

**The TACIT Trial: TAi ChI for people with demenTia**

**A randomised controlled trial comparing the effectiveness of Tai Chi alongside usual care with usual care alone on the postural balance of community-dwelling people with dementia**

**(The TACIT Trial)**

**STUDY PROTOCOL**

Version: 4.4 08.06.2018

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Study Sponsor: Dr Peter Phiri, Southern Health NHS Foundation Trust

Chief Investigator: Dr Samuel Nyman, Bournemouth University

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in GCP guidelines and trial SOPs.

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

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

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| --- | --- | --- | --- |
| Role | Name | Signature | Date |
| Chief Investigator | Dr Samuel Nyman |  | 24.11.2017 |
| Statistician | Professor Peter Thomas | A:\P.Thomas sig..jpg | 24.11.2017 |
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# ROLE OF STUDY SPONSOR AND FUNDER

*Role of the funder*

The National Institute for Health Research (NIHR) have agreed to fund the research project as part of a Career Development Fellowship awarded to the chief investigator. During the peer-review and interview process the chief investigator received critical comment on the proposal to take on board. However, from hereon in, the funder will have no influence on the trial, including: trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The chief investigator will have final decision on these matters. The research team need to simply work within the parameters of the funding given (i.e. strictly adhere to the timescale and budget), and notify the NIHR of any significant deviations from the original proposal. Note that the views expressed in this document are those of the trial management team and not necessarily those of the NHS, the NIHR or the Department of Health.

*Role of the sponsor*

Southern Health NHS Foundation Trust has agreed to act as sponsor for the research project on behalf of the three trusts supporting recruitment of patients into the trial, i.e. Southern Health NHS Foundation Trust (SHFT), Dorset HealthCare University NHS Foundation Trust (DHUFT), and Solent NHS Trust (Solent). The sponsor’s responsibilities are as defined in the UK policy framework for health and social care research (version 3.2 2017). However, funding from the NIHR will be managed by the chief investigator with the support of a research administrator, at Bournemouth University. Also, tasks associated with various sponsorship responsibilities have been delegated to the Peninsula Clinical Trials Unit (UKCRC registration no. 31) and are described in a formal agreement between the sponsor, Chief Investigator (CI), and Clinical Trials Unit (CTU).

The sponsor will work closely with the trial management group and will have influence on the design of the trial protocol and will support the conduct of the trial and the dissemination of its results. Therefore, the sponsor will have influence on trial design, conduct, and dissemination of results, but not on data analysis and interpretation or manuscript writing.

# STUDY SUMMARY

|  |  |
| --- | --- |
| Trial Title | A randomised controlled trial comparing the effectiveness of Tai Chi alongside usual care with usual care alone on the postural balance of community-dwelling people with dementia (The TACIT Trial).  |
| Short Title | The TACIT Trial: TAi ChI for people with demenTia |
| Trial Design | A two-centre parallel group randomised controlled trial with embedded process evaluation and intervention pilot phase |
| Trial Participants | Community-dwelling people with dementia (PWD) and their carers |
| Planned Sample Size | *Intervention pilot phase:*14 dyads (PWD plus their informal carer; e.g. spouse or relative) will receive the Tai Chi intervention for 4 weeks*RCT phase:*150 dyads total (PWD plus their informal carer), i.e.* 75 dyads to be randomised to the control group (usual care)
* 75 dyads to be randomised to the intervention group (usual care plus Tai Chi intervention for 20 weeks)
 |
| Intervention Description | Tai Chi delivered by a qualified Tai Chi instructor for 20 weeks. This will be a combination of classes (1 hour per week, with up to 10 dyads per class) and home-based exercises (to be facilitated by the carer, with the support of a home visit from the Tai Chi instructor in week 3-4 of the intervention). Participation will be supported with reminders for both class attendance (telephone calls by the research team) and to carry out the exercises at home (provision of an alarm clock). |
| Trial duration | Intervention pilot phase: 4 months RCT phase:19 months (13 months recruitment; 6 months follow-up) |
| Setting | Participants will be residing in their own homes, recruited primarily from memory assessment (or associated) services, and followed up in the community |
| Primary Outcome(PWD) | Dynamic balance at six-month post-baseline follow-up measured using the Timed Up and Go test (TUG) |
| Secondary Outcomes(PWD) | Measured at six-month post-baseline follow-up:* Functional balance using the Berg Balance Scale (BBS)
* Static balance using a test of postural sway (while standing on firm surface and on foam mat)
* Fear of falling using the Iconographical Falls Efficacy Scale (Icon-Fes)
* Global cognitive functioning using the Mini-Addenbrooke’s Cognitive Examination (M-ACE)
* Visual-spatial cognitive functioning using the Statue Task
* Capability-based general quality of life using the ICEpop CAPability measure for Older people (ICECAP-O)

Measured prospectively from baseline to six-month post-baseline follow-up:* Number and rate of falls
* Number and rate of fallers
* Number and rate of injurious falls
 |
| Secondary Outcomes(carers) | Measured at six-month post-baseline follow-up:* Dynamic balance using the TUG
* Static balance using a test of postural sway (while standing on firm surface and on foam mat)
* Capability-based general quality of life using the ICEpop CAPability measure for Older people (ICECAP-O)
* Carer burden using the Zarit Burden Interview (short-form)
 |
| Feasibility outcomes (in preparation of the definitive trial) | *Intervention pilot phase** Feasibility of recruitment method
* Acceptability to the dyads of the
	+ TACIT Tai Chi intervention
	+ baseline data collection method
	+ diary / telephone-based data collection methods (short-term)

*RCT phase** Feasibility of recruitment method
* Acceptability to the dyads of the diary / telephone-based data collection methods (long-term)
* For dyads in the intervention arm only; adherence to the TACIT Tai Chi intervention in terms of both class attendance and completion of home-based Tai Chi exercises
 |

**KEY WORDS:** Accidental Falls; Clinical Trial, Dementia; Feasibility; Postural Balance; Tai Chi

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# LIST OF ABBREVIATIONS

|  |  |  |
| --- | --- | --- |
| AE Adverse EventBBS Berg Balance ScaleCA Competent AuthorityCI Chief InvestigatorCRF Case Report FormDHUFT Dorset HealthCare University NHS Foundation Trust DMC Data Monitoring CommitteeDSUR Development Safety Update ReportED Emergency DepartmentGCP Good Clinical PracticeICECAP-O ICEpop CAPability measure for Older peopleICF Informed Consent FormICH International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.Icon-Fes Iconographical Falls Efficacy ScaleIDMC Independent Data Monitoring CommitteeISF Investigator Site FileISRCTN International Standard Randomised Controlled Trials NumberM-ACE Mini-Addenbrooke’s Cognitive ExaminationMARC Memory Assessment Research  CentreMAS Memory Assessment ServiceMSAS Memory Support and Advisory Service (Alzheimer’s Society)NHS R&D National Health Service Research & Development PI Principal InvestigatorPIC Participant Identification CentrePIS Participant Information SheetPPI Public and Patient InvolvementPWD Person (or people) with dementiaRCT Randomised Control TrialREC Research Ethics CommitteeSAE Serious Adverse EventSDV Source Data VerificationSHFT Southern Health NHS Foundation Trust Solent Solent NHS TrustSOP Standard Operating Procedure SSI Site Specific Information |  | TMF Trial Master FileTMG Trial Management GroupTSC Trial Steering CommitteeTUG Timed Up and Go test |

# TRIAL FLOWCHART

Figure 1 provides a flow diagram that summarises the study design.

Figure : Illustration of study design



# BACKGROUND

This study will contribute to a developing programme of research to identify the most appropriate and effective approaches for preventing falls and promoting physical activity among people with dementia (PWD). Previous attempts to provide conventional exercise have had mixed success but there is some evidence that Tai Chi-based interventions may be more appropriate for this population. This protocol describes a randomised controlled trial (RCT) that aims to test the effectiveness of Tai Chi to improve postural balance among community-dwelling PWD and to assess the feasibility of conducting a definitive trial. If the results of this study are favourable, then the subsequent study will be a multi-site, definitive trial to test the effect of the intervention on preventing falls.

Falls are the leading cause for A&E presentation in adults aged over 65 years [1]. Each year in the UK, over 600,000 fall-related injuries result in A&E attendance for adults aged over 60 years, accounting for around 5% of new attendees in the average A&E department [2]. A significant proportion of these patients have dementia - around 25-34% [3,4] - because PWD are more than twice as likely to fall and twice as likely to experience injurious falls compared to their cognitively intact peers [5,6]. The consequences are long-term and far-reaching; PWD are more likely to experience adverse health outcomes during their hospital stay and after discharge such as hospital readmission, institutionalisation, and mortality [7-9]. As falls cost the NHS more than £2.3 billion each year [10], fall prevention interventions could cut NHS costs and relieve pressure on A&E departments [11]. Thus, there is a pressing need to reduce PWD’s risk of admission to A&E and increase their quality of life.

UK Department of Health guidelines for participation in physical activity recommend Tai Chi for older people [12] and Tai Chi is also recommended by the NHS, particularly for inactive older people [13]. Tai Chi is an ancient form of Chinese mind-body exercise, where participants carry out smooth and continuous body movements along with deep breathing and mental concentration [14]; equivalent to moderate-intensity exercise and quiet meditation [15]. This form of exercise is particularly suited for PWD with the use of slow and repetitive movements [16].

We will test a Tai Chi intervention for four reasons:

1. Robust evidence identifies impaired postural balance as a core risk factor for falls among older people in general [17-19;20], and among PWD [21,22]. Tai Chi has been shown in systematic reviews with the general older adult population to improve balance [23] and prevent falls [24,25].

2. Impairments to balance and gait could be the main mechanism through which multiple other risk factors of falls are best understood [26]. While the main mechanism for Tai Chi to prevent falls is through improvement in balance, it has also been shown in systematic reviews to address other falls risk factors [27]: a reduction in fear of falls [28,29]; improvements in balance confidence [30]; self-esteem; physical and mental health-related quality of life [14;31], including depression, anxiety, and psychological well-being [32]; and enhancing cognitive function among those with and without dementia [33].

3. For community-dwelling older people, targeted single interventions for those at risk of falling have been shown to be as effective as multifactorial interventions in reducing falls, and may even be more acceptable and cost-effective [34].

4. While our intervention is complex [35], studies that test single, rather than multifactorial interventions [36] have greater potential to contribute to science because the mechanisms by which the intervention has its effect can be clearly demonstrated.

*Evidence-base for exercise to prevent falls*

There is robust evidence for interventions to prevent falls and fall-related injuries among community-dwelling people without dementia, and in particular exercise-based interventions [36,37]. However, research is required into the best ways to provide exercise-based interventions. For example, a recent large UK exercise trial found that home-based exercise did not increase activity or prevent falls [38]. For people with dementia, in a recent meta-analysis, exercise interventions were found to significantly prevent falls among older people with cognitive impairment in the community (pooled risk ratio = 0.68, 95% CI= 0.55-0.85) [39] and across settings (pooled rate ratio = 0.68, 95% CI= 0.51-0.91) [40]. However, the low number of studies included in the meta-analyses (three community-dwelling; seven across-settings) means that further research is critical to determine which type of physical activity best prevents falls among PWD.

*Tai Chi for older people in general*

Two Cochrane systematic reviews concerning community and institutional settings provide robust evidence for interventions to reduce the rate of falls and number of fallers [41;36]. In these reviews, 10 trials tested the effect of Tai Chi in either community or nursing care facilities. PWD were not the target patient group in any trial.

In community settings (n=8), Tai Chi reduced by almost 30%, both significantly the number of fallers (5 trials) and borderline significantly the rate of falls (6 trials) [36]. Non-significant findings were reported in two institutional settings for number of fallers (2 trials) and in one institutional trial for the rate of falls [41]. Those trials that had non-significant findings were limited by methodological weaknesses. In community-settings, authors reported poor participation rates [42] and a lack of statistical power despite clinically significant results [43,44]. Similarly, a recent trial that found non-significant results for Tai Chi [45], reported an intensity of the intervention far below the recommended dosage of 50 hours or more [46].

*Tai Chi for PWD*

In the Cochrane reviews, three trials included people with mild to moderate dementia. The community study found Tai Chi significantly reduced the time to first fall (adjusted risk ratio =0.51, 95% CI=0.36-0.73), although no sub-analysis was conducted by level of cognitive functioning [47]. While the two studies in nursing care facilities found non-significant results, these studies were limited by either use of only a post-intervention 12-week follow-up and small sample (n = 59) [48], or had very low average adherence of 24% to the Tai Chi sessions provided three times per week [49].

To identify research published after the two Cochrane reviews of fall prevention interventions and up until 29/02/2016, we searched five databases using: the terms ‘Tai Chi’ and ‘dement\*’ / ‘cognitive impair\*’ in keywords; and the Cochrane review terms of ‘falls’ and ‘Tai Chi’ in titles and abstracts. The searches resulted in 150 hits: Medline (n=62), CINAHL (n=25), the Cochrane Central Library (n=40), PsycInfo (n=23), and the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (n=0). Of the 150, only one study used Tai Chi with PWD to prevent falls and this was a pilot RCT based in nursing care facilities in Australia [50]. This pilot trial demonstrated the promise of Tai Chi with a post-intervention follow-up at 14 weeks (n=33). As the study had <32% statistical power, there were no significant differences between groups. We also searched the ClinicalTrials.gov registry of clinical studies to identify any unpublished / on-going studies, and no trial was registered targeting PWD with a Tai Chi intervention to prevent falls.

# RATIONALE

The research question for the overarching programme of research is, “Can a Tai Chi exercise intervention prevent falls among community-dwelling older PWD?” Before embarking on a large and expensive definitive trial with rate of falls as the primary outcome, we will first conduct a smaller RCT. We hypothesise that Tai Chi will help prevent falls by improving dynamic balance, and so dynamic balance will be used as a surrogate outcome in this trial, as it is highly predictive of rate of falls [17-19].

This research question is important because evidence supports the use of exercise interventions to improve balance and prevent falls among those with and without dementia, and Tai Chi may be the most effective way to achieve these outcomes. However, Tai Chi studies have been methodologically weak; there is a lack of studies that adopt robust designs and use post-intervention follow-ups [25]. This research programme will be the first in the UK to test if Tai Chi can prevent falls and the first in the world to use an RCT design to establish if Tai Chi can improve balance and prevent falls among PWD. Consultation with our public and patient involvement (PPI) group confirmed this topic to be important to patients as they saw potential for Tai Chi to help reduce fear of falling and to keep physically active.

Tai Chi has promise to improve care, because existing fall-prevention services are short-term (e.g. physiotherapy-led classes are only offered for around 12 weeks) and not dementia-friendly (they are not designed to be accessible for PWD to attend). NHS services to prevent falls tend to operate from falls clinics and offer multifactorial fall risk assessment (e.g. checks on blood pressure, vision, feet, bone health, etc.) and treat or refer for further assessment where required. While this is beneficial for treating medical conditions, there are few services available to promote increased physical activity. In addition, falls clinics only provide care to a small percentage of the population who are at most risk of falls [51]. Current activities provided for PWD and their carers offer social and intellectual stimulation (e.g. memory cafés and singing for the brain groups run by charities) but not the physical activity specifically designed to improve balance and prevent falls.

*Intervention condition*

The intervention will comprise 3 components: (1) Tai Chi classes, (2) home-based Tai Chi exercises, and (3) a behaviour change component. These are described in more detail below along with anticipated effect of the intervention on the primary outcome. The intervention has been designed for participants to accrue 50 hours or more of Tai Chi physical activity, because exercise-based interventions to prevent falls are more effective if: they have a higher dosage (50 hours or more); challenge balance (e.g. exercises are conducted while standing); and do not include walking [46]. This necessitated intervention delivery to be provided for 20 weeks: a weekly Tai Chi class (component 1), carer-led home-based Tai Chi exercises (component 2), and after the first two weeks of classes, a home visit by a Tai Chi instructor (component 3) to support and encourage participation in the home-based Tai Chi exercises. Telephone calls will also be provided by the research team to encourage class attendance during the trial in conjunction with safety monitoring (component 3), and an alarm clock will be provided to help remind participants to carry out Tai Chi at home. To allow sufficient time for participants in the intervention condition to be allocated a class and to complete the 20-week intervention, the post-intervention outcome assessments are scheduled at six months post-baseline i.e. to coincide as near as possible with the end of the intervention delivery (for participants in the intervention arm). The post-intervention assessment time-point is described throughout this protocol as the “six-month follow-up”. The actual timing of the follow-up in relation to baseline may vary depending on how successfully the classes can be organised. In any case, the follow up will be conducted as soon as possible on completion of the 20-week intervention and no later than six months plus a window of six weeks after the baseline visit.

*Control group condition*

Usual care will be the treatment received from existing services where accessed by the PWD and / or their carer (e.g. referral to a falls clinic, attending memory cafés, etc.). For pragmatic reasons and to test if the new intervention can provide patient benefit in addition to usual care, no alternative intervention or waiting list control group will be offered.

In order to maximise retention, participants allocated to the control arm will be offered £50 upon completion of their final follow up visit, to purchase Tai Chi lessons after the study has ended, should they wish to.

# OBJECTIVES AND OUTCOME MEASURES

## Primary Objective

To assess the effect of a Tai Chi intervention, delivered in addition to usual care, on the dynamic balance of older people with dementia compared to usual care alone.

## Secondary objectives

* To compare functional balance, static balance, fear of falling, global cognitive functioning, visual-spatial cognitive functioning, quality of life, and the number and rate of falls, fallers, and injurious falls between patients in the intervention and control groups.
* To compare dynamic balance, static balance, quality of life, and carer burden between carers in the intervention and control groups.
* To determine the acceptability and safety of the intervention for patients and carers in the intervention group.
* To assess feasibility of key aspects of the study design (i.e. recruitment, consent, randomisation, suitability of outcome measure data and methods of data collection) to inform the design a future clinical and cost-effectiveness definitive trial.

## Outcome measures

The choice of key outcome measures was informed in part by a search conducted on The COMET (Core Outcome Measures in Effectiveness Trials) database (www.comet-initiative.org) in December 2015, using the term “fall” and independently another search using the term “balance”. The following description of outcome measures, measured at baseline and six-months post-baseline, pertains to the RCT unless otherwise stated.

### Primary outcome

**The primary outcome is difference in performance at follow-up between the two arms on the Timed Up and Go\*** (TUG) test [52] by PWD at six months post-baseline. This is a continuous measure of time (in seconds) to complete the task. A cut-off point will not be used because there is no value that can be recommended for the study from the existing evidence [53,54].

\*NB: A detailed description of the TUG test and rationale for selecting it as the primary outcome measure is provided in Appendix 1.

### Secondary outcomes

The secondary outcomes are:

*PWD – balance tests\**

1. **Difference in score on the** **Berg Balance Scale** (BBS) [55] between the two armsat six months post-baseline. This is a 14 item scale with a 5-point response for each item (0-4), with the sum score used (minimum to maximum possible scores of 0 – 56, with 0-20 high fall risk, 21-40 medium fall risk, and 41-56 low fall risk). Total score will be analysed (potential range 0-56) and will be assumed to be interval scaled.
2. **Difference in postural sway** performance between the two armswhile standing on the floor and on a foam mat [21] at six months post-baseline. In both instances, a continuous value will be measured as total (antero-posterior + medio-lateral) normalised path length of the acceleration sway trace of the pelvis during the task. The unit of measurement will be in milli-g/second (mg/s).

\*NB: Further information relating to the BBS and Postural Sway tests is provided in Appendix 1.

*PWD – structured interview scales\**

1. **Difference in score on the Iconographical Falls Efficacy Scale** (Icon-Fes, short form) [56] between the two armsat six months post-baseline. This is a 10 item scale of fear of falling with a 4-point response for each question (1-4), with the sum score used (minimum to maximum possible scores of 10 - 40). It will be assumed that this is interval scaled data (scale of 10-40).
2. **Difference in score on the Mini-Addenbrooke’s Cognitive Examination** (M-ACE) [57] between the two armsat six months post-baseline. This measure of global cognitive functioning consists of five items: attention (assesses orientation, scored 0-4), memory (scored 0-7), fluency (assesses language, scored 0-7), visuospatial function (scored 0-5), and memory (assesses recall, scored 0-7), with a total score of 0-30. The sum score is used, with values on an interval scale of 0-30.
3. **Difference in score on the Statue task** [58] between the two armsat six months post-baseline. This measure of visual-spatial cognitive functioning presents participants with a series of visual scenes using a small handheld tablet. The participant is asked to look at scenes with three statues and a stool, and to answer a series of questions that assesses their ability to perceive objects in three-dimensional space and their relationships to each other. The computer automatically records the time taken to complete the task and number of errors made. A continuous measure is used for time taken to complete (in seconds) and a discrete measure for the number of errors made (frequency count).
4. **Difference in score on the ICEpop CAPability measure for Older people** (ICECAP-O) [59] between the two armsat six months post-baseline. This is a 5 item scale of quality of life with a 4-point response for each (1-4), with the sum score used (minimum to maximum possible scores of 5 - 20). It will be assumed the measure is interval scaled (scale of 5 - 20).

