

**STATISTICAL ANALYSIS PLAN**

**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 - TAi ChI for people with demenTia**

**ClinicalTrials.gov Number:** NCT02864056

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**IRAS and HRA Number:** **IRAS Project ID: 209193**

**Ethics Approval:** West of Scotland REC, 1st August 2016

**Sponsor:** Southern Health NHS Foundation Trust

**Chief Investigator:** Dr Samuel Nyman, Bournemouth University

**Current stage of SAP:** First Draft

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**Statistical Analysis Plan Final Sign-Off**:

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| --- | --- | --- | --- |
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| **Chief Investigator** | Samuel Nyman | 20th November 2018 |  |

**Amendments:**

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| **Amendment Number** | **Date** | **Sign-off** |
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1. **Study summary**

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| --- | --- |
| 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 |
| Trial Participants | Community-dwelling people with dementia (PWD) and their carers |
| Planned Sample Size | 1501 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 1-2 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 | 132 months (7 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)  Capability-based general quality of life using the ICEpop CAPability measure for Older people (ICECAP-O)  Global cognitive functioning using the Mini-Addenbrooke’s Cognitive Examination (M-ACE)  Visual-spatial cognitive functioning using the Statue Task (time taken and number of errors)  Measured prospectively from baseline to six-month post-baseline follow-up:  Number of falls per month  Number of injurious falls per month  Proportion of fallers  Time to first fall |
| 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) | * Feasibility of recruitment method (monthly recruitment rate and proportion recruited) * Completeness of TUG (primary outcome) and falls data * For dyads in the intervention arm only; dosage of Tai-Chi received and adherence to the TACIT Tai Chi intervention in terms of both class attendance and completion of home-based Tai Chi exercises * Estimation of parameters for falls data to inform sample size calculations – mean, dispersion, intra-cluster correlation |

1 Final number randomised was 85 dyads

2 Final trial duration was 21 months (15 months recruitment; 6 months follow-up)

Note: The overall study also includes a pilot phase to test out study procedures. However this will not be included in the main trial analysis and so are not considered in the Statistical Analysis Plan

1. **Aims and objectives**

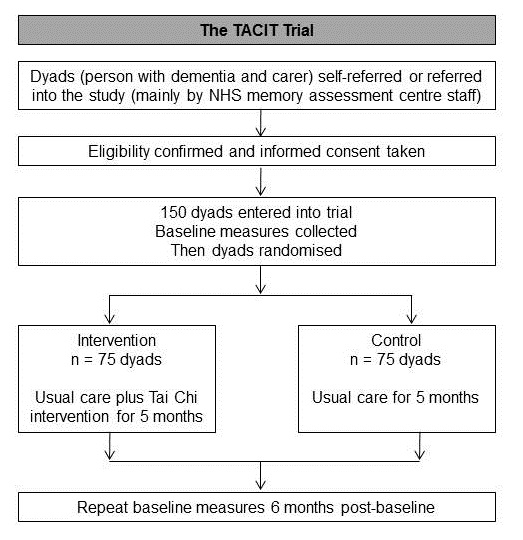
The research question for the overarching programme of research is, “Can a Tai Chi exercise intervention prevent falls among community-dwelling older PWD?” Before embarking on a large and expensive definitive trial with rate of falls as the primary outcome, we will first conduct a smaller RCT. We hypothesise 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

**2.1 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.

**2.2 Secondary objectives**

1. To compare functional balance, static balance, fear of falling, quality of life, global cognitive functioning, visual-spatial cognitive functioning, and the rate of falls and injurious falls, and proportion of fallers between the intervention and control groups.
2. To compare dynamic balance, static balance, quality of life, and carer burden between carers in the intervention and control groups.
3. To determine the acceptability and safety of the intervention for patients and carers in the intervention group.
4. To assess feasibility of key aspects of the study design (i.e. recruitment, consent, randomisation, suitability and completeness of outcome measure data, dosage of intervention and adherence to intervention, methods of data collection, estimation of sample size calculation parameters and economic analysis) to inform the design of a future clinical and cost-effectiveness definitive trial.
5. **Overall design and analysis:**

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Note: Number dyads actually randomised was 85

1. **Participant recruitment:**

**4.1 Summary of sample size considerations:**

See study protocol for full justification. 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. The two values were 4.09 and 5.88, 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). SDs at two different time points were presented (9.74 and 9.01) and we used the average of these figures of 9.38. 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 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 attempt to 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, which was conducted at the grant application stage of the study, we assumed that these would be negligible, because (a) much of the intervention was to occur outside the class environment, and (b) within the classes, there was no specific aim to encourage interaction between PWD (ie the group based format was one of economy and convenience rather than an essential component of a complex intervention). It was not possible to estimate a value for the intra-cluster correlation coefficient from the pilot phase of the project. Notwithstanding, we will take into account potential clustering effects in the statistical analysis.

Note: 85 dyads were randomised in the trial, and therefore statistical power will be reduced. Assuming a mean difference in TUG of 4, a SD of 9.38, a correlation of 0.7 and 80% of participants without primary outcome data equates to statistical power of 68%

**4.2 CONSORT flow chart:**

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.) (Figure 1).

