

## Original Article

# Evaluation of strategies to recruit and retain older people with dementia and their informal carers into a Tai Chi Trial to improve balance and prevent falls

Michelle Heward<sup>1,2</sup>, Layla Johnson<sup>3</sup>, Samuel R. Nyman<sup>4</sup><sup>1</sup>Ageing and Dementia Research Centre, Bournemouth University, UK;<sup>2</sup>Department of Rehabilitation and Sport Science, Bournemouth University, UK;<sup>3</sup>Department of Psychology, Bournemouth University, UK;<sup>4</sup>Bournemouth University Clinical Research Unit, Department of Medical Science and Public Health, Bournemouth University, UK

## Abstract

**Objectives:** Randomised control trials (trials) involving people with dementia lack detailed analysis of recruitment and retention strategies. To address this, we examined the effectiveness of strategies in “The TACIT Trial: Tai Chi for people with dementia”. **Methods:** We recruited dyads (people with dementia and carers) from 3 South of England sites utilising different strategies. Recruitment strategy effectiveness was measured by percent yield (number randomised of total referrals) and cost per randomised participant. Our retention strategy (maintaining contact with participants during weekly telephone calls) was measured by percent yield (number retained by six-month follow-up). **Results:** Of 359 dyads, 24% were randomised into the study (n=85). The most resource-intensive strategy (research nurses spending 30 minutes explaining the study) had the highest referral to randomisation rate. An incremental cost-effectiveness ratio suggested an alternative approach (nurses and doctors spending 5 minutes explaining the study) was most cost-effective. Retention rates were 86% (n=36/42; intervention group) and 81% (35/43; control group); main reasons for attrition were worsening health and lack of study interest. **Conclusions:** The results demonstrate person-centred strategies enabling staff to spend time with participants were effective in supporting recruitment and retention. Those designing future trials must consider such strategies and the associated costs.

**Keywords:** Dementia, Exercise, Falls, Recruitment and retention, Trial

## Introduction

Randomised control trials (henceforth trials) are the gold standard of evidence of effectiveness of clinical interventions and treatments. The evidence base of research on recruitment and retention to trials is developing<sup>1</sup>. Yet existing research is narrow in focus and there remains a need for researchers to evaluate recruitment and retention strategies to improve the evidence base and enable others to overcome these challenges<sup>1,2</sup>. Recruitment and retention of participants into trials can be problematic. Many studies report difficulties in recruiting adequate participants within the planned timeframe and in minimising attrition prior to final follow-up, both of which reduce statistical power<sup>1-4</sup>. Furthermore, detailed information on retention is not always reported. In a review of recruitment and retention

of participants to trials in six major journals, Toerien et al<sup>3</sup> noted that it was difficult to assess best practice as details were not reported well. Historically, the trend in trials research has been to report on what happens to the

*The authors have no conflict of interest.*

**Corresponding author:** Dr Michelle Heward, Ageing and Dementia Research Centre, Bournemouth University, BGB 507, 5th Floor Bournemouth Gateway Building, St. Pauls Lane, Bournemouth, BH8 8GP, UK

**ORCID ID:** 0000-0002-4492-3726

**E-mail:** mheward@bournemouth.ac.uk

**Edited by:** George Lyrītis

**Accepted** 14 July 2021

participants that complete the trial<sup>3</sup>. This leaves a paucity of studies evaluating vital information about the successes and failures of the recruitment and retention strategies utilised<sup>5</sup>.

### ***Challenges of recruitment and retention in clinical research***

A recent systematic review<sup>6</sup> focused on older people in clinical research identified barriers and facilitators to recruitment and retention in trials, based on 50 studies. Barriers were: (i) increased prevalence of age-related health problems; (ii) loss and lack of interest; (iii) death; (iv) perceptions of no benefit or relevance of interventions (v) distrust in research; (vi) families or physicians advising against participation; and (vii) lack of transportation. Conversely, facilitators included: (i) financial incentives; (ii) low staff turnover and flexible team; (iii) staff appreciation expressed to study participants through gifts, cards and letters; (iv) regularly informing participants on progress of study; and (v) provision of transportation. Notably, being able to adapt recruitment methods and having flexibility in appointment times had a positive impact on recruitment and retention<sup>6</sup>. A review of the 99 single and multifactorial trials included in the Cochrane systematic review of falls prevention interventions<sup>7</sup> suggested that on average 7 in every 10 community-dwelling older people are likely to accept the invitation to participate in falls prevention interventions; non-response, refusal and exclusion were 1 in 5 each; and by 12 months attrition was 9-11 percent with mortality included. To improve retention, Jancey et al<sup>8</sup> suggests that trials should undertake early assessments of characteristics to identify and support those at risk of attrition, which they defined as: those of lower socioeconomic status, overweight and less physically active, and lower walking self-efficacy scores and higher loneliness scores.