\*NB: Further information relating to the structured interview scales is provided in Appendix 3.

*PWD – falls\**

1. **Difference in number and rate of falls** prospectively recorded up to six months post-baseline between the two arms(binary outcome measure). A fall is defined as, ‘‘an unexpected event in which the participants come to rest on the ground, floor or lower level” [60, p.1619]. Falls will be recorded by PWD and their carer daily on a monthly calendar and posted every month to the research team. In addition, telephone calls will be made weekly with PWD and every 3 months with their informal carers and cross-checked with diaries to ensure falls are not under-reported as advised previously [61]. At the end of each month, at the weekly telephone call the PWD will also be asked about any falls in the past month, to provide four reporting methods on falls (weekly phone call with PWD, monthly calendar with dyad, monthly phone call with PWD, and 3-monthly phone call with carer).
2. **Difference in the number and rate of fallers** (people that have fallen at least once) between the two arms(binary outcome measure).
3. **Difference in the number and rate of injurious falls** between the two arms(count data). Fall injury will be recorded by telephone interview when recording falls as described above, using an existing set of definitions for severity of injury [62, p. 11]. Serious injury will be defined as any medically recorded fracture, head, or internal injury requiring accident and emergency or inpatient treatment. Moderate injury will be defined as any wounds, bruises, sprains, or cuts requiring a medical / health professional examination such as physical examination, x-ray, or suture. Minor injury will be defined as any minor bruises or abrasions that do not require health professional assistance, but may lead to a reduction in physical function (e.g. due to pain or fear of falling) for at least three days. No injury will be defined as no physical injury detected.

\*NB: Further information relating to collection of falls information is provided in Appendix 2.

*Carer – balance tests*

1. **Difference in TUG\*** [52] performance between the two armsat six months post-baseline, measured in the same way as detailed above.
2. **Difference in postural sway\*** performance between the two armswhile standing on the floor and on foam [21] at six-months post-baseline, measured in the same way as detailed above.

*Carer – structured interview scales*

1. **Difference in score on the ICECAP-O\*** [59] between the two armsat six months post-baseline, measured in the same way as detailed above.
2. **Difference in score on the Zarit Burden Interview (short-form)\*** [63,64] between the two armsat six months post-baseline. This is a 12 item scale with a 5-point response for each (0-4), with the sum score used (minimum to maximum possible scores of 0 - 48). An assumption will be made that the data are interval scaled (scale of 0 - 48).

\*NB: Further information relating to the balance tests is provided in Appendix 1, and further information relating to the self-completion questionnaires is provided in Appendix 3.

Except falls measurements that will be collected prospectively from baseline until six-months post-baseline, all measures will be taken at baseline and six months post-baseline. An intention-to-treat analysis approach will be taken to compare the intervention with the control group at six months post-baseline with adjustment for baseline scores on the interval scales (as covariates using the mean scores).

### Feasibility outcomes

Intervention Pilot Phase feasibility outcomes include:

1. **Feasibility of recruitment method:** Detailed information about the recruitment rate of dyads, including numbers approached, excluded, or declined (with reasons for declining where given) will be recorded.
2. **Acceptability of the TACIT Tai Chi intervention:** During the intervention pilot phase, qualitative data will be captured throughout the four-week intervention period using two methods. The first method will be fieldwork notes based on observations of the classes and informal feedback from the dyads and instructors at the end of each session. The second method will be a focus group at the end of the four weeks with each class to seek their feedback.
3. **Acceptability of the methods for data collection:** During the intervention pilot phase, field notes will be made by the researcher as to the acceptability to dyads of the baseline and diary- and telephone-based data collection methods. The researcher will record observations and comments made by dyads at the baseline home visit and during the four weeks, and will ask for feedback on data collection methods at the focus group.

 RCT phase feasibility outcomes include:

1. **Feasibility of recruitment method:** Detailed information about the recruitment rate of dyads, including numbers approached, excluded, or declined (with reasons for declining where given) will be recorded.
2. **Acceptability of the methods for data collection:** During the RCT phase, field notes will be made by the researcher as to the acceptability to dyads of the diary and telephone-based data collection methods. The number of missing diaries and telephone interviews will be recorded.
3. **Adherence to the TACIT Tai Chi intervention (for participants in the intervention arm only):** Dyads’ class attendance will be recorded each week during the intervention period by the instructors. Dyads will also complete a weekly exercise diary to record how many minutes Tai Chi they have carried out at home outside the classes. In addition, qualitative data will be collected. A researcher will observe 10% of the classes and make qualitative observations in relation to class-based adherence (including group social cohesion, participant enjoyment and engagement, rapport with the instructor and socialising and peer support at the end of each session). Informal feedback from dyads and instructors will be sought at the end of each session and recorded using fieldwork notes. At around week 16 of the Tai Chi intervention, joint interviews will be conducted with a purposive sample of around 15 dyads in their homes and will focus on adherence to the intervention and in particular the home-based Tai Chi exercises (including any wider benefits of the intervention to the PWD and carer beyond improving balance).

# TRIAL DESIGN

This is a randomised, assessor-blind, two-arm, parallel group, superiority trial, with an embedded intervention pilot phase.

As recommended by MRC guidelines for developing and evaluating complex interventions [35], this study will first test the effectiveness of the intervention using a surrogate outcome measure and test the feasibility of conducting a definitive trial. This study will be in two phases: (1) an Intervention pilot phase, to identify any aspects of the trial and intervention design that may require refinement; followed by (2) the RCT.

*1. Intervention pilot phase*

The protocol for recruitment, baseline data collection, and intervention delivery will be tested and refined with two groups of 7 dyads (one group in the Southampton area and one group in the Dorset area) who will all receive the intervention. Over four weeks, a Tai Chi class will be provided each week and home-based Tai Chi exercises will be carried out.

*2. RCT*

150 dyads will be randomised to either the control group (usual care) or intervention group (usual care plus the TACIT Tai Chi intervention) in a 1:1 ratio at each site.

## Randomisation sequence

In the intervention pilot phase, no randomisation will be used as each dyad will receive the intervention. There will be two classes (one per site), with up to a maximum of 7 dyads per class. Recruitment will continue with as many dyads as possible up to the maximum, and then each class will start. Once a class has started, recruitment will close for that class so that each dyad has equal experience and a minimum dose of 4 weeks intervention.

In the RCT, the TACIT Tai Chi intervention will be delivered to 75 dyads across 11-15 class cohorts, with a maximum of 20 dyads per class cohort. In this trial it will be important to achieve an equal balance of recruitment into the intervention and control arms, and to achieve equal balance of recruitment of participants between treatment conditions according to the following key prognostic variables: dementia type (due to eligibility criteria, this will be relatively homogenous in this study), age, fall history, and dementia severity. This is because fall risk will be elevated among those who are older, have fallen in the past 12 months, and present with more severe dementia symptoms [18-19]. Given that these key prognostic variables are positively correlated [18-19], only one variable - fall history at baseline: has / has not fallen within the previous 12 months - will be selected for a parsimonious and achievable strategy for balancing the treatment conditions. Therefore, to ensure balance within each recruitment site (and across the entire trial), minimisation will be used according to treatment allocation and fall history at each site.

For each class cohort, once a minimum of 4 dyads in total have been recruited, the dyads will be randomised to the intervention or control group. The first dyad within a class cohort will be allocated using simple randomisation, with the remaining dyads allocated using minimisation by treatment allocation and fall history at baseline. The intervention group will then be informed of the details of their Tai Chi classes. Between randomisation s and the fifth Tai Chi class, any further dyads recruited into the study will be randomised individually by minimisation (by treatment condition and dementia severity). Recruitment to a class will usually close once the fifth Tai Chi session has taken place, as it is deemed that dyads would have missed too much of the intervention (5/20 weeks) and be too far behind in ability to join that class. However, a dyad may join a class at a later point at the Tai Chi Instructor’s discretion (e.g., where there has been low attendance by existing dyads). Potential participants too late to be recruited into their nearest class, or who would prefer to travel to a different class, will be given the option to join another class if available.

Participants will be randomised in order of recruitment into the trial. To maintain concealment and reduce selection bias, allocation will be concealed using a centralised automatic web-based randomisation system designed and maintained by PenCTU. The procedure for randomisation is described in section 9.1.1. Details of the minimisation setup will be agreed with the CTU data programmer and the trial statistician.

## Blinding

In the intervention pilot phase, baseline measures will be taken unblinded as each dyad will receive the intervention. In the RCT phase, baseline measures will be recorded at the PWD’s home before randomisation is performed, so that these measures are taken blind to both the researcher and participants. The researcher will explain to the dyad that they may be randomised to either the control or intervention conditions, but the researcher will not be made aware of the allocation. Instead, PenCTU will inform dyads of their treatment condition in writing after the home visit (for baseline data collection). From then on, it will not be possible to keep PWD or carers blind to allocation in the trial. Given the nature of the intervention, the Tai Chi instructors delivering the intervention will also not be blinded throughout the trial. At the six-month post-baseline follow-up, the researcher that collected baseline data, and who remains blinded, will repeat the measurements at the six-month post-baseline follow-up. In addition, participants will be asked at the time of arranging the follow-up visit and reminded by the researcher at the home visit, not to disclose their treatment condition and to hide any evidence of participating in class or home-based Tai Chi. The PWD and the carer will be asked not to disclose their treatment condition. This will ensure that the assessor is blind to treatment condition at the follow-up home visit. Blinding will be checked against the researcher’s field notes; after data collection is completed for each follow-up visit, the researcher will make a note of their guess of the treatment condition for the dyad. They will also note if dyads had accidentally disclosed their treatment condition.

## Unblinding

For the intervention pilot phase, the data will be recorded by the research team using unique research ID numbers (‘trial number’) for each PWD and their informal carer. The demographic data only will be prepared in an SPSS file for the statistician unblinded.

For the RCT phase, the outcome measures will be sent to the CTU for data entry using the trial number for each PWD and their informal carer. The data will be prepared in an SPSS file for the statistician with treatment condition unblinded since information on class cohort is required for the analysis. Once the analysis is complete, the results will be revealed to the rest of the research team with trial arm identity concealed. After the results have been discussed and interpreted, the results will be unblinded for the research team to complete their interpretation and to begin dissemination of the findings.

# STUDY SETTING

This is a multi-centre study being conducted in the Southampton, Dorset, and Portsmouth areas (Southampton area: Southern Health NHS Foundation Trust (SHFT); Dorset area: Dorset HealthCare University Foundation Trust (DHUFT); and Portsmouth area: Solent NHS Trust (Solent)).

Participants will be identified and recruited primarily from the Memory Assessment Research Centre ((MARC), managed by SHFT) in the Southampton area, from the Memory Gateway – Memory Assessment Service (MAS, managed by DHUFT) and Memory Support and Advisory Service (MSAS, managed by Alzheimer’s Society) in the Dorset area, and from the Research & Improvement Team (Solent) in the Portsmouth area.

Baseline and follow-up appointments will be conducted in participants’ homes or at suitable local venues (NHS or non-NHS) if mutually convenient.

Home-based Tai Chi instruction will be delivered in participants’ homes. Tai Chi instructors will enter into honorary contracts with the three participating trusts and members of the TACIT research team will obtain research passports from the three participating trusts. The Chief Investigator will oversee conduct of the study. Data collection will be performed by two members of the research team (PhD students) trained in Good Clinical Practice and in the requirements of the protocol.

**Practical arrangements for the Tai Chi class venue.**

Tai Chi classes will be delivered in a number of local venues (NHS and non-NHS) with input from the PPI advisory group (in relation to accessibility, ease of access by public transport, etc.). More than one venue per site will be used to provide venues closer and at greater convenience to participants.

The Tai Chi instructor will maintain a sign-in sheet, logging attendance at each class, for trial purposes (i.e. to assess the ‘dosage’ of Tai Chi received by participants) and this log will also will also be used to account for participants in the case of emergency evacuation of the building (e.g.in case of fire, etc.).

An emergency contact number for the PWD and the carer (i.e. someone other than each other) will be noted on a separate log maintained by the Tai Chi Instructor. Should a PWD or carer suddenly require first aid in the Tai Chi class, the Tai Chi instructor will seek assistance from a first aider. In the case of medical emergency, the Tai Chi instructor will call 999 to contact the emergency services. If necessary, the participant’s emergency contact will be contacted by the Tia Chi instructor.

# PARTICIPANTS

The target group for this study is people with mild to moderate dementia and their informal carer. Persons with mild to moderate dementia are expected to be able to participate fully in the intervention and are more likely to demonstrate improvement on the outcome measures within the RCT [67]. Both the PWD and the carer must consent to participate in the study for the dyad to be included into the study. Both males and female adults will be included with no restriction on the maximum age. Informal carers may be the spouse, close relative, friend, or neighbour who will be with the PWD participant at least twice a week. It is also possible for there to be more than one informal carer to support the PWD for the whole or part of the trial. However, for the RCT, data will be collected from only one primary informal carer at baseline, and the same informal carer will be asked to repeat baseline measurements at the six-month follow-up (different carers will not provide data for the baseline and follow-up secondary outcome measures).

## Inclusion criteria

Patients must satisfy all of the following criteria to be enrolled in the study:

* Aged 18 years or above
* Living at home
* Have a diagnosis of a dementia
* Able to do standing Tai Chi (e.g. not be wheelchair bound)
* Willing to attend weekly Tai Chi classes
* Willing to attend a focus group (intervention pilot phase only)

In relation to dementia diagnosis, this will be indicated on their patient record held by the MARC / MAS / MSAS. We will recognise an existing diagnosis of dementia as follows: A diagnosis made by a Consultant Physician of either probable Alzheimer’s disease according to the NINCDS-ADRDA criteria [68] or probable Vascular Dementia according to the NINDS-AIREN criteria [69].

## Exclusion criteria

Patients who meet any of the following criteria will be excluded from study participation:

* Living in a care home
* In receipt of palliative care
* Indicate that they have:
	+ Severe dementia a
	+ A Lewy body dementia or dementia with Parkinson’s disease b
	+ Severe sensory impairment c
* Are already currently practising (on average once a week or more) or have been practising within the past six months (on average once a week or more) Tai Chi or similar exercise (Qigong, yoga, or Pilates)
* Are currently under the care of or have been referred to a falls clinic for assessment, or are currently attending a balance exercise programme (e.g. Otago classes)
* Lack mental capacity to provide informed consent

*a The Mini Addenbrooke’s Cognitive Examination (M-ACE) will be conducted at the initial visit (see section 7.3) after informed consent has been obtained. Scores of 9 or less will be regarded as being indicative of severe dementia and grounds for exclusion from the trial. Note that for this study, in the unlikely event that a participant scores 27 or above on the M-ACE, they will still be included in the study if they have a diagnosis of dementia.*

*b In relation to types of dementia, the fall rates in those with either Lewy body dementia or dementia with Parkinson’s disease are significantly higher than other forms of dementias and so would require a different intervention [e.g. 70].*

*c In relation to severe sensory impairment, people with visual or hearing impairments will be accommodated as far as possible. However, if impairment severity is such that it is unlikely, even with accommodation, that they would be able to follow the intervention or participate fully in data collection (such as the interviews) then they will be excluded. This will be assessed by the researcher at the initial screening telephone call (by asking dyads to self-report likelihood of impairments causing problems in following a Tai Chi class, and checking that a conversation can be held over the telephone, in the case of hearing impairment) and by the researcher at the home visit (when asking PWD to copy movements to perform the balance tests).*

##  Patients’ carers inclusion criteria

Informal carers must satisfy all of the following criteria to be enrolled in the study:

* Able to commit to supporting the PWD by participating in data collection throughout the study and in the intervention components if allocated to the intervention group (minimum of 2 times per week in-person, but ideally more)
* Able to do standing Tai Chi (e.g. not be wheelchair bound)
* Willing to attend weekly Tai Chi classes
* Willing to attend a focus group (intervention pilot phase only)

## Patients’ carers Exclusion Criteria

Carers who meet any of the following criteria will be excluded from study participation:

* Indicate that they have severe sensory impairment a
* Lack mental capacity to provide informed consent

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*a In relation to severe sensory impairment, people with visual or hearing impairments will be accommodated as far as possible. However, if impairment severity is such that it is unlikely, even with accommodation, that they would be able to follow the intervention or participate fully in data collection (such as the interviews) then they will be excluded. This will be assessed by the researcher at the initial screening telephone call (by asking dyads to self-report likelihood of impairments causing problems in following a Tai Chi class, and checking that a conversation can be held over the telephone, in the case of hearing impairment) and by the researcher at the home visit (when asking the carer to copy movements to perform the balance tests).*

An oversight of participants’ continued suitability for the study will be achieved via the various contacts that are scheduled to occur between the participant and the researcher as part of the study. The researcher will raise any concerns about participants not being able to safely continue with the study with the Chief Investigator, and this will be dealt with on a case-by case basis.

# participant recruitment

## Recruitment strategies

Recruitment of participants to both the intervention pilot phase and RCT phases will utilise multiple pathways. We will have two months to recruit for the intervention pilot phase and 15 months to recruit for the RCT.

*Recruitment from the Southampton area*

The primary means of recruitment will be through database searches of MARC (SHFT) database. This is a list of PWD who have already volunteered to participate in research and consented to be approached about potential participation.

*Recruitment from the Dorset area*

The primary means of recruitment will be through database searches of the Memory Gateway (MAS, DHUFT, and MSAS, Alzheimer’s Society) in the Dorset area, and liaising with patients who attend routine 3-month and 12-month MAS review appointments or those currently in contact with a memory advisor.

*Recruitment from the Portsmouth area*

The primary means of recruitment will be through liaising with patients who attend routine 6-month memory assessment service appointments or those currently in contact with the older people mental health service (OPMH, Solent).

Additional recruitment strategies include:

* Recruitment from participant identification centres (PICs) in the Wessex NIHR Clinical Research Network region. This will include both primary and secondary care. In primary care, staff at GP practices will opportunistically approach people with dementia who come into the practise for an appointment. They will also telephone or post invitation letters to eligibility patients identified from their database. In secondary care, staff at hospital outpatient clinics will opportunistically approach people with dementia who visit for an appointment. They will also telephone or post invitation letters to eligibility patients identified from their database.
* Recruitment via the Join Dementia Research (JDR) website, endorsed by the Health Research Authority, to facilitate patient recruitment into dementia studies (<http://jdr-delivery.nihr.ac.uk/>).
* Recruitment via potential participants’ direct responses to study promotion including leaflets / posters in dementia cafés, support groups, general practices, chemists, pharmacies, day-care centres, newspapers, radio, social media, and informal newsletters. Participants recruited via these means will have their dementia diagnosis (type of dementia, date of diagnosis, and most recent M-ACE or MMSE score if available) confirmed by their MAS (or other service where diagnosed) or through provision of written evidence, and will sign a consent form to allow the researchers to retrieve this information from their MAS (or other service where diagnosed) medical records.

## Patient identification and approach

*Recruitment via MAS / MARC / MSAS / PIC database searches:*

Potential participants will be identified and initially approached either by members of NHS staff within the MAS / MARC / outpatient clinic (PIC) teams, Alzheimer Society staff within the MSAS team, GP practice staff (PIC), or by NHS staff assigned as part of the CRN Study Support Service. PWD will be identified via searches of the respective databases. Search criteria may be tailored according to database structure but the most basic search criterion will ensure that only those with a dementia diagnosis are identified. PWD who are identified as being potentially eligible to take part will be initially approached either

* in person while attending or being visited for a review appointment,
* in person while attending a MSAS sign-posted activity,
* by post and follow-up telephone call,
* by telephone call alone
* invitation to a presentation about the project

*PWD attending or being visited for a review appointment*

During routine MAS / OPMH / NHS outpatient (PIC) clinics and home visits, and GP surgery appointments (PIC), staff will use the TACIT Leaflet to provide information about the study and establish initial expressions of interest and willingness to participate. Those who are potentially eligible and interested in participating will be provided with a copy of the Participant Information Sheet to take away and read at home. They will also be asked if they are willing for their contact details to be provided to a member of the TACIT research team who will ring them in due course (with a minimum interval of 48 hours from being provided with the PIS). Note that only patients attending review appointments will be approached (and not those who are attending a clinic to receive a diagnosis of dementia).

*PWD attending a MSAS sign-posted activity*

During a regular informal social event or a MSAS organised-event, MSAS staff will use the same protocol and materials as used by MAS staff in their clinics.