1. **Trial data collected:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable** | **Purpose** | **Source** | **Level of measurement** | **Recoding** | **Analysis assumptions** |
|  |  |  |  |  |  |
| **Stratification variables** |  |  |  |  |  |
|  |  |  |  |  |  |
| Had a fall in past 12 months | Stratification variable and baseline descriptive | Screening | Nominal | No  Yes |  |
| Study treatment site | Stratification variable | Screening | Nominal | Southampton area  Dorset area  Portsmouth area |  |
|  |  |  |  |  |  |
| **Person with dementia descriptives** |  |  |  |  |  |
|  |  |  |  |  |  |
| Gender (frequency) | Baseline descriptive | CRF | Nominal | Female  Male |  |
| Date of birth dd/mm/yyyy | Baseline descriptive | CRF | Date | Calculate age in years at baseline | Age assumed normally distributed |
| Relationship status (categories) | Baseline descriptive | CRF | Nominal | Single  Married/civil partnership  With partner  Divorced/dissolved partnership  Widowed |  |
| Current living arrangements  (categories) | Baseline descriptive | CRF | Nominal | Living alone  Living with family/ friends  Living in sheltered housing |  |
| Highest educational attainment (categories) | Baseline descriptive | CRF | Nominal | None  Primary school  Secondary school  University/ higher education  Further education/ professional qualification |  |
| Ethnicity (categories) | Baseline descriptive | CRF | Nominal | White  Asian  Black  Mixed  Chinese  Other European  Any other |  |
| Dementia type (categories) | Baseline descriptive | CRF | Nominal | Alzheimers  Vascular  Alzheimer+vascular  Other |  |
| Date of diagnosis (mm/yyyy) | Baseline descriptive | CRF | Date | Calculate time from diagnosis to baseline in years | Time from diagnosis not assumed to be normally distributed |
| Other long term health condition | Baseline descriptive | CRF | Nominal | 1. Number of conditions   None  One  Two  Three or more   1. Each condition   No  Yes | To be derived from free text descriptions |
| Existing injuries or other health problems that need to be considered | Baseline descriptive | CRF | Nominal | No  Yes |  |
| Whether use a walking aid | Baseline descriptive | CRF | Nominal | No  Yes |  |
| Number of medications currently taken | Baseline descriptive | CRF | Count | 0  1  2  3+ |  |
| Had a fall in past 12 months (yes / no) | Baseline descriptive and stratification variable (see above) | CRF | Nominal | See row below |  |
| If had a fall in past 12 months, was there an injury (no, minor, moderate, severe) | Baseline descriptive | CRF | Nominal | No fall  Yes fall – no injury  Yes fall – minor injury  Yes fall – moderate injury  Yes fall – severe injury  Yes fall – injury not known |  |
| Had a fall in past month (yes / no) | Baseline descriptive | CRF | Nominal | See row below |  |
| If had a fall in past month , was there an injury (no, minor, moderate, severe) | Baseline descriptive | CRF | Nominal | No fall  Yes fall – no injury  Yes fall – minor injury  Yes fall – moderate injury  Yes fall – severe injury  Yes fall – injury not known |  |
| Current level of moderate physical activity (categories) | Baseline descriptive | CRF | Nominal | Every day  2 times per week  3 times per week  Weekly  Monthly  Rarely/ never |  |
| Current level of vigorous physical activity (categories) | Baseline descriptive | CRF | Nominal | Every day  2 times per week  3 times per week  Weekly  Monthly  Rarely/ never |  |
| Ever done Tai Chi before | Baseline descriptive | CRF | Nominal | No  Yes |  |
| Confident in doing Tai Chi 20 mins per day  Mean (SD) | Baseline descriptive | CRF | Ordinal | Potential range 1-7.  1=agree  7=disagree | Assumed interval scaled and normally distributed |
| Intend to do Tai Chi 20 mins per day | Baseline descriptive | CRF | Ordinal | Potential range 1-7.  1=Agree  7=disagree | Assumed interval scaled and normally distributed |
|  |  |  |  |  |  |
| **Carer descriptives** |  |  |  |  |  |
|  |  |  |  |  |  |
| Gender (frequency) | Baseline descriptive | CRF | Nominal | Female  Male |  |
| Date of birth dd/mm/yyyy | Baseline descriptive | CRF | Date | Calculate age in years at baseline | Age assumed interval scaled and normally distributed |
| Relationship to PWD (categories) | Baseline descriptive | CRF | Nominal | Spouse/ partner  Son/ daughter  Brother/ sister  Friend  Neighbour  Other |  |
| Live with the PWD | Baseline descriptive | CRF | Nominal | No  Yes |  |
| Relationship status (categories) | Baseline descriptive | CRF | Nominal | Single  Married/civil partnership  With partner  Divorced/dissolved partnership  Widowed |  |
| Current living arrangements  (categories) | Baseline descriptive | CRF | Nominal | Living alone  Living with family/ friends  Living in sheltered housing |  |
| Highest educational attainment (categories) | Baseline descriptive | CRF | Nominal | None  Primary school  Secondary school  University/ higher education  Further education/ professional qualification |  |
| Ethnicity (categories) | Baseline descriptive | CRF | Nominal | White  Asian  Black  Mixed  Chinese  Other European  Any other |  |
| Ever done Tai Chi before | Baseline descriptive | CRF | Nominal | No  Yes |  |
| Confident in doing Tai Chi 20 mins per day | Baseline descriptive | CRF | Ordinal | Potential range 1-7.  1=Agree  7=Disagree | Assume interval scaled and normally distributed |
| Intend to do Tai Chi 20 mins per day | Baseline descriptive | CRF | Ordinal | Potential range 1-7.  1=Agree  7=Disagree | Assume interval scaled and normally distributed |
|  |  |  |  |  |  |
| **Outcomes - PWD** |  |  |  |  |  |
|  |  |  |  |  |  |
| Timed up and go (TUG) ss:msms | Primary outcome measured baseline and 6 months | CRF | Ratio | Convert to seconds | If walking aid used, or seat height or arm rest height non-standard, or if adaptations made to TUG then analyse TUG data and add footnote regarding number of each issue. Assumed normally distributed |
| Berg Balance Scale (BBS) | Secondary outcome measured 0 and 6 months | CRF | Ordinal | 14 items each with 5 categories from 0 (worst) to 4 (best). Total score ranges from 0 to 56 with high scores better. Total coded as missing if any of the 14 items are missing | Assumed interval scaled and normally distributed |
| Postural sway while standing on the floor | Secondary outcome measured 0 and 6 months | CRF | Ratio | Total NPL used. Units (milli-g per sec). Higher values mean more sway. | Assumed normally distributed. If swaymeter not been calibrated for the visit then data set to missing and footnote added to the table |
| Postural sway while standing on foam | Secondary outcome measured at 0 and 6 months | CRF | Ratio | Total NPL used. Units (milli-g per sec). Higher values mean more sway. | Assumed normally distributed. If swaymeter not been calibrated for the visit then data set to missing and footnote added to the table |
| Inconographical Falls efficacy Scale (Icon-FES) – concern about falling whilst doing 10 different activities | Secondary outcome measured at 0 and 6 months | CRF | Ordinal | 10 items scored 1-4 (1 not at All concerned, 2 somewhat concerned, 3 fairly concerned, 4 very concerned) Total 10-40, higher scores indicating greater concern. On original FES-I and Short FES-I scale was still usable if 75% and 71% items respectively had valid values. Thus we will use scale if at least 7/10 items completed. Calculate by adding valid values, divide by number of valid items and multiply by 10. Round up to the nearest integer. | Assumed interval scale and normally distributed |
| ICEpop CAPability measure for older people (ICECAP-O) | Secondary outcome measured at 0 and 6 months | CRF | Ordinal | 5 items coded 1-4, where 4 = full capability and 1 indicates no capability. Valid values required for all items. ICECAP-O tariffs calculated from Stata or SPSS code (see appendix) | Assumed interval scale and normally distributed |
| Mini-Addenbrooke’s Cognitive Examination | Secondary outcome measured at 0 and 6 months (see below) | Screening and CRF at 6 months | Ordinal | 5 items with a total score between 0-30. Total score is missing if any of the 5 items are missing. At screening severe dementia (score 0-9) is an exclusion criterion. In baseline descriptives coded as Mild – score 21+,  Moderate – score 10-20 | Assume interval and normally distributed. |
| Statue test – time taken (seconds) | Secondary outcome measured at 0 and 6 months | CRF | Ratio | Total time over all tasks | Case excluded if missing data on any task |
| Statue test – errors made | Secondary outcome measured at 0 and 6 months | CRF | Count | Total errors over all tasks | Case excluded if missing data on any task |
