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Protocol for the process evaluation of the promoting activity, independence and stability in early dementia and mild cognitive impairment (PrAISED 2) randomised controlled trial

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ABSTRACT

Introduction: We are conducting a randomised controlled trial (Promoting Activity, Independence and Stability in Early Dementia and Mild Cognitive Impairment - PrAISED 2) to test the effectiveness of an intervention to promote activity and independence amongst people with mild cognitive impairment and early dementia. A process evaluation is needed to determine how the intervention works. This protocol outlines the rationale, aims, objectives and methods of the process evaluation.

Methods: The process evaluation will use a mixed-methods design and comprise two studies: An *implementation study*, examining the process through which PrAISED 2 is delivered, and a *study on the mechanisms of impact and context*, focussing on the mediating mechanisms that contribute to study outcomes. Integration of separate analyses of quantitative and qualitative data will provide a holistic view of how the PrAISED 2 intervention works.

Conclusion: Results from this process evaluation will further the understanding of the factors that can impinge on the success of complex interventions. This will represent invaluable information for researchers undertaking further research around behaviour change among people with cognitive impairment and dementia.

1. Introduction

Dementia is a neurodegenerative disorder associated with loss of cognitive and executive function. An estimated 850,000 individuals are living with dementia in the United Kingdom and the number is predicted to increase over the next years, giving the ageing of the population [1]. The current annual cost of dementia in the UK is £26 billion [2], but dementia spending is expected to double by 2040 [1].

Over time, with the progression of muscle weakness, postural instability, poor vision and other neurological symptoms, the person living with dementia is exposed to increased risk of falling [3,4] and consequent fractures [5,6]. These may result in the person losing their mobility and independence. Although several multifactorial risk prevention interventions exist, they are poorly adapted to people with dementia [7].

Research has established that physical and functional activities improve executive functioning in people with dementia [8–11] and reduce the risk of falls and hospital admissions [12,13]. These activities may also have a positive impact on cognitive functioning, independence and quality of life [8,11,14–17].

At present, there is a need to establish an evidence base for interventions in improving functional capacity, independence and quality of life of people with early dementia and cognitive impairment, whilst trying to address issues emerging in real life scenarios, such as barriers to uptake and long-term adherence [18].

1.1. The PrAISED 2 study

The Promoting Activity, Independence and Stability in Early Dementia and Mild Cognitive Impairment (PrAISED 2) is a multi-centre, pragmatic, parallel-group, randomised controlled trial (RCT). The aim of the trial is to test the clinical and cost-effectiveness of a therapy

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intervention designed to promote activity and independence amongst people with early dementia or mild cognitive impairment. Details about the preceding work for PrAISED 2 have been published in the literature [19,20]. Information on the PrAISED 2 RCT is available online on the clinical trials register (http://www.isrctn.com/ISRCTN15320670?q=ISRCTN15320670&filters=&sort=&offset=1&totalResults=1&page=1&pageSize=10&searchType=basic-search). The full protocol of the PrAISED 2 RCT is available from the authors on request.

In brief, three hundred and sixty-eight participants diagnosed with mild cognitive impairment (MCI) or early dementia are recruited together with their primary carer through Memory Assessment Services (Memory Clinics), the National Institute for Health Research (NIHR) Join Dementia Research (JDR) register, from primary care physician practices and dementia support groups. The participants are individually randomised, stratified by site, have a co-resident carer and history of previous falls, and are involved in PrAISED 2 for 15 months (Fig. 1).

The active intervention includes individually tailored:

- Functional activities (e.g. shopping, walking the dog, hanging out washing);
- Physical exercises (including progressive strength, balance and dual-task exercises);
- Physical activity promotion;
- Risk enablement;
- Environmental assessment;
- Identification of opportunities to engage in the programme outside of supervised sessions and after the end of the programme.

The participants in the active intervention group receive up to 50 visits over a period of 52 weeks from a multidisciplinary team including physiotherapists, occupational therapists and rehabilitation support workers, all trained in delivering the intervention by the PrAISED 2 team. Supervision is tapered to the individual needs of participants, to promote habit-formation around physical activity. The control group only receives standard falls assessment and advice at baseline.

The primary outcome of the intervention is disability in activities of daily living, measured 12 months after randomisation through the Disability Assessment in Dementia (DAD) [21]. Secondary outcomes include rate of falls, quality of life, physical activity levels, mobility, mood, comorbidities, cognition, time to first fall, fractures and injurious falls, health and social service use, carer strain and cost-effectiveness.

Interventions to change behaviour, such as increasing physical activity in people with dementia, are typically complex, as they include a number of interacting components [22]. Because of its many interacting components (e.g. functional and physical exercises), the number of agents involved (e.g. people with dementia, carers, physiotherapists, occupational therapists and rehabilitation support workers), their characteristics, and the different contexts (social and cultural) within which the programme is implemented, PrAISED 2 can be defined as a *complex intervention*. Therefore, it conforms to the MRC recommendations for researching complex interventions [22].

1.2. Process evaluation of the PrAISED 2 study

A complex intervention such as PrAISED 2, presents several challenges when evaluating its effectiveness. The linear models of causality in RCTs, based on the positivist assumption: *'if intervention X is delivered, then outcome Y will occur'* has been criticised, as it overemphasises a direct link between cause and effect [23]. Whilst RCTs can determine whether the intervention is effective (or not), it has been pointed out that they fail to provide explanation as to why certain outcomes are obtained, because they do not take into consideration the mediation in the process of the agents of the intervention, as well as the "ecological" systems within which the agents interact and experience the intervention [23].

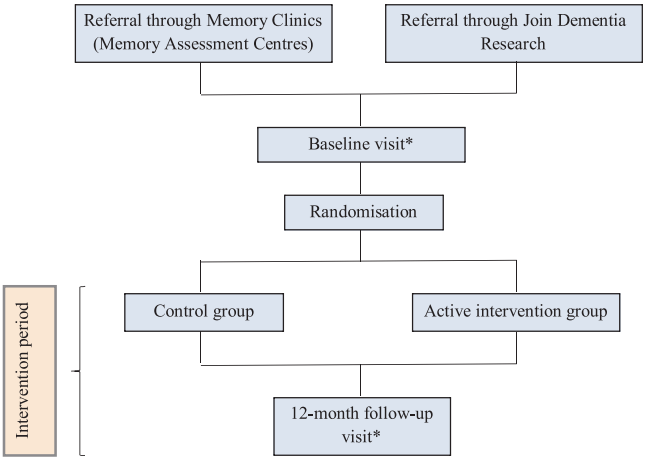

Fig. 1. PrAISED 2 activities.
* Includes informant and participant-reported measures on sociodemographics, medical history, medications, frailty, mobility, personality, cognition, quality of living, health, disability, falls efficacy, mood / affect, activities of daily living, muscle strength, physical activity, static and dynamic balance, carer strain, and carer's health.