*PWD contacted by post and telephone*

Individuals who are identified as potentially eligible may be sent a Participant Information Sheet and then followed-up by a telephone call with an NHS (site and PIC) / MSAS / GP practice (PIC) / CRN member of staff. Staff will use The TACIT leaflet to structure information provided during the telephone conversation. This initial contact will serve to inform potential participants about the trial, to further ascertain potential eligibility and to gain initial expressions of willingness to take part. They will also be asked if they are willing for their contact details to be provided to a member of the TACIT research team who will ring them in due course (with a minimum interval of 48 hours from being provided with the PIS).

*People contacted by telephone*

An NHS (site and PIC) / MSAS / GP practice (PIC) / CRN member of staff will provide brief information about the study using the TACIT leaflet to structure information provided during the telephone conversation. This initial contact will serve to inform potential participants about the trial, to further ascertain potential eligibility and to gain initial expressions of willingness to take part. The NHS staff member will post a copy of the Participant Information Sheet to those who are potentially eligible and express a willingness to take part. They will also be asked if they are willing for their contact details to be provided to a member of the TACIT research team who will ring them in due course (with a minimum interval of 48 hours from being provided with the PIS).

Regardless of the method used to contact the potential participant, all will be asked if they are willing for their contact details to be provided to a member of the TACIT research team who will ring them in due course (with a minimum interval of 48 hours of the PIS being handed out/posted). Potential participants who do not give this permission will be invited to contact the research team directly, using the contact details included in the Participant Information Sheet.

Given that dyads are to be recruited, the telephone conversation or in-person contact will endeavour to be made with both the PWD and their carer. However if only the PWD or their carer is available, then contact will only be made with one member of the dyad. If the PWD has difficulty communicating by phone or in person then contact will be sought with their carer subject to the PWD’s consent. The PWD will always be the first person in the dyad who the member of staff will ask to speak with, and then to their carer with the PWD’s consent.

*Invitation to a presentation about the project*

An additional means of recruitment via the MSAS is through informal groups for PWD and their carers. The MSAS team regularly support PWD and / or their carers to attend informal groups (e.g. carers support groups, singing for the brain groups for people with dementia, etc.), and these groups may be given a short presentation about the study and Q&A session to seek interest in participating in the study. The short presentation may be given by a member of the research team or a member of MSAS. Similarly, some potential participants may wish to discuss the project in a group environment, and to hold an informal meeting for the purpose of discussing the project. Such informal meetings will be in a public venue and only seek to raise awareness of the study and seek potential participants. After any informal meeting – whether for the purpose of this study or otherwise – staff will not recruit at the meeting. Instead, Patient Information Sheets will be handed out for PWD and their carers to read, and contact details taken for a member of the research team to discuss the matter further with potential participants by phone at least 48 hours later. Potential participants who do not give this permission will be invited to contact the research team directly, using the contact details included in the Participant Information Sheet.

*Recruitment from other channels*

PWD and their informal carers may self-refer in response to advertisements locally in various formats. Initial eligibility and willingness to participate in the study will be confirmed in a telephone call with a member of the research team. Those who are potentially eligible and interested in participating will be sent a copy of the Participant Information Sheet by post. They will also be asked to provide consent for the research team to check their eligibility using GP / medical records / one of the databases described above. Once the status of their diagnosis has been ascertained, a team member will call the potential participant by telephone to either book a home-visit where eligibility has been confirmed or to advise the individual that they are not eligible for this study as appropriate.

We will also be using 'Join dementia research' (JDR) as a recruitment tool. This is an on-line self-registration service that enables volunteers with memory problems or dementia, carers of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research. The purpose of JDR is to allow such volunteers to be identified by researchers as potentially eligible for their studies. Researchers can then contact volunteers, in line with the volunteers preferred method of contact, to further discuss potential inclusion. JDR is funded by the Department of Health working in partnership with the charities Alzheimer’s Society and Alzheimer’s Research UK and is Health Research Authority (HRA) endorsed. The on-line service and all associated documentation, methods of contacting volunteers and handling of data, were reviewed by a specially convened HRA committee which included experts in research ethics, data protection and information governance. Formal endorsement was issued by the HRA in a letter dated 20 May 2014.

### Recording details of identification and approach

Staff performing the screening and initial approach roles will be required to keep records of initial searches (number of patients meeting search criteria), the number of potential participants approached, and the number subsequently provided with Participant Information Sheets . Where potential participants express unwillingness to take part at any stage, they will be asked to provide a reason which will be recorded whilst ensuring that they are told that they do not have to provide a reason if they do not want to. Similarly, grounds for ineligibility identified during the initial approach telephone calls will also be recorded. These data will be entered onto the study database to inform the CONSORT diagram.

## Consent and eligibility

Procedures for confirming eligibility and obtaining consent will be the same for both the intervention pilot phase and the RCT phase. Having received contact details of potential participants from NHS / GP practice / CRN staff, or having been contacted directly by potential participants, a member of the TACIT research team will contact the potential participants, usually by telephone, to arrange an initial visit, typically at the potential participant’s home. Researchers will wait a minimum of 48 hours before contacting the potential participants to ensure they have had sufficient time to consider the information in the Participant Information Sheet. Both PWD and carer must be present at the initial visit.

At the visit, the researcher will check that the PWD and their carer have read the Participant Information Sheet and ask if they have any questions. If required, they will explain verbally to the PWD and their carer the study and what they would need to do if enrolled. The researcher will confirm that both PWD and carer are still willing to take part before taking informed consent. Researchers will be trained to collect informed consent from participants. Specifically, they will undergo training for the trial (including assessing capacity to give consent, how to conduct the balance tests safely, and how to administer the questionnaires / structured interviews), GCP online training, and for BU researchers, ethics e-Modules as well. Staff referring patients into the study (from MARC, MAS, MSAS, or PIC) will be asked to not refer any PWD that they deem unable to provide informed consent.

The process of gaining consent from the PWD will be conducted with an underlying assumption of capacity to consent unless it is clearly indicated that the person does not have capacity. The researcher will be responsible for adjudging the PWD’s capacity to provide informed consent and this will be achieved through discussion with the PWD, to determine whether or not the study information has been retained and understood. The PWD and carer will be asked to give written informed consent. Consent forms will be completed in triplicate, such that one form can be retained by each member of the dyad and the other by the researcher. Since the study relies on recruitment of dyads, failure to obtain consent from either PWD or carer will be grounds for exclusion. Researchers will follow the guidance of using process consent, which is established in the evidence base [71-73], in that consent will not be assumed for the duration of the visit or for the project after provision of initial informed consent. Informed consent will be re-confirmed throughout the project verbally.

After consent has been obtained, the researcher will conduct the M-ACE with the PWD to confirm that they meet the entry criterion in relation to dementia severity (see section 6.2). As this measure is not used in routine care in SHFT, and scores on the test may decline remarkably among people with Alzheimer’s disease, for consistency in the measurement time-points, the M-ACE test will be carried out with every PWD at baseline (when confirming eligibility). As version A is used in routine care in DHUFT, version B will be used at baseline and version C at follow-up (to reduce potential bias due to practice effects). By excluding people with severe symptoms of dementia, it is unlikely that people will deteriorate in their cognitive ability to the extent that they will no longer have capacity to consent by the end of the trial (six-month follow-up home visit). However, it will be stressed to participants that they can leave the trial at any time. If a participant withdraws from the study at any time, they will be asked if all data collected up until that moment can be included in the analysis.

The 5-item M-ACE will take approximately 15 minutes to complete, and requires the PWD to answer a series of questions that assess global cognition. A score of 10-26 will indicate the presence of mild (21-26) to moderate (10-20) dementia [74-76]. Scores of 9 or less will be regarded as being indicative of severe dementia and grounds for exclusion from the trial. Note that for this study, in the unlikely event that a participant scores 27 or above on the M-ACE (regarded as being indicative of normal cognition), they will still be included in the study if they have a diagnosis of dementia. Records will be maintained of the numbers of dyads who do not provide informed consent (with reasons where given) and the numbers of PWD that are excluded on the basis of M-ACE result or other reason.

Participants recruited from outside NHS / GP services will be required to sign a consent form to allow the research team to verify the PWD’s dementia diagnosis (type, when diagnosed, and most recent M-ACE or MMSE score if available) from their MAS (or other service where diagnosed) to provide written evidence of their diagnosis. This will not be required for participants recruited from MAS / MARC / MSAS / NHS (PIC) or GP (PIC) services, because only those with a dementia diagnosis according to their records will be approached. Those that do not consent to the research team obtaining this information from their MAS will instead be asked to show evidence of a dementia diagnosis such as a letter from their GP or MAS. Demographic data, confirmation of eligibility and the severity of PWD dementia (i.e. mild or moderate as scored by the MAC-E), will be entered onto the study database.

# Study schedule – INTERVENTION PILOT phase

This section describes the conduct of the non-randomised intervention pilot phase in chronological order, detailing procedures for data collection at each of the time points. Table 1 shows a summary of the study schedule. Note that the CTU will not be involved in the management of the study in the intervention pilot phase.

*Notes on Table 1*

1. *A falls diary will be completed for a calendar month and posted back to the research team at the end of the month. The research team will also telephone participants weekly to collect falls data.*
2. *When a participant indicates that they have experienced a fall (fall diary) or injury while performing Tai Chi at home (home exercise diary), or the Tai Chi instructor records an injury during class (class register), this will trigger a member of the research team to conduct a telephone interview with the dyad. A fall / (serious) related event will be recorded. If health services have been used, then a structured interview will be completed by telephone by the researcher with the PWD or their carer to collect detailed information on health service use.*
3. *Class attendance will be recorded by the Tai Chi instructor.*
4. *Weekly home exercise diaries will be returned in person each week at the classes during the 1-month intervention. The research team will telephone participants to follow up on any missing data.*
5. *Focus group participants will be asked about barriers / facilitators to participation in the classes and home-based exercises and anything that should be changed for the RCT.*
6. *Data from the weekly class registers, weekly home exercise diaries, weekly telephone interviews, and monthly fall diaries will be used for safety monitoring. A structured telephone interview will be completed by the researcher with the PWD or carer to ascertain whether reportable related events have occurred (see section 14).*

*Table 1: Study schedule for the intervention pilot phase*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Screening** | **Baseline** | **Intervention and follow up** |
| **TIMEPOINT** |  | ***t1*** | ***Intervention period*** | ***Post-intervention******(+1 month)******t2*** |
| **ENROLMENT:** |  |  |  |  |
| **Eligibility screen - PWD & carer** | X |  |  |  |
| **Informed consent - PWD & carer** |  | X |  |  |
| **Eligibility confirmation - PWD & carer**  |  | X |  |  |
| **Demographics - PWD & carer** |  | X |  |  |
| **Medical History - PWD** |  | X |  |  |
| **INTERVENTION:** |  |  |  |  |
| ***Usual care*** |  |  |  |  |
| ***Tai Chi classes and home exercises for 1 month*** |  |  |  |  |
| **ASSESSMENTS:** |  |  |  |  |
| ***M-ACE [structured interview] - PWD***  |  | X |  |  |
| ***BBS [balance test] - PWD*** |  | X |  |  |
| ***Postural sway [x2 balance tests] - Carer***  |  | X |  |  |
| ***TUG [balance test] - Carer***  |  | X |  |  |
| ***Postural sway [x2 balance tests] - PWD***  |  | X |  |  |
| ***TUG [balance test] - PWD*** |  | X |  |  |
| ***Icon-Fes [structured interview] - PWD*** |  | X |  |  |
| ***ICE-CAPO [structured interview] - PWD*** |  | X |  |  |
| ***Statue Task [test using tablet] - PWD*** |  | X |  |  |
| ***ICE-CAPO [self-completed questionnaire] - Carer*** |  | X |  |  |
| ***Zarit (short-form) [self-completed questionnaire] - Carer*** |  | X |  |  |
| **PROSPECTIVE DATA COLLECTION:** |  |  |  |  |
| ***Falls experienced [diary / weekly telephone interviews] – PWD1*** |  |  | X (1mth) |  |
| ***Health service use [telephone interview] – PWD2***  |  |  | X (1mth) |  |
| **PROCESS EVALUATION:** |  |  |  |  |
| ***Class attendance [register] – dyads3*** |  |  | X (1mth) |  |
| ***Qualitative - observations of classes & feedback – all participants*** |  |  | X (1mth) |  |
| ***Adherence to home exercises [diaries] – dyads4*** |  |  | X (1mth) |  |
| ***Qualitative – a focus group with each class (x2) – all participants5*** |  |  |  | X |
| **SAFETY MONITORING:** |  |  |  |  |
| ***Safety monitoring [diaries / weekly telephone interviews] – dyads6*** |  |  | X (1mth) |  |

## Intervention pilot phase baseline visit

### Baseline participant characteristics

The collection of baseline data will occur during the initial home visit immediately after informed consent and M-ACE screening. If however this is not mutually convenient, the visit may be separated into to two visits over a period of 1 working week.

Having obtained informed consent and performed the M-ACE (see section 7.3), the researcher will collect the following demographic information about the PWD; age, gender, ethnicity, highest educational qualification, household composition, and marital status. The researcher will also collect relevant medical details including falls history (number of falls experienced in the previous 12 months and past month, and if so whether an injurious fall), number and names of chronic conditions (comorbidities), whether they use a walking aid, number of daily medications that they take, current level of moderate and vigorous physical activity, and dementia diagnosis (which type and when diagnosed). Details relating to the informal carer will also be collected: age, gender, ethnicity, highest educational qualification, relationship to the PWD and whether living in the same home as the PWD (if not spouse then will ask about marital status and household composition, and how many minutes on average they see the PWD in-person each week). Both the PWD and carer will also be asked if they have ever done Tai Chi before and their intention and perceived behavioural control to do Tai Chi if offered the opportunity. All details will be recorded in a visit-specific case report form (CRF).

### Baseline questionnaires

The researcher will collect the Icon-Fes and ICECAP-O through structured interview with the PWD. Carers will self-complete the ICECAP-O and Zarit Burden Interview (short form). The researcher will ensure that the carer completes the questionnaires away from the PWD; these assessments may be completed by the carer while the PWD is undergoing the structured interview. After these questionnaires, the Statue task will be completed by the PWD with instructions given by the researcher. This task will involve asking the PWD to hold a tablet and complete a series of tasks by touching the screen to answer questions at the appropriate moment. The task will involve them viewing a scene and answering questions such as, “which statue is located nearest to the black wall?”

### Baseline balance tests

With the exception of the BBS, the baseline balance test assessments will be performed first by the carer and subsequently by the PWD. In this way, the carer can act as demonstrator for the PWD (for the TUG and postural sway tests). Assessments will be conducted in the following order:

1. Postural sway while standing on the floor – carer
2. Postural sway while standing on foam – carer
3. TUG – carer
4. Postural sway while standing on the floor – PWD
5. Postural sway while standing on foam – PWD
6. TUG – PWD
7. BBS – PWD

**Logistics of the postural sway tests:** These static balance tests only require a clear floor area for the participant to stand and be recorded standing for 30 seconds with their eyes open. This is performed once on the floor and once standing on a foam surface (provided), without shoes. The test will be recorded using a stopwatch and digital balance sensor (THETAmetrix).

**Logistics of the TUG test:** Three metres of clear walk way space will be required for the participant to perform the test. The participant walks at a comfortable walking speed and if required, uses a walking aid device during the task (this is placed nearby but not held at the start of the test). Three metres are marked on the floor using gaffa tape and a standard chair (seat height of 46cm approx.) placed at one end of the walk tape. Three metres is considered an acceptable distance for home-based testing which would ideally be measured in the lounge, but a hallway or other room would be acceptable. The test will be recorded using a stopwatch and digital balance sensor (THETAmetrix).

**Logistics of the BBS test:** These static balance tests require a clear floor area for the participant to sit and stand and hold positions / conduct tasks for specified time periods. A stopwatch will be used to time activities. Some tasks will require the participant’s standard dining chair or similar to be used. One task requires two chairs (one with and one without arm rests), which can be performed with a sofa or bed if two chairs are not available. A reaching task requires a ruler to record the length the participant can reach while leaning forward. Another task requires the participant to pick an object from the floor (this is suggested to be a shoe or slipper the participant has nearby) directly in front of them. The shoe / slipper can be used as a focal point for the task requiring participants to look over their shoulder. A stepping task requires a foot stool that will be provided. Note that some versions of the instructions incorrectly indicate a 15ft walkway is required, but as no walking / dynamic measures are used in the BBS this is not a requirement.

Conduct of the balance tests will be recorded by the researcher in a visit-specific CRF. Data from the THETAmetrix device will be downloaded immediately after each test and stored on the researcher’s university laptop / tablet. A training manual will be provided to researchers which will include detailed instructions for conducting and recording the tests. The manual will stipulate a single, approved methodology for each test and will identify precautions to be taken to minimise any risks to safety for staff and participants. Safety will be of paramount importance and will take precedence over collecting complete data for every item (i.e. if an item is deemed to be too demanding and to place a participant at risk, the researcher will skip this item and mark it as such on the CRF).

### Completion of the baseline visit

The researcher will remind the dyad of expectations in terms of daily / weekly / monthly record keeping to inform data collection throughout the intervention period. The researcher will be responsible for checking completed questionnaires before leaving the premises, and will make every effort to ensure missed or spoiled questions are addressed in the interests of maximising data completeness. The completed demographic questionnaire will be entered into the trial database held by the research team as soon as possible after completion of the visit. When a PWD is recruited into the study, part of the informed consent process will be that they provide consent for the research team to inform their GP of their participation in the study. Following successful completion of the visit, the researcher will be responsible for sending a standard letter to the PWD’s GP advising of participation and providing information about the study. The letter will request that if the GP recommends withdrawal from the study from the outset or at any point during the study period, that they inform the research team immediately (see section 10).

## Organisation of classes

For both sites, once a minimum number of dyads has been reached (4 dyads), the venue booking will be confirmed by the instructor, who will forward confirmation on to the research team. The research team will provide the instructor with the attendance record to be completed each week (list of names and a tick sheet to be returned weekly). The research team will write to participants to inform them about when and where the classes will take place, who the instructor will be (and their contact details), and information to help them prepare to attend the first class. Participants can contact the research team or the instructor ahead of the class with any queries. Data will be collected in the interim between baseline assessment and the first class (i.e. the falls dairies and weekly telephone calls), but the period between the baseline home visit and start of the class will be kept as short as possible.

## Intervention delivery

A comprehensive description of the intervention is provided in section 11. In this intervention pilot phase, the intervention will be delivered over a period of four weeks to all 14 enrolled participating dyads (two groups of 7 dyads, one group in Southampton and one group in Dorset). The intervention will be delivered as four Tai Chi classes, one class per week, plus a home visit by the Tai Chi instructor within weeks 1-2 to facilitate completion of the home-based Tai Chi exercises. Given that only 4 weeks of the 20-week programme will be delivered, participants will only receive a fifth of the intended intervention. However, this will be sufficient for intervention pilot testing of both the class-based and home-based components.

The Tai Chi instructor will be responsible for recording attendance at each class on a purpose-designed form which will be passed to the research team weekly. The Tai Chi instructor will also be responsible for arranging and conducting home visits with each of the participating dyads after the first class to deliver the home-based component of the intervention.

## Qualitative assessments

As indicated in the tabulated study schedule, qualitative data will be collected using two methods. Dyads will need to be willing to participate in both of these qualitative aspects of the intervention pilot phase when recruited. First, a researcher will observe the Tai Chi classes for the four weeks at each site. At the end of each class, the researcher will collect feedback from participants and the instructor. The observations and feedback will provide real-time / immediate data regarding dyads’ experiences of and feedback about the classes and how they might be improved. All data at this stage will be collected as detailed field notes. Secondly, at the end of the 4-week Tai Chi class at each site (once all sessions have been completed for the site in question), a focus group will be held to collect more detailed feedback from participants. The focus groups will be held at the same venue as the class and immediately after the final class. This will provide more reflective comments from participants and in particular obtain feedback in regard to adherence to the home-based exercises and feasibility of the trial protocols in general. Data gathered during this intervention pilot phase will serve to identify any aspects that could be changed for the RCT to improve adherence and reduce participant burden.

## Data collection during the intervention period

After the baseline assessments have been taken, at the home visit, participants will be asked to keep a daily record of any falls experienced during the study on a monthly calendar. These will be posted to the research team at the end of the month. At the first Tai Chi class, participants will also be asked to keep a record of the Tai Chi exercise they complete at home daily on a weekly calendar. These will be handed back to the instructor at each weekly class. To avoid under-reporting of falls [61], the completion of calendars will be supplemented by weekly telephone calls made by the research team to the PWD to chase missing data and to enquire if any falls or related events have been experienced. Any reporting of falls will trigger a telephone interview to ascertain further details of fall events [60], enquire as to whether any falls or adverse events led to an injury, health / social care use or cost to the dyad (specifically in relation to the fall only), and if any injuries were related to the TACIT Tai Chi intervention. Details of standard operating procedures for safety monitoring are detailed later in this protocol. Calendars and telephone interviews will be completed until the final follow-up home visit. Telephone interviews will be structured and data entered into a purpose-designed CRF. These data will then be entered into the trial database held by the research team and the CI will be informed immediately of any serious related events for safety monitoring. Any missing data that needs querying by telephone will be notified to a member of the research team to incorporate in the next scheduled telephone interview.

