stage 2 (July to August 2022)

Diversity data from the PrAISED participant group will be compared with diversity data from national census data, data from health services for people with dementia and data from research recruitment pathways (memory assessment services, GPs, Join Dementia Outreach, expressions of interest), specific to the five PrAISED sites. This will allow a map to be generated that demonstrates how representation of different groups reduces along the recruitment pathway.

Stage 3 (September to October 2022)

Semi-structured qualitative interviews will be conducted with representatives of health services (n=2-4), research networks (Clinical Research Network or Join Dementia Research) (n=2), older people, their family members, or 'community leaders' (n=4-6). The interviews will discuss in more detail the barriers and facilitators to individuals from different ethnic groups with dementia accessing rehabilitation/exercise services such as PrAISED and participation in research.

2.3 WORK PACKAGE C: ACCESS TO LONG-TERM SUPPORT AND PARTICIPATION IN ACTIVITIES

The objectives of this work package are to:

- Explore the exit strategy from the PrAISED intervention for patients (assess the advice given to patients for ongoing support and participation through signposting or referral to other services, and explore therapists' awareness of programmes/services that could support participation)
- Identify potential strategies to maintain long-term activity following the PrAISED intervention
- Identify key stakeholders and organisations who might promote or support provision of exercise/rehabilitation services for patients with dementia
- Explore current local, regional and national initiatives and policy which support the provision of dementia-friendly exercise/rehabilitation services.

The CFIR domains to be assessed include the outer setting, the inner setting and the individual characteristics.

INTERVIEWS WITH THERAPISTS (SEE ALSO WPA)

Using the interviews with therapists involved in delivering the PrAISED RCT and or the pilot service conducted as part of WPA, the intervention exit strategy and potential strategies to maintain patients' long term activity will be explored. Topics will include how patients complete their involvement in the PrAISED intervention and any advice given to promote their ongoing activity (e.g., signposting or referral), therapists' awareness of programmes/services that could support ongoing participation and examples of other services that patients have accessed, or how they have continued their activity.

INTERVIEWS WITH KEY ORGANISATIONS AND STAKEHOLDERS (SEE ALSO WPD)

We will identify key organisations and stakeholders initially through existing contacts of the research team. These include NHS and local authority health and social care

commissioners, other funders and commissioners, and key national organisations who support or promote the implementation of interventions in those with long-term conditions such as dementia related to exercise, falls, older people or preventative care. For example, Sport England[8], Active Partnerships Network[9]; local Active Partnership organisations such as Active Partnership Trust (Derbyshire and Nottinghamshire)[10], Active Together (Leicestershire and Rutland)[11]; and the Richmond Group of Charities[12] which includes Age UK and the Alzheimer's Society. Snow-balling methods will be used to identify additional organisations and stakeholders. We will conduct interviews with key stakeholders at local, regional and national levels (May to July 2022) (see WPD). The interviews will aim to identify current support and provision of programmes and services for patients with dementia which might complement the PrAISED intervention or support the exit strategy from the PrAISED intervention, and how the PrAISED intervention might support other existing initiatives. These interviews will also be used to explore other aspects related to intervention adoption (see WPD).

2.4 WORK PACKAGE D: IMPLEMENTATION (SPREAD) STRATEGIES FOR DISSEMINATION AND SCALE-UP OF THE PRAISED INTERVENTION

The objectives of this work package are to:

- Identify new clinical guidance/policy which might impact on the content or implementation of the PrAISED intervention
- Identify how training for the intervention might be delivered by clinical services (format, content, duration) and what could be put in place to support this to maintain the skills of the workforce
- Understand barriers and facilitators for adoption of the intervention by public health and dementia services commissioners in a range of organisations
- Develop a draft business case for commissioners of the intervention and seek input from key stakeholders on its' content
- Identify implementation (spread) strategies for the PrAISED intervention.

The CFIR domains to be assessed include the outer setting, the inner setting and the implementation process.

[8] www.sportengland.org
[9] www.activepartnerships.org
[10] www.activepartnerstrust.org.uk
[11] www.active-together.org
[12] https://richmondgroupofcharities.org.uk/physical-activity

UPDATE OF CURRENT CLINICAL GUIDELINES AND POLICY

In order to update intervention materials such as the implementation manual and develop the business case, an overview of new or updated clinical guidelines and policy is required. A search will be undertaken to identify any new or updated clinical guidelines such as the NICE guidelines related to dementia, falls or physical activity, and policies relevant to the PrAISED intervention. The interviews outlined below will also be used to identify any new evidence, clinical guidelines or recent changes to practice in this field.

INTERVIEWS TO EXPLORE ADOPTION OF THE INTERVENTION

We will conduct interviews (n=10-15) with key stakeholders at local, regional and national levels including NHS and local authority health and social care commissioners, other funders and commissioners, and key national organisations who support or promote the implementation of interventions for those with long-term conditions, such as dementia related to exercise, falls, older people or preventative care (see also WPC). The interviews will be conducted between May and July 2022 and will aim to explore what would be required to promote and support adoption of the PrAISED intervention and identify barriers and facilitators for its uptake. Participants will be provided with an overview of the current PrAISED intervention prior to the interview. Interview schedules will be tailored to be relevant to the participant and may include topics such as:

- Current evidence base and existing provision (awareness of clinical guidelines or policy that support or contradict the PrAISED intervention and recent updates)
- Potential benefits of the intervention for their service/organisation, fit with strategic priorities, return on investment, fit with existing services and pathways
- Requirements for adoption of the intervention in practice (contents of the implementation toolkit)
- Barriers and facilitators for adoption of the intervention in its current format
- Future delivery of training including who should deliver the training (e.g. peer to peer training, accredited provider) and in what format (e.g. face to face, online) and duration (one longer session, or several shorter sessions); how could training be funded, supported and quality assured; could other staff be trained to deliver the intervention e.g. exercise instructors; how could workforce skills be maintained (e.g. refresher or repeat training)
- Potential for translation of the intervention to different contexts (e.g. care homes) and populations (e.g. those with other long-term conditions)
- Prompts and facilitators for clinicians/therapists and other intervention delivery staff; for example, what is the best format, could the intervention be embedded

into the electronic records system; barriers and facilitators for the implementation of the intervention in practice

- Use of a website to disseminate educational materials and resources for commissioners, clinicians, therapists/exercise instructors and patients:
  - Investment in such a resource
  - Suitability for use by commissioners, therapists/exercise instructors and patients
  - Alternative solutions
- Other key information which should be included in the business case e.g. costs (including how this would be best presented).

DEVELOPING A DRAFT BUSINESS CASE

Following these initial interviews and based on the knowledge and experience of the PrAISED intervention during the feasibility and definitive RCTs, and the results of the PrAISED research programme to date, materials for a draft generic business case will be prepared including as far as possible:

- which organisations and pathways will be affected
- how the service can deliver better outcomes and increased activity
- planned outcomes
- the evidence base
- how the intervention will fit with existing services and pathways including support for participation beyond the intervention
- implementation of the intervention including staff training
- quality assurance procedures for the intervention
- the anticipated benefits to patients, health system and wider stakeholders
- anticipated impact on waiting lists or times
- potential financial savings or costs
- patient experiences
- impact on capacity, digital and infrastructure
- impact on equality and diversity
- risks and mitigations.

CONSULTATION ON DRAFT BUSINESS CASE

The draft business case will be evaluated and further developed in a consultation process (August to October 2022). Using snow-balling methods we will identify and interview 2-3 key decision makers and commissioners for exercise, falls, older people or preventative care in each of the areas where the main PrAISED intervention has been delivered (Nottingham, Derby, Lincoln, Bath and Oxford) (Total interviews n=10-15). Interviewees

will be invited to comment upon the draft business case. The draft business case will be amended in the light of the findings of the interviews (November to December 2022).

UPDATE OF INTERVENTION MATERIALS

Intervention materials including the intervention manual, intervention documentation, training manual, training materials and promotional materials will be updated as part of work package 1 in the PrAISED RCT but will be informed by the learning in this work package.