A process evaluation instead, is based on the assumption: *'if intervention X is delivered, the mediating variable(s) affects the way in which outcome Y will occur'*. In PrAISED 2, intervention outcomes are dependent upon certain mediating variables, such as the '*implementation* of the intervention' (e.g. how the intervention is delivered and / or the therapists' skills in delivering the intervention), the '*mechanisms of impact*' (e.g. how motivated the participant is to do the physical activities and / or the therapeutic relationship between the therapists and the participants) and the '*context*' within which the intervention is delivered (e.g. the home of the person with dementia) [24].

In PrAISED 2 therefore, the process evaluation represents an essential companion to the RCT, as it provides invaluable insight to the question "*How does the intervention work?*", by enabling the identification and explanation of the mediating factors that contribute to the (expected and observed) study outcomes [25].

We followed the MRC guidance on planning and designing process evaluation [24] (for the full checklist and how we addressed the recommendations, see Table 1). In this protocol we outline the aim and objectives of the PrAISED 2 process evaluation, the processes which are investigated, the methods used for the evaluation and how the data are analysed.

1.3. Aims and objectives

The aim of this process evaluation is to explain *why* the primary outcome of the PrAISED 2 (DAD score at the completion of the intervention period of 12 months) occurred. Reasons for positive, negative, anticipated or unexpected outcomes will be identified through the following objectives:

1 Evaluation of *implementation* (i.e. the process through which PrAISED 2 training and intervention is delivered);
2 Evaluation of *mechanisms of impact* (i.e. the mediating factors that produce the outcome) and *context* (i.e. environment and its characteristics).

2. Method

The MRC guidance on process evaluation [24] recommends that a clear description of the intervention and its causal assumptions in the form of a logic model[1] should be developed, to identify the appropriate areas of investigation of the process evaluation.

Table 1
Checklist of key recommendations and issues to consider in planning and designing a process evaluation (24).

Phase	Recommendation	How we addressed the recommendation
Planning	Carefully define the parameters of relationships with intervention developers or implementers: • Balance the need for sufficiently good working relationships to allow close observation against the need to remain credible as an independent evaluator • Agree whether evaluators will play an active role in communicating findings as they emerge (and helping correct implementation challenges) or play a more passive role	• Although it represents the synergetic work of different research team members, the process evaluation will be led by a newly appointed researcher, who has knowledge of the intervention, but who has not been involved in its development. This will facilitate evaluator's objectivity • Emerging results from the process evaluation will be fed back to the main trial team, to improve delivery of the intervention. They will also inform the implementation team, to optimise intervention delivery in different contexts
	Ensure that the research team has the correct expertise, including: • Expertise in qualitative and quantitative research methods • Appropriate inter-disciplinary theoretical expertise	• The process evaluation has been developed through the work of a multi-disciplinary team, ensuring the full range of expertise in conducting the process evaluation. The team comprises: - Two academic researchers with expertise in quantitative and qualitative methods - A Health Psychologist, with expertise in Behaviour Change Theories - A senior physiotherapist - A Professor in Geriatric Medicine - A Professor in Clinical Psychology and Neuropsychology - A professor in Medical Sociology - A professor in Rehabilitation Research - Two Patient and Public Involvement (PPI) members
	Decide the degree of separation or integration between process and outcome evaluation teams: • Ensure effective oversight by a principal investigator who values all evaluation components • Develop good communication systems to minimise duplication and conflict between process and outcomes evaluations • Ensure that plans for integration of process and outcome data are agreed from the outset	• Although the process and outcome evaluations are conducted by separate team members, the principal investigator of PrAISED 2 has oversight of both components • The PrAISED 2 team meets on a monthly basis. On these occasions, communication between members of the different work streams ensures that no conflict arises between the process and outcome evaluation • Plans have been made to integrate the process and outcome evaluation, as outlined in the discussion section of this protocol
Designing	Clearly describe the intervention and clarify its causal assumptions in relation to how it will be implemented, and the mechanisms through which it will produce change, in a specific context	We dedicated a section of the process evaluation protocol (1.1) to describe the intervention. The causal assumptions, describing the mechanisms through which the intervention will produce change, are listed in the logic model in Fig. 2
	Identify key uncertainties and systematically select the most important questions to address: • Identify potential questions by considering the assumptions represented by the intervention • Agree scientific and policy priority questions by considering the evidence for intervention assumptions and consulting the evaluation team and policy/practice stakeholders • Identify previous process evaluations of similar interventions and consider whether it is appropriate to replicate aspects of them and build upon their findings	• The PrAISED 2 Logic Model (Fig. 2) informed the development of the research questions of both the implementation study and the mechanisms of impact and context study • The process evaluation questions were informed by reviews of the literature carried out as preliminary groundwork for this study and by the work of the multi-disciplinary team, including the evaluation team and members of the Public and Patient Involvement (PPI) team • Owing to the limited literature around process evaluation and physical activity interventions in dementia, we identified the most recent process evaluations conducted in other fields of dementia research ([39,40,41]) and physical activity interventions for older people ([42] [43],)
	Select a combination of quantitative and qualitative methods appropriate to the research questions: • Use quantitative methods to quantify key process variables and allow testing of pre-hypothesised mechanisms of impact and contextual moderators • Use qualitative methods to capture emerging changes in implementation, experiences of the intervention and unanticipated or complex causal pathways, and to generate new theory • Balance collection of data on key process variables from all sites or participants where feasible, with detailed case studies of purposively selected samples • Consider data collection at multiple time points to capture changes to the intervention over time	The process evaluation is based on mixed-methods: • Quantitative methods will be used in the implementation study to identify key process variables, including Fidelity (i.e. the consistency of what is implemented with the planned intervention), Adaptations (i.e. alterations made to achieve better contextual fit), Dose (i.e. how much intervention is delivered) and Reach (i.e. the extent to which agents had contact with the intervention) • Qualitative methods (i.e. interviewing) will be used at different time points (month 6 and 12) in the mechanisms of impact and context study to capture emerging changes in implementation, experiences of the intervention and unanticipated or complex causal pathways. Regarding theoretical implication, the process evaluation will field-test the *PHYT in dementia* (Di Lorito et al., 2018) • We will adopt purposive sampling to recruit a sample which is representative of each research site and of different participants, including low adherers and high adherers to the intervention, those who self-withdraw and participants from the control group • We will collect data different time points (month 6 and 12)

The logic model and causal assumptions for PrAISED 2 are presented in Fig. 2. The goal of the process evaluation is to identify the factors relating to implementation, mechanisms of impact and context (in the orange box in Fig. 2) that mediate the relationship between activities and outcomes.

