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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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# PrAISED Checkpoint Report

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**Promoting Activity, Independence and Stability in Early Dementia (PrAISED)**
**Checkpoint Report**
RP-PG-0614-20007

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**Summary**
We have made excellent progress towards our programme aims, and have achieved all our milestones and targets on time. Our three key feasibility goals – establishing if we could recruit and randomise, deliver the intervention and collect data – have been met.

A practical manualised therapy intervention has been developed. Recruitment to a 3-arm feasibility randomised controlled trial (RCT) of 60 participants across two sites was completed on target. The two active intervention arms compare different levels of therapy supervision. The intervention is being successfully delivered at each site. Follow-up is ongoing (9/18 months complete at June 2017). Work on motivation and adherence, the process and economic evaluations, are on-going.

We have described a process to determine the (single) intervention we will test in the main (2-arm) trial. We have revised the draft protocol for the main trial. We have demonstrated our ability to run a successful and useful trial. We can recruit the patients (P), and deliver an individualised, evidence-based, plausible, feasible, and acceptable intervention (I), we know that the control situation is different from the intervention (C), and we can measure outcomes (O).

**Introduction**
The *NHS Five Year Forward View* (2014) and its '*Next Steps*' revision (2017) emphasise the importance of prevention to make NHS services sustainable – an 'invest to save' strategy. The Executive Summary of the '*Next Steps*' states 'As people live longer lives, the NHS needs to adapt to their needs, helping frail and older people stay healthy and independent' (p. 4) and 'We will also continue to maintain focus on diagnosis and post-diagnostic support for people with dementia and their carers. These are key drivers to keeping in their own homes, preventing crises and avoiding unnecessary admission to hospital' (p45). Such programmes need to be acceptable, accessible, effective, affordable, resource efficient and cost-effective or cost-saving (i.e., competitive with other potential calls on NHS staff and resources). This requires rigorous development, and clinical and economic evaluation.

The PrAISED programme seeks to develop and evaluate an innovative therapy intervention that aims to increase activity and independence whilst reducing falls in people with early dementia. The intervention draws on theoretical, empirical and practical expertise, targeting important outcomes, and addressing motivation and adherence. Following literature reviews and consultation with patients and public contributors, practitioners and experts, and an empirical proof of concept study, we designed an exercise-based intervention, and have conducted a feasibility and practicality trial. This serves both to test the practical aspects of delivering the intervention, and to provide evidence needed to undertake a successful large scale trial. The intervention is 'complex' with multiple interdependent parts, and our study follows the MRC complex intervention development and evaluation guidance (2008). These describe an iterative approach.

In this report, we detail the progress we have made over the first 15 months of the programme. We report in detail on feasibility trial outcomes; delivery of the intervention in practice, what we have learnt and what we propose to change for the main trial; the methods for finalising the intervention for the main trial; the progress of each of the work packages; how we have included PPI at every stage of the research process; our progress against milestones and study governance.

**Summary of work undertaken**

The programme is subdivided into seven work packages (WPs), of which six have commenced (WP5 is the main RCT). Progress on each of these is described in Appendix 1. As planned, these are at different stage of completion.

WP1 comprises intervention development. We have undertaken considerable work preceding the Programme, since 2012, with the support of an NIHR Programme Development Grant, and an Alzheimer's Society PhD fellowship (to Vicky Booth, 2014-7). The first six months of the PrAISED Programme included work developing activity analysis and risk enablement approaches, integrating this with exercise components and the adherence and motivation work, writing a therapy manual, developing and delivering training for clinicians and support workers who would deliver the intervention, providing on-going support to therapists, and filming video 'podcasts' of exercises.

WP2 is work to understand and promote motivation and adherence to the therapy intervention. We recruited an exercise psychologist, Dr Jennie Hancox, undertook a literature review, focus groups and interviews with people with dementia and their family members, and therapists. We are applying a battery of measures of motivation and psychological needs in the feasibility trial.

WP3 is a three-arm, randomised, controlled, feasibility trial (RCT), supported by NWORTH Bangor Clinical Trials Unit (CTU). The main objectives were to test the practicability of the therapy intervention, and to answer trial feasibility questions. We recruited 60 participants from memory clinics and the NIHR Join Dementia Research register. They were randomised to three groups (minimised on three variables: site, history of falls and living alone): a high-intensity supervision group (about 50 therapist visits over one year), a moderate-intensity supervision group (eleven visits over three months) and a control group (basic falls assessment). Baseline data were collected, follow-up is ongoing. Data management and statistical analysis plans have been written. The primary effectiveness outcome is limitation in activities of daily living, using the Disability Assessment for Dementia, DAD. Falls and activity undertaken are ascertained by calendar, with monthly telephone prompts to return the calendar.