## Duration of participation

After providing baseline data, dyads will receive the intervention for 4 weeks and so will participate in the study for approximately 4-8 weeks depending on how quickly they join one of the classes. Participation in the pilot intervention phase will end on completion of a focus group, and this phase of the project will end on completion of the second focus group.

# Study schedule – RCT phase

This section describes the conduct of the RCT in chronological order, detailing procedures for data collection at each of the time points. A summary of the study schedule is shown in Table 2. Note that in contrast with the intervention pilot phase, the CTU will support the management of the RCT phase.

*Table 2: Study schedule for the RCT phase (overleaf)*

*Notes on Table 2*

1. *A falls diary will be completed for a calendar month and posted back to the CTU at the end of the month. The unblinded researcher will also telephone participants weekly to collect falls data.*
2. *When a participant indicates that they have experienced a fall (fall diary) or injury while performing Tai Chi at home (home exercise diary), or the Tai Chi instructor records an injury during class (class register), this will trigger a telephone interview with the dyad conducted by the unblinded researcher. A fall / (serious) related event will be recorded. If health services have been used, then a structured interview will be completed by telephone by the unblinded researcher with the PWD or carer to collect detailed information on health service use.*
3. *Class attendance will be recorded by the Tai Chi instructor.*
4. *Weekly home exercise diaries will be returned to the Tai Chi instructor, by the participant, each week at the classes during the 5-month intervention. The unblinded researcher will telephone participants to follow up on any missing data.*
5. *The exit interview will be conducted by the blinded researcher and will ask about any change in health during the trial and willingness to pay for the intervention.*
6. *Data from the weekly class registers, weekly home exercise diaries, weekly telephone interviews, and monthly fall diaries will be used for safety monitoring. A structured telephone interview will be completed by the unblinded researcher with the carer to ascertain whether reportable related events have occurred (see section 14).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Screening** | **Baseline** | **Allocation** | **Post-allocation** |
| **TIMEPOINT** |  | ***t1*** |  | ***Weekly*** | ***During intervention******(+5 months)*** | ***Post-intervention (+6 months)******t2*** |
| **ENROLMENT:** |  |  |  |  |  |  |
| **Eligibility screen - PWD & carer** | X |  |  |  |  |  |
| **Informed consent - PWD & carer** |  | X |  |  |  |  |
| **Eligibility confirmation - PWD & carer**  |  | X |  |  |  |  |
| **Demographics - PWD & carer** |  | X |  |  |  |  |
| **Medical History - PWD** |  | X |  |  |  |  |
| **Allocation (dyads)** |  |  | X |  |  |  |
| **INTERVENTIONS:** |  |  |  |  |  |  |
| ***Intervention Group:*** | ***Usual care***  |  |  |  |  |  |  |
|  | ***+ Tai Chi classes and home exercises for 5 months*** |  |  |  |  |  |  |
| ***Control Group:*** | ***Usual care***  |  |  |  |  |  |  |
| **ASSESSMENTS:** |  |  |  |  |  |  |
| ***M-ACE [structured interview] - PWD***  |  | X |  |  |  | X |
| ***Icon-Fes [structured interview] - PWD*** |  | X |  |  |  | X |
| ***ICE-CAPO [structured interview] - PWD*** |  | X |  |  |  | X |
| ***Statue Task [test using tablet] - PWD*** |  | X |  |  |  | X |
| ***ICE-CAPO [self-completed questionnaire] - Carer*** |  | X |  |  |  | X |
| ***Zarit (short-form) [self-completed questionnaire] - Carer*** |  | X |  |  |  | X |
| ***Postural sway [x2 balance tests] - Carer***  |  | X |  |  |  | X |
| ***TUG [balance test] - Carer***  |  | X |  |  |  | X |
| ***Postural sway [x2 balance tests] - PWD***  |  | X |  |  |  | X |
| ***TUG [balance test] - PWD*** |  | X |  |  |  | X |
| ***BBS [balance test] - PWD*** |  | X |  |  |  | X |
| **PROSPECTIVE DATA COLLECTION:** |  |  |  |  |  |  |
| ***Falls experienced [diary / weekly telephone interviews] – PWD1*** |  |  |  | X (6mths) |  |  |
| ***Health service use [telephone interview] – PWD2***  |  |  |  | X (6mths) |  |  |
| **PROCESS EVALUATION:** |  |  |  |  |  |  |
| ***Class attendance [register] – dyads3*** |  |  |  | X (5mths) |  |  |
| ***Qualitative - observations of classes & feedback (purposive sample) – dyads*** |  |  |  | X (5mths) |  |  |
| ***Adherence to home exercises [diaries] – dyads4*** |  |  |  | X (6mths) |  |  |
| ***Qualitative – home-based interviews – (purposive sample) - dyads*** |  |  |  |  | X |  |
| ***Exit interview [structured] – dyads5*** |  |  |  |  |  | X |
| **SAFETY MONITORING:** |  |  |  |  |  |  |
| ***Safety monitoring [diaries / weekly telephone interviews] – dyads6*** |  |  |  | X (6mths) |  |  |

## RCT baseline visit

Conduct of the baseline visit in the RCT will be the same as for the intervention pilot phase in terms of the collection of baseline participant characteristics, performance of balance tests and completion of interviews and questionnaires (see sections 8.1.1 to 8.1.3). Once all baseline data is collected for a dyad, they will be randomised to either the intervention group or the control group and notified of allocation by telephone and/or post.

### Completion of the baseline visit

The researcher will remind the dyad of expectations in terms of daily / weekly / monthly record keeping to inform data collection throughout the intervention period. The researcher will ensure that the dyads understand that:

1. Data from participants in both arms of the trial is equally important for the research question to be answered.
2. If allocated to the control group, dyads will be offered £50 on completion of the 6-month follow-up visit, which may be used, if desired, to undertake Tai Chi sessions at a suitable location after the study is ended.
3. If allocated to the intervention group, the dyad will be contacted in due course with arrangements for attendance at a Tai Chi class.
4. Dyads should make every effort not to disclose their treatment allocation to (blinded) members of the research team in future.

The researcher will provide the participants with the Further Information Sheet and reiterate that both the PWD and the carer may contact the researcher with any queries relating to study involvement as required. The researcher will be responsible for checking completed questionnaires before leaving the premises, and will make every effort to ensure missed or spoiled questions are addressed in the interests of maximising data completeness. Completed questionnaires and CRF pages will be transferred to CTU as soon as possible after completion of the visit according to instructions provided by CTU. When a dyad is recruited into the study, part of the informed consent process will be that they provide consent for the research team to inform their GP of their participation in the study. Following successful completion of the visit, the researcher will be responsible for sending a standard letter to the PWD’s GP and the carer’s GP advising of participation and providing information about the study. Should a carer who is otherwise eligible and amenable to participate, refuse for their GP to be informed about the study, the carer will not be precluded from participating. The letter will request that if the GP recommends withdrawal from the study from the outset or at any point during the study period, that they inform the research team immediately (see section 10).

### Randomisation procedure

Random allocation to either the intervention group or the control group will be achieved using a centralised automatic web-based randomisation system designed and maintained by Peninsula Clinical Trials Unit (CTU). Access to the randomisation system requires an internet connection. A member of the CTU team will access the randomisation system using a unique username and password combination.

Once confirmation of eligibility and fall history is entered onto the study database, randomisation (using minimisation and stratified by site) will be performed on batches, or for individual dyads, as described in section 4.1. The CTU will then inform each dyad which treatment group they have been allocated to, by post.

## Organisation of classes for intervention group participants

As described in 4.1, for each class cohort, once a minimum of 4 dyads in total have been recruited, they will be randomised in a batch to the intervention or control group. The first dyad will be allocated using simple randomisation, with the remaining dyads allocated using minimisation by treatment condition and fall history at baseline. The venue booking will be confirmed by the instructor, who will forward confirmation on to the CTU and research team. A member of the research team or CTU will provide the instructor with the attendance record to be completed each week (list of names and a tick sheet to be returned weekly). The CTU will write to participants to inform them about when and where the classes will take place, who the instructor will be (and their contact details), and provide information to help them prepare to attend the first class. Participants can contact the research team or the instructor ahead of the class with any queries. Data will be collected in the interim between baseline assessment and the first class (i.e. the falls dairies and weekly telephone calls), but the period between the baseline home visit and start of the class will be kept as short as possible.

## Intervention delivery for intervention group participants

The intervention will be delivered over a 5-month (20 week) period and will comprise both class-based and home-based components. A comprehensive description of the intervention, including its delivery in the RCT phase is provided in section 11. The Tai Chi instructor will be responsible for recording attendance at each class on a purpose-designed form which will be passed to the research team weekly. The Tai Chi instructor will also be responsible for arranging and conducting home visits with each of the participating dyads after the second class to deliver the home-based component of the intervention. Participants will be reimbursed their travel costs on completion of appropriate reimbursement forms.

## Qualitative assessments for intervention group participants

Qualitative data will be collected via two methods. As with the pilot intervention phase, a researcher, who will have no involvement in collection of follow up outcome data, will observe the Tai Chi classes. In the RCT, a purposive sample of 10% of sessions will be observed during the 5-month intervention delivery period. These sessions will be two sessions from all 11 classes, with one session observed near the beginning (weeks 1-4) and one over half-way through (weeks 12-16). At the end of each observed Tai Chi class, the researcher will also collect feedback from participants and the instructor. Observations and feedback data will be collected as detailed field notes. These observations and feedback will provide real-time / immediate data related to dyads’ experiences of the classes in terms of perceived enjoyment / benefits as well as the social dynamics of the groups over time between dyads and the instructor. Secondly, toward the end of the 5-month intervention (at around week 16 of 20), home-based interviews will be conducted with a purposive sample of approximately 15 dyads to collect more in-depth feedback such as how the intervention was incorporated into dyads’ daily / weekly routines (or not) and the potential wider benefits (or unforeseen implications) of participating in the intervention. The purposive sample will be chosen by attempting to select a sample that represent the range of experiences of the intervention, including a mixture of: men and women who have dementia, carers who are spouses and those who are not (e.g. adult children), some relatively younger and older participants, those that reported a low / high level of motivation to do Tai Chi at the baseline demographic interview, and those that stopped attending classes / those that attended every class, etc. Participation in these interviews will be optional and not a requirement for participation in the RCT. The qualitative data will provide rich contextual detail and give voice to the participants’ views to help interpret the quantitative data and explore barriers and facilitators to adherence. These data will be particularly useful when designing the subsequent definitive trial.

## Data collection during the study period

Participants in both arms of the trial will be provided with calendars to complete on a daily basis. They will be asked to record if a fall was experienced by the PWD (yes / no), and then post back the calendar to CTU at the end of the month. In addition, a researcher will telephone the PWD weekly and the carer every 3 months to ask if the PWD has experienced any falls in the past week or 3 months respectively. When the weekly PWD phone call coincides with the end of a month, the PWD will also be asked if they have fallen in the past month. If a fall is reported by any mechanism, then the researcher will conduct a telephone interview with the PWD. The telephone interview will ascertain details of the fall, including: the date the incident took place; the circumstances of the fall (if while performing Tai Chi or not); if the fall led to an injury (using the definition noted above in 3.3); and if the fall resulted in any health or social care use or if any personal costs were incurred. For those that report a fall while carrying out Tai Chi at home or in class, a safety monitoring telephone interview by a researcher with either the PWD or their carer will ascertain further details (see below section). For those that report any health or social care use or if any personal costs were incurred, a further telephone interview will collect these details specifically in relation to the fall / Tai Chi injury only. This will be conducted by the unblinded researcher with either the PWD or their carer. The CTU will record if any fall calendars have not been returned / have been returned with ambiguous data and will prompt the researcher to ask for the missing data / clarify the data at the next telephone call.

In addition, dyads in the intervention arm will be asked to record on a separate weekly calendar their adherence to the Tai Chi home exercises. This weekly home exercise calendar will be returned in person to the Tai Chi instructor at the next class during the 5-month intervention, and sent by post weekly to CTU up until in the final follow-up home visit. A tick box will be included in these weekly diaries to indicate if either the PWD or the carer experienced an injury while carrying out Tai Chi at home. If one of these boxes is ticked then the CTU will alert the research team, who will conduct a safety monitoring telephone interview with either the PWD or their carer. If a serious injury was experienced while carrying out Tai Chi at home, then dyads will be asked to notify a member of the research team as soon as possible (either by telephone, email, or sending an alert card). This will prompt an unblinded researcher to conduct a safety monitoring telephone interview with either the PWD or their carer. The information will then be processed in accordance with the safety monitoring procedure detailed in section 14.

The CTU will record if any home exercise calendars have not been returned / have been returned with ambiguous data and prompt the unblinded researcher to ask for the missing data / clarify the data at the next telephone call. The Tai Chi instructor will briefly discuss the home exercise calendars with dyads at the end of each class and encourage adherence.

The Tai Chi instructor will also keep a record of attendance to the Tai Chi classes and post these to the CTU each week. Again, on this record will be included a tick box to indicate if any PWD or carer fell or experienced some form of injury during the class while performing Tai Chi. If one of these boxes are ticked then the CTU will alert the unblinded researcher who will conduct a safety monitoring telephone interview with either the PWD or their carer. If however there is a serious related event during a class, the Tai Chi instructor will contact the unblinded researcher as soon as possible after the class with as much information as possible. This researcher will contact the PWD to conduct a safety monitoring telephone interview to ascertain further information. The information will then be processed in accordance with the safety monitoring procedure detailed in section 14.

Lastly, within the intervention group only, data will be collected half-way through the intervention on a 5-item questionnaire to ask about the importance of features of the intervention such as enjoyment of the classes and confidence in being able to continue to do the home practice.

## RCT follow up visit (6 months)

The follow-up assessment will be conducted so as to coincide as near as possible with the end of the intervention delivery (for participants in the intervention arm). The post-intervention assessment time-point is described throughout this protocol as the “six-month follow-up”. The actual timing of the follow-up in relation to baseline may vary depending on how successfully the classes can be organised. In any case, the follow up will be conducted no later than six months plus a window of six weeks after the baseline visit. Dyads in the control group will receive their follow-up home visit as close as possible to other members of their class cohort.

Researchers will be responsible for arranging the six-month post-baseline follow-up home visit. In preparation for the visit, participants will receive a letter from the researcher asking participants not to disclose their allocated treatment group to the researcher, and to conceal any evidence of home-based Tai Chi exercises from the researcher at the visit, where applicable. When arranging the visit, typically by telephone, the researcher will remind participants of the need to keep the researcher blind to treatment group at the visit. The researcher conducting this visit will be the same as the researcher who conducted the baseline visit but will have been kept blind to trial allocation throughout the trial period. At this visit, the same questionnaire-based and balance assessments conducted at the baseline visit will be repeated (refer to sections 8.1.2 and 8.1.3). Assessments will be conducted in the following order:

1. M-ACE – PWD
2. Icon-Fes - PWD
3. ICECAP-O - PWD
4. Statue task - PWD
5. ICECAP-O – carer
6. Zarit burden interview - carer
7. Postural sway while standing on the floor – carer
8. Postural sway while standing on foam – carer
9. TUG – carer
10. Postural sway while standing on the floor – PWD
11. Postural sway while standing on foam – PWD
12. TUG – PWD
13. BBS – PWD

Before completing and recording the balance test assessments, the researcher will collect the M-ACE, Icon-Fes, ICECAP-O, and Statue task through structured interview with the PWD. Carers will self-complete the ICECAP-O and Zarit Burden Interview (short form). The researcher will ensure that the carer completes the questionnaires away from the PWD; these assessments may be completed by the carer while the PWD is undergoing the structured interview.

### Joint exit interview with PWD & carer

The exit interview will be an additional brief structured interview that will ask dyads about their willingness to pay for the intervention. It will also check if there has been a change in their medical status (e.g. medication usage or elective surgery) during the trial period, which may influence performance on the primary outcome.

### Completion of the 6-month follow up visit

The researcher will be responsible for checking completed questionnaires before leaving the premises, and will make every effort to ensure missed or spoiled questions are addressed in the interests of maximising data completeness. Completed questionnaires and CRF pages will be transferred to the CTU as soon as possible after completion of the visit according to instructions provided by the CTU.

## Duration of participation

Each recruited participant is expected to be involved in the study for around six months from the baseline visit to the final follow-up. Participation in the study will end on completion of the follow-up home visit.

## End of trial

The end of trial will be the final data collection visit for the final trial participant.

### Stopping criteria

Given that a six-month follow-up period will be used and no interim analysis is planned, the trial will not be stopped early on the grounds of clear indications that the intervention has an unexpectedly high / low effect. The trial will only be stopped early if the intervention is considered to be directly causing undue harm to patients as independently considered by the trial steering committee and / or NHS Research Ethics Committee.

# DISCONTINUATION / WITHDRAWAL

Participants in both the intervention pilot phase and the RCT will be free to withdraw from the study at any time, and this will be emphasised during the consent process. If a participant chooses to withdraw they will be asked to provide a reason and the reason for withdrawal will be noted. Participants do not have to provide a reason and this will be reiterated by the researcher (or authorised delegate) in the event that a participant requests to be withdrawn. Table 3 summarises the procedure that will be followed if one member of a dyad withdraws from the study.

Given the ‘group’ nature of the intervention, and the need to randomise participants in batches, it may be necessary on occasion to withdraw a dyad(s) if insufficient numbers are recruited for a particular class cohort. For example, if a dyad is consented and undergoes baseline assessment, but no subsequent dyads are recruited for the same class cohort within a reasonable timeframe, it may be necessary to withdraw the recruited dyad. Withdrawal forms will be completed in this scenario as described. The withdrawn dyad will be permitted to re-consent and undertake baseline assessment again if the opportunity to join another class cohort becomes available.

If a request for withdrawal from a PWD’s GP is received, the PWD in question will be notified by the research team and withdrawn from the study. However, we do not anticipate any withdrawals from the study in this way given the intervention uses only gentle exercise and the non-invasive nature of the outcome measures. If a GP recommends that a participant is withdrawn from the intervention, then we will ask participants if they will consent to continuing to participate in the study through provision of data only. The reason for withdrawal from the intervention / study will be recorded. The same process will be followed if a participant decides to no longer participate in the intervention / study (i.e. they will be asked if they would continue to participate through provision of data only, and a reason for withdrawal will be recorded). If a participant wishes to withdraw from the study we will ask whether they are willing for those data gathered up to the point of withdrawal to be retained. Participants will not be replaced. Data collected on participants prior to withdrawal will be retained for analysis.

*Table 3. Procedure for continued participation when one member of a dyad withdraws*

|  |
| --- |
| ***Dyads in the control group*** |
| **Member of dyad withdrawing** | **Resultant action** |
| Informal carer | Continue to collect data from the PWD* PWD will have capacity to consent to be part of the trial and so will be asked to still provide data.
 |
| PWD | Continue to collect data from the informal carer* The informal carer will have capacity to consent to be part of the trial and so will be asked to still provide data.
 |
| ***Dyads in the TACIT intervention group\**** |
| **Member of dyad withdrawing** | **Resultant action** |
| Informal carer | The dyad will be contacted by a member of the research team to discuss if someone else can support the PWD to do the Tai Chi intervention or if the PWD can do this alone. * If the PWD can continue alone they will do so.
* If someone else can assume the role of the informal carer (in addition to or in replacement to the original carer), then the PWD will continue in the study with the new partnership arrangement. Note that follow-up data collection must be with the same carer who participated at baseline (different carers can help the PWD and provide data during the trial, but not when comparing baseline and follow-up measurements).
* If the PWD cannot continue alone and another carer cannot be found, then the PWD and their carer will be withdrawn from the intervention but the PWD will be asked to continue to provide data.
 |
| PWD | Withdraw PWD & carer from the intervention but continue to collect data from the carer. |

\*Note: For the intervention pilot phase, only the rows in relation to the TACIT intervention group will apply (as there will be no control group).

# INTERVENTION

The intervention will comprise 3 components: (1) Tai Chi classes, (2) home-based Tai Chi exercises, and (3) a behaviour change component. It has been designed so that participants achieve 50 hours or more of Tai Chi physical activity, because exercise-based interventions to prevent falls are more effective if they have a higher dosage (50 hours or more), challenge balance (e.g. exercises are conducted while standing), and do not include walking [46]. The intervention will be run for 20 weeks and will comprise a Tai Chi class each week (component 1), carer-led home-based Tai Chi exercises (component 2), and after the initial two weeks of classes, a home visit by a Tai Chi instructor plus reminder telephone calls and an alarm clock to prompt participation (component 3).