This process evaluation will adopt a mixed-methods approach, including quantitative data, qualitative interviews and video-recording. Fig. 3 illustrates the different elements of the process evaluation.

2.1. Implementation study

The study on implementation (i.e. the process through which PrAISED 2 training and intervention is delivered) will focus on four domains:

- Fidelity (i.e. the consistency of what is implemented with the

[1] A diagrammatic representation of an intervention, describing anticipated delivery mechanisms (e.g. how resources will be applied to ensure implementation), intervention components (what is to be implemented), mechanisms of impact (the mechanisms through which an intervention will work) and intended outcomes [24].

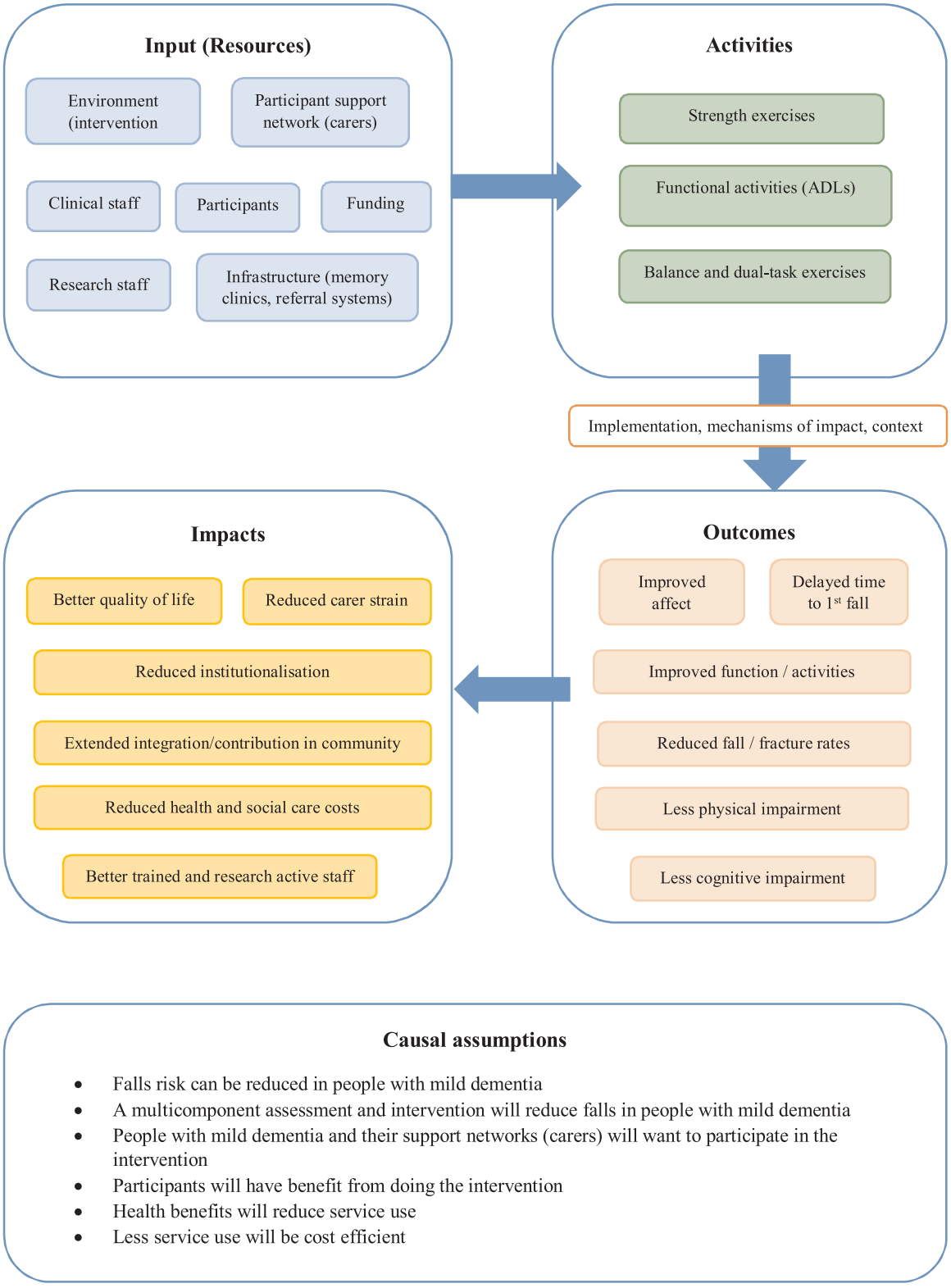

Fig. 2. The logic model for PrAISED 2.

planned intervention);
- Adaptations (i.e. alterations made to achieve better contextual fit);
- Dose (i.e. how much intervention is delivered);
- Reach (i.e. the extent to which agents come into contact with the intervention).

Most data around implementation will be gathered as part of the main trial (Table 2).

2.1.1. Participants

The implementation study will include all the participants with dementia in the intervention group (n = 184) and all the therapists (n = ˜30) involved in the PrAISED 2 RCT.