Recruiting people with long-term health conditions into exercise trials is a challenge<sup>9</sup>. A recent systematic review and meta analysis<sup>10</sup> focused on adherence to exercise interventions in older people with dementia and mild cognitive impairment (MCI), based on 41 studies (34 dementia (n=2149) and seven MCI (n=970)). The review found a lack of consistency of reporting adherence, attrition, and adverse events. Di Lorito et al<sup>10</sup> called for further research using more reliable measures to identify the factors or strategies that mediate adherence and attrition in these populations.

### ***Importance of a flexible recruitment and retention approach***

Exercise-based interventions are effective for preventing falls<sup>11</sup>. However, Burton et al<sup>12</sup> and Nyman et al<sup>13</sup> identified only five fall prevention exercise studies conducted with community-dwelling older people with dementia (three trials, one pilot trial, and one pre- and post-study respectively: Pitkala et al<sup>14</sup>; Suttanon et al<sup>15</sup>;

Wesson et al<sup>16</sup>; Yao et al<sup>17</sup>; and Mackintosh & Sheppard<sup>18</sup>. These studies suggest that recruitment and retention of people with dementia is more challenging than recruiting older people from the general population. Due to the progressive nature of dementia, people with the condition may rely on an informal carer to support activities of daily living. As such, there may be a need to recruit both a person with dementia and carer into exercise trials, together as a dyad. This presents further challenges associated with needing the consent and willingness of both the person with dementia and the carer. Retention may also be hindered by both individuals' circumstances, such as commitment, health (including impaired health, moving to residential care or death), availability, and willingness to participate in the research study. Illness and death are unavoidable adverse events that impact on all clinical trials, although are heightened in trials involving older people and people with dementia. Flexible strategies that support recruitment and retention are recommended, such as catch up sessions or participants being able to skip some sessions in the programme if they are unwell, and provided transport to enable attendance<sup>14,17,18</sup>.

### ***Rationale***

Existing falls prevention exercise studies involving community-dwelling people with dementia lack consistency in terms of the recruitment and retention data reported<sup>14,17,18</sup>. Notably, adverse events and incentives to participation were poorly reported. Reporting single recruitment and retention figures at the end of the study was most common (with the exception of Yao et al<sup>17</sup> whom also reported prior to commencement of the home-based). This lack of consistency in terms of reporting makes it difficult to make comparisons between studies and hampers the future development of effective exercise trials involving people with dementia. Providing detailed recruitment and retention figures could give more insight into associated barriers and facilitators and aid future trials.

### ***Aim and objectives***

The aim of this paper is to examine the recruitment and retention data from The TAI ChI for people with dementia (TACIT) trial<sup>13</sup> to identify effective recruitment and retention strategies. The objectives were to:

1. Evaluate the success of the TAI ChI for people with dementia (TACIT) trial recruitment and retention strategies.
2. Determine the cost-effectiveness of the TAI ChI for people with dementia (TACIT) trial recruitment and retention strategies.

Sharing detailed evaluation of recruitment and retention strategies supports the future development of exercise trials with people with dementia and enables wider inferences between falls prevention trials to be drawn.