*1. Tai Chi classes*

Two qualified Tai Chi instructors will deliver the weekly Tai Chi classes for 20 weeks at accessible venues in the local community (e.g. church halls or suitable rooms at NHS sites). Each class will last for 60 minutes, with 45 minutes Tai Chi class and 15 minutes for informal discussion. Dyads will be encouraged to participate in the informal discussions each week to foster mutual peer-support, and seek on-going advice from the Tai Chi instructor in regard to the home-based exercise component. Classes will ideally have 7 dyads per class (7 PWD plus their informal carers) but never more than 10 dyads per class.

We will partly follow the Positive Emotion-Motivated Tai Chi (PEM-TC) approach developed in the USA [77,78], in that teaching will be based on implicit learning techniques. Through repetition of movements and positive reinforcement, this approach capitalises on PWD’s capacity to continue to learn motor tasks with the use of muscle or kinaesthetic memory, i.e., unconsciously through making behaviours automatic, despite impaired ability to explicitly recollect such memories [77]. This is similar to learning to do other automatic behaviours such as riding a bike. A one-sample pre- and post-test study found that after a 16-week intervention using the PEM-TC approach, community-dwelling PWD significantly improved on balance tests at the end of the intervention [78]. Adherence rates were 86% and 84% for the class and home-based components respectively, suggesting that the approach was acceptable and effective among participants. Further study is now required to test if this approach will be effective in the UK and with the use of a robust RCT design.

*2. Home-based Tai Chi exercises*

After two weeks of classes, the Tai Chi instructor will arrange to visit each dyad in their own home. At the home visit, each dyad will be given a pack to help them practice at home what they have learnt in class. The pack will contain a colourful home exercise booklet, to serve as a reminder of what has been covered in the classes each week and to prompt practice of the Tai Chi moves at home. In addition, they will be provided with a small alarm clock that they may find helpful in reminding them to do the Tai Chi exercises each day. The carers will be asked to facilitate the PWD to carry out Tai Chi for 20 minutes each day, at a time and location suitable to them (e.g. in the lounge in the morning). If this is not possible, they will be asked to perform the exercises each week in three bouts of 40 minutes or two bouts of 60 minutes (minimum of 120 minutes total each week). They will be able to do more than the minimum number of minutes, but will be asked to ensure safety is of paramount importance and to notify the research team immediately of any injury to the PWD or carer while carrying out the Tai Chi at home. In the interest of safety, dyads will be asked not to practise Tai Chi at home until the Tai Chi instructor has made the home visit to risk assess their home environment.

*3. Behaviour change component*

After two classes and usually within the first 3-4 weeks of the intervention, each dyad will receive one 30-minute home visit by the Tai Chi instructor. The home visit will serve to enhance the practice of Tai Chi at home through a risk assessment of the environment where Tai Chi is being carried out at home, confirmation of instructions on the performance of 20 minutes daily Tai Chi, answering of any queries, and use of behaviour change techniques. At the home visit the Tai Chi instructor will re-affirm with dyads the benefits of doing Tai Chi, the central role of the home-based exercises to obtain these benefits, and possible consequences of not doing Tai Chi, as recommended in NICE guidelines [79]. To enhance uptake and adherence to the home-based Tai Chi exercises, the instructor will then facilitate the dyad with joint action planning and coping planning. These interventions are based on self-regulation theory that has robust empirical support for increasing physical activity [80-86]. For action planning, dyads will decide together when and where they will do their Tai Chi exercises. For coping planning, PWD and their carer will anticipate any personal barriers that may arise for them whilst carrying out the Tai Chi exercises and what they can plan to do to overcome them. The use of these proven behaviour change techniques have been recommended in NICE guidelines for physical activity promotion and behaviour change [79;87-88]. Other techniques recommended by these guidelines already embedded within the design of the intervention include self-monitoring (dyads will record their weekly completion of Tai Chi exercises), feedback on performance and adherence (from the instructor each week), and social support (from the instructor and peers in the class) [87].

In addition, the dyads will receive two forms of reminders that may help with their completion of the TACIT Tai Chi intervention. First, they will be provided with small alarm clocks that they can set as they wish to alert them to when in the day they are due to do their Tai Chi. For example, they could set the alarm to sound at 10:00am daily to remind them that they planned to do Tai Chi each day at that time. Second, if dyads do not attend a Tai Chi class for two consecutive weeks for an unknown reason (i.e. the instructor is not aware that they are ill or on holiday), then this will be alerted to the research team by the CTU. A member of the research team will telephone the dyad as part of safety monitoring to check on their wellbeing and to ensure that they have not experienced a serious related event. The researcher will then take this opportunity to remind the dyad of their Tai Chi class and encourage them to continue attending the class to benefit from the intervention.

## Assessment of treatment adherence

The process of measuring adherence to the intervention (class attendance and completion of home exercises) has already been described above in sections 8 and 9 above.

# CONTROL GROUP

Participants in the control group will be asked not to take up Tai Chior similar exercise (Qigong, yoga, or Pilates) during the period of the project. (Participants will be offered £50 on completion of the 6 month follow-up visit, which may be used, if desired, to undertake Tai Chi sessions at a suitable location after their involvement in the study has ended).

In terms of usual care, PWD join a different patient pathway under the two trusts.

*SHFT*

Besides inpatients who are diagnosed while in hospital, those in the community who are concerned about their memory or suspected to have dementia by their GP are referred to the MAS. The MAS will diagnose a person with dementia, and depending on the type and severity of dementia, may prescribe medication (see below). Otherwise, no further treatments are offered for the PWD, and in particular, no Tai Chi or other physical activity is prescribed. SHFT provides a Memory Matters course, designed to provide information, support, and advice to PWD and the same but a separate course for informal carers. The course provides information on aspects such as what dementia is, support for carer stress, relaxation / breathing exercises, clubs and community resources, maintaining physical health in dementia, and memory aids to help improve memory. In addition, for those living in some areas, they are also referred to a memory advisor who will provide telephone contact to check on the wellbeing of the PWD and their informal carer.

*DHUFT*

Besides inpatients who are diagnosed while in hospital, those in the community who are concerned about their memory or suspected to have dementia by their GP are referred to the MSAS. A memory advisor will conduct an initial screening for the person and their carer and provide on-going support, advice, information, guidance, and signposting to local services. If appropriate, MSAS then refer on to the MAS. The MAS will diagnose a person with dementia, and depending on the type and severity of dementia, may prescribe medication (see below). Otherwise, no further treatments are offered for the PWD, and in particular, no Tai Chi or other physical activity is prescribed. The PWD is then referred back to the MSAS who then provide post-diagnostic support, advice, information, guidance, and signposting to local services. MSAS typically provide reading materials and information advice in regard to current circumstances (e.g. welfare benefits) and future planning (e.g. advance care planning and establishing Lasting Power of Attorneys). MSAS also signpost to services, for example clubs / day centres, local support groups, carers courses (provided by St John’s Ambulance), hot meals services, and befriending services.

*Solent*

All patients diagnosed with dementia , seen either in hospital (The Limes, St James Hospital) or in the community (clinics at St James or at Paulsgrove) will be offered anti-dementia medications (if diagnosis is one of Alzheimer’s dementia, mixed [Alzheimer’s dementia plus vascular], Lewy Body Dementia, or Parkinson’s disease dementia). Regardless of type of dementia, all patients will be consented for referral to Solent Remind service (voluntary sector, commissioned by Portsmouth CCG) who will provide information about the illness, signpost patients and carers for other services provided by both Portsmouth city council as well as the carer centre, which includes day care, respite, carer information groups, and sitting service etc.

For those patients started on anti-dementia medications, they are monitored every six months by memory clinic either at the clinic or at home. All patients diagnosed with dementia will not be on the older people mental health (OPMH) service case load unless they are on memory enhancing medications or if they have other behavioural or psychological difficulties that require monitoring.

*Medication*

Usual care under SHFT, DHUFT, and Solent for PWD currently consists of medication (Acetylcholinesterase inhibitors) for the delay / management of dementia symptoms for those with mild to moderate Alzheimer’s disease or mixed dementia (Alzheimer’s disease and e.g. vascular dementia) only. Those with vascular dementia are discharged from the MAS or OPMH service back to the post-diagnostic support from the MSAS (DHUFT only) or Remind Service (Solent only). For those with Alzheimer’s disease, the medication that they would be prescribed in the first instance is Donepezil (was commonly known as Aricept, 5-10mg daily). If the patient experiences side effects to this then Galantamine (up to 24mg daily) or Rivastigmine (6-12mg daily or 4.6-9.5mg daily patches) may be offered, and patches can avoid gastric side effects (as they do not use the gastric method of absorption). Memantine may also be offered to patients with moderate to severe symptoms of Alzheimer’s disease, as it may be of benefit in reducing agitation though this has yet to be established.

# PROCESS EVALUATION

A logic model of the TACIT Tai Chi intervention is presented below in Figure 2 [89]. The process evaluation in this section refers to fidelity, as assessment of reach has already been described above in relation to recruitment, and assessment of dose has already been described above in relation to participant adherence to the intervention [89]. Data collection as to the first three components of the logic model is described below.

*Inputs*

On the Tai Chi class attendance record, a tick box will be included for the Tai Chi instructor to confirm that each of the following products was handed to each dyad on their first week: the home exercise booklet and alarm clock.

*Activities*

A Tai Chi class attendance record will be used to confirm that each class took place as intended. In addition, 10% of classes will be observed by a member of the research team and video recorded. This will entail two visits to all 11 classes, one visit near the beginning and one near the end of the 20-week course. On return of each inspected class, a researcher will analyse the video data and with a checklist confirm that the class was delivered as intended. This will include fidelity with:

* Intended content (e.g. weeks 1-6 should be covering foundational aspects of Tai chi)
* Ensuring safety of participants
* Instruction is tailored to participants (based on ability)
* Instruction includes progression (advancement in demands on participants in line with participants’ increased ability (on second visit in comparison with first visit)
* Participants are encouraged to practise Tai Chi at home
* The 15 minutes informal socialising time is used at the end of each class for peer-to-peer discussion and discussion with the instructor

After each home visit, the Tai Chi instructor will complete a checklist to confirm that the following took place at each visit:

* Risk assessment of area where home-based Tai Chi is being practised
* Answered any queries dyads had about practising Tai Chi
* Emphasised to dyads the importance of carrying out Tai Chi at home for the intervention to be effective
* Completed a joint action plan (one copy kept by dyad, one copy kept by instructor to return to CTU)
* Completed a joint coping plan (one copy kept by dyad, one copy kept by instructor to return to CTU)

Telephone contact will be made by the research team in weeks 2-18 to remind dyads to attend classes if they have consecutively failed to attend two classes for an unknown reason. The researcher will keep detailed records of when calls have been made and when calls have been unsuccessful on a given week.

*Outputs*

Each joint action plan, joint coping plan, and weekly home exercise diary will be recorded and analysed by a member of the research team.

*Figure 2. Logic model of the TACIT Tai Chi intervention*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Inputs** | **Activities** | **Outputs** | **Impacts** | **Outcomes** |
| *Human resources:** Tai Chi instructors to deliver the intervention
* Research team to make telephone calls to remind dyads to attend classes

*Products:** Booklet to support practise of home-based Tai Chi
* Alarm clocks to help remind dyads to practise Tai Chi at home

*Estates:** Venues in the NHS / community accessible by public transport and that have free car parking for hire of the Tai Chi classes
 | *Intervention contact:** Weekly 60min Tai Chi class for 20 weeks (45mins Tai Chi, 15mins socialising / Q&A with instructor)
* A home visit by Tai Chi instructor in week 3-4 to support Tai Chi practice at home through behaviour change techniques (joint action & coping planning with carer)
* Telephone contact by research team in weeks 2-18 to remind to attend classes if consecutively fail to attend 2 classes for unknown reason

*Intervention led by carer:** PWD to practise Tai Chi 20mins per day
* Daily self-monitoring & weekly instructor feedback: PWD to complete a daily diary of Tai Chi practised at home and hand to instructor at Tai Chi class weekly
 | * Joint action plan for practising Tai Chi at home
* Joint coping plan for practising Tai Chi at home
* Diaries of Tai Chi practised at home
 | * Increased participation in Tai Chi; physical activity designed to improve balance and prevent falls
* Increased support to do Tai Chi via weekly instructor-led classes
* Increased social support to practise Tai Chi through weekly contact with instructor and peers at the classes, and telephone reminders
* Increased support to do Tai Chi at home via action and coping planning, self-monitoring, instructor feedback, and alarm clock reminder
 | *Direct:** Reduction in risk of falls via increased dynamic balance (postural stability)
* Further reduction in risk of falls via:

(a) increased functional balance (postural stability)(b) increased static balance (postural stability)(c) reduced fear of falls(d) delayed deterioration in global cognitive functioning(e) delayed deterioration in visual-spatial cognitive functioning* Reduction in risk of falls in the carer via:

(a) increased dynamic balance (postural stability)(b) increased static balance (postural stability)*Indirect (via the above):** Reduction in rate of falls
* Increased quality of life
* Increased quality of life in the carer
* Reduced carer burden
 |

1. **SAFETY MONITORING**

The monitoring of participants’ safety will be achieved primarily through weekly telephone contacts between unblinded researchers and dyads and participants’ weekly record keeping. Participation in the trial is considered to be of relatively low risk and participants are not expected to be harmed as a result of taking part. As such, the recording and reporting of adverse events will be limited, as described in the following sections, to:

* (Serious) Related Events related to the Tai Chi intervention or the balance test assessments.
* Unexpected Serious Related Events

Definitions and guidance in relation to (serious) related event reporting is provided in Appendix 4. Note that (serious) related events will be in relation to either the PWD, their informal carer, or both. A trial-specific Work Instruction describing the collection, assessment, recording, and reporting of related events will be produced by CTU and provided to researchers prior to participant recruitment.

## Falls that occur during the study

Participants are very unlikely to fall during the study. However, the following plan is in place should a fall occur during the study:

*Falls that occur during a home visit (while conducting the balance tests)*

The researcher is to follow the same instructions provided in the falls calendar to participants. This explains what to do in the event that they are with someone who has had a fall.

*Falls that occur during a Tai Chi class*

The Tai Chi instructor is to follow the same instructions provided in the falls calendar to participants. This explains what to do in the event that someone has a fall. Should a participant fall, not be injured, and be able to get up, they will be advised to sit on a chair at the side of the class to rest until they feel able to re-join the class. However, should a participant fall and the situation be more serious (they are injured and / or cannot get up), then the class will be paused to attend to the participant. The instructor will seek the assistance of a first aider (as detailed below) and if necessary dial 999 for an ambulance to assist the participant to get up again and / or attend to their injury. Given the nature of the incident, location in the room, and duration into the session, it may be appropriate for the instructor not to continue with the class, but instead spend the remainder of the session talking with the rest of the class and advising them on how to do Tai Chi safely, especially when practising at home. They will also make a point of advising the participant who fell and their dyad partner of how to practise Tai Chi in class and at home safely without falling either at the end of that session or at the beginning of the next session. They may also advise the dyad stop practising Tai Chi at home until the instructor feels they have demonstrated in class they are able to safely practise Tai Chi.

*Falls that occur while dyads are practising Tai Chi at home*

Dyads are to follow the instructions provided in the falls calendar. This explains what to do in the event of a fall.

## Adverse events related to the Tai Chi intervention

THIS SECTION APPLIES TO PARTICIPANTS IN THE INTERVENTION GROUP ONLY

In the case of Tai Chi classes, the instructor will note if any incidents occurred during the class (e.g. if someone fell), and will mark this on the attendance sheet.

Expected Related Events arising from carrying out Tai Chi are:

* Muscle strain / fatigue from exercising muscles (e.g. foot pain)
* Musculoskeletal pain (e.g. back pain from bending)
* Sprained joint (e.g. knee, ankle, or shoulder pain) from movement of joints
* Mild faintness or dizziness that is resolved with sitting and resting for a few minutes
* Cut / graze / bruise if the person knocks into furniture while doing Tai Chi at home
* Fall that results in an injury but does not meet the criteria for an SAE

Serious Expected Related Events arising from carrying out Tai Chi are:

* Fall that results in an injury and also meets the criteria for an SAE

In the case of Tai Chi classes, if a related event occurs during a class then the instructor will inform the research team as soon as possible. If a serious related event occurs during a class then the instructor will alert the research team immediately after the class. In the case of Tai Chi practised at home, dyads will be asked to mark on their weekly calendar if an injury was experienced by either the PWD or their carer that week. In the case of a serious related event, they will be asked to alert the research team as soon as possible preferably by telephone or email, or via an alert card. In addition, a researcher will be in telephone contact with PWD weekly. Any related events brought to the research team’s attention will be discussed in this regular weekly telephone call, and any serious related events will require a telephone call to the PWD or their carer as soon as possible (within 24 hours of the research team being notified). Any related events or serious related events from participating in the TACIT Tai Chi intervention will be recorded via a detailed telephone interview.

The safety monitoring telephone interview will include a purpose-designed CRF with a checklist of the above expected related events plus space for ‘other’ events which participants consider to have been caused by partaking in Tai Chi. The telephone interview will ascertain and record the severity of these events (mild, moderate or severe), whether the event has resolved or is on-going and whether the event should be regarded as ‘serious’ or not. The researcher will also ascertain which (if any) of the reported Tai Chi related events were considered to be caused by performance of Tai Chi. Events considered to be caused by Tai Chi will be regarded as Related Events, and those that are serious will be regarded as Serious Related Events and will be reported as described in the following sections. In addition, health and social care use and costs incurred by participants will be recorded in the telephone interview in relation to any falls experienced or injuries while carrying out Tai Chi.

In this study, unless caused by performance of Tai Chi (as described in section 14.1 above), hospital admissions, ED attendances, and GP visits will not be treated as adverse events in terms of their assessment and classification i.e. where hospital admissions, ED or GP attendances are identified, that are not related specifically to performance of Tai Chi, researchers will not attempt to ascertain the relationship of those events to either trial participation or to the intervention, nor will they make assessments of severity or outcome.

## Related events in regard to balance test assessments

THIS SECTION APPLIES TO ALL PARTICIPANTS

Researchers will be trained in the safe conduct of the balance tests which are performed at baseline (in both the intervention pilot phase and RCT) and at 6-month follow up (in the RCT only). As such, adverse events caused by performance of the balance tests are not expected. Any adverse events caused by performance of the balance tests will be recorded by researchers in the CRF. Such events will be regarded as Related Events. Where such events meet the criteria for seriousness (see appendix 4 for definitions and guidance), they will be reported as Unexpected Serious Related Events in an expedited manner to the REC and Trial Steering Committee (TSC) as described in the following sections.

## Processing of adverse events and reporting to Investigator and Sponsor

In the intervention pilot phase, monitoring will be completed by the research team, and in the RCT, monitoring will be completed with the support of the CTU. On receipt of a completed serious related event form, the research team (intervention pilot phase) or CTU (RCT) will assign a unique serious related event number and confirm receipt of the event to the reporting site and to the study sponsor. If complete information is unavailable at the time of reporting in the intervention pilot phase, then further information will be collected by the research team. If complete information is unavailable at the time of reporting in the RCT, all appropriate information relating to the serious related event will be forwarded to the CTU as soon as possible to coordinate collection of this further information for each event.

Events which are serious and / or related to the Tai Chi intervention or to study procedures will be communicated immediately to the CI who will be required to decide if such an event is unexpected. A clinician (Dr Vassallo, Consultant Physician, Medicine for the Elderly, and when unavailable, site PI Dr McFarlane, Consultant Old Age Psychiatrist) will be consulted for their medical opinion to assist with this decision-making. In the case of an unexpected Serious Related Event, the event will be reported to the Research Ethics Committee by a member of the CTU within 15 days of the PI (or authorised delegate) becoming aware of the event, using the serious related event report form for non-CTIMPs supplied by HRA. The report will be copied to the sponsor and TSC. Summary reports listing all reportable related events will be compiled by the CTU and sent to the CI and sponsor on a monthly basis, and to the TSC 6-monthly (or more frequently at the request of the TSC).

SAEs, including (Serious) Related Events and Unexpected Serious Related Events, will be recorded from the point of recruitment into the study after the first home visit (where baseline measures are taken). All serious related events will be recorded up until the focus group (intervention pilot phase) or final follow-up (RCT; final home visit at six months post-baseline). Monitoring will end at this time point given that participants in the intervention arm will not be expected to continue performing home-based Tai Chi exercises after the focus group / final follow-up. Participants will be advised that if they withdraw from the intervention / study then they are still expected to inform the research team of AEs that occur during the study period; this will be communicated in a letter at the point of withdrawal. For each serious / related event, the following information will be collected on a standard form and emailed to the sponsor, and to PenCTU (for archiving):

* 1. full details in medical terms and case description
	2. event duration (start and end dates, if applicable)
	3. action taken
	4. outcome
	5. seriousness criteria
	6. causality (i.e. relatedness to Tai Chi intervention)
	7. whether the event would be considered expected or unexpected.