IMPLEMENTATION TOOLKIT AND WEBSITE DEVELOPMENT

In order to facilitate future dissemination and scale-up of the PrAISED intervention in research and practice, an implementation toolkit will be developed. This may contain the intervention delivery manual, the business case, training materials and other guidance materials and documents such as patient leaflets, to support commissioning and implementation of the intervention in routine clinical practice. It is anticipated that e-tools will be developed and the toolkit will be hosted on a website. However, the feasibility and acceptability of this approach will be explored as part of this work package. In developing materials and the website, consideration will be given to diversity (e.g. providing materials in different languages), the potential international relevance of the PrAISED intervention, and how the reach and impact of PrAISED might be monitored.

2.5 DATA COLLECTION AND ANALYSIS

SECONDARY DATA ANALYSIS (WPA)

The research team will be provided with anonymised data including patient characteristics (gender, age on referral, ethnicity, age left school, estimated ability at school, further education, occupation and age of retirement, difficulty reading/writing and postcode area), dates and duration of therapists visits, and status (active, completed, withdrawn (with reason)). This data will be transferred to the University of Nottingham under an existing Data Sharing and Processing Agreement between Nottinghamshire Healthcare NHS Foundation Trust and the University of Nottingham and with approval from the Trust's Research and Evidence and Information Governance teams. The number and characteristics of patients referred to the service, who agree to participate in the service and who complete the service will be summarised using

descriptive statistics to assess reach. Details about session delivery and reasons for withdrawals will be used to describe fidelity and adherence (WPA).

OBSERVATION OF PLANNING MEETINGS (WPA)

In WPA, planning meetings regarding the pilot delivery service involving the PrAISED team at Nottinghamshire Healthcare NHS Foundation Trust will be observed (with agreement from participants) and field notes made. The researcher present will not influence any decisions being made regarding adaptations of the intervention for delivery in practice but may provide advice when asked. The researcher will record the date and time of the meeting, and number of attendees. Anonymised electronic notes will be made electronically during the meetings to collect information about decisions regarding adaptation of the intervention and the reasoning behind the decisions. These will be summarised to outline adaptations made to the service, key decisions and changes made during the service delivery period. In addition, relevant University research team meetings will be observed and anonymised electronic notes made (with agreement from participants) to record the challenges faced regarding the transition from the RCT to delivering the intervention in practice from a researcher perspective. These observations will be collected by researchers who were not part of the PrAISED RCT.

REVIEW OF DOCUMENTATION (WPA)

Minutes of meetings, e-mail correspondence and outputs (e.g. new process documentation and intervention materials) related to the pilot service delivery will be reviewed and anonymised key data extracted and recorded electronically relating to decisions made regarding adaptation of the intervention e.g. new processes and the reasoning behind the decisions.

SECONDARY DATA ANALYSIS (WPB)

The research team will analyse existing data from the main RCT to explore diversity in the PrAISED study population. This will be compared to national census data, data from health services for people with dementia and data from research recruitment pathways (memory assessment services, GPs, Join Dementia Outreach, expressions of interest), specific to the 5 PrAISED sites where available.

INTERVIEWS (WPA, WPB, WPC, WPD)

Across all work packages, interviews will be conducted via an approved online communication system (e.g. Cisco Webex) or face-to-face at a time that is convenient

for the participant, and will last between 45 and 90 minutes. They will be recorded and transcribed using the online transcribe facility, or by a University of Nottingham approved professional transcriber. Participants will be provided with an information sheet (Appendix 1) prior to the interview and will be required to give explicit written or verbal consent before the interview commences (Appendix 2). A semi-structured interview topic guide will be developed for each type of interview taking into consideration the CFIR constructs[13] that are the focus of the research question (Appendix 3). Thematic analysis will be undertaken using NVivo software and Braun and Clark's (2006)[14] approach. The CFIR will provide the analysis framework.

3. GOVERNANCE AND CONSENT

Approval from the Bradford Leeds Research Ethics Committee will be sought to undertake the research activities outlined in this supplementary protocol. All interviewees will be provided with an information sheet and be asked to give explicit verbal or written consent to participate. The PrAISED team involved in the pilot delivery service at Nottinghamshire Healthcare NHS Foundation Trust will be provided with an information sheet and consent will be obtained for researchers to observe and make anonymised notes in meetings and for meeting minutes/e-mail correspondence to be reviewed pertaining to the implementation of the PrAISED service. Information sheets and consent forms are provided in Appendix 1 and 2 respectively.

Approval to deliver the pilot clinical service has been obtained from Nottinghamshire Healthcare NHS Foundation Trust Clinical Effectiveness Committee. A service evaluation will be conducted by the Trust that will be approved by their Research and Evidence and Information Governance teams. Anonymised data for secondary analysis will be shared with the University of Nottingham under an existing Data Sharing and Processing Agreement between the Trust and the University. Data will be accessed, stored and used appropriately and only as defined by approved study protocols and/or data sharing and processing agreements.

4. MANAGEMENT

Prof Rowan Harwood will oversee the study as Chief Investigator for the PrAISED research programme. The implementation study will be led by Prof John Gladman and Prof Tahir Masud as part of the PrAISED2 RCT programme WP7 (Dissemination and

[13] https://cfirguide.org/guide/app/#/

[14] Braun, V. and Clarke, V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101

Implementation). Dr Elizabeth Orton and Prof Stephen Timmons will provide additional technical expertise and scientific critique. Professor Sarah Goldberg and Dr Emma Adams will act as Programme Managers.

A weekly study management meeting will take place. Overall direction will be via the PrAISED Programme management group, which currently meets every 6 weeks. PPIE members will contribute to the sub-study through meetings. All other aspects of the implementation sub-study will be conducted in accordance with the management and governance provisions laid out in the approved PrAISED2 Trial Protocol.

5. POTENTIAL OUTPUTS

- Publication on the adaptation of the intervention for delivery in routine clinical practice including barriers and facilitators (WPA)
- Publication on diversity in dementia research (barriers and enablers to recruitment and retention) (WPB)
- Grant application to exploring further engagement of specific groups of people with dementia in services or research dependent on the outcome of earlier stages (WPB)
- Grant application for large scale implementation and dissemination study (WPD)
- Implementation toolkit including intervention manuals, training materials and draft business case (WPD)
- Website hosting the implementation toolkit and with information for commissioners, intervention delivery staff (therapists/exercise instructors), patients and researchers (WPD)

6. ACKNOWLEDGEMENTS

This document has been reviewed by members of the PrAISED team. This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Reference Number RP-PG0614-20007). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

7. APPENDICES

APPENDIX 1. PARTICIPATION INFORMATION SHEETS (PIS)

APPENDIX 2. CONSENT FORMS

APPENDIX 3. INTERVIEW SCHEDULES (DRAFTS)

APPENDIX 1.1

WPA STAFF MEETING OBSERVATION AND DOCUMENT REVIEW PIS

PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

IRAS Reference: 236099

Participant Information Sheet (WPA Observations); Version 2.0, Dated 11-Apr-2022 NUH03004S

Principal Investigator: Professor John Gladman

Contact details

Investigator

Name: Dr Emma Adams

Contact: Emma.Adams@nottingham.ac.uk

Investigator

Name: Dr Robert Vickers

Contact: Robert.Vickers@nottingham.ac.uk

1. What is the purpose of the study?

People with memory problems can struggle with everyday activities and may stop doing things they want to do. They are more prone to accidents and have a higher risk of falling. We developed a therapy programme aimed at maintaining activity and preventing falls and have tested this in research studies, which you are or have been involved in managing or delivering. We are now exploring how this programme can be adapted for use in routine clinical practice which you are involved in managing or delivering as part of a pilot service.

We would like to observe meetings, review minutes of meetings and review e-mail correspondence in relation to the delivery of the pilot service and how this is adapted from the original programme. Anonymised information from these observations and reviews will be extracted and used to help us better understand the changes that are needed to deliver the programme in routine clinical practice.

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, Bradford Leeds Research Ethics Committee, and the Health Research Authority (HRA) Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute of Health Research (NIHR), which is part of the NHS will fund this research.