## Methods

### *Trial design*

The TACIT trial was a randomised, assessor-blind, two-arm, parallel group, superiority trial, which compared the effectiveness of Tai Chi alongside usual care, with usual care alone, on postural balance of community-dwelling people with dementia (ClinicalTrials.gov identifier: NCT02864056)<sup>13</sup>. People with dementia were required to participate in the study with an informal carer as a dyad. Each participant was required to provide informed consent. It was intended to recruit 150 dyads to randomise into either the control group (n=75) or intervention group (n=75). The Tai Chi intervention involved attending weekly Tai Chi Classes over 20 weeks and Tai Chi at home for 20 mins per day. Dyad adherence and experience of the intervention was explored during a pilot intervention phase in which 14 dyads received a Tai Chi intervention for 4 weeks. Lessons learnt from the pilot phase shaped the trial<sup>19</sup>. This study was reviewed and approved by the National Health Service (NHS) West of Scotland Research Ethics Committee 4 (reference: 16/WS/O139) and the Health Research Authority (IRAS project ID: 209193). A summary of the protocol is available with details to access the full protocol and dataset<sup>20</sup>.

### *Eligibility criteria*

People with dementia were included if they were: aged 18 or above, living at home, had a diagnosis of dementia (indicated on their medical record held by the National Health Service or general practitioner), physically able to independently stand to do Tai Chi, and willing to attend weekly Tai Chi classes. Individuals with dementia were excluded if they were: living in a care home, in receipt of palliative care, had severe dementia (baseline M-ACE score of  $\leq 9$ )<sup>21</sup>, had a Lewy body dementia or dementia with Parkinson's disease, had severe sensory impairment (e.g. blind or deaf to preclude participation in Tai Chi classes), were currently practising or had been practising within the past six months Tai Chi or similar exercise (Qi Gong, yoga, or Pilates) on average once a week or more, were currently under the care of or had been referred to a falls clinic for assessment, currently attending a balance exercise programme (e.g. Otago classes), or lacked mental capacity to provide informed consent. Informal carers were included if they were: living with the person with dementia or could visit at least twice per week, were able to support the person with dementia by participating in data collection throughout the trial and in the intervention components (if randomised), able to do standing Tai Chi, and willing to attend weekly Tai Chi classes. Carers were excluded if they had severe sensory impairment or lacked mental capacity to provide informed consent.

### *Participant recruitment*

Recruitment for the trial took place between 6<sup>th</sup> April 2017 and 17<sup>th</sup> July 2018, this included a six-month

extension period to increase participant numbers as recruitment was slower than originally expected. To further support recruitment the following amendments were also made to the protocol: reduced the eligibility criteria to a minimum age of 18 years and minimum Mini Addenbrooke's Cognitive Examination (M-ACE) score of 10, reimbursed participants for their travel to classes (intervention group only), and incentivised continued participation to the final follow-up with £50 to purchase Tai Chi lessons after the study had ended (control group only). Participants were identified and referred through recruitment sites in three localities in the South of England. Census<sup>22</sup> data shows that in 2011, locality 1 had an urban and suburban population of 253,651, locality 2 had an urban, suburban, and rural population of 744,041, and locality 3 had an urban and suburban population of 205,100. Staff at each locality were provided with training from the chief investigator who visited for a site initiation visit. The Chief Investigator trained all staff face-to-face in a group session and conducted telephone calls to train other staff unable to attend.

### *Recruitment strategies utilised in each locality*

In each locality, a mix of active recruitment strategies (referrals/participant registries/targeted mailings) and passive recruitment strategies (media/support group talks/posters) were utilised. The five different recruitment strategies used across the three localities were: National Health Service (NHS) Trusts; General Practitioner Participant Identification Centre targeted mail out; Join Dementia Research database; Memory Support and Advisory Service database; and a public relations campaign (Table 1). Across all 3 localities staff working in each NHS Trust used the NHS research/clinic database to identify eligible patients to approach about the study, those interested in taking part/finding out more information were then referred to the research team who contacted them by telephone, although each Locality had a different approach (as outlined below).

General Practitioner Participant Identification Centres (GP PICs) supported recruitment across all three localities. Initially this recruitment was opportunistic in that patients would be made aware of the study when they attended appointments at the GP surgery, however low recruitment figures using this approach meant that it was later changed and GP PICs were enlisted to undertake a targeted mail out instead (between 26/01/2018 – 08/03/2018). This involved writing to all patients with dementia who meet the inclusion criteria. Staff at each GP PIC searched the patient database to identify those who met the eligibility criteria. They then sent those who met the eligibility criteria a letter with information about the study. Those interested in taking part/finding out more information then contacted the research team directly (self-referral).