WP4 is a process evaluation, comprising therapy and activity logs, interviews with participants (including of those who withdraw, if willing) and therapists, and videos of therapy sessions for analysis.

WP6 is an economic evaluation. Preliminary work has scoped appropriate methods, including Markov modelling and Social Return on Investment analyses. Collaboration with the NIHR VALID Programme has been established (Prof Steve Morris at University College London).

WP7 comprises work on implementation and dissemination.

**Achievements in feasibility RCT**

<u>Continuation criteria</u>

In the protocol we set discontinuation criteria to be applied if irremediable problems were encountered. These have all been satisfactorily surpassed.

i. recruitment (<2.5 participants per week across two feasibility sites)
ii. retention (<77%)
iii. intervention set up at sites
iv. data collection including falls ascertainment (>20% missing primary outcome).

Recruitment and retention

We recruited 24 participants from Derby and 36 participants from Nottingham, over 26 weeks, with the help of the Clinical Research Network Division 4. 42 were recruited from memory clinics, 18 from the NIHR Join Dementia Research register. N=19, 21 and 20 were randomised to each of the three trial arms. We have had nine (15%) withdrawals across all arms, five complete and four partial.

Intervention delivery

Agreements were made with Nottinghamshire Healthcare NHS Foundation Trust and Derbyshire Healthcare NHS Foundation Trust (both mental health trusts) to deliver the intervention via their Allied Health Professional departments. Excess treatment costs were agreed with Nottingham City, Nottinghamshire County and combined Derbyshire CCGs. Four training sessions for therapists and rehabilitation support workers were delivered, and a real-time, on-line support system for therapists established (using the University's e-learning platform, Moodle). 81% of scheduled therapy sessions were delivered. We have sought informal feedback on intervention delivery, in the form of site reports (Appendix 1). Formal investigation of intervention delivery is being undertaken as part of the process evaluation.

Data collection (Statistical report appendix 4)

Baseline data were collected on the 60 feasibility RCT participants. We report missing data by scale (i.e. any missing item means that the scale is not complete; for the feasibility trial we did not use imputation). These data are preliminary, have not yet been fully checked, and are likely to be over-estimates of missing data.

Unfortunately six participants were recruited without an informant, with the consequence that that primary outcome measure (DAD) could not be completed. Eligibility criteria were ambiguous, which was a learning point. Two further participants did not complete all items on the DAD scale, a total of 13% missing, or 4% excluding those recruited without an informant.

88% of monthly falls calendars have been returned. Missing data rates on other scales were: 5% on the self-reported Nottingham extended ADL scale; 2% on EQ5D; zero on Demqol; 12% Demqol-proxy; 5% Incidental and Planned Activity Questionnaire, IPAQ; 8-20% of CANTAB cognitive subscales (we had problems with the tablet computers used in administration); 7% frailty score; 12% Berg Balance Scale; 3% falls efficacy scale; 22% on pedometers (various problems including resetting); zero on Mini-Mental State Examination; 2-7% on anxiety and depression; 2% on verbal fluency; 25% on carer strain; and 20-40% on psychological needs scales.

There was good balance between the randomisation groups on most variables, especially the stratifying variables. Mean age was 74 vs 76 vs 76; mean DAD score was 79 vs 79 vs 75; mean cognitive score (MMSE) was 25 vs 26 vs 26; mean quality of life (Demqol) was 89 vs 87 vs 87; mean

Berg Balance Score was 52 vs 47 vs 50; fear of falling (FESI) 24 vs 29 vs 25. A gender imbalance was noted (63% vs 38% vs 70% female), and mean activity scores (IPAQ) were 2325 vs 1187 vs 1262.

Learning from the feasibility RCT

In the protocol we described frameworks for learning from the feasibility trial and progression to the main trial, including the ADePT protocol [Bugge 2013]. We stated that we would change plans and procedures in the light of findings and experience.