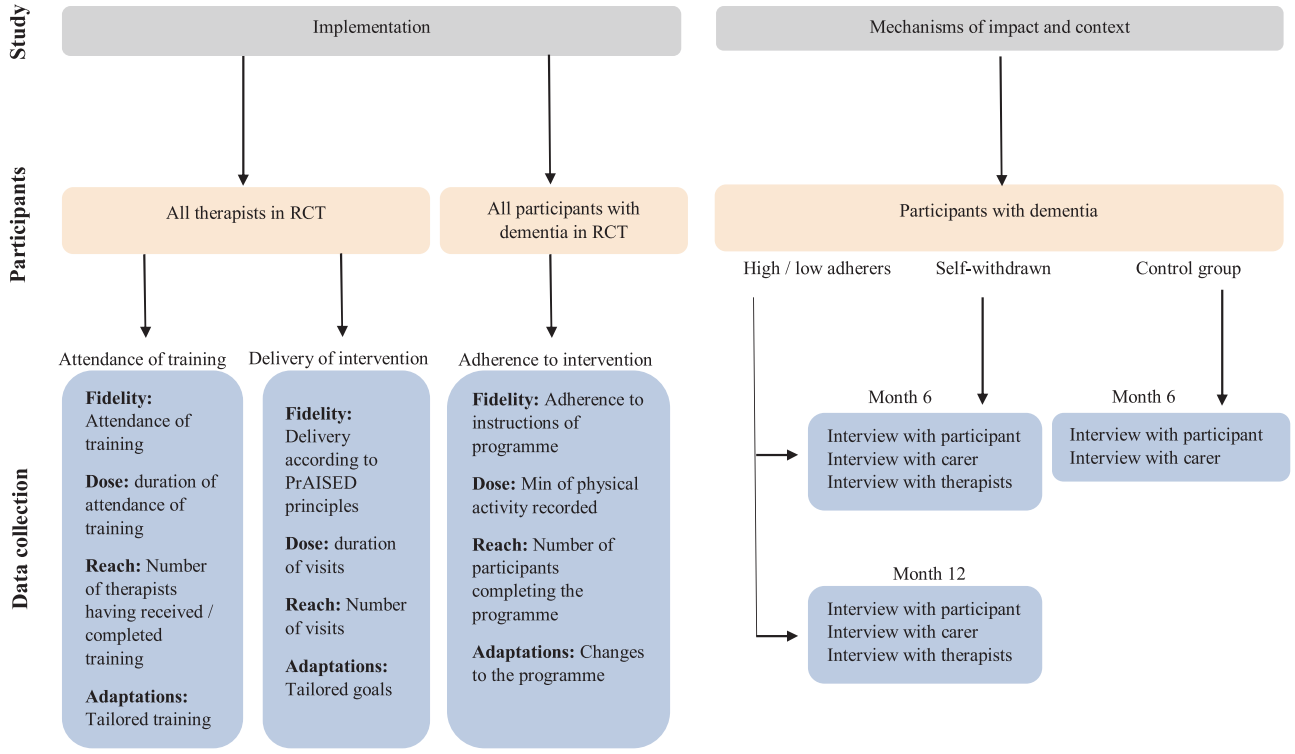

Fig. 3. Method of Process Evaluation.

2.1.2. Data collection

Data from the participants with dementia will be gathered as follows:

- Adherence to intervention as per instructions (Fidelity), investigated through qualitative interviewing (See section entitled *"Study on mechanisms of impact and context"*);
- Adherence to advised activity levels (Dose), investigated through minutes of PrAISED 2 activity per week as recorded on calendar;
- The extent to which participants with dementia come into contact with the intervention (Reach), investigated by gathering the number of participants who completed the programme;
- Alterations that participants made to achieve better contextual fit (Adaptations), investigated through qualitative interviewing (See section entitled *"Study on mechanisms of impact and context"*).

Data from the therapists will be gathered as follows:

1 Evaluation of the training received, including delivery of training as planned, attendance at training and the completion rates of associated training tasks are recorded.
2 Delivery of training as planned (fidelity and dose): hours of training as planned (3 full days plus 5 half days); hours of training delivered for each site;
3 Attendance of training (fidelity and dose): number of active (not back-up) therapists per site per training session and number of active therapists attending the training per site per training session. This will be recorded through attendance sheets the therapists are required to sign each of the training sessions.
4 Completion rates of associated training tasks (reach): all therapists are required to complete a training questionnaire at the end of the PrAISED training sessions. Information on how many attempts are made to pass the questionnaire and the total score for each therapist will be recorded.
5 Tailoring of training (adaptations): adaptations made to the format of training to respond to the unique characteristics of the sites involved in PrAISED 2 will be recorded.
6 Evaluation of the delivery of intervention will include the number and length of intervention visits delivered at participants' homes, the goals set for participants and intervention content.
7 Number and length of intervention visits (implementation process, fidelity, dose and reach): A record of the date, length in minutes, and therapist [Physiotherapist (PT), Occupational Therapist (OT) and Rehabilitation Support Worker (RSW)] is recorded for each visit. The information is collated by the research team each week. We will access the data to monitor visits. In addition, we will examine therapists' decision tool, which documents changes to the frequency of the intervention sessions.
8 Goals set for participants (adaptations): Goals are documented by the therapists that have been set with the participants and collated centrally by the research team. We will analyse the goals' descriptively.
9 Intervention content (fidelity, adaptations): Two visits for each therapist involved in PrAISED 2 will be video-recorded at two different points in time during the intervention with a three months' gap. To ensure that the process is as unobtrusively as possible to the participants and the therapists, we will adopt a *'Fly on the Wall'* approach, by setting up the videorecorder in a neutral position and at a reasonable distance from participants.

2.1.3. Data analysis

Quantitative data will be transferred onto and analysed through IBM SPSS Statistics version 22 [26]. Descriptive statistical analysis will be used to measure fidelity, dose and reach.

Video content will be analysed using the A(x4) framework [27], a heuristic to interpret ethnographic observations, focused on four elements: Atmosphere (i.e. context, the environment), Actors (i.e. participant, therapist, carer), Artifacts (i.e. objects), and Activities (i.e. functional and physical exercises). The four elements will be assessed against the core principles set out in the PrAISED 2 therapists' training manual by two independent raters within the research team through a three-point-Likert-type scale (i.e. *'visit following core principle', 'visit*

Table 2
Implementation study.

	Training		Intervention	
	Delivery (PrAISED 2 team)	Attendance (Therapists)	Delivery (Therapists)	Adherence (Participants)
Fidelity	Delivery of training as planned *	Attendance of training as planned *	Delivery of intervention against PrAISED 2 principles (through video content)	Adherence to intervention as per instructions (through interview)
Dose	Days / hours of training per site *	Days / hours of attendance per therapist *	Days / hours of visit *	Minutes per week recorded on calendar *
Reach	Number of sites receiving training *	Number of therapists attending training and number of therapists completing training tasks *	Number of visits *	Number of participants who completed the programme *
Adaptations	Any adaptations made when providing training *		Goals for participants and any adaptations made to tailor the programme (through video content)	Adaptations that participants made to the original programme (through interview)

* Data gathered during RCT.

partly following core principle', 'visit not following core principle') (Appendix 1). For example, in order to score *'progression'*, the independent raters will assess if during the session, the therapist worked toward the goal set for the participants, as recorded in the therapist spreadsheet.

2.2. Study on mechanisms of impact and context

As per the MRC guidance on process evaluation [24], to gather the full range of perspectives from all the agents included in the intervention and to obtain a sample that is representative of the participants in the RCT (e.g. in relation to the different services involved in PrAISED 2), purposive sampling will be adopted in this study.