| Falls count and number of days falls data collected | Secondary outcome | Falls diary and telephone interviews. | Count | See note below table for description of how diary and interview data will be combined. Number of days over which falls data recorded will be needed to calculate falls rate per month. Also for each participant recode:  No fall during trial  One or more falls in trial | Assume negative binomial distribution for count data. Assume binomial distribution for dichotomous coding. |
| Injurious falls count and number of days falls data collected | Secondary outcome | Falls diary and telephone interviews | Count | See falls data above. Includes only falls resulting in minor, moderate or severe injuries. Rate of injurious falls per month calculated. Also for each participant recode:  No injurious fall during trial  One or more injurious falls in trial | Assume negative binomial distribution. |
|  |  |  |  |  |  |
| **Other measures - PWD** |  |  |  |  |  |
|  |  |  |  |  |  |
| Other physical activity classes | Other outcome | Exit interview | Nominal (multiple responses possible) | Tai-Chi/ Qi Gong  Yoga  Pilates  Aerobics – seated  Aerobics – stood up | Will be coded any activity classes v none |
| Other physical activity at home | Other outcome | Exit interview | Nominal (multiple responses possible) | Walking  Tai-Chi/ Qi Gong  Yoga  Pilates  Aerobics – seated  Aerobics – stood up | Will be coded any activity v none |
| Changes to health | Other outcome | Exit interview | Nominal (multiple responses possible) | Medications  Walking aid  Anxiety/depression  Dementia symptoms  A&E/ outpatient  Inpatient  Elective surgery  Major life event  Other change | Will be coded any change v none |
|  |  |  |  |  |  |
| **Outcomes – Carer** |  |  |  |  |  |
|  |  |  |  |  |  |
| Postural sway while standing on the floor | Secondary outcome measured at 0 and 6 months | CRF | Ratio | Total NPL used. Units (milli-g per sec). Higher values mean more sway. | Assumed normally distributed. If swaymeter not been calibrated for the visit then data set to missing and footnote added to the table |
| Postural sway while standing on foam | Secondary outcome measured at 0 and 6 months | CRF | Ratio | Total NPL used. Units (milli-g per sec). Higher values mean more sway. | Assumed normally distributed. If swaymeter not been calibrated for the visit then data set to missing and footnote added to the table |
| Timed up and go (TUG) ss:msms | Secondary outcome measured at 0 and 6 months | CRF | Ratio | Convert to seconds. | Assumed normally distributed. If walking aid used, or seat height or arm rest height non-standard, or if adaptations made to TUG then analyse TUG data and add footnote regarding number of each issue |
| ICEpop CAPability measure for older people (ICECAP-O) | Secondary outcome measured at 0 and 6 months | Carer CRF | Ordinal | 5 items coded 1-4, where 4 = full capability and 1 indicates no capability. ICECAP-O tariffs calculated from Stata code (see appendix) | Assumed interval scale and normally distributed |
| Zarit Carer Burden Interview – Short Form.  Higher scores indicate greater burden | Secondary outcome measured at 0 and 6 months | Carer CRF | Ordinal | 12 items coded 0-4 (0 never to 4 nearly always). Potential range 0-48. Total score missing if any items missing | Assumed interval scale and normally distributed |
|  |  |  |  |  |  |
| **Other measures – carer** |  |  |  |  |  |
|  |  |  |  |  |  |
| Other physical activity classes | Other outcome | Exit interview | Nominal (multiple responses possible) | Tai-Chi/ Qi Gong  Yoga  Pilates  Aerobics – seated  Aerobics – stood up | Will be coded any activity classes v none |
| Other physical activity at home | Other outcome | Exit interview | Nominal (multiple responses possible) | Walking  Tai-Chi/ Qi Gong  Yoga  Pilates  Aerobics – seated  Aerobics – stood up | Will be coded any activity v none |
| Changes to health | Other outcome | Exit interview | Nominal (multiple responses possible) | Medications  Walking aid  Anxiety/depression  Dementia symptoms  A&E/ outpatient  Inpatient  Elective surgery  Major life event  Other change | Will be coded any change v none |
|  |  |  |  |  |  |
| **Tai Chi class specific data** |  |  |  |  |  |
|  |  |  |  |  |  |
| Number of classes attended | Adherence data | Class Register | Count | (a) Dosage - Number of classes attended  (b) Adherence - number of classes attended/ possible classes | Each person will have up to 20 classes to attend. For calculation (b), if someone was recruited to the trial after the first class, then number of classes missed prior to randomisation will be subtracted from denominator. Number of classes can be converted to minutes of exercise by multiplying by 45 minutes per class. |
| Adherence to home exercises | Adherence data | Diaries | Count | 1. Dosage - Minutes of home exercise during study, 2. Adherence – number of minutes of home exercise / number of minutes could have conducted | Once the home visit by the Tai Chi instructor has taken place, participants are expected to do 20 mins Tai Chi at home daily (target of 120 mins per week, assuming they don’t do any on the day of the class). Denominator incorporates number of days between first Tai Chi lesson and completion of primary outcome measure but subtracting the number of days attended Tai Chi. |
| I enjoy coming to Tai Chi classes | Mid-point questionnaire | Mid-point questionnaire | Ordinal | 7 point scale. 1=agree, 7=disagree | Assumed interval scaled and normally distributed |
| Confidence in taking part for the next 10 weeks | Mid-point questionnaire | Mid-point questionnaire | Ordinal | 7 point scale. 1=agree, 7=disagree | Assumed interval scaled and normally distributed |
| Intention to take part | Mid-point questionnaire | Mid-point questionnaire | Ordinal | 7 point scale. 1=agree, 7=disagree | Assumed interval scaled and normally distributed |
| Motivation from home exercise log | Mid-point questionnaire | Mid-point questionnaire | Ordinal | 7 point scale. 1=agree, 7=disagree | Assumed interval scaled and normally distributed |
| Use of alarm clock | Mid-point questionnaire | Mid-point questionnaire | Ordinal | 7 point scale. 1=agree, 7=disagree | Assumed interval scaled and normally distributed |
|  |  |  |  |  |  |
| **Serious adverse events** |  |  |  |  |  |
|  |  |  |  |  |  |
| Number of serious adverse events related to Tai Chi (Tai Chi group only) | SAE | SAE reporting to sponsor | Count | Present events during the classes and events during home practice separately |  |
| Serious adverse events related to balance tests | SAE | SAE reporting to sponsor | Count |  |  |
| Other serious adverse events | SAE | SAE reporting to sponsor | Count |  |  |
|  |  |  |  |  |  |
| **Adverse events** |  |  |  |  |  |
| Number of adverse events related to Tai Chi (Tai Chi group only) | AE | AE reporting to sponsor | Count | Present events during the classes and events during home practice separately |  |
| Adverse events related to balance tests | AE | AE reporting to sponsor | Count |  |  |
| Other adverse events | AE | AE reporting to sponsor | Count |  |  |
|  |  |  |  |  |  |
| **Willingness to pay** |  |  |  |  |  |
|  |  |  |  |  |  |
| Willingness to pay for Tai Chi classes for 5 months | For patient and carer jointly | Exit interview | Nominal | Yes  No |  |
| If yes to above, how much willing to pay (£) | For patient and carer jointly | Exit interview | Ratio |  | Not assumed normally distributed |
| Willingness to pay for own transport costs | For patient and carer jointly | Exit interview | Nominal | Yes  No |  |
| Willingness to pay for Tai Chi instructor home visit | For patient and carer jointly | Exit interview | Nominal | Yes  No |  |
| If yes to above, how much willing to pay (£) | For patient and carer jointly | Exit interview | Ratio |  | Not assumed normally distributed |
| Willingness to pay for Tai Chi classes for 5 months if reduces falls by 20% | For patient and carer jointly | Exit interview | Nominal | Yes  No |  |
| If yes to above, how much willing to pay (£) | For patient and carer jointly | Exit interview | Ratio |  | Not assumed normally distributed |
| Willingness to pay for own transport costs if reduces falls by 20% | For patient and carer jointly | Exit interview | Nominal | Yes  No |  |
| Willingness to pay for Tai Chi instructor for home visit if reduced falls by 20% | For patient and carer jointly | Exit interview | Nominal | Yes  No |  |
| If yes to above, how much willing to pay (£) | For patient and carer jointly | Exit interview | Ratio |  | Not assumed normally distributed |
|  |  |  |  |  |  |
| **Allocation concealment** |  |  |  |  |  |
|  |  |  |  |  |  |
| Outcome assessor successfully guessed group allocation |  | Assessor field notes |  | Yes  No |  |