Shanyinde's (2011) 14-point methodology checklist supports the systematic identification and appraisal of the evidence of strengths and problems arising out of a feasibility RCT (Appendix 2, table 1). This identified no problems with:

- recruitment
- data for sample size calculation
- patients' willingness to consent
- randomisation processes
- calculation of intervention costs
- logistics of running the study.

We are still studying acceptability of the intervention, adherence, and retention, but the evidence to date is favourable, based on therapy logs, the self-reported activity calendar, therapist feedback, withdrawal rate, and process evaluation interviews.

We identified the following issues that will be addressed in the main trial:

- some participants (6/60) were recruited without an informant, making it impossible to complete the primary outcome (DAD) and some other measures; the eligibility criteria for participants for the main trial will be clarified accordingly;
- the duration of baseline assessment visits was long and potentially burdensome;
- maintaining blinding of research assistants to treatment allocation, for the purposes of unbiased outcome assessment, was difficult. In particular, the research assistant collecting monthly data by telephone is inevitably unblinded. We propose employing an additional research assistant to enable separation of staff who are and are not blinded to allocation;
- some therapists have noted a lack of experience in setting appropriate goals and plans for 'high functioning' individuals;
- a few therapists refused consent to be video-recorded for the process evaluation

Thabane et al (2010) proposed four purposes of pilot work:

1) Process – trial-related issues such as recruitment and retention
2) Resources – time and budget issues, questionnaire completion time
3) Management – staffing, data management
4) Scientific – safety, dose, estimate of treatment effect and variance.

Through this process (Appendix 2, table 2) we identified that:

- there were some rectifiable problems with missing data;
- the time it took to complete the questionnaires was long and potentially burdensome

- capacity for making follow-up telephone calls was a problem, particularly alongside the need to maintain blinding to treatment allocation;
- recruitment and data collection are labour intensive;
- we must make adjustments to the MACRO database to ensure missing data are correctly classified
- co-ordination of service delivery and accounting for time for documentation and collaboration between therapists is challenging.

In the feasibility trial protocol, we identified a further study-specific feasibility question: *Can we develop and implement a successful and safe therapist and rehabilitation support worker training programme?*

Training has been successfully delivered, and real-time support system instituted. However, a need for greater 'clinical supervision' for rehabilitation support workers by registered allied health professionals has been identified.

Changes for main trial

The ADePT criteria (Bugge 2013) set out responses to a feasibility trial in the protocol for a definitive trial. We have used literature searching, expertise within the research group, advice from Patient and Public representatives and the Programme Steering Committee, and analysis of feasibility data to arrive at solutions to the identified problems.

Our response to feasibility issues are detailed in Appendix 2, table 3. In summary, we will:

i) make having an informant an inclusion criterion to ensure complete and accurate data collection
ii) reduce the number of scales and questionnaires used at baseline and follow-up to reduce participant burden.
iii) improve the training of researchers to minimise missing data (especially of the primary outcome measure)
iv) refine the MACRO data entry software to enable better identification and explanation of missing data
v) adapt our therapist training to include how to work with 'higher functioning' individuals
vi) seek additional resources to have an 'unblinded' research assistant to assist with real-time telephone data collection.
vii) write into the employment contract that therapists will be monitored (including video recording) as part of process evaluation.

Success in a feasibility trial is defined by meeting feasibility objectives. We have provided systematic evidence that we have met these objectives, and can successfully deliver the therapy intervention and a randomised controlled trial. We have identified improvements and remediable problems, which will be rectified by modifications to the therapy programme and trial protocol. We propose that we continue on to the main trial with appropriate modifications.

**Process to finalise the intervention for the main trial**

We stated that we will derive criteria to decide between the different levels of supervision for the intervention based on data which will be available in April 2018:

i. reported adherence and exercise achieved
ii. acceptability (judged from questionnaire and interviews; WP4 process evaluation 'mechanisms of impact' interviews)
iii. activity levels (Incidental and Planned Activity Questionnaire and pedometer)
iv. changes in the Berg Balance Scale score and Timed Up and Go (TUG) test
v. changes in fitness judged by post-TUG test pulse rate.

This section describes the process to determine the therapy intervention for the main RCT starting in September 2018. We will use experiences from delivering the intervention to refine the intervention, its implementation and clinician training.