2.2.1. Participants

For each research site, we will include:

1 Participants with dementia, further divided in:
2 *Low adherers* (i.e. participants who have undertaken less than 150 min of physical activity per week on average as recorded on calendar, before the first set of interview on month 6);
3 *High adherers* (i.e. participants who have undertaken more than 150 min of physical activity per week on average as recorded on calendar, before the first set of interview on month 6);
4 *Those who self-withdraw* before the first set of interview on month 6. We exclude participants who are withdrawn because the therapists overseeing their care decide that they are no longer able to take part (due to illness, injury, progression of disease or inability to adhere, despite adjustment and tailoring), or who are withdrawn because of the risk to safety or staff.
5 *Participants from the control group*.

Differentiating between subgroups will enable the process evaluation to identify those factors that affect participants' experience of the intervention.

Participants' capacity to consent will be assessed before each interview. We will not categorically exclude those participants who do not have capacity or show fluctuating capacity at the point of the interview, for the following reasons: Firstly, they might still be able to provide precious insight into the individual mechanisms of the intervention; secondly, their (fluctuating) cognition has an impact and affects their behaviour / response toward the intervention; finally, from an ethical standpoint, we aim to give voice to all those whose life is primarily affected by our research.

2 Therapists [1] of each participant with dementia will be selected to be involved in the process evaluation (except for participants in the control group, who are not supported by a therapist) or, in the impossibility to involve all therapists of the participants, the *lead therapist*, identified as the therapist spending more time with the participant during the intervention.
3 The main carer(s) of participants with dementia from the intervention group will be involved in the process evaluation.

In line with Guest, Bunce and Johnson [28], we argue that, given the lack of guidance around data saturation (e.g. when it is reached), there is a need to adopt appropriate 'tests of adequacy' for sample sizes in qualitative research. Based on the notion of 'conceptual density' (i.e. gathering data until a *sufficient depth* of understanding of the domains under investigation is reached) [29], we will adopt a *Conceptual Depth Scale* developed by Nelson [30] (Table 3), which assigns a score ranging from 1 (low) to 3 (high) to establish whether conceptual density is reached in relation to:

- *'Range'* (e.g. extent of diversity of data sources);
- '*Complexity'* (e.g. extent of networks / links across data);
- '*Subtlety'* (e.g. extent of similarity across data);

Table 3
Conceptual Depth Scale (Nelson, 2016).

Criteria (with sources of evidence)	Low (1)	Medium (2)	High (3)
Range (e.g. frequency and variety of codes; multiplicity of data sources)	Few examples to sup-port concepts. Only a single data-type		Abundant examples to sup-port concepts. Multiple data-types
Complexity (e.g. coding trees; positional maps; matrices)	Descriptive codes; simple or basic connections between codes; low level analysis		Sophisticated networks; abstract conceptual categories which synthesise a range of codes and concepts
Subtlety (e.g. memos; social worlds diagrams)	Conceptual language is regarded as unproblematic and one dimensional		Conceptual language is understood as rich, ambiguous and multi-dimensional
Resonance (literature)	Weak resonance; emerging theory is re-mote from existing literature and theoretical frameworks		Strong resonance; emerging theory makes sense along-side existing literature; there are correlations with other theoretical frameworks, albeit with variations and novel-ties
Validity (e.g. applicability test)	Low level theorising and inward facing; the findings have limited application to the re-search participants or those familiar with similar contexts.		Abstract level theorising and outward facing; the findings make sense to those in the social context of the re-search, or ones broadly similar.

- *'Validity'* (e.g. extent to which data are transferable to other settings)

Data will be collected until a data density score of 3 is obtained in all four domains by two independent raters within the research team.

2.2.2. Data collection

The investigation of the mechanisms of impact and context will be based on qualitative means of investigation (i.e. interviews with participants). Two sets of interviews will be carried out at two points in time (at month six and month 12 of the intervention), except for participants who withdrew before the first round of interview (i.e. month six of the intervention) and participants in the control group, who will only be interviewed at month 12.

They will consist of:

- Individual interviews with participants with dementia from each of the subsample described in the *'Participants'* section and individual interviews with their respective carers. Paired interviewing with the participant with dementia and the carer will be considered, according to participants' preferences or if deemed necessary by the research team (e.g. in the presence of deteriorating cognition of the participant with dementia, which may have an impact on data gathering). The interviews with participants from the control group will be used to investigate the effectiveness of the motivation and support strategies adopted in PrAISED 2 - as opposed to Treatment As Usual (TAU) (i.e. standard brief falls assessment and advice).
- Qualitative interviews with the intervention group participants' therapists (i.e. occupational therapist, physiotherapist and rehabilitation support worker) in a group format for each multidisciplinary team working on a single case. This methodology is ideal, as the PrAISED 2 intervention is dependent on the synergetic work of therapists. Where practicalities and logistics do not allow for therapists to meet in a group, individual interviews with the lead therapist will be carried out.

The topic guide for the qualitative interviews is informed by the *PHYT in dementia* (PHYsical activity behaviour change Theory in dementia), whose development work we reported elsewhere [31]. In brief, the *PHYT in dementia* identified a set of variables (mechanisms and contextual factors), which mediate intervention outcomes: Autonomy/control/independence, motivation, self-efficacy, capability, expectations, personal beliefs, support, personal and intervention characteristics (for operational definitions and the relevance of these constructs in PrAISED 2, see Appendix 2). For each of these variables, we developed several prompts to stimulate discussion. We excluded two constructs, because their data are gathered during the main study trial:

- *'Capability'* (i.e. the actual knowledge and skills that participants have to take part in PrAISED 2, as opposed to self-efficacy, which is about perception of one's capability), which includes physical capacity (e.g. frailty, mobility, muscle strength, balance) and cognitive impairment.
- *'Personal characteristics'* that may affect successful involvement in the programme, such as sociodemographics, medical history and medications, and history of mental health problems.

We developed different interview schedules for the three different participants' groups: Participants with dementia (Appendix 3), carers (Appendix 4) and therapists (Appendix 5). The development of the interview schedule was carried out as a collaborative effort between the research team and the Patient and Public Involvement (PPI) members for PrAISED 2. The input of the PPI members was crucial to ensure that the interview prompts were relevant and meaningful to participants and that the language and format of the prompts, were accessible for the participants.