A public relations campaign about the study was undertaken to increase the number of self-referrals. From February – June 2017, we visited local informal voluntary-

Recruitment strategy	Description	Locality utilised		
		1	2	3
National Health Service Trusts	<ul style="list-style-type: none"> <li>Eligible patients identified from National Health Service research/clinic database and approached by NHS Trust staff about the project, those interested then referred to the research team who contacted them by telephone.</li> </ul>	✓ NHS Trust database	✓ Clinicians	✓ Research and Development staff
General Practitioner Participant Identification Centre targeted mail out	<ul style="list-style-type: none"> <li>GP PIC<sup>1</sup> staff searched the patient database to identify those who met the eligibility criteria and sent them a letter with information about the study. Those interested then contacted the research team directly (self-referral).</li> </ul>	✓	✓	✓
Join Dementia Research database	<ul style="list-style-type: none"> <li>NHS/Research team staff periodically searched the research database, identified patients who met the eligibility criteria and contacted them about the study, those interested were referred to the research team who contacted them by telephone</li> </ul>	✓ NHS Trust staff identified, contacted, and referred potential participants.	✓ Research team initially identified, contacted, and referred potential participants and were later supported by NHS Trust staff.	✓ NHS Trust staff identified, contacted, and referred potential participants.
Memory Support and Advisory Service (MSAS) database	<ul style="list-style-type: none"> <li>MSAS staff periodically searched the clinic database, identified eligible patients and contacted them about the study, those interested were referred to the research team who contacted them by telephone</li> </ul>		✓	
Public relations campaign	<ul style="list-style-type: none"> <li>Activities to increase self-referrals:               <ul style="list-style-type: none"> <li>Research Talks at support groups</li> <li>Radio and television interviews</li> <li>Social media (dedicated study Facebook page)</li> <li>Posters and flyers distributed in the NHS Trusts and GP Surgeries.</li> </ul> </li> </ul>	✓	✓	✓

<sup>1</sup>GP PIC; General Practitioner Patient Identification Centre.

**Table 1.** Recruitment strategies utilised per locality.

sector organised groups mainly in locality 2 (e.g. Singing for the Brain, Memory Café). In locality 1 the research team visited 3 groups and talked to 21 people; in locality 2 this was 14 groups and 217 people; and locality 3 this was 1 group and 1 person. A live local BBC radio interview was conducted in July of 2017 and a recorded feature on local BBC television in February 2018, the latter was also posted on Facebook. The Join Dementia Research database was accessed in all three localities: in localities 1 and 3 NHS Trust staff identified, contacted and referred potential participants; whilst in locality 2 this was initially undertaken by members of the research team and later supported by NHS Trust staff. In locality 2 the Memory Support and Advisory Service also identified, contacted, and referred potential participants.

### **Recruitment approach utilised by NHS Trusts**

Across all three localities NHS Trust staff accessed the NHS research/clinic databases to identify patients that met the study eligibility criteria and inform them of the study, however the approach used in each locality was different (Table 1). In locality 1, NHS Trust staff approached by phone and posted further information for approximately 5 minutes. NHS Trust staff identified eligible patients mainly through participant registries. Research and Development (R&D) staff would regularly search the NHS Trust and Join Dementia Research database to identify eligible patients and then approach them about the study by telephone, following up with further information sent