The therapy intervention has already undergone extensive development (Appendix 3). The feasibility RCT tests two levels of supervision for the core therapy content (moderate- and high-intensity supervision). The therapy is exercise-based, focussing on strength and balance, which both helps prevent falls and enhances executive cognitive function. We include training in 'dual tasking'; 'dual task cost' (a deterioration in function when doing two things at once) is an important and potentially reversible deficit commonly found in early dementia and mild cognitive impairment, which is strongly associated with risk of falling. This is integrated with assessment and advice on everyday activities, aiming to restore or maintain functional ability, and manage risk. Our preliminary research indicated that the focus on maintaining activity and independence is important to maximise uptake [Peach 2017]. Alongside the feasibility RCT, we are using mixed research methods to study motivation and adherence to the therapy programme, including level of professional supervision, tailoring, goal setting, communication style, carer engagement, and the use of prompts, workbooks and video demonstration. We aim to help participants become independent in undertaking the programme in the longer term, alone or with carer or video prompting.

The therapy intervention tested in the feasibility RCT was based on evidence from literature reviews (Booth et al., 2016; Kearney et al., 2013; Sherrington et al., 2008; Van der Wardt et al, 2017), empirical evidence from the programme development study (Van der Wardt et al, 2015; Hood et al., 2014; Gondek et al., 2014; Peach et al., 2017), the work of a doctoral student (Booth, 2017) and development work at the start of the PrAISED research programme. We included evidence from patient, carer and practitioner focus groups, workshops and interviews with clinicians, and advice from psychologists. The synthesis of the evidence is currently being prepared for publication (Booth et al., in preparation, draft at appendix 3). A logic model has been developed to show the key components categorised into inputs, activities, outputs, outcomes and impacts (see appendix 3).

There is little evidence regarding the necessary intensity of supervision to effectively deliver and sustain the intervention. The feasibility RCT studies two different intensities. These were based on previous work with people with dementia, a successful Finnish RCT, FINALEX, which provided two professional visits per week for a year (which maintained ability in activities of daily living, and reduced falls, compared with group exercise and treatment as usual control; Pitkala et al 2013), and an ongoing Australian study, iFOCUS (Wesson 2013, Close 2014)

Preliminary findings from clinician feedback and participant interviews in the feasibility RCT suggest that we need to be able to specify explicitly how tailoring of the intervention to the individual and their circumstances will work. Many participants will not require intensive supervision to achieve the necessary 'dose' of three hours of exercise a week. We will develop a protocol for tailoring the intervention, which will provide a clear stratification process for participants into different intensities of support required. Variables that might be used for tailoring include: health and co-morbidities, abilities and disabilities, interests, whether there is a co-resident carer, carer strain, social commitments, previous exercise habits and habitual levels of activity, motivational factors and initial uptake of the exercise programme. The process evaluation and outcome data on which the tailoring protocol will be based is ongoing, with results available by April 2018.

The MRC guidelines for developing complex interventions (MRC, 2006), and subsequent publications describe processes for intervention development (such as Intervention Mapping [Hurley 2016] and 6SQID [Wight 2015]). An iterative intervention mapping process will be used to include the new information and adapt the logic model, programme outcomes and objectives, the programme design and production, the programme implementation plan as well as the evaluation plan (Bartholomew et al., 2016). For each of the intervention mapping steps a convergence matrix (Farmer et al., 2006) will be used to explore areas of agreement, partial agreement, disagreement and 'silence' (absence of information). Emerging evidence from the feasibility study will be added to the previous evidence for the two levels of supervision used in the feasibility study.

Anticipated information contributing to the intervention finalisation process will be drawn from:

1. Participant interviews - interviews with participants and carers explore acceptability of the intervention, motivation to complete exercises and to participate in physical activities, carer involvement and mechanisms of changes in health behaviours.

2. Clinician focus groups and interviews - these will explore the facilitators and barriers for the intervention delivery, core components for an effective intervention, data on how to undertake and document 'tailoring', and requirements for successful implementation from the perspective of the clinicians.

3. Video recordings of intervention sessions - video recordings will investigate the fidelity of the intervention delivery as well as the communication between participants (and carers if applicable) and clinicians.

4. Participant activity calendars - participants record their PrAISED exercises as well as other physical activity on the calendars. The information will indicate which treatment group shows a higher level of self-directed physical activity.

5. Pedometer data - pedometer data is collected at 0, 26 and 50 weeks and will indicate if there is a difference in physical activity between groups.