The questions should be regarded only as general guideline for the interviews. Some answers may be anticipated earlier in the discussion and others may turn out to be not relevant. The interviewee may also raise additional topics and issues which they feel are particularly relevant and these will be followed up in the discussion. Therefore, a flexible approach will be adopted during the interviews, which will be oriented to the responses of the participants.

Similarly, the questions may be subject to change if the participants with dementia and the carer are interviewed as a dyad, in which case a selection of questions from the interview schedule for participants with dementia and for the carers will be made, or if the therapists are interviewed individually, in which case the schedule will reflect the one-on-one interview format.

In line with MRC guidelines [24], the prompts are broad in scope, to ensure that the participants feel free to express their ideas without being constrained by pre-set questions and to gather insights into unanticipated causal processes and consequences. The prompts are applicable to participants at the two different time points of data collection and they can be used for participants who have different degrees of adherence to the programme (i.e. for participants with dementia, high adherers, low adherers, those who withdrew).

The qualitative interviews are expected to last around 40–60 minutes, depending on aspects such as participants' engagement in the process, their cognition on the day of the session and their level of personal insight around their involvement in PrAISED 2. They will be audio-recorded and transcribed in full to ensure that information is not missed in the process of data analysis.

2.2.3. Data analysis

Data will be analysed through framework analysis [32]. This method is ideal in social and health care qualitative research studies with large data sets, when a holistic perspective of findings requires the use of a systematic approach to data analysis. Framework analysis will

ensure in-depth exploration of data, in the presence of a transparent audit trail of the process of analysis [32].

Data analysis will follow the steps for good practice in Framework Analysis identified by Gale, Heath, Cameron, Rashid, and Redwood [33] as follows:

1 *Verbatim transcription* of the interviews by a professional transcriber, who will also anonymise data. Large margins and double line spacing in the transcripts will be left to create room for coding and note taking. Once transcripts are passed to the research team, the main researcher (CDL) will check that these are accurate and fully anonymised.
2 *Familiarisation with the transcript* by the main researcher, who will write down analytical notes on one margin of each transcript.
3 *Coding of a sample of three transcripts* by the main researcher, a second researcher within the research team and a member of the PPI group of PrAISED 2, who will independently underline relevant pieces of text and write coding labels for each on the left margin of the transcript. The coding labels reflect the constructs included in the topic guide. However, to prevent the omission of important data, if novel constructs emerge from the transcripts, new coding labels will be generated. The right margin will be used to annotate ideas.
4 *Development of a working analytical framework* through team work of the three independent raters, who will create a set of initial codes and provide operational definitions for each. Two more transcripts will be coded by two coders to check whether the initial working analytical framework is suitable. This iterative process will culminate in the identification of a stable set of codes, clustered into umbrella categories.
5 *Use of the working analytical framework* by the main researcher to code the whole set of transcripts. Double coding will be carried out by another researcher, who will code 10% of the set of transcripts. Inter-rater reliability will be calculated through the use of the Cohen's Kappa coefficient [34] and measured against the parameters set by Landis and Koch [35]: 0.81–1.00 = almost perfect; 0.61 – 0.80 = substantial; 0.41 – 0.60 = moderate; 0.21 – 0.40 = fair; 0.00 – 0.20 = slight; < 0.00 = poor. Relevant pieces of texts will be transferred into umbrella categories and codes created on the qualitative research software NVivo 12 [36].
6 *Charting of data into the framework matrix* by the main researcher on NVivo. The matrix will map out codes (one per column) and participants (one per row). The relevant quotes will be extrapolated from NVivo and transferred onto the corresponding cells in the matrix.
7 *Interpretation of data* by the main researcher, who will develop themes from the matrix by making connections within and between participants and categories. This will be an iterative process, with regular discussion and review with members of the research team. The final themes will be fed back to the research team and PPI members to reach consensus.

2.3. Mixed-methods data analysis

The mixed-methods data analysis will adopt a *Concurrent Triangulation Design* [37]. This approach prescribes that qualitative and quantitative data are analysed separately and then compared and/or combined. Among its several applications, triangulation is helpful expanding knowledge around a process or phenomenon through:

1 Supplementing qualitative findings through quantitative findings (and vice versa). In PrAISED 2, for example, quantitative data from implementation may find that fidelity rates (i.e. therapists delivering the intervention as they should) are lower among participants with frequent history of falls. The qualitative data may find that therapists have difficulties in delivering the intervention to participants with more severe cognitive impairment because the participants' carers fear that the physical activities may further expose the person they care for to the risk of falls.
2 *"Following a thread",* an approach whereby findings from the quantitative analysis can inform the generation of (further) qualitative analysis and vice versa [38]. In PrAISED 2, for example, the qualitative interviews with the participants with dementia who withdrew from the study may find that they felt that the intervention was not tailored to their own preference. It would be useful to "follow this thread", go back to implementation data and run a post-hoc analysis of the rating of the video-recordings of the therapists, to test whether they were scored as "*Visit not following core principle"* in the item *"Focused on tailored physical activity"*.

3. Discussion

This protocol outlines the rationale, design and methods for the process evaluation of the Promoting Activity, Independence and Stability in Early Dementia and Mild Cognitive Impairment (PrAISED 2) Randomised Controlled Trial. This protocol follows the MRC guidance for process evaluation of complex intervention [24], which aims to promote standardised reporting in process evaluations, so that results from similar studies can be compared.

We expect this process evaluation to be characterised by a number of strengths. Within PrAISED 2, results will contribute an explanation of the quantitative findings of the RCT: the factors mediating positive, negative or indeterminate effects of different components of the study. In the presence of negative outcomes from the RCT, for example, the process evaluation will represent an invaluable source of information to determine whether the intervention was inherently faulty (e.g. if the assumptions of the logic model were inaccurate), if there was implementation failure (e.g. how PrAISED 2 was delivered by the therapists) and / or if the issue was related to participants (e.g. poor motivation) or context-related factors (e.g. stigma around dementia). This exercise would be most helpful to reflect on and pick up failings and improve the intervention (e.g. to refine the logic model, if needed).

In the context of positive outcomes, the process evaluation will identify those core elements that made the intervention successful. For example, if it was determined that the emotional support of carer(s) was crucial in promoting participants' adherence to the intervention, these findings can represent transferable information for the development and implementation of future programmes aimed at promoting physical activity among people with dementia.

Another strength of the process evaluation is that the data will be collected through several different tools, including attendance logs, participants' calendars, qualitative interviews and video recording and from a diverse range of sources, such as therapists, participants with dementia and carers. This will allow us to capture a comprehensive amount of information and the full range of stakeholder perspectives. It will also enable some triangulation of quantitative and qualitative data, which will generate analytical depth and dialectic of learning.