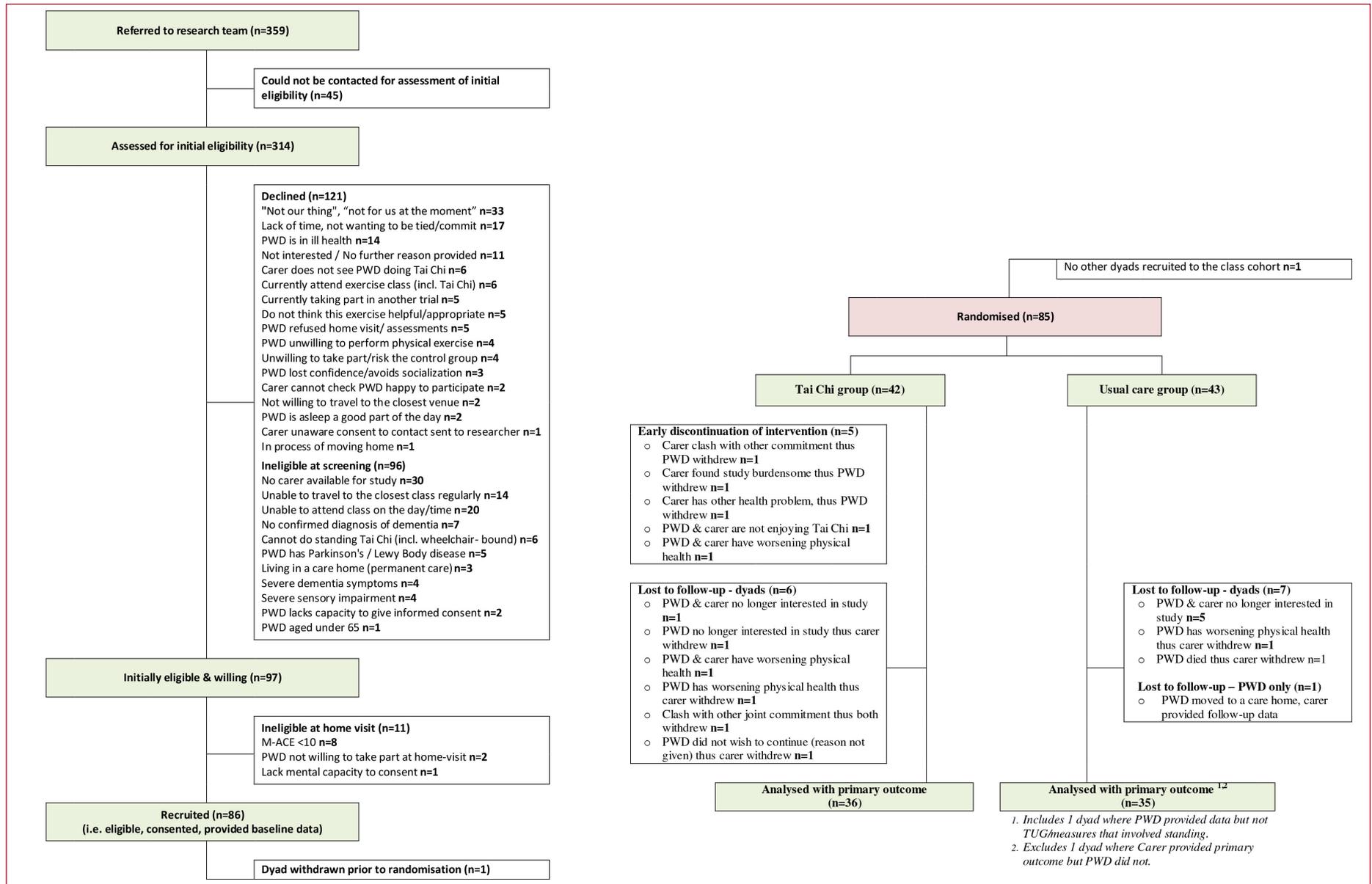


Figure 1. The TACIT Trial CONSORT flow diagram in full. Source: First published as supplementary material with the main trial outcome paper in *Clinical Interventions in Aging*<sup>13</sup>.

in the post for them to read, this took approximately five minutes per potential participant. R&D staff at this NHS Trust maintain these databases and frequently add new patients to them. Additional activity included R&D staff leaving posters and flyers at memory clinics (who recruit into the database) and attending some memory support courses to talk about the study.

In locality 2, nurses and doctors approached at end of routine clinics and review appointments at 3 and 12 months for approximately 5 minutes. Nurses and doctors approached eligible patients at end of routine clinics and review appointments at 3 and 12 months, which took about five minutes per potential participant. This did not include those patients who had just been diagnosed with dementia. Identifying patients through the Join Dementia Research database was undertaken by the research team in this locality, however R&D staff from the NHS Trust did support by contacting some of these patients about the study and completing some paperwork.

In locality 3, research nurses approached at 6-month review or at a later home visit explaining study for approximately 30 minutes. Research nurses approached eligible patients at their 6-month review meeting, once the clinician had introduced them to say they were interested to find out more about the study. The R&D staff would then spend approximately 30 minutes explaining the study to them there and then, or at a later home visit if they were short of time. Eligible patients on the NHS Trust and Join Dementia Research database in the locality were also contacted by letter to inform them of the study.