6. Physical performance measures (leg and hand grip dynamometry, Timed Up and Go test), 'intermediate outcomes' which indicate the size of change achieved

7. Motivation and psychological needs questionnaires, including Self-Report Habit Index (SRHI) data collected by telephone, and psychological needs and exercise regulation scales collected at baseline and after 12 months. The SRHI will show if there is a difference between groups in terms of developing an exercise routine.

The timeline for development of the final intervention will be:

1. Intervention mapping identifying gaps in the evidence and developing a tailoring protocol for the intervention will be completed by end September 2017. We expect that we will have sufficient evidence from the feasibility trial on which to make a decision about most, if not all, unresolved questions. The results of the intervention mapping process will be presented to the co-applicants at a Programme Management Group in October 2017.

2. If further evidence gaps are identified, an internal working group will meet to prepare a series of questions on the intervention for an external expert group to consider.

3. We will present to the Programme Steering Committee in November 2017: our intervention mapping results, our conclusions on whether there are gaps in the evidence and if there are gaps, the questions to be presented to an external expert group. The PSC will provide external validation on the decisions we have made.

4. We will convene a group of about ten clinicians and researchers from different disciplines, experienced in working with people with dementia, to challenge proposals and discuss outstanding questions. The expert panel will include occupational therapists, physiotherapists, old age psychiatrists, GPs, geriatricians, exercise experts, and PPI representatives. If necessary, we will conduct a Delphi study (Diamond et al., 2014 or Delp et al 1977) to get consensus on the components of the intervention which have an insufficient evidence base. The questions developed by the research team and validated by the PSC will be sent to the expert panel to achieve a consensus of 70% or more. Each round will ask for reasons of judgement and a maximum of three rounds will be completed. If needed, the Delphi study will be conducted between January and March 2018. The PSC's view was that the Delphi study was unlikely to be required.

5. At the end of this process, if any questions remain without consensus, the research group will decide the course of action based on all available evidence.

6. The final intervention will be described using the TIDieR guidelines (Hoffmann et al., 2014) in June 2018. The clinician training and intervention manual will be adapted accordingly in July 2018.

*Tailoring*

Tailoring of the intervention is likely to be an important feature for the following reasons:

1. Clinical. Older people with dementia will have a variety of problems, co-morbidities, capabilities and disabilities, due to dementia and other conditions associated with advancing age, and general

level of fitness. They may suffer intercurrent acute illness or injury and therefore clinical presentation may vary over the course of an intervention programme.

2. Complexity. The intervention is complex (MRC, 2008) with multiple components that can be prescribed or included at different levels. Tailoring can accommodate the variance in clinical presentation as well as the variance in intervention content, allowing for progression and change over time.

3. Choice. A primarily preventative intervention will succeed better if it is enjoyable or valued. Older people vary in their previous and recent experience of exercise, their interests, needs and goals. Competing social, leisure or domestic priorities may prevent engagement or consistent participation.

4. Inclusion. To be accessible to as wide a range of people as possible, an intervention must take account of different social situations (including living alone), sensory impairment (vision, hearing), and stigma (or perceived stigma).

5. Adherence. An exercise intervention will not be effective if it is not undertaken. Tailoring to these and other factors has been identified as a successful way to promote uptake and adherence. Some people may develop a routine or habit rapidly, and may be sufficiently prompted by written, photographic or video materials. However, everyone is different and an approach that embraces and accommodates those differences will encourage participation and ensure the RCT is looking at the effectiveness of the intervention, rather than being dominated by adherence to it.

6. Efficiency. Intensive supervision is labour-intensive and costly. It may be justified if the intervention is effective at delivering health gain cost-effectively, but will represent a scarce resource that should only be deployed when needed. Tailoring is a tool that will ensure the correct, most efficient, and ultimately cost-effective, level of supervision is provided.

Understanding tailoring, and how to use it in clinical practice, is a key part of the motivation and adherence work package. 'Tailoring' might also be called 'individualisation' in standard rehabilitation practice, and is also an important feature of person-centred dementia care. Work done during the feasibility RCT will allow us to work out the rules and processes required to provide the right level of supervision for each individual. In rehabilitation, 'progressive' refers to exercises which become harder over time, and 'shaping' refers to exercises that become more intricate over time. Supervision is needed to encourage progression and shaping as well as to support adherence. This reflects a further dimension of tailoring.