Note on coding of falls data:

Falls are collected on people with dementia (PWD) during the trial. We will use Zieschang et al as the basis for coding. Falls data are collected in four ways during the trial from baseline until final follow-up:

1. Weekly phone call with PWD\*

2. Monthly phone call with PWD\*

3. Monthly fall calendar returned by post

4. 3-monthly phone call with carer

(\*In some instances this was only able to be provided by the carer (because PWD and / or carer insisted and so data were collected this way to avoid missing data))

While the above four variables will be used to create a new combined falls variable, it is important that these original four variables are left intact. This will aid our analysis as to the accuracy of falls data collection by each method in isolation and in combination (not part of main trial data analysis).

From the above four variables, a new variable is to be created that converges the information from the four reporting methods. Where a fall is recorded more than once, it will only appear once in this variable (no duplications). This variable will be created by PenCTU by manually coding each PWD’s falls data. They will first use data from one reporting method (e.g. the calendars) and then compare against each of the other coding methods. The following rules will be applied when coding to determine if a fall from a different reporting method is of a fall already counted (a duplicate not be counted again) or a new unique fall (to be counted as a new event):

If a fall is reported to have occurred on the same day between two different reporting methods = assume this is a duplication, on the assumption that 1 fall occurs per day unless indicated otherwise.

If two falls are reported to have occurred on a consecutive day to each other between reporting methods but have the same description of event = assume this is a duplication, and reporting error in terms of the exact date (more recent reporting likely to be most accurate, i.e. weekly phone calls).

Total number of falls on monthly calendar match total number of falls from weekly / monthly phone calls but occur on different days = if no indication of duplication, then treat all falls that occur on different days as new fall events. This is because falls are under-reported.

Reference:

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.

1. **Missing data:**

Outcome data will be sought for all randomised participants even if they discontinued Tai-Chi classes. No imputation methods will be used for the main analysis (though see section on sensitivity analysis). We will assume that the missing data mechanism is “Missing Completely at Random” (MCAR).

1. **Interim analysis:**

No interim analyses are planned.

1. **Blinding:**

The statistical analysis will be conducted by the trial statistician/ data analyst un-blinded to treatment arm. This is necessary because class cohort for participants in the Tai Chi arm of the trial is needed for the statistical analysis to take into account clustering. 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 rest of the trial team by the trial statistician.

1. **Main analysis of outcomes:**

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.

Figure A shows the main aspects of the design at the time recruitment started, where (an average of) 5 PWD were to be recruited per Tai Chi class with 5 classes in each of 3 treatment sites (15 classes in total). The final design, resulting from the challenges of recruiting 150 PWD within the time scale, is shown in Figure B. In the 3 sites there were 1 class, 3 classes (all run by the same instructor) and 6 classes (4 run by 1 instructor, a small class run by a second instructor, and a class run with both instructors). Given the large overlap between treatment site and instructor, and the smaller than anticipated sample size which might be a challenge for a too complex analysis, the analysis will consider treatment site and class cohort, but not instructor identity.

Figure A – Trial design at planning stage (T=Therapist, C=Class cohort, P=Participant)

 Figure B – Trial design at end of recruitment



To maintain blinding of other team members, class cohort sizes indicated are half the number who could have been randomised to Tai Chi rather than actual numbers.

Descriptive statistics will be presented for all baseline outcome data for each trial arm separately. No statistical testing of baseline data will be done (see tables 1 and 2)

**9.1 Primary outcome**

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. Baseline TUG and falls history in the past 12 months will also be included in the model. See Table 3.

Method – Restricted Maximum likelihood estimation

Dependent – TUG at 6 months

Treatment effect – (Tai-Chi + usual care) v (Care as usual)

Co-factors – Site (Dorset area v Southampton area v Portsmouth area)

Falls History in the past 12 months (Yes v No)

Covariates – Baseline TUG

Multilevel considerations – Participants in the Tai Chi arm of the trial attend Tai Chi classes in groups. This potential clustering effect will be taken into account by introducing a random effect for class into the model for the Tai Chi arm only1.

Should sample size and model complexity result in difficulties fitting the model it will be progressively simplified by (a) ignoring clustering, (b) dropping site, (c) dropping falls history, (d) ignoring baseline values.

1 Lee, KI., Thompson, SG. The use of random effects models to allow for

clustering in individually randomized trials. Clinical Trials 2005; 2: 1 63-1 73

**9.2 Secondary outcomes**

The method of analysis will be similar to primary outcomes on the following secondary outcomes (see tables 3 and 4):

**PWD**

Berg Balance Scale (BBS)

Postural sway on firm surface

Postural Sway on a foam surface

Icon-Fes

ICECAP-O

M-ACE

Statue task – time taken

Statue task – errors made

(Scores on the Statue task will be analysed but reported separately to the main outcome paper)

**Carer**

TUG

Postural sway on firm surface and foam

Postural sway on foam surface

ICECAP-O

Zarit carer burden

For each of these PWD and carer secondary outcome measure the baseline value of that measure will be used as a covariate (rather than PWD TUG). .

In addition the following secondary outcomes will be looked at in PWD

Number and rate per month of falls

Number and rate per month of injurious falls

Proportion of fallers

Proportion of injurious fallers

Falls count data will be analysed using negative binomial models, taking into account clustering, site and falls history (past 12 months) at baseline. The number of days over which falls were measured will be used as the “offset” parameter in the model.

Proportion of participants who fall will be analysed using a binomial model taking into account clustering, site and falls history at baseline.

**9.3 Sub-group analyses**

One subgroup analyses is pre-planned for the primary outcome variable (TUG). Fall history (whether or not the PWD has fallen in the 12 months prior to baseline (yes / no)) will be entered as an interaction term in the statistical model (intervention effect x falls history). The interaction tests will test if the intervention effect among PWD on the TUG is modified by whether they had fallen in the 12 months prior to baseline. Fall history is widely established as a major risk factor for falls.

**9.4 Additional analyses:**

1. We will conduct a per protocol analysis that will exclude participants from the Tai Chi group if they received fewer than 50 hours of classes and home exercise combined (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). The purpose of this analysis is to estimate the effect of the intervention when a therapeutic dose is received. This analysis will also exclude participants where there has been a significant protocol violation (for example participant incorrectly recruited etc). In the case that fewer than 50% of participants in the Tai Chi group received the therapeutic dose, this analysis will be replaced by one where participants in the Tai Chi group will be excluded if they received less than 50% of the expected dose of Tai Chi. During the 20 weeks of Tai Chi classes the expected weekly dosage consists of 45 mins of classes plus 6x20 minute home exercise sessions. In the 6 weeks between end of the classes and 6 month data collection point the expected dosage is 20 minutes per day. This is a total expected dose of 69 hours over the course of the study. Thus participants will be excluded from this analysis if they receive 34 hours or less of exercise.