### **Screening and randomisation**

Potential participants were either referred by a professional or self-referred by leaving a message on the trial telephone answerphone. Once a referral was received a member of the research team telephoned to check eligibility. The research team then visited eligible dyads in their home. At the home visit, the research team took informed consent, administered the M-ACE to confirm eligibility<sup>21</sup>, and answered any further questions about the study. Randomisation was processed via a centralised web-based randomisation system designed and maintained by the UKCRC-registered Peninsula Clinical Trials Unit. After completion of the home visit, a member of the trials unit randomised dyads and wrote to them to advise their treatment allocation.

### **Retention strategies**

During the trial the research team telephoned each dyad weekly to collect data on falls<sup>23</sup>. The intention was for the research team to collect this information from the person with dementia, however in some instances carers wanted to provide this information instead. The research team completed 1058 weekly calls with people with dementia and 742 weekly calls with carers<sup>23</sup>. Keeping close contact with participants had a secondary objective to support retention

and enabled the research team to remind dyads about classes, boost morale and avoid drop out. The intervention group were kept up to date with class start dates and/or reminded to still attend the classes if they had missed any. The control group were regularly reminded that their role in the trial was as important as those in the intervention group.

### **Data collection and statistical analysis**

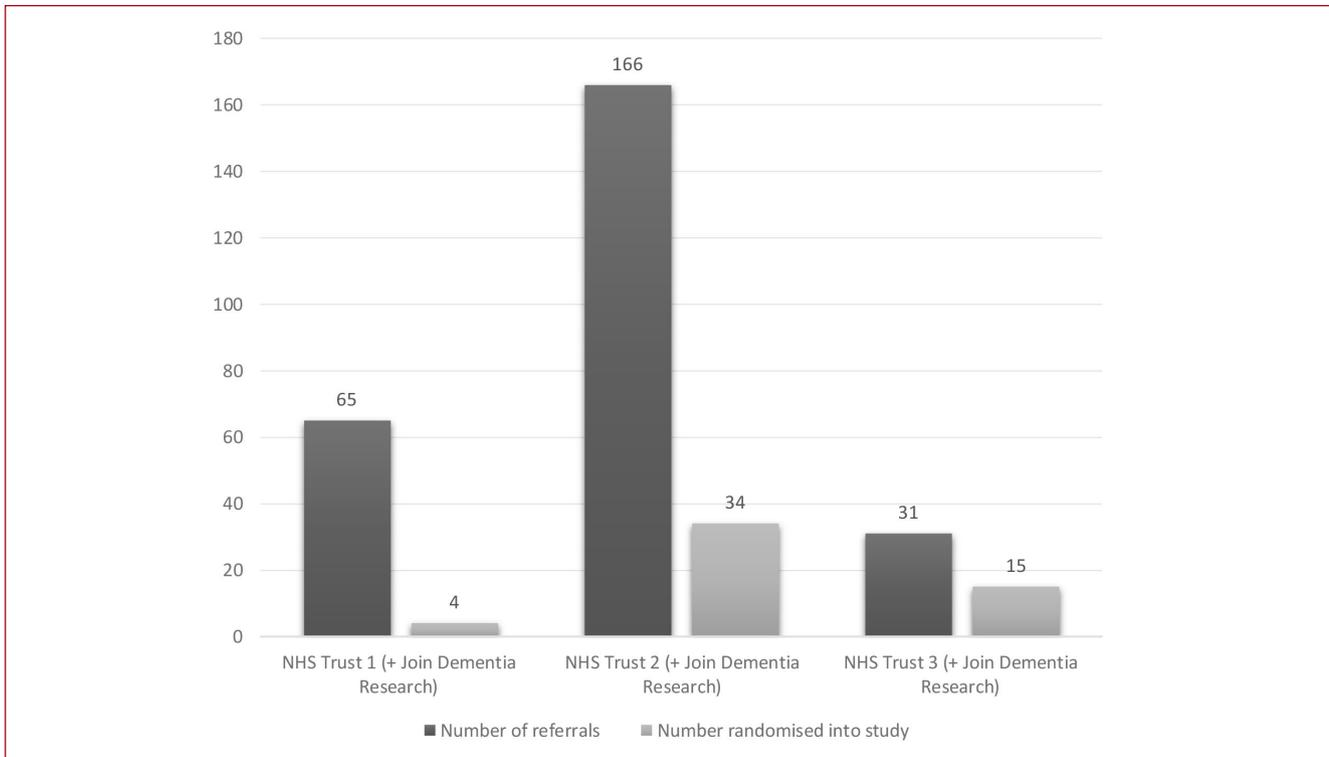
A participant database recording the flow of referrals through to randomisation including reasons for ineligibility and declining participation was kept in Microsoft Excel by the research team. Effectiveness of recruitment and retention strategy was measured by percent eligible at each stage of recruitment and percent yield (number of participants randomised as a proportion of total number of referrals). Cost-effectiveness of recruitment strategies was estimated as cost per consented participant based on estimates of time spent on recruitment activity. Cost-effectiveness analysis was undertaken to compare recruitment strategies, using incremental cost-effectiveness ratios<sup>24</sup> to compare the difference in cost (incremental cost) with difference in outcomes (incremental effectiveness) and dividing the former by the latter to estimate the cost per consented participant. NHS Staff costings were taken from the Schedule of Events Cost Attrition Template<sup>25</sup>. Only costs related to referral to the research team were included as the strategy for recruitment thereafter was the same across localities and so uninformative. Cost-effectiveness of our retention strategy was estimated as cost per dyad randomised into the study based on estimates of the time spent by the researcher on the weekly telephone calls. Descriptive statistics present the recruitment flow from referral to randomisation.