We present two case studies illustrating how tailoring might work. Both participants took part in the moderate-intensity supervision arm of the feasibility RCT. In case study 1, the participant lives with his wife, used to enjoy activities and exercise and appears motivated to start exercising again. It is likely that this participant would continue to undertake the programme independently. In case study 2 the participant lives with her husband, who suffers considerable carer-strain. She has no activities that they used to enjoy and appears to have low self-efficacy. Such a participant is likely to require a higher level of supervision.

<u>Case study 1</u>

William (not his real name) is aged 74 years of age and in the early stages of dementia. He lives with his wife, Jane, and two dogs. They have a daughter who lives nearby. Prior to engagement in the

programme both William and Jane had been struggling with depression. William also had arthritis in his left knee and his daily activities had decreased following being diagnosed with dementia. He was randomised to the moderate group and received 14 contacts from clinicians (six Occupational therapy/O T, five physiotherapy/PT face-to-face, plus three phone calls). Following assessment by the physiotherapist, William was given a set of individually tailored exercises. He had also recently purchased an exercise bicycle and was keen to use it regularly. Over the course of the intervention the clinicians worked with William to help him perform the exercises and use his exercise bike on a daily basis. They also discussed William's activities of daily living and came up with practical strategies to help him to continue to do what he wanted to do. For example, William enjoys walking the dog independently every morning. This is something that is important to him but both William and his wife were concerned about him getting lost when out and about on his own. The clinicians encouraged William to type up the two circular walking routes that he uses. Both William and his wife have a copy and before going out on his walk each morning William tells his wife which walk he is doing. As part of the programme he has also learnt to use a mobile phone so that he can call his wife or daughter if he gets lost. William and his wife were interviewed one month following the end of the intervention. William reported feeling confident doing the exercises and that he does them every day for 30-45 mins. He also spends 30 minutes every evening on his exercise bike. He said that he is really enjoying doing the exercises and feels that they are now a way of life and part of his daily routine. Within the four month period William reported a variety of physical and psychological benefits including: improved balance and no longer needing a knee support or pain relief, improved mood, and lower levels of stress. His wife also explained that she feels happier knowing that he's safer.

Case study 2

Carole is 71 years old and has a diagnosis of dementia. She lives with her husband, George, and has a daughter and son who live nearby. Carole was randomised to the moderate group and received 14 contacts from clinicians (six OT, five PT face-to-face, plus three phone calls). She has poor vision in one eye and as a result has difficulty judging distances and walking in a straight line. Following a physiotherapy assessment, Carole was given a set of individually tailored exercises to help address these issues. Due to her memory problems and fear of falling she is unable to perform the exercises independently. Carole and George were interviewed one month following the end of the intervention. George explained that although he has been trying to help his wife do the exercises, they have not yet managed to get into a regular routine of doing them. He also feels that he is not able to challenge and support his wife to the same level that the physiotherapist was able to. He expressed that further visits from the physiotherapist would be of great benefit to both his wife and himself. An assessment by the OT revealed that Carole has always loved reading and doing puzzles but due to her memory problems is no longer able to. Joint discussion led to Carole trying reading short poems and doing word searches which reported in the interview to have enjoyed doing. The OT assessment also identified that Carole has trouble locating items within her house. To help Carole find things more easily picture labels of the contents of each cupboard were put up with the house. However, Carol's husband reported that the picture labels have not helped much. Further visits with the participant would have enabled the OT to try out other possible memory support strategies with Carole.

*Intervention finalisation summary*
We have developed a thorough and transparent process to refine the intervention based on the research evidence, expert and service user opinion. We have presented evidence that tailoring of the intervention is possible and a framework for developing a tailoring protocol

**Additional resources required**
We will request a contract variation to seek funding for an additional one whole time equivalent research assistant to be based in Nottingham, to undertake monthly follow up telephone calls, in order to maintain blinding. We require this from months 30 to 60; approximate total cost, including on-costs, will be £98000

**Governance**
A Programme Management Group, comprising the co-applicants and key members of research staff has met monthly.

Research Ethics Committee approval was gained for all aspects of the study apart from the main trial on 16-3-2016. Four substantive and one non-substantial amendments have been requested and granted. Health research Authority approval and site capacity and capability agreement has been gained.