3. Why have I been asked to take part?

You have been chosen because you are currently involved in managing or delivering the pilot PrAISED service for people with memory problems.

4. Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to give consent to confirm that you understand what is involved when taking part in this study. If you decide to take part, you are free to leave the study at any time and without giving a reason.

If you withdraw, we will use the information you have already given us, unless you object.

5. What do I have to do?

You will take part in delivering the PrAISED service and activities related to this as you would normally do in routine practice. Members of the research team will observe meetings and review minutes of meetings and e-mail correspondence related to the implementation of the pilot service, as well as other outputs of meetings and discussions such as process documents or programme materials. We will make anonymised field notes to document discussions about adaptations or future planned changes to the service and any barriers or challenges that arise during delivery of the pilot service.

6. What are the possible benefits?

You may be interested in, and learn from, the experiences of others involved in delivering PrAISED. You will be contributing to research in an area of high priority and need.

7. What are the disadvantages?

Taking part will take time, but we do not anticipate any risks in taking part in this study.

8. What will happen to my data?

If you consent to take part in this study, all the information about your participation will always remain strictly confidential. The information will be held securely on paper, and electronically at the University of Nottingham under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will not be identified by name in any of the field notes recorded. If you withdraw consent from the study, your data will remain on file and will be included in the final study analysis.

In line with research guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Research information can be useful to other researchers. The research funding body (NIHR) requires us to put your data in a store (the UK Data Archive), where others can use it, in an anonymised form, which means that no-one will be able to identify or contact you if they use it.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports such in a way that no-one can work out that you took part in the study.
You can stop being part of the study at any time, without giving a reason, but we will keep the information about you that we already have.
You can find out more about how we use your information:

- via our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- by visiting www.nuh.nhs.uk/gdpr

9. What will happen if I don't want to carry on with the study?

You are free to leave the study at any time and without giving a reason. If you do not take part, or withdraw, this will not affect your involvement in PrAISED in any way.

10. What happens when the study is finished?

The results of this study will be used to further evaluate the activity and exercise programme for people with memory problems. The study results may be published in a scientific journal or presented at a conference.

The data will be anonymous and none of the people involved in the interviews will be identified in any reports or publications. Should you wish to see the results, or the publications, please ask your researcher.

11. What if there is a problem?

If you have a concern about any aspect of this study, please contact Dr Emma Adams or Dr Robert Vickers (see contact details above), who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the sponsor team. Email researchsponsor@nuh.nhs.uk, or by phoning 0115 970 9049.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

12. Further Information

You are encouraged to ask any questions you wish before, during or after the research takes place. If you have any questions about the study, please speak to your study researcher who will be able to provide you with up to date information about the study. If you require any further information or have any concerns while taking part in the study, please contact the Principal Investigator Professor John Gladman. Email: John.Gladman@nottingham.ac.uk, or by phoning 0115 823 0242

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed with the study records.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

APPENDIX 1.2

WPA STAFF INTERVEW PIS

PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

IRAS Reference: 236099

Participant Information Sheet (WPA Interviews); Version 2.0, Dated 11-Apr-2022 NUH03004S

Principal Investigator: Professor John Gladman

Contact details

Investigator

Name: Dr Emma Adams

Contact: Emma.Adams@nottingham.ac.uk

Investigator

Name: Dr Robert Vickers

Contact: Robert.Vickers@nottingham.ac.uk

1. What is the purpose of the study?

People with memory problems can struggle with everyday activities and may stop doing things they want to do. They are more prone to accidents and have a higher risk of falling. We developed a therapy programme aimed at maintaining activity and preventing falls and have tested this in research studies, which you are or have been involved in which you are or have been involved in researching, managing or delivering. Based on this experience, we are interested in your opinion of the intervention. We would like you to take part in an interview about your perspectives on adapting the activity and exercise programme into routine clinical practice. Information from these discussions will

be used to help us better understand the changes that might be needed to deliver the programme in the future.

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, Bradford Leeds Research Ethics Committee, and the Health Research Authority (HRA) Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute of Health Research (NIHR), which is part of the NHS will fund this research.

3. Why have I been asked to take part?

You have been chosen because you are currently or have been involved in managing, delivering or researching the activity and exercise programme for people with memory problems as part of the PrAISED study.

4. Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to give consent to confirm that you understand what is involved when taking part in this study. If you decide to take part, you are free to leave the study at any time and without giving a reason.

If you withdraw, we will use the information you have already given us, unless you object.

5. What do I have to do?

We will invite you to an interview, which will last 45-90 minutes, depending on how much you want to tell us. The interviews will be conducted via an online communication system or face-to-face at a time that is convenient for you.

With your agreement, the interview will be recorded. Interview recordings will be anonymised. During the interview, we will ask your opinion on the PrAISED programme, how it is being adapted or might be adapted for delivery in routine clinical practice and any problems or anticipated problems associated with this adaptation. We will also ask about how you think PrAISED could be delivered and sustained in the future.

6. What are the possible benefits?

You may be interested in, and learn from, the experiences of others involved in delivering PrAISED. You will be contributing to research in an area of high priority and need.

7. What are the disadvantages?

Taking part will take time, but we do not anticipate any risks in taking part in this study.

8. What will happen to my data?

If you consent to take part in this study, all the information about your participation will always remain strictly confidential. The information will be held securely on paper, and electronically at the University of Nottingham under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be given a study number, which will be used as a code to identify you on your interview script, and a pseudonym (false name). If you withdraw consent from the study, your data will remain on file and will be included in the final study analysis.

In line with research guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Research information can be useful to other researchers. The research funding body (NIHR) requires us to put your data in a store (the UK Data Archive), where others can use it, in an anonymised form, which means that no-one will be able to identify or contact you if they use it.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports such in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep the information about you that we already have.

You can find out more about how we use your information:

- via our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- by visiting www.nuh.nhs.uk/gdpr

9. What will happen if I don't want to carry on with the study?

You are free to leave the study at any time and without giving a reason. If you do not take part, or withdraw, this will not affect your involvement in PrAISED in any way.

10. What happens when the study is finished?

The results of this study will be used to further evaluate the activity and exercise programme for people with memory problems. The study results may be published in a scientific journal or presented at a conference.

The data will be anonymous and none of the people involved in the interviews will be identified in any reports or publications. Should you wish to see the results, or the publications, please ask your researcher.

11. What if there is a problem?

If you have a concern about any aspect of this study, please contact Dr Emma Adams or Dr Robert Vickers (see contact details above), who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the sponsor team. Email researchsponsor@nuh.nhs.uk, or by phoning 0115 970 9049.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

12. Further Information

You are encouraged to ask any questions you wish before, during or after your interview. If you have any questions about the study, please speak to your study researcher who will be able to provide you with up to date information about the study. If you require any further information or have any concerns while taking part in the study, please contact the Principal Investigator Professor John Gladman. Email: John.Gladman@nottingham.ac.uk, or by phoning 0115 823 0242

If you decide you would like to take part, please read the consent form. At the interview you will be then be asked to give verbal consent (online interviews) or sign the consent form (face-to-face interviews). You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed with the study records.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

APPENDIX 1.3

WPB STAKEHOLDER INTERVIEW (DIVERSITY) PIS

PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

IRAS Reference: 236099

Participant Information Sheet (WPB Interviews); Version 2.0, Dated 11-Apr-2022 NUH03004S

Principal Investigator: Professor John Gladman

Contact details

Investigator

Name: Rupinder Bajwa

Contact: Rupinder.Bajwa@nottingham.ac.uk

Investigator

Name: Louise Howe

Contact: Louise.Howe@nottingham.ac.uk

1. What is the purpose of the study?

People with memory problems can struggle with everyday activities and may stop doing things they want to do. They are more prone to accidents and have a higher risk of falling. We developed a therapy programme aimed at maintaining activity and preventing falls and have tested this in research studies, however participation in the research by people from different ethnic backgrounds was low. We are interested in your opinion about how we can increase the ethnic diversity of people who take part in these types of programmes and in research studies.