This work also presents some implications in theory advancement. The process evaluation will be used to field-test the *PHYT in dementia*, the behaviour change theoretical model that our research team developed (Di Lorito et al., 2018). It will therefore present preliminary evidence as to the applicability of the model to promote physical activity among people with dementia.

Some of the limitations include the fact that the evaluating team will not be completely independent of the PrAISED 2 RCT, potentially generating assessors' bias. We will try to minimise this risk by reducing the involvement of the assessors in the main trial and by carrying out multiple raters' evaluations. Another limitation of this process evaluation is the presence of cohort effect. PrAISED 2 being delivered in a specific geographic location and in a specific point in time, the context, culture, views and practice of its participants and clinicians that emerge from the process evaluation may not necessarily be generalisable to different circumstances and valid in the future. Although PrAISED is a large trial, carried out in a number of different sites throughout

England, findings may not necessarily represent transferable information for researchers wishing to undertake similar research in different contexts.

Contributors

All the co-authors equally contributed to the development of the protocol of this process evaluation and have seen and approved the final version of the paper.

Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

The PrAISED 2 trial and process evaluation have received ethical approval number 18/YH/0059. The ISRCTN Registration Number for PrAISED 2 is 15320670.

Provenance and peer review

This article has undergone peer review.

Research data (data sharing and collaboration)

Individual participants' data may be used in the dissemination of findings, in which case they will be totally anonymised to safeguard participants' confidentiality. Research documents will be made available upon request. These include the data analysis plans, participants' information sheets and informed consent forms and study reports. These will be available following publication (no end date) to anyone who wishes to access the data. Requests to access the data should be directed to claudio.dilorito@nottingham.ac.uk.

Appendix 1 Rating form for video-recordings around fidelity check

Principle	Rater 1			Rater 2		
	Visit following core principle	*Visit partly following core principle*	*Visit not following core principle*	*Visit following core principle*	*Visit partly following core principle*	*Visit not following core principle*
Intensive						
Focused on tailored physical activity						
Challenging						
Progressive						
Promoting independence						
Improving independence						
Supporting activities of daily living						
Supporting dual tasking						
Accessing the environment						
Embracing positive risk taking						
Using motivational theories						
Assisting in habit formation						
Using tapering to promote self-management						
Promoting long-term engagement						

Appendix 2 Variables mediating intervention outcomes, their operational definition and how they apply in PrAISED 2

Construct	General operational definition	How it applies in PrAISED 2
Autonomy / control / independence	Being causal agents of one's behaviour	Degree of control and independence that participants feel they have over the intervention (development and implementation) and as a result of the intervention
Motivation	Processes that energise and direct behaviour	Degree of motivation that participants have during involvement in the programme, what motivates them, and what has a positive/negative impact on their motivation
Self-efficacy	Confidence in one's ability to execute a given behaviour	How confident the participants feel to carry out the activities of the programme, what makes them confident (or not) and what has an impact on their confidence level. Includes (perceived) physical, cognitive ability and competence
Capability	One's actual ability to perform a behaviour through essential knowledge and skills	Degree of (actual, as opposed to perceived) ability of participants to carry out the activities of the programme. Includes (actual) physical, cognitive ability and competence
Expectations	Outcomes or expectations around the behaviour	Participants' expectations around the programme. Includes goals, benefits, barriers and facilitators
Support	(Practical and emotional) support from others (e.g. carer, therapist, society) which affects behaviour	Support in place to help the participant take part in the programme. Includes practical support (e.g. instructions, information, and reminders), emotional support (e.g. therapeutic alliance, relatedness, and care) and environmental characteristics that may impinge on behaviour change.
Personal beliefs	Beliefs of the person which mediate behaviour	

		The self-regulated mechanisms that the participant uses in relation to initiation, adherence and withdrawal from the programme (e.g. personal views around dementia, risk and physical activity), and how they change as a result of involvement in the programme.
Personal characteristics	Personal characteristics which affect behaviour	Personal characteristics of the participant (e.g. personality, mental health, cognition, mobility, medications)
Characteristics of intervention	Characteristics of intervention which influence behaviour	Characteristics of intervention which influence participants' involvement in the programme. Includes how much the participant felt it is tailored to their needs, goal, preferences and aspirations, how helpful and enjoyable, how it fit into their routine.

Appendix 3 Interview schedule for participants with dementia

Pre-interview

- Researcher introduces himself and engages in small talk to break the ice with participant (e.g. give thanks for being invited over, gives compliments about the home, and asks how the person is doing on the day).
- Researcher explains his professional role and the purpose of the visit
- Researcher goes through the Information Sheet with the participant. The following will be clearly explained:
- The interview will be audio-recorded to have an accurate record of what was said
- Anything mentioned during the interview is confidential and no one except members of the PrAISED research team will know what was said
- In using any information in a report, the participant's anonymity will be maintained
- Participation is totally voluntary
- The participant can withdraw at any time and the research team can use the information collected thus far, unless the participant specifically withdraws consent for this.
- Researcher asks if participant has any concerns / questions / doubts.
- Researcher seeks informed consent
- Researcher asks participant if they are comfortable being interviewed alone or they prefer the presence of a carer during the process

Interview

• *General questions*

- Do you feel that being involved in the study has been beneficial?
- If so, what are the positive results of the activities?
- Have you experienced any negative effects of the activities?
- Do you think the programme has enabled you to enjoy more your daily activities?
- I would like to start by asking your views around exercise…

• *Personal beliefs*

- How important do you think being active is to help people stay healthy?
- How important do you think being active is to help people stay independent?

• *Motivation*

- Why did you decide to take part in the programme?
- Were you encouraged by anyone to take part or was it your own choice?
- What helps you keep going with the programme?
- On a scale from 1 to 10, how much do you feel you want to continue with the Activities, once the programme has finished?

• *Autonomy and control*

- Is it important for you to decide what you do or do you prefer to leave it to others?
- (If yes to previous question), how much have you been able to make those decisions?
- How could we make you feel more involved?

• *Intervention characteristics*

- Does the programme of physical activities suit your needs and preferences?
- What part of the programme of physical activities do you like the most?
- What part do you like the least and how could this be improved?

• *Self-efficacy and emotional support*

- Do you feel you are able to do the activities as well as you would expect?
- Do you have any concerns or anxiety about taking part in the programme/doing the activities?
- Did you receive encouragement and support from your therapist(s) and carer(s)?

- Is there anything that would help you feel more confident to do the activities?