1. The main analysis will assume data is missing completely at random. We will also conduct additional analyses 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 missing data assumption

**10. Analysis of feasibility aspects of a future falls trial**

The feasibility of conducting a future full scale randomised trial will be assessed in a number of different ways

**10.1 Recruitment and data completeness**

Recruitment rate for the subsequent definitive trial will be estimated using the recruitment rate (95% CI) from this RCT.

We will produce a chart of cumulative number recruited against expected number for the duration of the recruitment period.

We will calculate the proportion of patients assessed for eligibility who were recruited ie Number recruited/ number assessed for eligibility

We will calculate proportion of eligible patients who were recruited ie number recruited/ number eligible

Questionnaire response rate will be calculated:

1. Proportion of participants with completed TUG (primary outcome in current study) at 6 months follow-up
2. Proportion of participants with complete falls data (primary outcome for future trial) at 6 months follow-up for each methods of data capture (calendar, phone interviews)

Further analysis of missing data will also help with planning of the future trial. Those with falls data will be compared to those without falls data to see if there were any associations with

(a) treatment site (Dorset, Southampton, Portsmouth)

(b) Falls in previous 12 months at baseline (Y,N)

(c) Trial arm allocation (Tai Chi, usual care)

(d) MACE score at baseline (mean(SD))

(e) Baseline TUG (mean(SD))

**10.2 Tai Chi dosage and adherence**

In the Tai Chi group, adherence to the suggested programme of exercise will be estimated by calculating:

1. Tai Chi class attendance = number of classes attended/ number of possible classes

(b) Adherence to home exercise programme = number of days with at least 20 minutes of exercise/ possible number of days of exercise

Dosage of intervention received will be summarised as:

1. Number of Tai Chi classes attended

(b) Minutes of home exercise conducted during the study

In addition the overall amount of exercise received will be summarised as:

(a) Total number of minutes of Tai Chi and home exercise

(b) Whether participant had a dose of at least 50 hours of Tai Chi and home exercise combined

**10.3 Sample size considerations**

It is likely that falls rate will be used as the primary outcome for the future trial. To help with sample size considerations for that trial, estimates of mean falls rate, dispersion parameter and intra-cluster correlation coefficient will be calculated. They will be used for a preliminary sample size calculation for that trial. In addition we will calculate the intra-cluster correlation coefficient for TUG, as this might be helpful for sample size calculations in other trials.

**10.4 Assessor blinding**

For each participant, the outcome assessor will state which group they think they had been allocated to. If blinding of the assessor was being maintained then this would amount to a guess with a 50% chance of being correct. For each trial group and overall we will calculate the proportion where the guess was correct.

**10.5 Safety and adverse events**

Serious adverse event data will be summarised as:

1. Number of PWD who had a serious adverse event that was related to the Tai Chi classes (Tai Chi group only)
2. Number of PWD who had a serious adverse event that was related to the home Tai Chi practice (Tai Chi group only)
3. Number of PWD in both groups combined who had a serious adverse event related to assessment of balance
4. Number of PWD in each group and combined who had an unrelated serious adverse event.
5. Number of carers who had a serious adverse event that was related to the Tai Chi classes (Tai Chi group only)
6. Number of carers who had a serious adverse event that was related to the home Tai Chi practice (Tai Chi group only)
7. Number of carers in both groups combined who had a serious adverse event related to assessment of balance
8. Number of carers in each group separately and combined who has an unrelated serious adverse event.

It is anticipated that the number of serious adverse events will be small and no statistical testing will be conducted.

**10.6 Adherence to allocated intervention**

The proportion of PWD and carers in each trial arm who (a) attended Tai-Chi or Qi Gong classes outside of the trial, (b) attended other physical activity classes, (c) did Tai-Chi or Qi Gong at home outside of the trial and (d) did other physical activity at home outside of the trial.

**10.7 Primary outcome confounders**

Assessment of the primary outcome of TUG can potentially be influenced by a variety of factors such as medication, walking aids, anxiety/depression, dementia symptoms, hospital visits (A&E, outpatient, inpatient, elective surgery), major life event etc. Participants will provide information on whether there have been changes in these factors between baseline and 6 months, and the proportion in each trial arm will be presented.

**11.Other variables**

Mid-point questionnaire data consisting of 5 statements related to attending the classes will be summarised using means and standard deviations. In addition we will calculate the proportion of participants rating the statements between 1 and 3 (ie tending to agree).

Willingness to pay for various aspects of Tai Chi will help in formulating a future delivery model, both for a future trial and in clinical practice. Data will be presented for both trial arms separately.

**12.Criteria for progressing to a cost-effectiveness trial**

The results from TACIT will be used to inform the design of a full scale effectiveness and cost-effectiveness trial with falls count as the primary outcome measure, including whether such a trial is feasible. The dimensions to be considered are:

1. Recruitment – based on the required sample size (estimated from TACIT data), recruitment rate per month and proportion of potential participants recruited we will calculate the number of recruitment centres required and length of recruitment in each centre
2. Outcome data completion – If completion of falls data in the combined variable from all the different reporting methods is less than 70% we will consider whether this can be improved in the future trial (for example as a result of feedback from the research team or qualitative work). If not we will not progress to a future trial. If completion of health service usage data is less than 70% we will consider whether this can be improved. If not then we will not progress with the economic component of the future trial.
3. Adherence/ dosage – We will consider adherence and dosage when deciding whether to progress to a future trial. We will consider factors such as the proportion of participants in the Tai Chi group who received a “therapeutic dose” of 50 hours of exercise; the proportion who achieved at least 50% of expected exercise minutes (34 hours or less); and with reference to the literature and the adherence seen in other interventions.
4. Scaling up – If feedback from the research team and trial participants indicates that conducting a larger version of the trial is unrealistic with the current design, we will consider ways in which it can be simplified.
5. Lack of signal – If results give no indication of benefit in the Tai Chi arm we will not progress to a future trial, particularly with respect to the mechanistic outcome of dynamic balance. Given that the study was unable to meet the recruitment target of 150 dyads, we recognise that these comparisons may be underpowered, and so we will consider between group differences, within group differences, and differences in those where adherence to the intervention was good (eg more than 34 hours of exercise).

Note that percentages with complete data, percentage receiving therapeutic dose and effect size will take into account imprecision of these estimates by also considering confidence intervals.

The final decision on progressing to a full trial will be taken after consideration of feasibility data within the trial, discussion within the Trial Management Group, discussion with the Trial Steering Committee and discussion with the PPI Advisory Group.

**Health Economics Analysis Plan**

In this trial, we will assess the feasibility of collecting the data required for a health economic analysis and conduct a cost-consequence 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. A comprehensive consideration of health service use will be calculated in relation to presentation to the GP, out of hours, or A&E and will include medication and walking aids. 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”. 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”.

Recommendations will be derived from the feasibility study on how a full health economic analysis might be conducted in any subsequent definitive trial. This will include the choice of outcome measures (ICECAP, falls, QALYs), the cost of the intervention and its effect on use and cost of NHS services. The results of the willingness to pay questions will provide a basis for discussion of how the intervention might be delivered and outcomes measured in any future trial.