We would like you to take part in an interview to talk about the barriers and facilitators for accessing rehabilitation/exercise programmes, and participation in related research, for individuals with dementia from different ethnic groups. Information from these discussions will be used to help us better design the programme and research studies in the future.

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, Bradford Leeds Research Ethics Committee, and the Health Research Authority (HRA) Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute of Health Research (NIHR), which is part of the NHS will fund this research.

3. Why have I been asked to take part?

You have been chosen because you are a representative of health services or a research network, or you are an older person, or older person's family member or community leader representing different ethnic groups.

4. Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to give consent to confirm that you understand what is involved when taking part in this study. If you decide to take part, you are free to leave the study at any time and without giving a reason.

If you withdraw, we will use the information you have already given us, unless you object.

5. What do I have to do?

We will invite you to an interview, which will last 45-90 minutes, depending on how much you want to tell us. The interviews will be conducted via an online communication system or face-to-face at a time that is convenient for you.

With your agreement, the interview will be recorded. Interview recordings will be anonymised. During the interview, we will ask your opinion on the PrAISED programme, the barriers and facilitators for accessing rehabilitation/exercise programmes, and participation in related research, for individuals with dementia from different ethnic groups.

6. What are the possible benefits?

You may be interested in, and learn from, the experiences of other participants. You will be contributing to research in an area of high priority and need.

7. What are the disadvantages?

Taking part will take time, but we do not anticipate any risks in taking part in this study.

8. What will happen to my data?

If you consent to take part in this study, all the information about your participation will always remain strictly confidential. The information will be held securely on paper, and electronically at the University of Nottingham under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be given a study number, which will be used as a code to identify you on your interview script, and a pseudonym (false name). If you withdraw consent from the study, your data will remain on file and will be included in the final study analysis.

In line with research guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Research information can be useful to other researchers. The research funding body (NIHR) requires us to put your data in a store (the UK Data Archive), where others can use it, in an anonymised form, which means that no-one will be able to identify or contact you if they use it.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports such in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep the information about you that we already have.

You can find out more about how we use your information:

- via our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- by visiting www.nuh.nhs.uk/gdpr

9. What will happen if I don't want to carry on with the study?

You are free to leave the study at any time and without giving a reason. If you do not take part, or withdraw, this will not affect you in any way.

10. What happens when the study is finished?

The results of this study will be used to further evaluate the activity and exercise programme for people with memory problems. The study results may be published in a scientific journal or presented at a conference.

The data will be anonymous and none of the people involved in the interviews will be identified in any reports or publications. Should you wish to see the results, or the publications, please ask your researcher.

11. What if there is a problem?

If you have a concern about any aspect of this study, please contact Rupinder Bajwa or Louise Howe (see contact details above), who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the sponsor team. Email researchsponsor@nuh.nhs.uk, or by phoning 0115 970 9049.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

12. Further Information

You are encouraged to ask any questions you wish before, during or after your interview. If you have any questions about the study, please speak to your study researcher who will be able to provide you with up to date information about the study. If you require any further information or have any concerns while taking part in the study, please contact the Principal Investigator Professor John Gladman. Email: John.Gladman@nottingham.ac.uk, or by phoning 0115 823 0242

If you decide you would like to take part, please read the consent form. At the interview you will be asked to give verbal consent (online interviews) or sign the consent form (face-to-face interviews). You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed with the study records.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

APPENDIX 1.4

WPD STAKEHOLDER INTERVIEW (ADOPTION) PIS

PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

IRAS Reference: 236099

Participant Information Sheet (WPD Interviews); Version 2.0, Dated 11-Apr-2022 NUH03004S

Principal Investigator: Professor John Gladman

Contact details

Investigator

Name: Dr Emma Adams

Contact: Emma.Adams@nottingham.ac.uk

Investigator

Name: Dr Robert Vickers

Contact: Robert.Vickers@nottingham.ac.uk

1. What is the purpose of the study?

People with memory problems can struggle with everyday activities and may stop doing things they want to do. They are more prone to accidents and have a higher risk of falling. We developed a therapy programme aimed at maintaining activity and preventing falls and have tested this in research studies. We are now exploring how to promote uptake of the programme in health and social care and how this programme can be adapted for use in routine practice.

We would like you to take part in an interview about your experiences of commissioning, promoting, supporting, providing or delivering exercise/activity or rehabilitation programmes for those with long-term conditions, particularly dementia. Information from these discussions will be used to help us better understand the changes that are needed to promote uptake and delivery of the PrAISED programme in clinical practice and other relevant settings.

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, Bradford Leeds Research Ethics Committee, and the Health Research Authority (HRA) Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute of Health Research (NIHR), which is part of the NHS will fund this research.

3. Why have I been asked to take part?

You have been chosen because you work for or are connected with an organisation that commissions, promotes, supports, provides or delivers exercise/activity or rehabilitation programmes for people with dementia or other long-term conditions.

4. Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to give consent to confirm that you understand what is involved when taking part in this study. If you decide to take part, you are free to leave the study at any time and without giving a reason.

If you withdraw, we will use the information you have already given us, unless you object.

5. What do I have to do?

We will invite you to an interview, which will last 45-90 minutes, depending on how much you want to tell us. The interviews will be conducted via an online communication system or face-to-face at a time that is convenient for you.

With your agreement, the interview will be recorded. Interview recordings will be anonymised. During the interview, we will ask your opinion on what information is needed to support decision-makers in commissioning, promoting or providing exercise/activity or rehabilitation programmes for those with long-term conditions, particularly dementia. We will also ask about barriers and facilitators to the adoption of programmes aimed at maintaining activity and preventing falls.

6. What are the possible benefits?

You may be interested in, and learn from, the experiences of other participants. You will be contributing to research in an area of high priority and need.

7. What are the disadvantages?

Taking part will take time, but we do not anticipate any risks in taking part in this study.

8. What will happen to my data?

If you consent to take part in this study, all the information about your participation will always remain strictly confidential. The information will be held securely on paper, and electronically at the University of Nottingham under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be given a study number, which will be used as a code to identify you on your interview script, and a pseudonym (false name). If you withdraw consent from the study, your data will remain on file and will be included in the final study analysis.

In line with research guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Research information can be useful to other researchers. The research funding body (NIHR) requires us to put your data in a store (the UK Data Archive), where others can use it, in an anonymised form, which means that no-one will be able to identify or contact you if they use it.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports such in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep the information about you that we already have.

You can find out more about how we use your information:

- via our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- by visiting www.nuh.nhs.uk/gdpr

9. What will happen if I don't want to carry on with the study?

You are free to leave the study at any time and without giving a reason. If you do not take part, or withdraw, this will not affect you in any way.

10. What happens when the study is finished?

The results of this study will be used to further evaluate the therapy programme we have developed for people with memory problems. The study results may be published in a scientific journal or presented at a conference.

The data will be anonymous and none of the people involved in the interviews will be identified in any reports or publications. Should you wish to see the results, or the publications, please ask your researcher.

11. What if there is a problem?

If you have a concern about any aspect of this study, please contact Dr Emma Adams or Dr Robert Vickers (see contact details above), who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the sponsor team. Email researchsponsor@nuh.nhs.uk, or by phoning 0115 970 9049.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

12. Further Information

You are encouraged to ask any questions you wish before, during or after your interview. If you have any questions about the study, please speak to your study researcher who will be able to provide you with up to date information about the study. If you require any further information or have any concerns while taking part in the study, please contact the Principal Investigator Professor John Gladman. Email: John.Gladman@nottingham.ac.uk, or by phoning 0115 823 0242

If you decide you would like to take part, then please read the consent form. At the interview you will be then be asked to give verbal consent (online interviews) or sign the consent form (face-to-face interviews). You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed with the study records.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

APPENDIX 2.1

WPA STAFF MEETING OBSERVATION AND DOCUMENT REVIEW

CONSENT FORM

PrAISED Implementation Study Consent Form

Meeting observation and document review (Pilot Study)

Version 1.0 28-03-2022

Project title: PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

Principal Investigator: Professor John Gladman

Please select tick ✓ box to confirm.