• *Support (Practical)*

- Do the therapists give you practical support? For example, do they show you how to
- do the activities, when to do them and where to do them?
- Does your (carer role) give you practical support? For example, does he / she remind
- you how to do the activities, when to do them and where to do them?
- What could be done to better support you?

• *Independence*

- How has the study programme affected you? (e.g. on your health and activity)
- Has it given you greater independence?
- Have you noticed a change in your quality of life?
- Are there any activities you would like to be able to do that are not part of the programme?

• *Expectations*

- Have you any personal goals you would like to achieve from the study?
- If yes, what goals are you looking to gain?
- Do you think you can achieve these goals and do you need support to do this?

Final remarks

- Any final thoughts and feedback on the programme?
- Would you be happy to meet up again in three months' time to see how you are doing?

Appendix 4 Interview schedule for carer(s) of participant with dementia

Pre-interview

- Researcher introduces himself and asks participant to confirm that he / she is the participant's carer and how much he / she does for the person
- Researcher gives background information on the study, explains the purpose of the visit
- Researcher goes through the Information Sheet with the participant. The following will be clearly explained:
- The interview will be audio-recorded to have an accurate record of what was said
- Anything mentioned during the interview is confidential and no one except members of the PrAISED research team will know what was said
- In using any information in a report, the participant's anonymity will be maintained
- Participation is totally voluntary

The participant can withdraw at any time and the research team can use the information collected thus far, unless the participant specifically withdraws consent for this.

- Researcher asks if participant has any concerns / questions / doubts.
- Researcher seeks informed consent

Interview

1. General questions

1 How are you getting on with the programme of increased physical activities given to the person you care for?
2 Is the programme achieving your expectations?
3 What are your views on the programme? Do you think it is successful?
4 Can you describe the programme activities that (person you care for) is doing?
5 I would like to know more about your involvement in PrAISED and to ask you some questions.

• *Motivation*

- Could you tell me about why you decided to be involved in the research study and its activity programme?
- What had a positive impact on your involvement?
- What had a negative impact on your involvement?

• *Autonomy and control*

- Are you interested in being involved in the design of different aspects of the
- activity programme?

- (If happy to be involved), Do you feel that the therapists listened to you and
- worked with your suggestions when designing the activity programme?
- (If unhappy to be involved), do you think that the therapists' expected too much of you? In what way?

• *Self-efficacy*

- Do you give (person you care for) practical support with their physical activities (e.g. how, when, what)?
- (If yes), Do you feel confident doing this?
- Are there any ways you could be better supported to carry out your activities of daily living?

• *Independence*

- How has the study programme affected you? (e.g. on your health and activity)
- Have you noticed a change in your quality of life?

• *Expectations*

- How did you feel about (Person you care for) taking part in PrAISED?
- Did you have any thoughts about what might be achieved?
- What do you think the effects have been?
- Was there anything that made it difficult for (Person you care for) to carry out the programme activities?
- Was there anything that helped (Person you care for) carry out the programme activities?

• *Support (Practical and emotional)*

- Did you have any support which enabled you to be involved in the programme?
- How well did the therapists explain how the programme worked and how to support the person you care for when taking the programme of exercises and activities in the PrAISED study?
- Do you think you could have been better supported and have you had any thoughts on how we could do this?

• *Personal beliefs*

- What are your views around physical activity (e.g. benefits, challenges, risks) in dementia?
- Did your views change during the programme?
- Do you plan to continue with the programme of activities with the person you care for, after the study has ended?

• *Intervention characteristics*

- Has (person you care for) taking part in PrAISED had any impact on you? (e.g. increased, decreased, same level of care or other aspects)?
- Were there parts of the programme that you liked? Could you tell me why?
- Were there some you disliked? I would value knowing what these are and if you have any suggestions for change.

Final remarks

- We would value any further thoughts and comments that you would like to make. These are an important contribution to our evaluation of the study.
- Would you be happy to meet up again in three months' time for further feedback?

Appendix 5 Interview schedule for therapists

Pre-interview

- Researcher introduces himself and asks participant to introduce themselves and explain their professional experience with dementia
- Researcher explains the purpose of the interview and answers any questions / doubts the participant might have
- Researcher seeks informed consent from participant(s), explains that the session is going to be digitally audio-recorded and emphasises that involvement is totally confidential and voluntary and that the participant(s) may withdraw at any time, if they wish so.

Interview

1. General questions

1 What is your understanding of PrAISED?
2 Can you explain your experiences of the programme so far?
3 What are your views on the programme's effectiveness?
4 I would like to start by asking around your views on physical activity (for physiotherapist), on activities of daily living (for Occupational Therapist and support worker)…

• *Personal beliefs*

- Do you feel that your views have altered since taking part in PrAISED?

• *Motivation*

- Why did you get involved in the programme?
- What aspects of the training and delivery of PrAISED have a positive impact on your motivation?
- What aspects of the training and delivery of PrAISED have a negative impact on your motivation?
- Is there anything that could be done to increase/maintain your motivation to continue using the programme?

• *Expectations*

- What expectations do you have of your role in PrAISED?
- Have your expectations been fulfilled?
- What are your professional goals in PrAISED?
- Did you anticipate any barriers to delivering the programme? Can you explain these?
- Did you anticipate any facilitators to delivering the programme? Can you explain these?
- Did you anticipate that the intervention would improve the quality of life of the participants and their carers?

• *Autonomy and control*

- How do you tailor the programme of activities to the individual participants?
- Did you have as much input as you would like in tailoring PrAISED for individual patients?
- To what extent do you feel that your input as an experienced therapist is valued by patients / carers?

• *Self-efficacy*

- How competent in your professional role do you feel, to deliver the intervention?
- What could be improved in the training to boost your confidence to deliver the intervention?

• *Support (Practical and emotional)*

- How supportive is the PrAISED team?
- How supportive is your clinical team?
- How do you find the training you received in PrAISED (e.g. initial training, ongoing support)?
- How collaborative do you feel that the person with dementia and their carer are?
- What could be done to make you feel better supported whilst involved in PrAISED?

• *Intervention characteristics*

- How much do you feel that the intervention fits into your aspirations and professional development as a therapist?
- Are there any aspects of the programme that you like, or which you think work effectively?
- Are there any aspects of the programme that you do not like, or which do not work effectively?
- How could the programme be improved?
- How does your involvement in PrAISED fit into your working routine? Do you feel overburdened as a result of taking part?

Final remarks

- Any final thoughts on the programme?
- Would you be happy to meet up again in three months' time for further feedback?

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