Any change of condition or other follow-up information should be emailed to the sponsor as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached. Serious, related and unexpected events will be emailed to the NHS Research Ethics Committee within 15 days of the CI becoming aware of the event..

**Responsibilities of the project team**

Tai Chi instructors

1. Will inform the research team of any serious related event discovered during the 20-week intervention period. They will report these immediately by telephone or email as soon as possible after a class has finished (on the same day as the class). Related events occurring during a Tai Chi class will be noted in the weekly attendance record.

Prof Mike Vassallo (clinician appointed by CI), and when unavailable, Dr Brady McFarlane - independent clinical reviewer:

1. Clinical oversight of the safety of patients participating in the trial, including an on-going review of the risk / benefit.
2. Using medical judgement in assigning seriousness, causality and expectedness of SAEs where it has not been possible to obtain local medical assessment.
3. Clinical review of a line listing of all life threatening or SAEs resulting in death within 1 week of their occurrence, and of all other SAEs on a monthly basis.

Sponsor:

1. Central data collection and verification of SAEs according to the trial protocol onto a database.
2. Reporting safety information to the CI, delegate or independent clinical reviewer for the on-going assessment of the risk / benefit according to the Trial Monitoring Plan.
3. Reporting safety information to the independent oversight committee identified for the trial (Trial Steering Committee (TSC)) according to the Trial Monitoring Plan.
4. Expedited reporting of serious related events to the REC within required timelines.
5. Notifying Investigators of serious related events that occur within the trial.

Trial Steering Committee (TSC):

1. In accordance with the Trial Terms of Reference for the TSC, periodically reviewing safety data regarding safety issues.
2. Cumulative review of all safety information by the TSC on a 6 monthly basis.

The CI will report all deaths of a participant, albeit PWD or carer, to the sponsor irrespective of whether the death is related to disease progression, the intervention, or an unrelated event. This report will be immediate. No care will be provided to participants in addition to NHS usual care. Serious related events and unexpected serious related events will be monitored and reported until they have been resolved or before study closure, whichever occurs first.

If a member of the Tacit Team (including the Tai Chi Instructors) has any concerns regarding the welfare a TACIT participant, he/she will advise the Chief Investigator immediately. The Chief Investigator will consult the Sponsor to determine whether action is appropriate. Where concerns are raised about an adult being at risk of abuse or harm the Chief Investigator will contact the local adult safeguarding team for the area in which the adult resides. If, however, an adult is considered to be in immediate danger the researcher identifying the potential harm will contact the police by telephoning 999.

# STATISTICS AND DATA ANALYSIS

A Statistical Analysis Plan will be produced separately before follow-up data collection is complete if not before. The plans presented here are indicative and subject to change as the statistical analysis plan is developed. The trial will be registered and the study protocol will be published. Participants will be analysed in the group they were randomised to, and (with the consent of participants) we will attempt to collect complete data on everyone and use those data in the analyses.

## Sample Size

*Intervention pilot phase*

Fourteen dyads will be recruited with one class per site (one in the Southampton area and one in the Dorset area). The two classes will be delivered to a maximum of 7 dyads per class (14 PWD and their carer).

*RCT phase*

A formal sample size calculation was undertaken. The calculation was based on detecting a difference in mean TUG test scores between the Tai Chi plus usual care and usual care arms of the study. We could find no studies looking at minimum clinically important difference, but did find two studies that had estimated smallest detectable change (i.e. the smallest change that we can be reasonably sure is not measurement error). The two values were 4.09 [90] and 5.88 [91], and we used a conservative value of 4. To find an estimate of SD for TUG, we found several relevant papers but the values were sensitive to the mix of age and severity of dementia, with one study that seemed to most closely match our population and be based on a reasonable sample size (n=58) [91]. SD at two different time points were presented (9.74 and 9.01) and we used the average of these figures of 9.38 [91]. In our analysis we will enter baseline TUG as a covariate and assume a correlation of 0.7; test-retest reliability of TUG is excellent [91,92] but we acknowledge the time points in our study will be longer than prior studies and so we have used a more modest correlation.

Therefore, using a mean difference in TUG of 4, a SD of 9.38, a correlation of 0.7 and a 2-sided 5% significance level, the study will have 90% power when the sample size is 120 (60 per group). Allowing for up to 20% withdrawal / non-completion of outcome measures, we will recruit 150 PWD into the trial (75 per group). These calculations were conducted using nQuery Advisor 7.0. The intervention will partly take place in classes, and there is a possibility of clustering effects. However for the purposes of the sample size calculation we have assumed that these will be negligible, because (a) much of the intervention occurs outside the class environment, and (b) interaction between PWD is not a specific purpose of the intervention. However we will look at this aspect in the statistical analysis. No interim analyses are planned.

Based on information found in those studies used to determine study sample size, the clinical effectiveness of the intervention on the TUG was estimated as having a standardised effect size of *d* = 0.43 (medium effect) using Chinn’s [93] conversion formula (ln(0.27)/1.81). One previous study reported improved balance from a Tai Chi intervention was shown to lead to a significant reduction in falls, based on Berg Balance Scale results (predictive of non-fallers in the Tai Chi intervention group (odds ratio = 0.27, 95% CI = 0.07 – 0.96)). While the effect size equated to d = -0.72 using Chinn’s [93] conversion formula, it was only within the intervention group and the sample was from the healthy older adult population.

A CONSORT flow chart will be produced showing the flow of recruitment into the RCT (numbers available, approached, eligible, randomised, along with reasons if not approached or not eligible) and through the study (numbers with outcome data, reasons for withdrawing etc.). Recruitment rate for the subsequent definitive trial will be estimated using the recruitment rate (95% CI) from this RCT as per guidance [94]. Descriptive statistics will be presented for all baseline outcome data for each trial arm separately. No statistical testing of baseline data will be done. Additional descriptive statistics will be presented on the following:

* Mean (SD) age
* Gender (frequency)
* Education level (categories)
* Household composition (categories)
* Marital Status (categories)
* Ethnicity (categories)
* Falls History (yes / no: fallen in past month; yes / no: fallen in past 12 months)
* Injurious falls history (yes / no: injured from fall in the past month / 12 months)
* Co-morbid conditions (frequency)
* Whether use a walking aid (yes / no)
* Mean (SD) number of daily medications consumed
* Current level of moderate physical activity (categories)
* Current level of vigorous physical activity (categories)
* Dementia type (categories)
* Mean (SD) M-ACE score
* Mean (SD) time since diagnosis
* Carer mean (SD) age
* Carer gender (frequency)
* Carer ethnicity (categories)
* Carer education level (categories)
* Carer relationship to PWD (spouse, sibling, offspring, other family, friend, other)
* Carer residence (same house or not)
* Carer marital status
* Average weekly in-person contact between carer and PWD if not living together
* Carer household composition

The following data will not be reported in the main trial outcome paper but will be included in further secondary analyses: visual spatial cognitive functioning (statue task); comparison of the different methods of data collection on incidence of falls; qualitative data; and uptake and adherence to the intervention (whether the PWD or carer had done Tai Chi before, mean (SD) intention and perceived behavioural control to do Tai Chi, and intervention group responses to the questionnaire delivered half way through the intervention).

## Statistical analysis

The intervention pilot phase will present descriptive statistics on the demographic data only. In the RCT, the inferential analyses described below will be presented. In addition, descriptive data from the exit interviews will be presented (willingness to pay and any changes in physical activity or medical status), along with weekly data collected over the 6-month study period (intervention adherence, number of falls, number of fallers, and number of injurious falls experienced [62]).

### Primary outcome analysis

In the RCT, mean TUG scores at 6 months, the primary outcome, will be compared between the two trial arms using a mixed (multi-level) model approach taking into consideration, for those in the Tai Chi arm, the class they attended. TUG and fall history (in last 12 months) at baseline will also be included in the model. We will assume that the missing data mechanism is “Missing Completely at Random” (MAR). . Because of the inclusion of variables that would reveal treatment the statistical analysis will be conducted by the trial statistician and health economist un-blind to treatment arm. However, the results of the statistical analysis will be presented to the rest of the trial team blinded to treatment arm. Once the interpretation of the results has been agreed within the trial team then the treatment arms will be un-blinded to the whole trial team.

### Secondary outcome analysis

In the RCT, the method of analysis will be similar to primary outcomes on the following secondary outcomes:

*PWD*

* BBS
* Postural sway on firm surface and foam
* Icon-Fes
* ICECAP-O
* M-ACE
* Statue task\*
* Falls (number and rate)
* Fallers (number and rate)
* Injurious falls (number and rate)

*Carer*

* TUG
* Postural sway on firm surface and foam
* ICECAP-O
* Zarit carer burden

\*Scores on the Statue task will be analysed but reported separately to the main outcome paper.

In the Tai Chi arm we will calculate

* Adherence to classes (i.e. x attended out of y possible)
* Adherence to home exercise (i.e. x minutes exercise out of y possible)

We will also conduct a per protocol analysis that will exclude participants from the Tai Chi group if they received fewer than 50 hours (the intended minimum dosage of the intervention). Intervention dosage will be calculated by adding minutes of class-based Tai Chi completed (45 minutes per session, ascertained by class attendance records) with minutes of home-based Tai Chi exercises completed (ascertained by weekly completed calendars).

Subgroup analysis: One subgroup analysis is pre-planned to test if the primary outcome variable (TUG) is modified by fall history at baseline (whether or not the PWD has fallen in the past 12 months (yes / no)). This is also the variable used for minimisation in addition to treatment condition. Fall history is widely established as a major risk factor for falls [18,19], and the TACIT intervention may or may not be more effective among those with an increased risk of falling. Fall history will be entered as an interaction term in a statistical model (intervention effect x fall history).

Interim analysis: No interim analyses are planned.

Missing data: Outcome data will be sought for all randomised participants even if they withdrew from Tai-Chi classes. The method of analysis using mixed models assumes data are “missing completely at random (MCAR)”. However we will conduct further analysis of the primary outcome using a less stringent “missing at random (MAR)” assumption. We will use multiple imputation methods to fill in missing data. The purpose of this analysis is to see how sensitive the results might be to the MCAR assumption.

## Qualitative analysis

*Intervention pilot phase*

The views of the dyads from the focus groups will be analysed thematically using NVivo.10 software to identify any aspects of the trial and intervention protocols that need refinement and barriers and facilitators to dyad participation in the intervention. Fieldwork notes will be transcribed and incorporated into the analysis (observations of classes and weekly discussions with dyads).

*RCT*

Joint interviews with dyads in their homes will be analysed in the same way as the intervention pilot phase focus groups. Fieldwork notes will be transcribed and will also be incorporated into the analysis (observations of classes and weekly discussions with dyads) in the same way as the pilot intervention phase.

# HEALTH ECONOMICS EVALUATION

In this trial, we will assess the feasibility of collecting the data required for a health economic analysis. This will include detailed descriptive statistics on completion of the health service use telephone interviews, which will include social care costs and costs incurred by dyads. Note that all health service use costs will be either in relation to falls (both intervention arms) or in relation to injury while carrying out Tai Chi only. The total cost of providing the intervention to each patient will be estimated from weekly records collected and in relation to: (a) the average cost of hire of the building for the classes (taken from the costs incurred in this study), and (b) the instructor’s time spent on delivering the intervention as a function of hourly rate. Health service use will be calculated in relation to presentation to the GP, out of hours, or A&E. Cost of GP and out of hours service use will be estimated against the number of visits and length of each visit by their associated cost as extracted from, “Unit costs of Health and Social Care 2013” [95]. Cost of A&E service use will be estimated against the number of visits and length of each visit by their associated cost as extracted from, “NHS reference costs 2012 to 2013” [96]. We will also present data on the quality-adjusted of life years (QALYS) of PWD and their carers in both arms of the trial by using the ICECAP-O. All health economic analyses will be presented descriptively in terms of completion (missing data) and outcomes (e.g. mean and SD in relation to baseline and follow-up), as the study has not been powered to conduct a full health economic analysis. A full health economic analysis will be conducted in the subsequent definitive trial.

# DATA MANAGEMENT

Qualitative observations of Tai Chi classes will be recorded manually using field notes and inputted into NVivo.10 for analysis (all notes will include ID/reference numbers in place of participant names). The focus group in the intervention pilot phase will be audio recorded, and the home-based interviews in the RCT will be audio recorded. Each focus group and home-based interview will be transcribed verbatim, and stored and analysed using NVivo.10 (each file will be edited to remove identifying characteristics such as names of people mentioned). All audio recordings will be transferred to a university laptop and erased from the recording device the same day of the focus group / interview. All baseline and outcome data will be anonymised using a unique research ID number. Informed consent forms will be stored separately to other records in relation to the trial to avoid potential identification of participants.

All baseline data for the intervention pilot phase will be stored and managed by Bournemouth University. Only demographic data will be entered and analysed by a researcher, using a bespoke database created by the trial statistician.

All baseline and outcome data for the RCT will be sent by post to PenCTU for data processing.

Double data entry will be used to improve the accuracy of data entry from the CRF. PenCTU will seek clarification on any data queries with the researcher. PenCTU will be responsible for data tracking, data cleaning, and data extraction for analysis and for UKCRN accrual updates. A copy of all paper data collection forms will be kept at Bournemouth University. Hard copies will be kept in a secured filing cabinet in a secured office at Bournemouth University (both phases) and PenCTU (RCT only). Copies of original study data retained at study sites will be securely stored for the duration of the study prior to archiving. On completion of the research, extraneous data will be ethically destroyed.

For both phases of the project, electronic files with Bournemouth University (including all electronic data for the pilot intervention phase) will be stored in a folder on the university network only accessible to Bournemouth University trial investigators via network authentication. Data held on BU laptops will also be protected through encryption and network authentication and transferred to the secure trial folder as soon as possible. All trial data on the network drive will be backed up centrally via the server daily, which is secured and maintained by Bournemouth University. Data will be collected and stored in accordance with the CTU Data Management SOP, in line with the Data Protection Act 1998/General Data Protection Regulation 2018. For the RCT, electronic records will be stored by the CTU in a SQL Server database, housed on a restricted access, secure server maintained by Plymouth University. Data in the database will be backed up daily by the Plymouth University web team and will be accessible for up to 6 months. The study website will be encrypted using SSL. Data will be collected and stored in accordance with the CTU Data Management SOP, in line with the Data Protection Act 1998. Direct access to the trial data will be restricted to members of the research team and the CTU, with access granted to the sponsor on request. Access to the CTU database will be overseen by the CTU data manager and trial coordinator. The trial statistician will take overall responsibility for the statistical analysis. The two PhD students working on the project will take overall responsibility for qualitative analysis and analysis of behaviour change aspects of the process evaluation.

## Study Numbering

Each participant will be allocated a unique study number on consenting to the study and will be identified in all study-related documentation by their study number and initials.

## Data Collection

Data will be recorded on study specific data collection forms (CRFs), usually by the research team at each site. All persons authorised to collect and record trial data at each site will be listed on the study site delegation logs, signed by the relevant PI. Source data will include all data recorded straight into the CRF. Other data collected will be self-reported by one or both member of the dyad.

## Data entry

*Intervention pilot phase*

Completed CRFs will be checked and signed at the research sites by a member of the research team before data entry into the trial database. Balance Sensor and Statue task data electronically recorded will be written by hand on the CRF alongside the other data.

*RCT*

Completed CRFs will be checked and signed at the research sites by a member of the research team before being sent to the CTU. Original CRF pages, questionnaire booklets, and balance test result forms will be posted to the CTU at agreed timepoints for double-data entry on to a password-protected database, with copies retained at the relevant study site. Balance Sensor and Statue task data electronically recorded will be written by hand on the CRF to input into the trial database alongside the other data. All forms and data will be tracked using a web-based trial management system. Double-entered data will be compared for discrepancies using a stored procedure. Discrepant data will be verified using the original paper data sheets.

## Data Confidentiality

All investigators and trial site staff must comply with the requirements of the Data Protection Act 1998/General Data Protection Regulation 2018 with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act’s core principles. The details of how data will be securely managed are described above. Participant names and addresses will be collected for the purpose of managing questionnaires, intervention delivery, and process evaluation focus groups / interviews. Investigators will ensure that the participants’ anonymity is maintained on all other documents. Within Bournemouth University and the CTU, anonymised and identifiable study data will be stored separately to prevent the identification of participants from research records, in locked filing cabinets within a locked office.

## Access to Data

Anonymised electronic records and paper copies of records will be open to inspection and monitoring from a recognised representative from either Southern Health NHS Foundation Trust, Bournemouth University, the CTU, or the National Institute for Health Research. While the CI will be the primary contact for requests for inspection, PenCTU and the sponsor will also participate in inspections where required.

## Archiving

Following completion of trial data analysis, the CI will be responsible for evaluating and selecting data, including data documentation, for long-term curation and preservation. Selected data will be deposited in a secure data archive or repository for a period of 5 years after the end of the trial. No trial records should be destroyed until the CI has given authorisation and data which will not be preserved will be disposed of securely.

## Access to the final data set

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

# MONITORING and quality assurance

All study procedures will be conducted in compliance with the protocol and according to the principles of the International Conference on Harmonisation Good Clinical Practice (ICH GCP). Procedures specifically conducted by the CTU team (e.g. data management, study management, and study monitoring) will be conducted in compliance with CTU standard operating procedures (SOPs).

Prospective, planned deviations or waivers to the protocol will not be permitted, in accordance with UK regulations on Clinical Trials (e.g. participants will only be enrolled into the study if they meet the eligibility criteria). Any protocol deviation will be documented as a Non-Compliance Report. Protocol deviations will be monitored by the CTU and reported to the Chief Investigator and sponsor immediately. In each instance, with agreement from the TMG, this may prompt additional staff training or amendment to the trial procedures for clarification. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action, and could potentially be classified as a serious breach.

A “serious breach” is a deviation from protocol which is likely to affect to a significant degree:

1. the safety or physical or mental integrity of the subjects of the trial; or
2. the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial. The sponsor is responsible for notifying REC of a serious breach of the following, within seven days of the matter coming to their attention:

* 1. the conditions and principles of GCP in connection with that trial; or
	2. the protocol relating to that trial, as amended from time to time.

In the RCT, the PI (or authorised delegate) will check completed case report forms for missing data or obvious errors before the forms are sent to the CTU. Data will be monitored centrally for quality and completeness by the CTU. The CTU will notify the appropriate researcher about missing data or erroneous data and if required, the researcher will contact the participant / dyad for clarification. Every effort will be made to recover data from incomplete forms where possible. The CTU data manager will oversee data tracking and data entry and initiate processes to resolve data queries where necessary. Central data monitoring and on-site monitoring will be undertaken by the CTU trial manager or deputy in accordance with the data monitoring plan. The data monitoring plan will be based on a risk assessment for this study and will be agreed by the TMG. Participating sites will be required to permit the CTU trial manager or deputy, or representative of the sponsor, to undertake study-related monitoring to ensure compliance with the approved study protocol and applicable SOPs, providing direct access to source data and documents as requested.

# STUDY ORGANISATIONAL STRUCTURE

## Trial Management Group (TMG)

The remit of the TMG will be the everyday running of the project to progress the trial to standard, within the timeframe, and to budget (see Appendix 5 for the Gantt chart for the project encompassing both phases). The CI on behalf of the TMG will report to the Trial Steering Committee (TSC) at TSC meetings (see below). Minutes of each TMG meeting will be circulated to TMG members in a timely manner and will be filed in the Trial Master File held by PenCTU. The TMG will meet monthly and will be chaired by the CI, and will include members of the research team involved with day-to-day running of the project and sponsor. Financial management will be the responsibility of the CI with support from a project administrator in the Research and Knowledge Exchange Office, Bournemouth University.

## Trial Steering Committee (TSC)

The TSC will oversee the conduct and safety of the trial, ensuring that milestones are achieved and general scientific probity is maintained. The TSC will meet four times in six-month intervals in years 2 and 3 of the project, to approximately reflect key points in the trial respectively: during analysis of the intervention pilot phase (before the RCT starts), after delivery of the intervention has just started (month 4 of the RCT), after six-month follow-up data collection has just started (month 10 of RCT), and when analysis for the main outcome paper is complete (3 months after the RCT has ceased). The TSC will meet by teleconference.

The remit of the TSC will be to hold the Trial Management Group (TMG) to account with project completion and patient safety. In particular, the TMG will report to the TSC progress against key milestones and any related events. Minutes will be taken by the CTU Trial Manager at each TSC meeting and will accompany the chair’s interim report that will be sent to the sponsor shortly after each meeting. The TSC will be chaired by Dr Frances Healey (NHS England) who is independent of both the sponsor and investigators. The TSC will also include four members independent of the sponsor and investigators, representing service users, academics, and clinicians. The remaining members will be a small number of members of the research team and observers. A separate charter describing membership and detailed terms of reference will be developed and agreed prior to, or soon after, study commencement.