1. I confirm that I have read and understand the information sheet 'PrAISED Implementation Study WPA Meeting Observation/Document Review PIS v1.0' dated 28th March 2022 and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without my involvement in delivering the PrAISED service being affected. ☐

3. I understand that the results of this research may be looked at by authorised individuals from the Sponsor for the study and the UK Regulatory Authority in order to check that the study is being carried out correctly. ☐

4. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the study, unless I specifically withdraw consent for this. ☐

5. I consent to researchers observing and making anonymised notes in meetings related to the planning and implementation of the PrAISED service and for any related meeting minutes and e-mail correspondence to be reviewed and anonymous data extracted. ☐

6. I consent to the storage, including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information will be included in the study report or other publications. ☐

7. I agree to take part in the study. ☐

Name of participant:	Date:	Participant's signature:
	Click or tap to enter a date.	

Name of researcher:	Date:	Researcher's signature:
	Click or tap to enter a date.	

APPENDIX 2.2

WPA INTERVIEW CONSENT FORM (VERBAL)

PrAISED Implementation Study Consent Form (Verbal)

Interview

Version 1.0 28-03-2022

Project title: PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

Principal Investigator: Professor John Gladman

During recording, the researcher will read each of the following statements and the participant will provide verbal consent (i.e. say yes) to each statement:

1. Do you confirm you have read and understood the information sheet '[*insert PIS name and version number*]' dated [*insert date*] for the above study and have had the opportunity to ask questions?

2. Do you understand that your participation is voluntary and that you are free to withdraw at any time?

3. Do you understand that the results of the interview may be looked at by authorised individuals from the Sponsor for the study and the UK Regulatory Authority in order to check that the study is being carried out correctly?

4. Do you understand that even if you withdraw from the above study, the data collected from you will be used in analysing the results of the interview, unless you specifically withdraw consent for this?

5. Do you consent to the recording and transcription of the interview?

6. Do you consent to the storage, including electronic, of personal information for the purposes of this study and understand that any information that could identify you will be kept confidential, and no personal information will be included in the study report or other publications?

7. Do you agree to take part in the study?

APPENDIX 2.3

WPA INTERVIEW CONSENT FORM (FACE TO FACE)

PrAISED Implementation Study Consent Form (Face to Face)

Interview

Version 1.0 28-03-2022

Project title: PrAISED (Promoting Activity, Independence and Stability in Early Dementia) Implementation study

Principal Investigator: Professor John Gladman

Please select tick ✓ box to confirm.

1. I confirm that I have read and understand the information sheet '[*insert PIS name and version number*]' dated [*insert date*] for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time. ☐

3. I understand that the results of the interview may be looked at by authorised individuals from the Sponsor for the study and the UK Regulatory Authority in order to check that the study is being carried out correctly. ☐

4. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the interview study, unless I specifically withdraw consent for this. ☐

5. I consent to the recording and transcription of the interview. ☐

6. I consent to the storage, including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and no personal information will be included in the study report or other publications. ☐

7. I agree to take part in the study. ☐

Name of participant:	Date:	Participant's signature:
	Click or tap to enter a date.	

Name of researcher:	Date:	Researcher's signature:
	Click or tap to enter a date.	

APPENDIX 3.1

WPA CLINICAL/RESEARCH MANAGERS (PILOT SERVICE SITES)

INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Clinical/Research Managers (Pilot Service)

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with Clinical/Research Managers to talk about how the intervention works or might work in clinical practice.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
1. Can I ask you to introduce yourself and describe your experience of working with people with dementia?	• Can you tell me about your professional background and work at the Trust?
2. What is your role in the PrAISED programme?	
3. What do you think are the aims of the PrAISED programme?	• How important do you think the PrAISED programme is for people with dementia?
4. How do you feel about the PrAISED programme being delivered in your setting as a routine service?	• How well does the PrAISED programme fit with existing work processes and practices in the Trust? • How does it work together or conflict with current programmes or processes?
5. How long have you been involved in the PrAISED programme?	Were you involved in PrAISED when it was part of the research study? [If yes] *Ask questions in section B

B. CHANGES FROM THE RESEARCH INTERVENTION TO SERVICE DELIVERY *Only ask these questions to staff who were involved in the research study	
Question	**Prompts**
Thinking back to PrAISED as a research study…	
6. What changes did you need to make to delivering the PrAISED programme as a service in clinical practice?	• Referral/screening processes • Eligibility criteria? Clinical Assessments? • Content of patient letters? • Therapists materials? e.g. decision tool • Patient materials? e.g. Patient home file • Intervention frequency, duration, session content etc.
7. What were the main barriers you experienced in changing PrAISED from a research study to a service?	•
8. What were the main facilitators you experienced in changing PrAISED from a research study to a service?	•
9. How did you find the change from delivering a 12-month intervention in the research study to a 6-month study in the pilot delivery service?	• Is 12 or 6 months better? Perceptions about benefits/ disadvantages for therapists/patients with longer/ shorter programme?

C. PILOT DELIVERY SERVICE	
Question	**Prompts**
I'd like to ask you about the pilot service you have been delivering….	
10. How is the delivery of PrAISED going so far?	• Which aspects of PrAISED do you feel are working well? • Which aspects of PrAISED do you feel are not working well?
11. Has the PrAISED programme been delivered in the way you thought it would be?	• *[If Yes]* Can you describe this? • *[If No]* Why not?
12. Are there any specified components of the PrAISED programme that you have not been able to deliver as they were intended (as specified in the training)?	• Prompt for number, length and frequency of intervention components. • *[If not]* Why not?
13. How did/do you use the intervention manual and materials in the pilot delivery service?	• Is/was anything else needed? • Who/where did you seek help from when you had a question? • Which materials were used/how were these adapted? • What other materials might be needed to support intervention delivery?
14. What are the main barriers to delivering the PrAISED programme as a service?	• Can you explain these?
15. What helps to facilitate delivering the PrAISED programme as a service?	• Can you explain these?
16. Did you put anything in place to check the quality of the programme being delivered?	• *[If Yes]* Can you describe this? • *[If No]* Was there a reason for this? What could be put in place for Quality Assurance purposes?
17. Do you think the PrAISED programme will be effective in your setting?	• What evidence do you have to support this?

D. FUTURE DELIVERY OF THE PROGRAMME	
Question	**Prompts**
Thinking now about the future delivery of the programme…	
18. Are there components of the PrAISED programme that you think should be altered for use in wider clinical practice or other Trusts?	• What kinds of changes or adaptations are needed?
19. What issues or complications might arise delivering the PrAISED programme in clinical practice?	
20. What else would be needed to support the commissioning of PrAISED in your Trust/other Trusts?	• Commissioning process, business case, what types of evidence?
21. What would persuade you to promote commissioning of an intervention like PrAISED in the future?	• What role does research evidence/other kinds of evidence play in that decision?
22. What do you think the policy drivers are in this area?	• Why do you think is it important to commission PrAISED (local/national priorities)?
23. What advice would you give to another NHS Trust planning to deliver the PrAISED programme?	•
24. In what ways do you think the PrAISED programme would replace or complement other programmes?	•
25. Do you think PrAISED could be delivered by other professional groups?	• *[If Yes]* Please give examples of who e.g., exercise instructors? • *[If No]* Why not?
26. How do you think the PrAISED training could be delivered in future?	• Format and structure e.g. face to face or e-training/digital • Content • Frequency / refresher sessions • Community of Practice/Network of PrAISED therapists?

	• What else is needed in terms of training to help therapists deliver the programme?

E. EXIT STRATEGY FROM PrAISED / LONG-TERM SUSTAINABILITY FOR PATIENTS	
Question	**Prompts**
I would like to ask you some questions about what happens when patients complete their involvement in the PrAISED programme…	
27. Do you have an exit strategy for the patients on completion of the PrAISED programme?	• *[If Yes]* Can you describe this? What is the purpose and scope of the strategy? • *[If No]* Do you think an exit strategy could be developed? What should this involve?
28. Are you aware of any dementia-friendly services that patients could be referred to after completing the PrAISED programme?	• *[If Yes]* Can you describe these?