**Templates for tables of results**

**Table 1: Descriptive statistics for PWD**

|  |  |  |
| --- | --- | --- |
|  | Usual care (n=??) | Tai Chi + usual care (n=??) |
| Gender n (%)  Male  Female |  |  |
| Age mean (SD) |  |  |
| Relationship status n(%)  Single  Married/civil partnership  With partner  Divorced/dissolved partnership  Widowed |  |  |
| Current living arrangements n (%)  Living alone  Living with family/ friends  Living in sheltered housing |  |  |
| Highest educational attainment n (%)  None  Primary school  Secondary school  University/ higher education  Further education/ professional qualification |  |  |
| Ethnicity n (%)  White  Asian  Black  Mixed  Chinese  Other European  Any other |  |  |
| Type of dementia n (%)  Alzheimers  Vascular  Alzheimer+vascular  Other |  |  |
| Time since diagnosis (years) median (IQR) |  |  |
| Other long term conditions (see also Table A1) n (%)  No  One  Two  Three or more |  |  |
| Uses a walking aid n (%)  No  Yes |  |  |
| Number of medications currently taken n (%)  0  1  2  3+ |  |  |
| Falls in past 12 months  None  Yes, no injury  Yes, minor injury  Yes, moderate injury  Yes, severe injury  Yes, injury not known |  |  |
| Falls in past month  None  Yes, no injury  Yes, minor injury  Yes, moderate injury  Yes, severe injury  Yes, injury not known |  |  |
| Current level of moderate physical activity n (%)  Every day  2 times per week  3 times per week  Weekly  Monthly  Rarely/ never |  |  |
| Current level of vigorous physical activity n (%)  Every day  2 times per week  3 times per week  Weekly  Monthly  Rarely/ never |  |  |
| Dementia severity (Mini-Addenbrooke’s Cognitive examination n (%)  Mild (21-30)  Moderate (10-20)  Mean/ median (SD) |  |  |
| Study site n (%)  Southampton  Dorset  Portsmouth |  |  |

**Table 2: Descriptive statistics for carers**

|  |  |  |
| --- | --- | --- |
|  | Usual care (n=??) | Tai Chi + usual care (n=??) |
| Gender n (%)  Male  Female |  |  |
| Age mean (SD) |  |  |
| Relationship to PWD n (%)  Spouse/ partner  Son/ daughter  Brother/ sister  Friend  Neighbour  Other |  |  |
| Living with PWD n (%)  Yes  No  If no, average weekly face-to-face contact (mins) Median (IQR) |  |  |
| Relationship status n(%)  Single  Married/civil partnership  With partner  Divorced/dissolved partnership  Widowed |  |  |
| Current living arrangements n (%)  Living alone  Living with family/ friends  Living in sheltered housing |  |  |
| Highest educational attainment n (%)  None  Primary school  Secondary school  University/ higher education  Further education/ professional qualification |  |  |
| Ethnicity n (%)  White  Asian  Black  Mixed  Chinese  Other European  Any other |  |  |

**Table 3: Primary and secondary outcome measures – person with dementia**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Baseline | 6 month follow-up |
| **Primary** |  |  |  |
| Timed Up and Go (TUG) 1  Lower values indicate greater dynamic balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))  Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
|  |  |  |  |
| **Secondary** |  |  |  |
| Berg Balance Scale (BBS) – potential range 0-56.  High scores indicate better balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))  Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Postural sway standing on floor (mg/s) 2  High scores indicate worse balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))  Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Postural sway standing on foam (mg/s) 3  High scores indicate worse balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Iconographical Falls Efficacy Scale (Icon-FES) – potential range 10-40  High scores indicate greater concern | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| ICEpop CAPability measure for Older people (ICECAP-O)  Higher scores indicate worse capability | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Mini-Addenbrooke’s Cognitive Examination  Higher scores mean milder dementia | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Statue test time taken (secs) | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Statue test number of errors | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Number of falls per month of follow-up | Usual care (mean(variance)), number of falls  TUG+Usual care (mean(variance)), number of falls    Falls rate ratio (95% CI)  p-value | -  - |  |
| Number of injurious falls per month of follow-up | Usual care (mean(variance)), number of falls  TUG+Usual care (mean(variance)), number of falls    Falls rate ratio (95% CI)  p-value | -  -  - |  |
| Proportion participants falling | Usual care (n(%))  TUG+Usual care (n (%))    Odds ratio (95% CI)  p-value | -  - |  |
| Proportion participants having injurious fall | Usual care (n(%))  TUG+Usual care (n (%))    Odds ratio (95% CI)  p-value | -  - |  |

1 x in usual care group and x in tai-chi group had TUG measured using non-standard procedures. In usual care group x used walking aid, x had non-standard seat height or arm rest height, and x had adaptations made to TUG. Figures for Tai Chi group were x, x, and x respectively.

2 x in usual care group and x in Tai-Chi group deleted because swaymeter not calibrated prior to visit

3 x in usual care group and x in Tai-Chi group deleted because swaymeter not calibrated prior to visit

**Table 4: Secondary outcome measures – carer**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Baseline | 6 month follow-up |
| Timed Up and Go (TUG) 1  Lower values indicate greater dynamic balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))  Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Postural sway standing on floor (mg/s) 2  High scores indicate worse balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))  Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Postural sway standing on foam (mg/s) 3  High scores indicate worse balance | Usual care (mean(SD))  TUG+Usual care (mean(SD))  Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| ICEpop CAPability measure for Older people (ICECAP-O)  Higher scores indicate worse capability | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |
| Zarit Carer Burden  Higher scores indicate greater burden | Usual care (mean(SD))  TUG+Usual care (mean(SD))    Mean difference (95% CI)  p-value  Standardised effect size | -  -  - |  |

1 x in usual care group and x in tai-chi group had TUG measured using non-standard procedures. In usual care group x used walking aid, x had non-standard seat height or arm rest height, and x had adaptations made to TUG. Figures for Tai Chi group were x, x, and x respectively

2 x in usual care group and x in Tai-Chi group deleted because swaymeter not calibrated prior to visit

3 x in usual care group and x in Tai-Chi group deleted because swaymeter not calibrated prior to visit