# ETHICAL AND REGULATORY CONSIDERATIONS

## Ethics and HRA review

Before the start of the trial (including the intervention pilot phase), approval will be sought from the NHS Research Ethics Committee (REC) and the Health Research Authority (HRA). An application to have the trial adopted by NIHR Wessex CRN will also be made. Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion (note that amendments may also need to be reviewed and accepted by the HRA before they can be implemented in practice at sites). All correspondence with the REC will be retained in the Trial Master File and relevant copies retained in the Investigator Site File. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. PenCTU will produce the APRs as required and notify the REC of the end of the study. If the study is ended prematurely, PenCTU will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

## AMENDMENTS

The trial protocol and other essential documentation may be amended from time to time. The need for amendment will be identified by TMG and the nature of any amendment will be discussed with the sponsor who will be responsible for adjudging the substantiality of any amendment. Amendments will be made by the CI or member of the TMG on the CI’s behalf. CTU will be responsible for controlling trial-related documentation and for communicating changes to relevant stakeholders (REC, HRA, trial registries, etc.). With regard to the protocol, each amendment will be accompanied by a protocol amendment document (in addition to the amended protocol) in which rationale for the amendment and a listing of each edit made will be documented. The protocol itself will also include a summarised amendment history identifying the current and previous versions.

## PEER REVIEW

The grant proposal for this project was peer-reviewed by external experts. In addition, as a requirement to have the trial adopted on to the NIHR Wessex CRN portfolio, the trial protocol has been peer-reviewed by an independent expert.

# PUBLIC AND PATIENT INVOLVEMENT

We had Public and Patient Involvement (PPI) input when developing the grant proposal for the trial. In particular, we held a small group discussion with PWD and their carers known to the Bournemouth University Dementia Institute (BUDI). The consultation group had two PWD and four carers (two were spouses and two were daughters of men with dementia). The idea of doing a Tai Chi intervention was presented to the group, with an explanation of Tai Chi provided by a qualified instructor. The group found the idea of a Tai Chi intervention appealing, and have influenced the application in four ways:

1. We originally conceived dyads to be the PWD and their spouse. However, comments indicated that Tai Chi could be of wider benefit to families. Dyads will now be the PWD and a main carer, who need not be a spouse or partner (e.g. may be an adult child that visits regularly).
2. We were originally planning to offer a mainly home-based intervention, and follow the format used by Yao et al. [77-78] that provided classes for only 4 out of the 16-week intervention, with 12 weeks of home-based activity. However, comments were strongly in favour of attending classes. Several members of the group attended social events (e.g. coffee groups) and felt that they needed these opportunities to get out the house and socialise. We will now use a mainly class-based approach to deliver the intervention, supplemented by carer-facilitated, home-based daily Tai Chi exercises.
3. The importance of transport to the venue was stressed by the group. We will now ensure that each venue for the classes has readily accessible parking and is on a frequent bus route.
4. Funding; it was suggested that PWD be asked to pay to attend classes but not the carers. We will now ask PWD and their carers about their willingness to pay for the intervention at the final follow-up.

Since the project began, a PPI advisory group of ten people (4 PWD, 5 spouses of PWD, and a daughter of a PWD) have inputted into the development of this trial protocol on three occasions and will continue to have PPI input throughout the trial at regular intervals.

*Design and Management of the research*

Active involvement of PWD and their carers is essential to the success of this project,given that we propose an intervention for PWD and the active involvement of carers in its delivery (home-based exercises). We will also be seeking the support of carers for data collection from PWD. Throughout each stage of the project, representatives of PWD and their carers represented in our PPI advisory group will have input into the project through regular meetings. These meetings will be chaired by the CI and supported by the PPI lead of the Bournemouth University Clinical Research Unit.

*Developing participant information resources*

The PPI advisory group have helped to refine materials for the project. In particular, materials used to recruit participants, information sheets and informed consent forms, and materials to support the home-based exercises to be facilitated by carers of PWD.

*Contributing to the reporting of the research and Dissemination of research findings*

The PPI advisory group will contribute to refinement of the intervention in response to the findings from the intervention pilot phase, and facilitate interpretation of the results of the RCT. Their views will be particularly sought in relation to process outcomes and qualitative findings. They will also be invited to contribute to the development of materials to provide at public engagement events and the lay summaries of the project findings. The group will also be invited to act as co-authors on the feature articles to be submitted to publications targeting NHS healthcare professionals and dementia care workers (see dissemination plan). The advisory group and participants will be invited to contribute to public engagement events held by Bournemouth University each year in July. In addition, the PPI advisory group will be invited to help present the findings from this project at the annual International Conference on Falls and Postural Stability in September 2018.

# STATEMENT OF INDEMNITY

Arrangements will be made by the sponsor to obtain the necessary insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research (SHFT as sponsor) or from the design of the research (Bournemouth University, the host institution for the CI). Insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research will be covered separately for the delivery of the intervention and collection of data. For delivery of the intervention, each Tai Chi instructor will be acting on behalf of the NHS trusts (SHFT, DHUFT, or Solent) via a temporary contract. Therefore, insurance to meet potential legal liability will be provided by the respective NHS trust for each patient depending on recruitment site (Southampton, Dorset, or Portsmouth areas). For collection of data, all home visits and other contact with participants made by researchers based at Bournemouth University will be covered by Bournemouth University’s indemnity. Bournemouth University will purchase the equipment needed for collection of data and will insure it to meet the potential legal liability arising in relation to the equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of the equipment). The equipment needed for delivery of the intervention is of low risk (printed exercise booklet and alarm clock) and will be covered by Bournemouth University’s indemnity.

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

# DISSEMINATION

## Dissemination policy

A separate publication agreement was part of the formal agreement between all parties involved in the trial at contract stage. This includes agreement over intellectual property. In addition, at the same time, a separate dissemination plan has been agreed between all parties involved in the trial. The CI is required to provide formal progress reports to the funder on an annual basis but not a final report of the trial (the findings will be disseminated in journal articles). We intend to notify participants involved in the trial of the study findings through our public engagement events and a newsletter on study completion.

A Data Management Plan will be prepared to facilitate access, sharing and preservation. This will be explicitly referred to in the Statistical Analysis Plan and in the resultant publication of the main trial outcome. This will include specific detail of how potential bona fide research teams will be able to access the following from the CI’s institution (Bournemouth University) online repository after an embargo period of approximately 24 months from the publication of the main trial outcome paper:

* Statistical analysis plan
* Where applicable, statistical code (for final analysis of primary outcome measure)
* Anonymised participant-level dataset and data documentation

Note that the trial protocol and main outcome paper from the trial will have already been published and made open-access, and will be referenced when the above is made available. Access will be restricted to researchers who sign a confidentiality agreement and confirm their intention to use the data is for secondary data analysis for non-commercial research purposes using a Creative Commons licence.

## Authorship guidelines

This is covered in a separate publication plan. No professional writers will be used.

# FINANCE

## Financial and other competing interests

Members of the TMG declare no competing interests. The Tai Chi instructors who will deliver the intervention will be working under the private company of Elemental Tai Chi. This company already provides Tai Chi classes and private tuition in the areas where participants will be recruited. Therefore, this company may be impacted by the dissemination of its results. However, Elemental Tai Chi will not be involved in the collection of outcome data (i.e., no involvement with baseline data or follow-up data collection) or analysis of the trial outcomes. They will also not be involved in the dissemination of results (i.e. they will not have input into the journal articles written or presentations made to scientific audiences). Elemental Tai Chi will be involved in the public engagement events hosted every year, but again, they will not present the findings of the study (this will be done by a member of the TMG and members of the PPI advisory group). However, while not written by Elemental Tai Chi, they will be allowed to circulate any dissemination activity from the trial (e.g. allowed to forward on presses releases to contacts, upload a lay summary written by the TMG / PPI advisory group on to their website, and signpost members of the public to the published findings, etc.). Declarations of competing interests will be made at TSC meetings and will be included on every publication from the trial (including the trial protocol) by the academic journal. TSC members will not be able to join the committee if they have a competing interest.

# POST-TRIAL CARE

Given further research will be required - a subsequent definitive trial - to determine the benefit to patients of the intervention, the intervention will cease to be provided to the intervention group after five months. This will be clearly communicated to PWD and their carers before informed consent is taken.

# REFERENCES

[1] Samaras, N., Chevalley, T., Samaras, D., & Gold, G. (2010). Older patients in the emergency department: A review. *Annals of Emergency Medicine,* *56* (3), 261-269.

[2] Scuffham, P., Chaplin, S., & Legood, R. (2003). Incidence and costs of unintentional falls in older people in the United Kingdom. *Journal of Epidemiology and Community Health, 57* (9)*,* 740-744.

[3] Davies, A. J., & Kenny, R. A. (1996). Falls presenting to the accident and emergency department: Types of presentation and risk factor profile. *Age and Ageing*, *25* (5), 362-366.

[4] Johansen, A., Wakeman, R., Boulton, C., Plant, F., Roberts, J., & Williams, A. (2013). *National hip fracture database national report*. London: Royal College of Physicians.

[5] Taylor, M. E., Delbaere, K., Close, J. C. T., & Lord, S. R. (2012). Managing falls in older people with cognitive impairment. *Ageing Health*, *8* (6), 573-588.

[6] Winter, H., Watt, K., & Peel, N. M. (2013). Falls prevention interventions for community-dwelling older persons with cognitive impairment: A systematic review. *International Psychogeriatrics*, *25* (2), 215-227.

[7] Medical Advisory Secretariat. (2008). Caregiver- and patient-directed interventions for dementia: An evidence-based analysis. *Ontario Health Technology Assessment Series*, *8* (4), 1-98.

[8] Drame, M., et al. (2011). Predictors of institution admission in the year following acute hospitalisation of elderly people. *Journal of Nutrition, Health & Aging*, *15* (5), 399-403.

[9] Watkin, L., Blanchard, M. R., Tookman, A., & Sampson, E. L. (2011). Prospective cohort study of adverse events in older people admitted to the acute general hospital: Risk factors and the impact of dementia. *International Journal of Geriatric Psychiatry*, *27* (1), 76-82.

[10] National Institute for Health and Care Excellence. (2013). *Falls: Assessment and prevention of falls in older people*. Manchester: National Institute for Health and Care Excellence.

[11] Farag, I., Howard, K., Ferreira, M. L., & Sherrington, C. (2015). Economic modelling of a public health programme for fall prevention. *Age and Ageing*, *44* (3), 409-414.

[12] Department of Health, Physical Activity, Health Improvement and Protection. (2011). *Start active, stay active: A report on physical activity for health from the four home countries' chief medical officers*. London: Department of Health, Physical Activity, Health Improvement and Protection.

[13] NHS Choices. (2013). *A guide to tai chi*. [online]. Available from: http://www nhs uk/Livewell/fitness/Pages/taichi aspx, accessed the 7th November 2014.

[14] Lee, L. Y., Lee, D. T., Woo, J. (2010). The psychosocial effect of Tai Chi on nursing home residents. *Journal of Clinical Nursing*, *19* (7-8), 927-38.

[15] Li, J. X., Hong, Y., & Chan, K. M. (2001). Tai chi: Physiological characteristics and beneficial effects on health. *British Journal of Sports Medicine*, *35* (3), 148-56.

[16] Tadros, G., Ormerod, S., Dobson-Smyth, P., Gallon, M., Doherty, D., Carryer, A., et al. (2013). The management of behavioural and psychological symptoms of dementia in residential homes: Does Tai Chi have any role for people with dementia? *Dementia, 12* (2), 268-279.

[17] Delbaere, K., Close, J. C., Heim, J., Sachdev, P. S., Brodaty, H., Slavin, M. J., et al. (2010). A multifactorial approach to understanding fall risk in older people. *Journal of the American Geriatrics Society, 58* (9), 1679-1685.

[18] Skelton, D. A., & Todd, C. J. (2004). *What are the main risk factors for falls amongst older people and what are the most effective interventions to prevent these falls?* Copenhagen: Health Evidence Network, World Health Organization.

[19] Lord, S. R., Sherrington, C., Menz, H. B., & Close, J. C. T. (2007). *Falls in older people: Risk factors and strategies for prevention*  (2nd ed). Cambridge, UK: Cambridge University Press.

[20] Skelton, D. A., & Beyer, N. (2003). Exercise and injury prevention in older people. *Scandinavian Journal of Medicine & Science in Sports, 13*, 77-85.

[21] Taylor, M. E., Delbaere, K., Lord, S. R., Mikolaizak, A. S., Brodaty., & Close, J. C. (2014). Neuropsychological, physical, and functional mobility measures associated with falls in cognitively impaired older adults. *Journals of Gerontology: Series A, Biological Sciences and Medical Sciences*, *69* (8), 987-995.

[22] Whitney, J., Close, J. C., Jackson, S. H., & Lord, S. R. (2012). Understanding risk of falls in people with cognitive impairment living in residential care. *Journal of the American Medical Directors Association*, *13* (6), 535-540.

[23] Liu, H., & Frank. A. (2010). Tai chi as a balance improvement exercise for older adults: A systematic review. *Journal of Geriatric Physical Therapy, 33* (3), 103-109.

[24] Hackney M. E., & Wolf S. L. (2014). Impact of Tai Chi Chu'an practice on balance and mobility in older adults: An integrative review of 20 years of research. *Journal of Geriatric Physical Therapy,37* (3), 127-35.

[25] Leung D. P., Chan, C. K., Tsang, H. W., Tsang, W. W., & Jones, A. Y. (2011). Tai chi as an intervention to improve balance and reduce falls in older adults: A systematic and meta-analytical review. *Alternative Therapies in Health and Medicine*, *17* (1), 40-48.

[26] Speechley, M. (2011). Unintentional falls in older adults: A methodological historical review. *Canadian Journal on Aging, 30* (1), 21-32.

[27] Kannus, P., Sievänen, H., Palvanen, M., Järvinen, T., & Parkkari, J. (2005). Prevention of falls and consequent injuries in elderly people. *Lancet*, *366* (9500), 1885-93.

[28] Kendrick, D., Kumar, A., Carpenter, H., Zijlstra, G. A., Skelton, D. A., Cook, J. R., et al. (2014). Exercise for reducing fear of falling in older people living in the community. *Cochrane Database of Systematic Reviews, 11*, Art. No.: CD009848. DOI: 10.1002/14651858.CD009848.pub2.

[29] Zijlstra, G. A. R., van Haastregt, J. C., van Rossum, E., van Eijk, J. T., Yardley, L., & Kempen, G. I. (2007). Interventions to reduce fear of falling in community-living older people: A systematic review. *Journal ofthe American Geriatrics Society*, *55 (*4), 603-15.

[30] Büla, C. J., Monod, S., Hoskovec, C., & Rochat, S. (2011). Interventions aiming at balance confidence improvement in older adults: An updated review. *Gerontology, 57* (3), 276-86.

[31] Lee, L. Y., Lee, D. T.,& Woo, J. (2009). Tai Chi and health-related quality of life in nursing home residents. *Journal of Nursing Scholarship*, *41* (1), 35-43.

[32] Wang, F., Lee, E. K., Wu, T., Benson, H., Fricchione, G., Wang, W., et al. (2014). The effects of tai chi on depression, anxiety, and psychological well-being: a systematic review and meta-analysis. *International Journal of Behavioral Medicine, 21* (4), 605-617.

[33] Wayne, P. M., Walsh, J. N., Taylor-Piliae, R. E., Wells, R. E., Papp, K. V., Donovan, N. J., et al. (2014). Effect of tai chi on cognitive performance in older adults: systematic review and meta-analysis. *Journal of the American Geriatrics Society, 62* (1), 25-39.

[34] Campbell, A.J, & Robertson, M.C. (2007). Rethinking individual and community fall prevention strategies: A meta-regression comparing single and multifactorial interventions. *Age and Ageing*, *36* (6), 656-662.

[35] Medical Research Council. (2008). *Developing and evaluating complex interventions: New guidance*. London: Medical Research Council.

[36] Gillespie, L. D., Robertson, M. C., Gillespie, W. J., Sherrington, C., Gates, S., Clemson, L. M., et al. (2012). Interventions for preventing falls in older people living in the community. *Cochrane Database of Systematic Reviews*, *9*, Art. No.: CD007146. DOI: 10.1002/14651858.CD007146.pub3.

[37] El-Khoury, F., Cassou, B., Charles, M. A., & Dargent-Molina, P. (2013). The effect of fall prevention exercise programmes on fall induced injuries in community dwelling older adults: Systematic review and meta-analysis of randomised controlled trials. *BMJ, 347*, Published Online October 29, DOI: 10.1136/bmj.f6234.

[38] Iliffe, S., Kendrick, D., Morris, R., Masud, T., Gage, H., Skelton, D., et al. (2014). Multicentre cluster randomised trial comparing a community group exercise programme and home-based exercise with usual care for people aged 65 years and over in primary care. *Health Technology Assessment, 18* (49). DOI: 10.3310/hta18490.

[39] Burton, E., Cavalheri, V., Adams, R., Browne, C. O., Bovery-Spencer, P., Fenton, A. M., et al. (2015). Effectiveness of exercise programs to reduce falls in older people with dementia living in the community: A systematic review and meta-analysis. *Clinical Interventions in Aging*, *10*, 421-434.

[40] Chan, W. C., Yeung, J. W., Wong, C. S., Lam, L. C., Chung, K. F., Luk, J. K., et al. (2015). Efficacy of physical exercise in preventing falls in older adults with cognitive impairment: A systematic review and meta-analysis. *Journal of the American Medical Directors Association*, *16* (2), 149-154.

[41] Cameron, I. D., Gillespie, L. D., Robertson, Murray, G. R., Hill, K. D., Cumming, R. G., et al. (2012). Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database of Systematic Reviews*, 12, Art. No.: CD005465. DOI: 10.1002/14651858.CD005465.pub3.

[42] Logghe, I. H., Verhagen, A. P., Rademaker, A. C., Zeeuwe, P. E., Bierma-Zeinstra, S. M., Van Rossum, E., et al. (2011). Explaining the ineffectiveness of a Tai Chi fall prevention training for community-living older people: A process evaluation alongside a randomised clinical trial (RCT). *Archives of Gerontology and Geriatrics, 52* (3), 357-362.

[43] Wolf, S. L., Sattin, R. W., Kutner, M., O’Grady, M., Greenspan, A. I., & Gregor, R. J. (2003). Intense tai chi exercise training and fall occurrences in older, transitionally frail adults: A randomized controlled trial. *Journal of the American Geriatrics Society, 51* (12), 1693-1701.

[44] Woo, J., Hong, A., Lau, E., & Lynn, H. (2007). A randomised controlled trial of Tai Chi and resistance exercise on bone health, muscle strength and balance in community-living elderly people. *Age and Ageing, 36* (3), 262-268.

[45] Taylor, D., Hale, L., Schluter, P., Waters, D. L., Binns, E. E., McCracken, H., et al. (2012). Effectiveness of tai chi as a community-based falls prevention intervention: A randomized controlled trial. *Journal of the American Geriatrics Society, 60* (5), 841-848.

[46] Sherrington, C., Whitney, J. C., Lord, S. R., Herbert, R. D., Cumming, R. G., & Close, J. C. (2008). Effective exercise for the prevention of falls: A systematic review and meta-analysis. *Journal of the American Geriatrics Society, 56* (12), 2234-2243.

[47] Wolf, S.L., Barnhart, H. X., Kutner, N. G., McNeely, E., Coogler, C., & Xu, T. (1996). Reducing frailty and falls in older persons: An investigation of Tai Chi and computerised balance training. *Journal of the American Geriatrics Society*,*44* (5), 489-497.

[48] Choi, J. H., Moon, J. S., & Song, R. (2005). Effects of Sun-style Tai Chi exercise on physical fitness and fall prevention in fall-prone older adults. *Journal of Advanced Nursing, 51* (2): 150-157.

[49] Nowalk, M. P., Prendergast, J. M., Bayles, C. M., D’Amico, F. J., & Colvin, G. C. (2001). A randomized trial of exercise programs among older individuals living in two long-term care facilities: the FallsFREE program. *Journal of the American Geriatrics Society, 49* (7), 859-865.

[50] Saravanakumar, P., Higgins, I. J., van der Riet, P. J., Marquez, J., & Sibbritt, D. (2014). The influence of tai chi and yoga on balance and falls in a residential care setting: A randomised controlled trial. *Contemporary Nurse, 48* (1), 76-87.

[51] Royal College of Physicians. *National audit of the organisation of services for falls and bone health for older people*. London: Royal College of Physicians; 2006.

[52] Podsiadlo, D., & Richardson, S. (1991). The timed up and go - a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society, 39* (2)*,* 142-148.