F. CLOSING QUESTIONS	
Question	**Prompts**
29. Is there anything we haven't covered that you think we ought to know about PrAISED or what we have discussed today?	

APPENDIX 3.2

WPA THERAPISTS (PILOT SERVICE SITES)

INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Clinicians/Therapists (Pilot Service)

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with clinicians/therapists to talk about how the intervention works or might work in clinical practice.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
30. Can I ask you to introduce yourself and describe your experience of working with people with dementia?	• Can you tell me about your professional background and work at the Trust?
31. What is your role in the PrAISED programme?	
32. What do you think are the aims of the PrAISED programme?	• How important do you think the PrAISED programme is for people with dementia?
33. How do you feel about the PrAISED programme being delivered in your setting as a routine service?	• How well does the PrAISED programme fit with existing work processes and practices in the Trust? • How does it work together or conflict with current programmes or processes?
34. How long have you been involved in the PrAISED programme?	• Were you involved in PrAISED when it was part of the research study? [If yes] *Ask questions in section B

B. CHANGE FROM RESEARCH INTERVENTION TO PILOT SERVICE *Only ask these questions to staff who were involved in the research study	
Question	**Prompts**
I'd like to ask you about the research intervention and pilot service you have been delivering….	
35. What changes did you need to make in order to deliver the PrAISED programme as a service in clinical practice instead of a research study?	• Referral/screening processes • Eligibility criteria? Clinical Assessments? • Content of patient letters? • Therapists materials? e.g. decision tool • Patient materials? e.g. Patient home file • Intervention frequency, duration, session content etc.
36. What were the main barriers you experienced in changing PrAISED from a research study to a service?	•
37. What were the main facilitators you experienced in changing PrAISED from a research study to a service?	•
38. How did you find the change from delivering a 12-month intervention in the research study to a 6-month study in the pilot delivery service?	• Is 12 or 6 months better? Perceptions about benefits/ disadvantages for therapists/patients with longer/ shorter programme?

C. PILOT DELIVERY SERVICE	
Question	**Prompts**
I'd like to ask you about the pilot service you have been delivering….	
39. How is the delivery of PrAISED going so far?	• Which aspects of PrAISED do you feel are working well? • Which aspects of PrAISED do you feel are not working well?
40. Has the PrAISED programme been delivered in the way you thought it would be?	• *[If Yes]* Can you describe this? • *[If No]* Why not?
41. Are there any specified components of the PrAISED programme that you have not been able to deliver as they were intended (as specified in the training)?	• Prompt for number, length and frequency of intervention components. • *[If not]* Why not?
42. How did/do you use the intervention manual and materials in the pilot delivery service?	• Is/was anything else needed? • Who/where did you seek help from when you had a question? • Which materials were used/how were these adapted? • What other materials might be needed to support intervention delivery?
43. What are the main barriers to delivering the PrAISED programme as a service?	• Can you explain these?
44. What helps to facilitate delivering the PrAISED programme as a service?	• Can you explain these?
45. Do you think the PrAISED programme will be effective in your setting?	• What evidence do you have to support this?

D. FUTURE DELIVERY OF THE PROGRAMME	
Question	**Prompts**
Thinking now about the future delivery of the programme…	
46. Are there components of the PrAISED programme that you think should be altered for use in wider clinical practice or other Trusts?	• What kinds of changes or adaptations are needed?
47. What issues or complications might arise delivering the PrAISED programme in clinical practice?	
48. What advice would you give to another therapist planning to deliver the PrAISED programme?	
49. In what ways do you think the PrAISED programme would replace or complement other programmes?	
50. What skills/experience/qualifications do you think someone needs to undertake the role of therapist/RSW on PrAISED?	
51. Do you think PrAISED could be delivered by other professional groups?	• *[If Yes]* Please give examples of who e.g., exercise instructors? • *[If No]* Why not?

E. PARTICIPANT RESPONSE /INVOLVEMENT	
Question	**Prompts**
52. How would you describe participant response to the PrAISED programme?	• For example, indicators such as levels of participation and enthusiasm • What enablers have supported patients participating in the PrAISED programme? • What barriers have patients faced participating in the PrAISED programme?
53. Were any changes made to the way PrAISED was delivered based on user feedback?	• What changes were made and why?

F. THERAPISTS' SELF EFFICACY	
Question	**Prompts**
54. How competent do you feel in your professional role to deliver the PrAISED programme?	
55. How have you found the training you received in PrAISED (e.g., initial training and ongoing support)?	• Did you feel you had enough training to effectively deliver the programme? • Is there anything else you think is needed in terms of training and support to help therapists deliver the programme?
56. What do you think is needed to deliver the PrAISED training in future?	• Format and structure e.g. face to face or e-training/digital • Content • Frequency / refresher sessions • Community of Practice/Network of PrAISED therapists?

	• What else is needed in terms of training and support to help therapists deliver the programme?

G. EXIT STRATEGY FROM PrAISED / LONG-TERM SUSTAINABILITY FOR PATIENTS	
Question	**Prompts**
I would like to ask you some questions about what happens when patients complete their involvement in the PrAISED programme…	
57. Do you have an exit strategy for the patients on completion of the PrAISED programme?	• *[If Yes]* Can you describe this? What is the purpose and scope of the strategy? • *[If No]* Do you think an exit strategy could be developed? What should this involve?
58. What advice or information do you offer patients during or at the end of the PrAISED programme to support them in maintaining their activity and health?	• What, when, where? • Signposting or referral?
59. Are you aware of any dementia-friendly services that patients could be referred to after completing the PrAISED programme?	• *[If Yes]* Can you describe these? • How might these compete with or complement PrAISED?

H. CLOSING QUESTIONS	
Question	**Prompts**
60. Is there anything we haven't covered that you think we ought to know about PrAISED or what we have discussed today?	

APPENDIX 3.3

WPA CLINICAL/RESEARCH MANAGERS (NON-PILOT SERVICE SITES)

INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Clinical/Research Managers

(Non-Pilot Service Sites)

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……..., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with Clinical/Research Managers to talk about how the intervention works or might work in clinical practice.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
61. Can I ask you to introduce yourself and describe your experience of working with people with dementia?	• Can you tell me about your professional background and work at the Trust?
62. What is your role in the PrAISED programme?	
63. How long were you involved in the PrAISED research programme for?	
64. What do you think are the aims of the PrAISED programme?	• How important do you think the PrAISED programme is for people with dementia?
65. How would you feel about the PrAISED programme being delivered in your setting as a routine service?	• How well does the PrAISED programme fit with existing work processes and practices in the Trust? • How does it work together or conflict with current programmes or processes?

B. FUTURE DELIVERY OF THE PROGRAMME	
Question	**Prompts**
Thinking about the future delivery of the programme…	
66. What changes do you think would need to be made in order to deliver the PrAISED programme as a service in clinical practice instead of a research study?	• Referral/screening processes • Eligibility criteria? Clinical Assessments? • Content of patient letters? • Therapists materials? e.g. decision tool • Patient materials? e.g. Patient home file • Intervention frequency, duration, session content etc.
67. Are there components of the PrAISED programme that you think should be altered for use in wider clinical practice or other Trusts?	• What kinds of changes or adaptations are needed?
68. What issues or complications might arise delivering the PrAISED programme in clinical practice?	
69. What do you think would be the main barriers in delivering the PrAISED programme in routine clinical practice?	• Can you explain these?
70. What would help to facilitate delivering the PrAISED programme in routine clinical practice?	• Can you explain these?
71. What might you put in place to check the quality of the programme being delivered?	• Quality assurance processes
72. What else would be needed to support the commissioning of PrAISED in your Trust/other Trusts?	• Commissioning process, business case, what types of evidence?
73. What would persuade you to promote commissioning of an intervention like PrAISED in the future?	• What role does research evidence/other kinds of evidence play in that decision?
74. What do you think the policy drivers are in this area?	• Why do you think is it important to commission PrAISED (local/national priorities)?
75. What advice would you give to another NHS Trust planning to deliver the PrAISED programme?	•

76. In what ways do you think the PrAISED programme would replace or complement other programmes?	•
77. Do you think PrAISED could be delivered by other professional groups?	• *[If Yes]* Please give examples e.g., exercise instructors? • *[If No]* Why not?
78. How do you think the PrAISED training could be delivered in future?	• Format and structure e.g. face to face or e-training/digital • Content • Frequency / refresher sessions • Community of Practice/Network of PrAISED therapists? • What else is needed in terms of training or support to help therapists deliver the programme?