We constituted a Programme Steering Committee, chair Prof Steve Iliffe, which has met on three occasions. We constituted an independent Data Monitoring Committee, chair Dr Jonathan Treml, which has met on twice. Data Management, and statistical analysis plans have been written for the feasibility trial and approved.

Both committees complimented the study team on progress, in particularly recruitment on time. Progress, problems and ideas have been discussed, including the approval of substantial amendments and the request for additional resources. The PSC endorsed the Checkpoint Report, including the approach to finalising the therapy intervention.

**Milestones**
In the application and protocol the milestones for the first 24 months were as follows:

*Months–6 to 0*; Recruitment to posts; ethics; R&D approval **ACHIEVED**

*Months 0-6*: finalise high-intensity and moderate-intensity interventions; consensus conference and Delphi process; finalise assessment tools; database construction, commissioning and validation of randomisation and data capture systems, staff training for data entry. Recruit and train research assistants and rehabilitation support workers for feasibility study. Site set up. **ACHIEVED**

Deliverable: Trial intervention manual. Feasibility study protocol. Database. **ACHIEVED**

*Months 6-12*: Recruitment to multi-centred feasibility trial (n=60); **ACHIEVED**

*Month 18:* Deliverable: interim report, confirmation of recruitment rate; intervention delivery

**ACHIEVED**
*Months 18-24*: Feasibility study 12 months follow-up. **TO COMMENCE AS PLANNED SEPT 2017**

*Months 0-42*: Optimising uptake and adherence study. **ONGOING**

*Months 6-66*: Process evaluation. **ONGOING**

By *Month 30*: Deliverables: Final trial intervention protocol and manual. Main trial final protocol. Trial protocol paper. Report on adherence and sustainability support. **PROTOCOL PAPER SUBMITTED. DRAFT TRIAL PROTOCOL UPDATED.**

**Patient and Public Involvement**

We are proud of our excellent PPI and believe we have followed the true spirit of PPI in the PrAISED programme, actively included PPI at every stage of the research process. This has helped us make our intervention and our research procedures acceptable to patients and their carers.

Maureen Godfrey (MG) and Marianne Dunlop (MD) are members of the PMG and actively contribute to all discussions about the study. MG is a named co-applicant on the programme. She has worked with the team for six years and has contributed from the initial idea for the research. MD joined the team a year ago. MG and MD bring experience of the dementia carer's role both through their family involvement and their respective previous careers within social services and the NHS. MG and MD are embedded in every work package, bringing their lived experience as carers to the programme. Scott Smith (Alzheimer's Society) is also a member of the PMG. PPI is a standing item on the agenda.

We have two PPI members on the PSC – Peter Riley (a monitor for the Alzheimer's Society and former carer of his wife who had dementia) and Pippa Foster (regional manager Alzheimer's Society).

Our PPI co-applicant MG reviewed all patient-facing documentation and lay summaries prior to submitting the documentation to ethics. She accompanied the chief investigator and programme manager to the REC meeting on 16th February 2016. MG, MD and SS reviewed and proposed changes to the PrAISED logo and strapline.

The training intervention was developed in collaboration with PPI members. MG was actively involved in the intervention development meetings and focus groups. In order to produce material that was sensitive to the participant and carers needs, MG and her husband, both aged 70, modelled for photographs in their home and garden showing the PrAISED exercises and occupational therapy tasks. These have been used for leaflets, worksheets and promotional posters as well as clinical training, and have been received very positively. Similarly using MG's home, both she and MD, from their lived experiences, role played the participant and carer in order to allow the clinicians to trial their programme in a realistic setting. Again this was an interactive process where their comments were adopted by the therapists. All patient leaflets used in the intervention have been reviewed by MG and MD. MG has recently been filmed doing the PrAISED exercises to provide further resources for therapists and patient participants.

MD has experience of senior health care management, and was a member of a recruitment panel for several PrAISED clinical posts. MD and MG have also assisted with training sessions for staff bringing to them the carers perspective and have recently made a pod cast about the study and their shared roles. We have written an article promoting PPI, using PrAISED as reference.

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**APPENDICES**

Please note, appendices are only available on request from van der Wardt, V.
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**Appendix 1:** Reports from the workpackages, site therapy delivery report

**Appendix 2:** Tables of responses to feasibility questions

**Appendix 3:** Draft intervention development paper, Logic model

**Appendix 4:** Statistical analysis report

**Appendix 5:** Draft main trial protocol

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