**Table 5: Feasibility measures**

|  |  |
| --- | --- |
| **Feasibility measure** |  |
|  |  |
| **(a)Recruitment and data completeness** |  |
| Proportion recruited (number recruited/number approached) % (95% CI)) |  |
| Number recruited per month (mean (95% CI)) |  |
| Completeness of primary outcome(TUG) n (% (95% CI)) |  |
| Completeness of falls data (proposed primary outcome of future trial) n(% (95% CI)) |  |
|  |  |
| **(b)Dosage and adherence** |  |
| Dose – number of classes attended (median (IQR)) – Tai Chi group only |  |
| Dose – total minutes of home exercise during study (median(IQR)) – Tai Chi group only |  |
| Dose – total minutes of tai chi classes and home exercise during study (median(IQR), min, max) – Tai Chi group only |  |
| Dose – proportion receiving at least 50 hours of tai-chi and home exercise n (%) – Tai Chi group only |  |
| Adherence – percentage of Tai Chi class attended for each individual (number classes attended/ number could have attended) – median(IQR), min, max – Tai Chi group only |  |
| Adherence – percentage of days conducting home exercise for at least 20 minutes (number of days conducted/ (number of days could have conducted) – median(IQR), min, max – Tai Chi group only |  |
|  |  |
| **(c) Sample size considerations** |  |
| Intra-Cluster correlation Coefficient for TUG at 6 months – Tai Chi group only |  |
| Intra-cluster correlation coefficient for falls per month - Tai Chi group only |  |
| Overall mean falls per month (both groups combined) |  |
| Dispersion parameter for falls per month(both groups combined) |  |
| Estimated total sample size for future trial with falls rate as primary outcome measure (5% 2-sided significance level, 90% power)1 |  |
|  |  |
| **(d)Assessor blinding** |  |
| Outcome assessor successfully guessed group allocation n(%)   1. Overall 2. Tai Chi arm 3. Control arm |  |
|  |  |
| **(e)Safety (adverse and serious adverse events)** |  |
| Number of serious adverse events related to Tai Chi classes (Tai Chi arm only)  PWD  Carer |  |
| Number of serious adverse events related to Tai Chi home exercises (Tai Chi arm only)  PWD  Carer |  |
| Number of serious adverse events related to balance tests (both arms combined)  PWD  Carer |  |
| Other serious adverse events   1. Overall   PWD  Carer   1. Tai Chi arm   PWD  Carer   1. Control arm   PWD  Carer |  |
| Number of adverse events related to Tai Chi classes (Tai Chi arm only)  PWD  Carer |  |
| Number of adverse events related to Tai Chi home exercises (Tai Chi arm only)  PWD  Carer |  |
| Number of adverse events related to balance tests (both arms combined)  PWD  Carer |  |
| Other adverse events   1. Overall   PWD  Carer   1. Tai Chi arm   PWD  Carer   1. Control arm   PWD  Carer |  |
|  |  |
| **(g)Adherence to allocated intervention** |  |
| Tai-chi/ Qi Gong classes outside trial n(%)  PWD   1. Tai Chi arm only 2. Control arm only   Carer   1. Tai Chi arm only 2. Control arm only |  |
| Other physical activity classes outside trial n(%)  PWD   1. Tai Chi arm only 2. Control arm only   Carer   1. Tai Chi arm only 2. Control arm only |  |
| Tai-chi/ Qi Gong home exercise outside trial n(%)  PWD   1. Tai Chi arm only 2. Control arm only   Carer   1. Tai Chi arm only 2. Control arm only |  |
| Other physical activity at home outside trial n(%)  PWD   1. Tai Chi arm only 2. Control arm only   Carer   1. Tai Chi arm only 2. Control arm only |  |
|  |  |
| **(h) Potential primary outcome confounders** |  |
| Changes in any health factors that might influence primary outcome measure (medication, walking aid, anxiety/depression, dementia symptoms, A&E, outpatient, inpatient, elective surgery, major life event) n(%)  PWD   1. Tai Chi arm only 2. Control arm only   Carer   1. Tai Chi arm only 2. Control arm only |  |
|  |  |
| 1. **Protocol violations** |  |
| Type and number of violations |  |

1 List of assumptions regarding falls rate, dispersion and intra-cluster correlation coefficient used in sample size calculation

**Table 6: Willingness to pay for Tai Chi**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Overall** | **Tai Chi arm only** | **Control arm only** |
| Willing to pay for Tai Chi classes for 5 months  Yes n(%)  Median (IQR) amount willing to pay (£) |  |  |  |
| Willing to pay for own transport costs  Yes n(%) |  |  |  |
| Willing to pay for tai-Chi instructor home visit  Yes n(%)  Median (IQR) amount willing to pay (£) |  |  |  |
| Willing to pay for Tai Chi classes for 5 months if reduced falls by 20%  Yes n(%)  Median (IQR) amount willing to pay (£) |  |  |  |
| Willing to pay for own transport costs if reduced falls by 20%  Yes n(%) |  |  |  |
| Willing to pay for tai-Chi instructor home visit if reduced falls by 20%  Yes n(%)  Median (IQR) amount willing to pay (£) |  |  |  |

**Supplementary and other tables**

**Table A1 – Long term health conditions at baseline (ranked by most frequent)**

|  |  |  |
| --- | --- | --- |
|  | Usual care (n=??) | Tai Chi + usual care (n=??) |
| Condition 1 n (%)  Yes |  |  |
| Condition 2 n (%)  Yes |  |  |

**Table A2 – Tai Chi history, confidence and intentions**

(To be completed separately from main trial analysis)

|  |  |  |
| --- | --- | --- |
|  | Usual care (n=??) | Tai Chi + usual care (n=??) |
| Person with dementia |  |  |
|  |  |  |
| Ever done Tai Chi before n (%)  No  Yes |  |  |
| Confidence in doing Tai Chi 20 mins per day Mean (SD) |  |  |
| Intend to do Tai Chi 20 mins per day Mean (SD) |  |  |
| Carer |  |  |
|  |  |  |
| Ever done Tai Chi before n (%)  No  Yes |  |  |
| Confidence in doing Tai Chi 20 mins per day Mean (SD) |  |  |
| Intend to do Tai Chi 20 mins per day Mean (SD) |  |  |

**Table A3: Mid-study questionnaire for Tai Chi group**

(To be completed separately from main trial analysis)

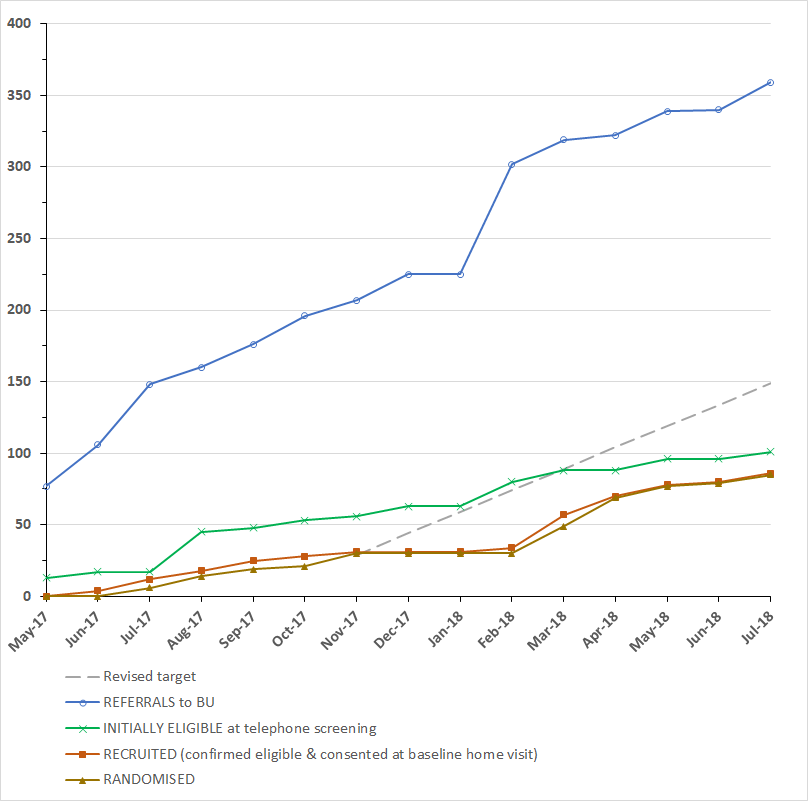
|  |  |  |
| --- | --- | --- |
|  | Mean (SD) | N (%) agreeing with statement (scores 1 to 3) |
| I enjoy coming to Tai-Chi classes |  |  |
| I am confident I can take part in classes for the next 10 weeks, if I want to |  |  |
| I intend to come to Tai-Chi classes for the next 10 weeks |  |  |
| Handing home exercise log to Tai Chi instructor motivates me |  |  |
| I use the alarm clock to remind me to exercise |  |  |