C. EXIT STRATEGY FROM PrAISED / LONG-TERM SUSTAINABILITY FOR PATIENTS	
Question	**Prompts**
I would like to ask you about what happens when patients complete their involvement in the PrAISED programme…	
79. Did you have an exit strategy for the patients on completion of the PrAISED programme?	• *[If Yes]* Can you describe this? What is the purpose and scope of the strategy? • What advice or information was offered to patients? • *[If No]* Do you think an exit strategy could be developed? What should this involve?
80. Are you aware of any dementia-friendly services that patients could be referred to after completing the PrAISED programme?	• *[If Yes]* Can you describe these?

D. CLOSING QUESTIONS	
Question	**Prompts**

81. Is there anything we haven't covered that you think we ought to know about PrAISED or what we have discussed today?	

APPENDIX 3.4

WPA THERAPISTS (NON-PILOT SERVICE SITES)

INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Clinicians/Therapists (Non-Pilot Service Sites)

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with clinicians/therapists to talk about how the intervention works or might work in clinical practice.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
82. Can I ask you to introduce yourself and describe your experience of working with people with dementia?	• Can you tell me about your professional background and work at the Trust?
83. What was your role in the PrAISED programme?	
84. How long were you involved in the PrAISED research programme for?	
85. What do you think are the aims of the PrAISED programme?	• How important do you think the PrAISED programme is for people with dementia?
86. How would you feel about the PrAISED programme being delivered in your setting as a routine service?	• How well does the PrAISED programme fit with existing work processes and practices in the Trust? • How would it work together or conflict with current programmes or processes?

B. FUTURE DELIVERY OF THE PROGRAMME	
Question	**Prompts**
Thinking about the future delivery of the programme…	
87. What changes do you think would need to be made in order to deliver the PrAISED programme as a service in clinical practice instead of a research study?	• Referral/screening processes • Eligibility criteria? Clinical Assessments? • Content of patient letters? • Therapists materials? e.g. decision tool • Patient materials? e.g. Patient home file • Intervention frequency, duration, session content etc.
88. What issues or complications might arise delivering the PrAISED programme in clinical practice?	
89. What do you think would be the main barriers in delivering the PrAISED programme in routine clinical practice?	• Can you explain these?
90. What would help to facilitate delivering the PrAISED programme in routine clinical practice?	• Can you explain these?
91. What advice would you give to another therapist planning to deliver the PrAISED programme?	
92. In what ways do you think the PrAISED programme would replace or complement other programmes?	
93. What skills/experience/qualifications do you think someone needs to undertake the role of therapist/RSW on PrAISED?	
94. Do you think PrAISED could be delivered by other professional groups?	• *[If Yes]* Please give examples of who e.g., exercise instructors? • *[If No]* Why not?

C. THERAPISTS' SELF EFFICACY	
Question	**Prompts**
95. How competent did you feel in your professional role to deliver the PrAISED programme?	
96. How did you find the training you received in PrAISED (e.g., initial training and ongoing support)?	• Did you feel you had enough training to effectively deliver the programme? • Is there anything else you think is needed in terms of training and support to help therapists deliver the programme?
97. What do you think is needed to deliver the PrAISED training in future?	• Format and structure e.g. face to face or e-training/digital • Content • Frequency / refresher sessions • Community of Practice/Network of PrAISED therapists? • What else is needed in terms of training and support to help therapists deliver the programme?

D. EXIT STRATEGY FROM PrAISED / LONG-TERM SUSTAINABILITY FOR PATIENTS	
Question	**Prompts**
I would like to ask you some questions about what happens when patients complete their involvement in the PrAISED programme…	
98. Did you have an exit strategy for the patients on completion of the PrAISED programme?	• *[If Yes]* Can you describe this? What is the purpose and scope of the strategy? • *[If No]* Do you think an exit strategy could be developed? What should this involve?
99. What advice or information did you offer patients during or at the end of the PrAISED programme to support them in maintaining their activity and health?	• What, when, where? • Signposting or referral?
100. Are you aware of any dementia-friendly services that patients could be referred to after completing the PrAISED programme?	• *[If Yes]* Can you describe these? • How might these compete with or complement PrAISED?

E. CLOSING QUESTIONS	
Question	**Prompts**
101. Is there anything we haven't covered that you think we ought to know about PrAISED or what we have discussed today?	

APPENDIX 3.5

WPB HEALTH SERVICE REPRESENTATIVES

INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Health Service Representatives

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with health service representatives involved in delivering exercise/activity and rehabilitation interventions.

We would like to talk about how we can increase the diversity of people with dementia who take part in therapy programmes aimed at maintaining activity and preventing falls and in related research studies.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
1. Can I ask you to introduce yourself and describe your experience of working with people with dementia?	• Can you tell me about your professional background?
2. What is your role in delivering exercise/activity or rehabilitation programmes?	
3. What your understanding is of diversity?	• Ethnicity, socioeconomic, LGBTQ+

B. PARTICIPATION IN EXERCISE/ACTIVITY OR REHABILITATION INTERVENTIONS	
Question	**Prompts**
4. In your experience, why might someone from an ethnic minority, choose to take part/not take part in exercise/activity or rehabilitation interventions?	•
5. What do you think are some of the barriers to participation maybe?	•
6. What do you think some of the enablers might be?	•
7. In your experience, why might someone from a lower socioeconomic background, choose to take part/not take part in exercise/activity or rehabilitation interventions?	•
8. What do you think are some of the barriers to participation maybe?	•
9. What do you think some of the enablers might be?	•
10. How could we design exercise/activity or rehabilitation interventions to meet the needs of people from ethnic minority communities and lower socioeconomic backgrounds?	•

C. PARTICIPATION IN RESEARCH	
Question	**Prompts**
11. In your experience, why might someone from an ethnic minority, choose to take part/not take part in dementia research?	•
12. What do you think are some of the barriers to participation maybe?	•
13. What do you think some of the enablers might be?	•
14. In your experience, why might someone from a lower socioeconomic background, choose to take part/not take part in dementia research?	•
15. What do you think are some of the barriers to participation maybe?	•
16. What do you think some of the enablers might be?	•
17. How could we design research studies to improve the participation of people from ethnic minority communities and lower socioeconomic backgrounds?	•

D. CLOSING QUESTIONS	
Question	**Prompts**

18. Is there anything we haven't covered that you think we ought to know about diversity in exercise/activity or rehabilitation interventions or dementia research?	

APPENDIX 3.6

WPB RESEARCH NETWORKS

INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Research Network Representatives

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with staff from Clinical Research Networks (CRNs), Join Dementia Research (JDR) or other similar research networks involved in participant recruitment for exercise/activity or rehabilitation research programmes (such as PrAISED), or dementia research.