[53] Beauchet, O., Fantino, B., Allali, G., Muir, S. W., Montero-Odasso, M, & Annweiler, C. (2011). Timed up and go test and risk of falls in older adults: A systematic review. *Journal of Nutrition, Health and Aging*, *15* (10), 933-938.

[54] Schoene, D., Wu, S. M., Mikolaizak, A. S., Menant, J. C., Smith, S. T., Delbaere, K., et al. (2013). Discriminative ability and predictive validity of the timed up and go test in identifying older people who fall: Systematic review and meta-analysis. *Journal of the American Geriatrics Society*, *61* (2), 202-208.

[55] Berg, K., Wood-Dauphine, S., Williams, J.I., & Gayton, D. (1989). Measuring balance in the elderly: Preliminary development of an instrument. *Physiotherapy Canada*, *41*(6), 304-311.

[56] Delbaere, K., Smith, S. T., & Lord, S. R. (2011). Development and initial validation of the iconographical falls efficacy scale. *Journals of Gerontology: Series A, Biological Sciences and Medical Sciences*, *66* (6), 674–680.

[57] Hsieh, S., McGrory, S., Leslie, F., Dawson, K., Ahmed, S., Butler, C. R., et al. (2015). The Mini-Addenbrooke’s Cognitive Examination: A new assessment tool for dementia. *Dementia and Geriatric Cognitive Disorders*, *39*, 1-11.

[58] Reed, T., & Spiers, H. (Unpublished, thesis). *Development of a spatial judgement task for use in Alzhiemer’s disease: The effect of permanency in spatial environments with age*.

[59] Coast, J., Flynn, T. N., Natarajan, L., Sproston, K., Lewis, J., & Louviere, J. J., et al. (2008). Valuing the ICECAP capability index for older people. *Social Science & Medicine*, *67*(5), 874-882.

[60] Lamb, S. E., Jørstad-Stein, E. C., Hauer, K., Becker, C.,& Prevention of Falls Network Europe and Outcomes Consensus Group. (2005). Development of a common outcome data set for fall injury prevention trials: The Prevention of Falls Network Europe consensus. *Journal of the American Geriatrics Society, 53* (9), 1618-1622.

[61] Zieschang, T., Schwenk, M., Becker, C., Oster, P., & Hauer, K. (2012). Feasibility and accuracy of fall reports in persons with dementia: A prospective observational study. *International Psychogeriatrics, 24* (4), 587-598.

[62] Schwenk, M., Lauenroth, A., Stock, C., Moreno, R. R., Oster, P., McHugh, G., et al. (2012). Definitions and methods of measuring and reporting on injurious falls in randomised controlled fall prevention trials: A systematic review. *BMC Medical Research Methodology*, *12*, e50.

[63] Higginson I. J., Gao, W., Jackson, D., Murray, J., & Harding, R. (2010). Short-form Zarit caregiver burden interviews were valid in advanced conditions. *Journal of Clinical Epidemiology*, *63* (5), 535–542.

[64] Mancini, M., Horak, F. B., Zampieri, C., Carlson-Kuhta, P., Nutt, J. G., & Chiari, L. (2011). Trunk accelerometry reveals postural instability in untreated Parkinson’s disease. *Parkinsonism and Related Disorders*, *17* (7), 557-562.

[65] National Institute for Health and Clinical Excellence. (2011). *Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer’s disease* (last updated May 2016). London: National Institute for Health and Clinical Excellence.

[66] Perneczky, R., Wagenpfeil, S., Komossa, K., Grimmer, T., Diehl, J., & Kurz, A. (2006). Mapping scores onto stages: Mini-mental state examination and clinical dementia rating. *American Journal of Geriatric Psychiatry*, *14* (2), 139-44.

[67] Poynter, L., Kwan, J., & Vassallo, M. (2013). How does cognitive impairment impact on functional improvement following the rehabilitation of elderly patients? *International Journal of Clinical Practice*, *67* (8), 811-815.

[68] McKhann, G. M., et al. (2011). The diagnosis of dementia due to Alzheimer’s disease: Recommendations from the National Institute on Aging-Alzheimer’s Association workgroups on diagnostic guidelines for Alzheimer’s disease. *Alzheimer’s and Dementia, 7* (3), 263-269.

[69] [Román, G. C](http://www.ncbi.nlm.nih.gov/pubmed?term=Rom%C3%A1n%20GC%5BAuthor%5D&cauthor=true&cauthor_uid=8094895)., Tatemichi, T. K., Erkinjuntti, T., Cummings, J. L., Masdeu, J. C., Garcia, J. H., et al. (1993). Vascular dementia: Diagnostic criteria for research studies: Report of the NINDS-AIREN international workshop. [*Neurology*,](http://www.ncbi.nlm.nih.gov/pubmed/8094895) *43* (2), 250-260.

[70] Allan, L. M., Ballard, C. G., Rowan, E. N., & Kenny, R. A. (2009). Incidence and prediction of falls in dementia: A prospective study in older people. *PLoS ONE*, *4* (5), e5521.

[71] Allan, K. (2001) *Communication and consultation: Exploring ways for staff to involve people with dementia in developing services.* York: The Policy Press and Joseph Rowntree Foundation.

[72] Dewing, J. (2002). From ritual to relationship: A person centred approach to consent in qualitative research with older people who have a dementia. *Dementia, 1* (2), 157-171.

[73] Dewing J. (2007). Participatory research: A method for process consent with persons who have dementia. *Dementia*, *6* (1), 11-25.

[74] Huaer, K., Schwenk, M., Zieschang, T., Essig, M., Becker, C., & Oster, P. (2012). Physical training improves motor performance in people with dementia: A randomized controlled trial. *Journal of the American Geriatrics Society, 60* (1), 8-15.

[75] National Collaborating Centre for Mental Health. (2007). *Dementia: The NICE-SCIE guideline on supporting people with dementia and their carers in health and social care*. London: British Psychological Society & Royal College of Psychiatrists.

[76] Mitchel, A. J. (2009). A meta-analysis of the accuracy of the mini-mental state examination in the detection of dementia and mild cognitive impairment. *Journal of Psychiatric Research*, *43* (4), 411-431.

[77] Yao, L., Giordani, B., Alexander, N. B. (2008). Developing a Positive Emotion-Motivated Tai Chi (PEM-TC) exercise program for older adults with dementia. *Research and Theory for Nursing Practice: An International Journal, 22* (4), 241-55.

[78] Yao, L., Giordani, B. J., Alqase, D. L., You, M., & Alexander, N. B. (2013). Fall risk-relevant functional mobility outcomes in dementia following dyadic tai chi exercise. *Western Journal of Nursing Research, 35* (3), 281-296.

[79] National Institute for Health and Clinical Excellence. (2007). *Behaviour change at population, community and individual levels (NICE public health guidance 6)*. London: National Institute for Health and Clinical Excellence.

 [80] Michie, S., Abraham, C., Whittington, C., McAteer, J., & Gupta, S. (2009). Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychology, 28* (6), 690-701.

[81] Greaves, C. J., Sheppard, K. E., Abraham, C., Hardman, W., Roden, M., Evans, P. H., et al. (2011). Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health,11*, e119.

[82] Brown, M. .J., Sinclair, M., Liddle, D., Hill, A. J., Madden, E., & Stockdale, J. (2012). A systematic review investigating healthy lifestyle interventions incorporating goal setting strategies for preventing excess gestational weight gain. *PLoS One, 7* (7), e39503.

[83] Chase, D. J-A. (2015). Interventions to increase physical activity among older adults: A meta-analysis. *Gerontologist*, *55* (4), 706-718.

[84] Locke, E. A., & Latham, G. P (Eds.). (1990). *A theory of goal setting and task performance*. Englewood Cliffs, NJ: Prentice Hall.

[85] Carver, C. S., & Scheier, M. F. (1982). Control theory: A useful conceptual framework for personality-social, clinical, and health psychology. *Psychological Bulletin*, *92* (1), 111-135.

[86] Schwarzer, R. (2008). Modeling health behavior change: How to predict and modify the adoption and maintenance of health behaviors. *Applied Psychology: An International Review, 57* (1), 1-29.

[87] National Institute for Health and Care Excellence. (2014). *Behaviour change: Individual approaches*. Manchester: National Institute for Health and Care Excellence.

[88] National Institute for Health and Clinical Excellence. (2006). *Four commonly used methods to increase physical activity: Brief interventions in primary care, exercise referral schemes, pedometers and community-based exercise programmes for walking and cycling*. London: National Institute for Health and Clinical Excellence.

[89] Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., et al. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, *350*, h1258. DOI: <http://dx.doi.org/10.1136/bmj.h1258>.

[90] Ries, J. D., Echternach, J. L., Nof, L., & Gagnon Blodgett, M. (2009). Test-retest reliability and minimal detectable change scores for the timed “up & go” test, the six minute walk test, and gait speed in people with Alzheimer disease. *Physical Therapy, 89* (6), 569-579.

[91] Blankevoort, C. G., van Heuvelen, M. J., & Scherder, E. J. (2013). Relibility of six physical performance tests in older people with dementia. *Physical Therapy, 92* (1), 69-78.

[92] [Rydwik](http://informahealthcare.com/action/doSearch?Contrib=Rydwik%2C+E), E., Bergland, A., Forsén, L., & Frändin, K. (2011). Psychometric properties of timed up and go in elderly people: A systematic review. *Physical and Occupational Therapy in Geriatrics*, *29* (2), 102-125.

[93] Chinn, S. (2000). A simple method for converting an odds ratio to effect size for use in meta-analysis. *Statistics in Medicine*, *19*, 3127-3131.

[94] Health Research Authority. (2014). *Guidance: Specific questions that need answering when considering the design of clinical trials*. London: Health Research Authority.

[95] Curtis, L. (2013). *Unit costs of health and social care 2013*. Canterbury: Personal Social Services Research Unit, University of Kent.

[96] Department of Health. (2013). *NHS reference costs 2012 to 2013*. London: Department of Health.

[97] van Iersel, M. B., Benraad, C. E., & Rikkert, M. G. (2007). Validity and reliability of quantitative gait analysis in geriatric patients with and without dementia. *Journal of the American Geriatrics Society*, *50* (4), 632-634.

[98] Mirelman, A., Weiss, A., Buchman, A. S., Bennett, D. A., Giladi, N., & Hausdorff, J. M. (2014). Association between performance on timed up and go subtasks and mild cognitive impairment: Further insights into the links between cognitive and motor function. *Journal of the American Geriatrics Society*, *62* (4), 673-678.

[99] Csuka, M., & McCarty, D. J. (1985). A simple method for measurement of lower extremity muscle strength. *American Journal of Medicine*, *78* (1), 77–81.

[100] Guralnik, J. M., Ferrucci, L., Simonsick, E. M., Salive, M. E., & Wallace, R. B. (1995). Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability. *New England Journal of Medicine*, *332* (9), 556-561.

[101] Ostchega, Y., Harris, T. B., Hirsch, R., Parsons, V. L., Kington, R., & Katzoff, M. (2000). Reliability and prevalence of physical performance examination assessing mobility and balance in older persons in the US: Data from the third national health and nutrition examination survey. *Journal of the American Geriatrics Society*, *48* (9), 1136-1141.

[102] Berg, K., Wood-Dauphine, S., Williams, J. I., & Gayton, D. (1989). Measuring balance in the elderly: Preliminary development of an instrument. *Physiotherapy Canada*, *41* (6), 304–311.

[103] Hayes, K. W., & Johnson, M. E. (2003). Measures of adult general performance tests. *Arthritis & Rheumatism*, *49* (5S), S28-S42.

[104] Panel on Prevention of Falls in Older Persons, American Geriatrics Society and British Geriatrics Society. (2011). Summary of the Updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. *Journal of the American Geriatrics Society, 59* (1), 148-157.

[105] Barry, E., Galvin, R., Keogh., C., Horgan, F., & Fahey, T. (2014). Is the timed up and go test a useful predictor of risk of falls in community dwelling older adults: A systematic review and meta- analysis. *BMC Geriatrics*, *14*, e14.

[106] Galán-Mercant, A., & Cuesta-Vargas, A. I. (2014). Differences in trunk accelerometry between frail and non-frail elderly persons in functional tasks. *BMC Research Notes*, *7*, e100.

[107] Doheny, E. P., McGrath, D., Greene, B. R., Walsh, L., McKeown, D., Cunningham, C., et al. (2012). Displacement of centre of mass during quiet standing assessed using accelerometery in older fallers and non-fallers. *Annual international Conference of the IEEE Engineering in Medicine and Biology Society*, 3300-3303.

[108] Sibley KM, Howe T, Lamb SE, Lord SR, Maki BE, Rose DJ, et al. (2015) Recommendations for a Core Outcome Set for Measuring Standing Balance in Adult Populations: A Consensus-Based Approach. PLoS ONE 10(3): e0120568. doi:10.1371/journal.pone.0120568.

[109] Telenius, E. W., Engedal, K., & Bergland, A. (2015). Inter-rater reliability of the Berg Balance Scale, 30 s chair stand test and 6 m walking test, and construct validity of the Berg Balance Scale in nursing home residents with mild-to-moderate dementia. *BMJ Open*, *5*(9), e008321.

[110] Huaer, K., Yardley, L., Beyer, N., Kempen, G., Dias, N., Campbell, M., et al. (2010). Validation of the falls efficacy scale and falls efficacy scale international in geriatric patients with and without cognitive impairment: Results of self-report and interview-based questionnaires. *Gerontology, 56* (2), 190-199.

[111] Davis, J. C., Bryan, S., McLeod, R., Rogers, J., Khan, K., & Liu-Ambrose, T. (2011). Exploration of the association between quality of life, assessed by the EQ-5D and ICECAP-O, and falls risk, cognitive function and daily function, in older adults with mobility impairments. *BMC Geriatrics*, *12*, e65.

[112] Bédard, M., Molloy, D. W., Squire, L., Dubois, S., Lever, J. A., & O’Donnell, M. (2001). The Zarit burden interview: A new short version and screening version. *Gerontologist*, *41* (5), 652–657.

# APPENDICES

Appendix – Description of dynamic, static and functional balance outcome measures

**Timed Up and Go test (TUG)**

Both dynamic and static balance have been shown to be important modifiable risk factors for falling among community-dwelling older PWD [21], and can be measured with valid and reliable tools amongst this patient group [97,91]. The primary outcome will be dynamic balance that will be measured using the TUG [52] and its subcomponent tasks [98] - timed unsupported sit to stand [99], walking [100-101], 180 degree turn [102], and timed unsupported stand to sit [102]. The TUG is quick and simple to administer in the community [103] and has been recommended for screening for falls risk [104] and assessing gait and balance for preventing falls [10]. While no particular measure of dynamic balance has been recommended in the literature, systematic reviews have identified that the TUG has excellent reliability [92], a strong correlation with falls in retrospective studies [53], is more effective at ruling in falls (0.74 specificity) among individuals classified at high risk of falls [105], and is more suitable with older people who are relatively less healthy and have lower functioning [54]. Performance on the TUG and its subcomponent tasks are important to measure as persons with mild cognitive impairment (but not dementia) have been shown to be impaired in certain subtasks of the TUG despite efficient overall test scores [98;106]. In this trial, data will be gathered using a stop-watch and Balance Sensor (THETAmetrix) that contains an accelerometer to digitally record biomechanical movement, and is a small, inexpensive device that is wireless and corrects for tilt dynamically. Such devices have been shown to produce reliable and valid data for the TUG and its subcomponents [98;106]. The data on the device will be downloaded immediately after each test and stored on the researcher’s laptop / tablet and labelled using the participant’s unique ID number.

**Postural Sway Test**

Static balance will be measured using postural sway while standing on the floor and again while standing on foam [21]. This will be recorded using a Balance Sensor (THETAmetrix), mounted on the sacral to digitally record body sway, which is quick to use (2mins per test) and been shown to be as reliable as laboratory forceplates [64,107]. The TUG and sway tests will be conducted with both the PWD and their carer, but the BBS will only be conducted with the PWD.

**Berg Balance Scale (BBS)**

The BBS is a 14-item objective measure designed to assess functional balance and fall risk in adult populations [50]. It has been recommended in a recent consensus as one of two core outcome sets for measuring standing balance in adult populations [108]. This consensus was identified from the COMET (Core Outcome Measures in Effectiveness Trials) database [www.comet-initiative.org](http://www.comet-initiative.org)), and reported that this scale would be more useful among those with limited functioning (it is prone to ceiling effects among the generally healthy population) [108]. The BBS takes an overall assessment of an individual’s balance; “underlying motor systems, static stability, dynamic stability, functional stability limits, anticipatory postural control, and sensory integration” [108, p.13]. We chose the BBS for this study based on its likely ease of use among people with dementia, existing published evidence of its suitability for use with people with dementia [97,109], and its feasibility for use in people’s homes.

Appendix – Collection of information pertaining to falls

The collection of falls data is in accordance with recommendations made in an article by Lamb et al. (2005) [60] identified in a search of the COMET database (Core Outcome Measures in Effectiveness Trials; [www.comet-initiative.org](http://www.comet-initiative.org)). The article was developed by the Prevention of Falls Network Europe (ProFaNE) group and provides recommendations for falls researchers to adopt. In our trial, the definition of a fall (as suggested by Lamb et al) is: ‘‘an unexpected event in which the participants come to rest on the ground, floor or lower level” [60, p.1619]. Falls will be recorded by dyads daily using prospective monthly calendars returned on a monthly basis by post to the CTU. Where falls are reported by dyads or calendars are not returned, researchers will conduct a telephone interview to collect further information about the fall / collect missing data. In addition, telephone calls will be conducted weekly with the PWD and every 3 months with their carer to collect data on fall incidents (and monthly by telephone with the PWD) as recommended for falls data collection with PWD [61]. This data collection method will provide data on the number and rate of falls, number and rate of fallers, and number and rate of injurious falls using an existing recommendation on categorisation of injuries [62].

Appendix – Description of structured interview / questionnaire-based outcome measures

The questionnaire data for PWD will be collected face-to-face in a structured interview, as previous researchers have recommended against the use of postal self-completion methods for falls research among PWD [61,110].

**Iconographical Falls Efficacy Scale** (**Icon-Fes)**

The Iconographical Falls Efficacy Scale assesses fear of falling and is better at identifying people at higher risk of falls compared with the Falls Efficacy Scale-International and does not produce a floor effect [56].

**Mini-Addenbrooke’s Cognitive Examination (M-ACE)**

This is a brief measure of global cognitive functioning that is more sensitive to the Mini Mental State Examination and is less likely to have ceiling effects, which makes it particularly useful with people with mild cognitive impairment [57].

**Statue task**

This is a brief measure of visual-spatial cognitive functioning that uses a tablet to administer the task [58]. This is a measure of specific cognitive functioning from the hippocampus, which is therefore a more sensitive measure to change than a global assessment of cognitive functioning.

**ICEpop CAPability measure for Older people** **(ICECAP-O)**

The ICEpop CAPability measure for Older people (ICECAP-O) [59] is a measure of quality of life from the perspective of capability to be independent, which is associated with fall risk, general balance and mobility, and sensitive to cognitive status [111]. It is also a measure recommended in guidelines on economic evaluation of fall prevention interventions [62] and Quality-adjusted life years (QALY)s can be derived for economic evaluation.

**Zarit Burden Interview (short-form)**

Carer burden will be measured using the Zarit Burden Interview (short-form) [63,112], which is the most commonly used tool for this purpose [63], and is shorter but just as reliable and valid as the full-length version [63,112].

Appendix 4 – Definitions and guidance in relation to adverse event reporting

The terminology used to describe (serious) related events reflects the terminology used in trials of investigation medicinal products as defined in the EU Clinical Trials directive (2001/20/EC).

*Definitions*

**Related Event:** Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons that are possibly / probably / definitely related to any research procedures or to the intervention. The causal relationship between reported events and trial participation are provided in Table 4:

*Table 4: Standardised guidance for assessment of the causal relationship between a reported event and an individual’s participation in the trial*

|  |  |
| --- | --- |
| **Relationship** | **Description** |
| Unrelated | There is no evidence of any causal relationship |
| Unlikely | There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial treatment / procedure). There is another reasonable explanation for the event (e.g. the participant’s clinical condition or other concomitant treatment). |
| Possible | There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment / procedure). However, the influence of other factors may have contributed to the event (e.g. the participant’s clinical condition or other concomitant treatments). |
| Probable | There is evidence to suggest a causal relationship and the influence of other factors is unlikely. |
| Definitely | There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. |

**Serious Related Event**: Any related event will be regarded as serious if it:

1. results in death;
2. is life threatening a;
3. requires hospitalisation or prolongation of existing hospitalisation b; or
4. results in persistent or significant disability or incapacity;

a Life-threatening in the definition of a serious related event refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.

b In the TACIT trial, attendance at a hospital Emergency Department (ED) will also constitute ‘serious’ classification.

Appendix 5 - Gantt chart for the project (intervention pilot phase and RCT phase)

 