**Figure 1: CONSORT Flow Diagram**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Referred to BU team (n=359)**  *x% of those interested* | | |  |  |
|  |  |  |  |  | **Could not be contacted for assessment of initial eligibility (n=37)** |
|  |  |  |  |  |
|  | **Assessed for initial eligibility (n=307)**  *86% of those interested* | | |  |  |
|  |  |  |  |  | **Declined (n=119**  **"**Not our thing", “not for us at the moment” **n=32**  Lack of time, not wanting to be tied/commit **n=17**  PWD is in ill health **n=12**  Not interested / No further reason provided **n=10**  Carer does not see the PLWD doing/performing Tai Chi exercise **n=6**  Currently participating in exercise class (incl. Tai Chi) **n=6**  Currently taking part in another trial **n=5**  Do not think this type of exercise is helpful/appropriate **n=5**  PWD refused home visit/cognitive assessment/diagnosis **n=5**  PWD unwilling to get involved in physical exercise **n=4**  Unwilling to take part in trials / risk being in the control group **n=4**  Not of interest for PWD & far from venue **n=3**  PWD lost confidence/avoids socialization **n=3**  Carer not able to check if PWD is happy to participate **n=2**  Not willing to travel to the closest venue **n=2**  PWD is asleep a good part of the day **n=2**  Carer unaware that consent to contact was sent to researcher **n=1**  In process of moving home **n=1**  **Ineligible at screening (n=94)**  No carer available for study **n=30**  Unable to travel to the closest venue on a regular basis **n=15**  Unable to attend the classes on the day/time suggested **n=14**  No confirmed diagnosis of dementia **n=7**  Unable to do standing Tai Chi (incl. wheelchair- bound) **n=6**  PWD has Parkinson's disease/Lewy Body disease **n=4**  Living in a care home (permanent care) **n=3**  Severe dementia symptoms **n=3**  Severe sensory impairment **n=2**  PWD lacks capacity to give informed consent **n=1**  PWD aged under 65 **n=1** |
|  |  |  |
|  | **Initially eligible & willing (n=94)**  *28% of those assessed for initial eligibility* | | |  |  |
|  |  |  |  |  | **Ineligible at home visit (n=8)**  M-ACE <10 n=4  PWD not willing to take part at home-visit **n=2**  Lack mental capacity to consent **n=1**  PLWD <65 years old **n=1** |
|  |  |  |
|  | **Recruited (n=86)**  **(i.e. eligibility confirmed, consented, provided baseline data)**  *91% of those initially eligible* | | |  |  |
|  |  |  |  |  | **Dyad withdrawn prior to randomisation (n=1)**   * No other dyads recruited to the class cohort **n=1** |
|  |  |  |  |  |
|  | **Randomised (n=85)**  *99% of consented dyads*  **Tai-Chi + usual care (n= )**  **Usual care (n= )** | | |  |  |
|  |  |  |  |  | **Lost to follow-up (n=)**   * PWD & carer no longer interested in study **n=** * PWD & carer have worsening physical health **n=** * PWD has worsening physical health thus carer withdrew **n=** * PWD no longer interested in study thus carer withdrew **n=** * PWD not enjoying Tai Chi, carer found study burdensome **n=** |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  | **Early discontinuation of intervention (n=)**   * Carer clash with other commitment thus PWD withdrew **n=** * Carer found study burdensome thus PWD withdrew **n=** * Carer has other health problem, thus PWD withdrew **n=** * Misc **n=** * PWD & carer are not enjoying Tai Chi **n=** * PWD & carer have worsening physical health **n=** |
|  |  |  |  |  |
|  | **Analysed with primary outcome (n=)**  **Tai Chi + Usual care (n= )**  **Usual care (n= )** | | |  |  |
|  |  |  |  |  |  |
|  |  | | |  |  |

Figures acquired at end of recruitment

Figure 2. Recruitment by month



Appendix

**ICECAP-O: Calculation of Tariffs**

This code, when substituted into a Stata do file, will allow calculation of ICECAP-O tariffs for each respondent in a study, based on their answers to the five classification questions. Statistical analyses can then be conducted on these tariffs. Indeed they can be conducted on the five index values also, to ascertain sensitivity of these to differences in factors

Data should be set up with one study participant per row. As specified on the ICECAP-O questionnaire, coding should be such that the 'top' level (full capability for an attribute) should take the value '4', down to the bottom level (no capability) which should take the value '1'. NB this coding is the opposite of that used in instruments such as the EQ-5D (where 1 is top level). The five variables, containing a respondent's five ICECAP-O responses should be named attachment, security, role, enjoyment, control. Use of this coding means that any ICECAP-O state can be represented by its coding. Thus '44444' represents the state described by full capability on all 5 attributes. 44144 represents the state described by no capability on the role attribute, but full capability on attachment, security, enjoyment and control.

matrix UTILS=(-0.0128, 0.1340,0.2325,0.2535\/\*

\*/0.0321,0.0661,0.1071,0.1788\/\*

\*/0.0151, 0.1296, 0.1793, 0.1923\/\*

\*/0.0168, 0.1185, 0.1643, 0.1660\ /\*

\*/ -0.0512, 0.1076, 0.1848, 0.2094)

gen att\_index=UTILS[1,attachment[\_n]]

gen sec\_index=UTILS[2,security[\_n]]

gen rol\_index=UTILS[3,role[\_n]]

gen enj\_index=UTILS[4,enjoyment[\_n]]

gen con\_index=UTILS[5,control[\_n]]

gen tariff=att\_index+sec\_index+rol\_index+enj\_index+con\_index

SPSS Syntax

\* ICECAP-O syntax

\*recoding

\* (replace ICECAPO1\_E1\_C8, ICECAPO2\_E1\_C8 etc. with the variable name of your database)

COMPUTE xICECAPO\_1 = ICECAPO1\_E1\_C8.

COMPUTE xICECAPO\_2 = ICECAPO2\_E1\_C8.

COMPUTE xICECAPO\_3 = ICECAPO3\_E1\_C8.

COMPUTE xICECAPO\_4 = ICECAPO4\_E1\_C8.

COMPUTE xICECAPO\_5 = ICECAPO5\_E1\_C8.

Execute.

\* recode capability values

RECODE xICECAPO\_1 (1=-0.0128) (2=0.1340) (3=0.2325) (4=0.2535).

RECODE xICECAPO\_2 (1=0.0321) (2=0.0661) (3=0.1071) (4=0.1788).

RECODE xICECAPO\_3 (1=0.0151) (2=0.1296) (3=0.1793) (4=0.1923).

RECODE xICECAPO\_4 (1=0.0168) (2=0.1185) (3=0.1643) (4=0.1660).

RECODE xICECAPO\_5 (1=-0.0512) (2=0.1076) (3=0.1848) (4=0.2094).

Execute.

\* Calculate tarrifs

COMPUTE ICECAPO\_tarrifs = xICECAPO\_1+xICECAPO\_2+xICECAPO\_3+xICECAPO\_4+xICECAPO\_5.

Execute.

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