We would like to talk about how we can increase the diversity of people with dementia who take part in research studies related to therapy programmes aimed at maintaining activity and preventing falls.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
102. Can I ask you to introduce yourself	• Can you tell me about your professional background?
103. What is your experience of working on research studies in exercise/activity or rehabilitation or for people with dementia?	
104. What your understanding is of diversity in research?	• Ethnicity, socioeconomic, LGBTQ+

B. PARTICIPATION IN EXERCISE/ACTIVITY OR REHABILITATION RESEARCH	
Question	**Prompts**
105. In your experience, why might someone from an ethnic minority, choose to take part/not take part in exercise/activity or rehabilitation research?	•
106. What do you think some of the barriers to participation may be?	•
107. What do you think some of the enablers might be?	•
108. In your experience, why might someone from a lower socioeconomic background, choose to take part/not take part in exercise/activity or rehabilitation research?	•
109. What do you think some of the barriers to participation may be?	•
110. What do you think some of the enablers might be?	•
111. What is the impact of an invitation to take part in a study?	• Skills, knowledge, confidence, language
112. How could we design exercise/activity or rehabilitation research studies to improve the participation of people from ethnic minority communities and lower socioeconomic backgrounds?	•

C. PARTICIPATION IN DEMENTIA RESEARCH	
Question	**Prompts**
113. In your experience, why might someone from an ethnic minority, choose to take part/not take part in dementia research?	•
114. What do you think some of the barriers to participation may be?	•
115. What do you think some of the enablers might be?	•
116. In your experience, why might someone from a lower socioeconomic background, choose to take part/not take part in dementia research?	•
117. What do you think some of the barriers to participation may be?	•
118. What do you think some of the enablers might be?	•
119. What is the impact of an invitation to take part in a study?	• Skills, knowledge, confidence, language
120. How could we design research studies to improve the participation of people from ethnic minority communities and lower socioeconomic backgrounds?	•

D. CLOSING QUESTIONS	
Question	**Prompts**

121. Is there anything we haven't covered that you think we ought to know about diversity in exercise/activity, rehabilitation or dementia research?	

APPENDIX 3.7

WPB COMMUNITY LEADERS, OLDER PEOPLE, FAMILY MEMBERS INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Community leaders, older people or family members

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with community leaders from underserved ethnic minority and lower income groups.

We would like to talk about how we can increase the diversity of people with dementia who take part in therapy programmes aimed at maintaining activity and preventing falls and in related research studies.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
1. Can I ask you to introduce yourself?	•

B. PARTICIPATION IN EXERCISE/ACTIVITY OR REHABILITATION INTERVENTIONS	
Question	**Prompts**
2. Have you ever been involved with or taken part in an exercise/activity or rehabilitation programme?	• What involvement did you have? • What was your experience of the programme? • What did you like/dislike about the programme?
3. What do you think some of the barriers to participation in an exercise/activity or rehabilitation programme might be?	• Generally • For people with dementia
4. What do you think some of the enablers might be?	• Generally • For people with dementia
5. Why might someone from an ethnic minority, choose to take part/not take part in exercise/activity or rehabilitation programmes?	•
6. How could we design exercise/activity or rehabilitation programmes to make them accessible for people from ethnic minority communities?	•

C. PARTICIPATION IN RESEARCH	
Question	**Prompts**
7. What do you think research is and what is it for?	•
8. What do you think might taking part in research involve?	•
9. Have you ever been asked to take part in a research study?	• What was good/bad about it? • How did you feel about it afterward? • Did you have the opportunity to discuss taking part? • What was it like? • What could have been done differently?
10. Why do you think people from ethnic minority communities might choose to take part/not take part in a research study?	• Generally • People with dementia
11. What would make you more likely to take part in a research study?	• Qualities of researcher/team? • Place of research (home, hospital, community centre, GP practice, etc) • What information should we provide? • Incentives
12. How could we design research studies to make them accessible for people from ethnic minority communities?	• Generally • People with dementia

D. CLOSING QUESTIONS	
Question	**Prompts**
13. Is there anything we haven't covered that you think we ought to know about diversity in exercise/activity or rehabilitation interventions for people with dementia or in research?	

APPENDIX 3.8

WPD LOCAL, REGIONAL AND NATIONAL STAKEHOLDERS INTERVIEW SCHEDULE (DRAFT)

PrAISED Implementation Study

Representatives from Key Stakeholder Organisations & Commissioners

Interview Schedule V1.0 12-04-22 DRAFT

Pre-interview

My name is ……., I am a ……. working on the PrAISED programme.

This interview is being conducted as part of the PrAISED implementation study; in this study we are aiming to carry out interviews with commissioners and representatives of key stakeholder organisations. We would like to talk about the current support for and provision of exercise/activity and rehabilitation programmes and services for patients with dementia, and what would be required to commission, promote and support adoption of the PrAISED intervention.

With your agreement, we would like to record the session. The interview is strictly confidential. Your participation is voluntary and you can withdraw at any time.

Have you had a chance to read the information sheet I sent you?

Do you have any questions you would like to ask me about the research or interview?

[Complete interview Verbal or Face-to-Face Consent Form]

Interview Questions DRAFT

A. INTRODUCTION	
Question	**Prompts**
122. Can I ask you to introduce yourself and describe your role in commissioning, supporting, promoting or delivering dementia-friendly exercise- and activity-based interventions?	• Can you tell me about your professional background and work in your organisation?
123. Have you previously heard of, or been involved in, the PrAISED programme?	• [If Yes] Can you tell me about this? • [If No] Provide brief summary of the programme.

B. REQUIREMENTS FOR ADOPTION	
Question	**Prompts**
Thinking now about the requirements for future adoption of dementia-friendly services…	
124. Do you think there is a need for new dementia-friendly exercise- and activity-based interventions?	• Why do you think it is important to commission, promote or deliver new dementia-friendly exercise- and activity-based interventions?
125. What kind of local or national policy or measures would influence your decision to commission or implement a new exercise- and activity-based intervention for people with dementia?	• What do you think the policy drivers are in this area (local/national priorities)? • Performance measures, regulations, or guidelines?
126. Who are the key influential organisations/stakeholders who should be involved in the commissioning or implementation of a new dementia-friendly exercise- and activity-based intervention?	• To what extent will they influence others' use of the intervention? • The success of the implementation?
127. What are the main factors which influence whether a new service is commissioned/funded and implemented?	•

C. FUTURE FUNDING AND COMMISSIONING	
Question	**Prompts**
I would like to ask you some questions about what helps to get dementia-friendly services funded or commissioned…	
128. What dementia-friendly exercise- and activity-based interventions do you currently commission/fund, promote or deliver?	•
129. What would persuade you to commission/fund, promote or deliver new exercise- and activity-based interventions (like PrAISED) in the future?	• What role does research evidence/other kinds of evidence play in that decision?
130. What else would be required to support the commissioning and promotion of new exercise- and activity-based intervention for people with dementia?	• Commissioning/funding process, business case • What types of evidence are needed?

D. BARRIERS AND FACILITATORS TO ADOPTION	
Question	**Prompts**
I would like to ask you some questions about commissioning and implementing new dementia-friendly services…	
131. What are the main barriers to commissioning or implementing new exercise- and activity-based interventions for people with dementia into clinical practice?	•
132. What are the main facilitators for commissioning or implementing new exercise- and activity-based interventions for people with dementia into clinical practice?	•

133. What advice would you give to the provider of a new exercise- and activity-based intervention for people with dementia in relation to getting the intervention commissioned, supported and promoted?	•

E. LONG-TERM SUSTAINABILITY	
Question	**Prompts**
I would like to ask you some questions about the long-term sustainability of dementia-friendly services…	
134. What do you think it would take to make an exercise- and activity-based intervention for people with dementia sustainable as a service?	• Who should pay for it in the future? • Could it be self-funding? • Is the delivery model sustainable? • Is there a demand for it?
135. How do you think the PrAISED training could be delivered?	• Who could provide the training? • Format and structure e.g., face to face or e-training/digital? • Content? • Frequency/refresher sessions? • Community of Practice?
136. Which professional groups do you believe will be able to deliver new exercise- and activity-based interventions for people with dementia?	• Please give examples of who e.g., exercise instructors?
137. Are you aware of any dementia-friendly services that patients could be referred to after completing an exercise- and activity-based intervention to support long-term participation in activity?	• [If Yes] Can you please describe these?

F. CLOSING QUESTIONS	
Question	**Prompts**
138. Is there anything we haven't covered that you think we ought to know about commissioning, promoting or delivering PrAISED in routine practice or what we have discussed today?	
139. Is there anyone else who you think we should interview in relation to this topic?	