## **Results**

A total of 359 dyads were referred to the trial research team, of which 24% (n=85) were enrolled into the study (Figure 1). After being consented and recruited one dyad had to be withdrawn before being randomised because no other dyads were recruited to their class cohort. In this paper we report on the data from the 85 dyads randomised into the study. The mean age of people with dementia was 78 (range 59-97), the majority of whom were male (60%, n=51) and had a diagnosis of Alzheimer's Disease (66%, n=56), Alzheimer's Disease and Vascular dementia (18%, n=15) or Vascular dementia (7%, n=6). The mean age of carers was 71 (range 43-89), the majority of whom were female (79%, n=67) and living with the person with dementia (87%, n=74). Carers were a spouse or partner (79%, n=67), an adult child (9%, n=8) or a sibling (7%, n=6) of the person with dementia. Detailed demographic characteristics are reported elsewhere<sup>13</sup>.

### **Overall recruitment strategies**

The number of referrals received from the three localities varied. Most referrals were received from locality



**Figure 2.** Frequencies of recruitment per NHS Trust (referral to randomisation).

2 (64%, n=230); although locality 3 had a higher referral to randomisation conversion rate (47%) (Table 2). Each of the five recruitment strategies had varying success rates. Referrals from NHS Trusts made up 54% (n=195); NHS Trust 2 referred the most (28%, n=99) although NHS Trust 3 had a higher conversion rate (48%). Four hundred and fifty-three invitation letters were sent by 9 GP PICs (range 12-90 letters sent per GP PIC). Referrals from GP PICs made up 10% (n=37) of the total referrals received; 12 were randomised (range 0-8 per GP PIC) into the study, with a conversion rate of 32% (range 0.0 - 43% per GP PIC). In locality 2, Join Dementia Research database referrals (n=67) equated to 18% of the total referrals received and 6 were randomised into the study making a conversion rate of 9%. Due to the way that the data was reported to the research team it was not possible to split Join Dementia Research database referrals from the NHS Trust referrals in localities 1 and 3. Referrals from the Memory Support and Advisory Service database made up 1% (n=3) of the total referrals received, and 2 were randomised in to the study with a conversion rate of 67%. Referrals from the public relations campaign made up 15% (n=54) of the total number of referrals received, of which 17 were randomised into the study making a conversion rate of 13%. Most of these came from locality 2 (12%, n=43), although locality 3 had a higher conversion rate (50%).

### ***Different recruitment approaches in each NHS Trust***

The recruitment approaches utilised in each NHS Trust had differing success rates. NHS Trust 1 referred 18% (n=65) of the total referrals received but with the lowest conversion rate of 6% (Figure 2). NHS Trust 2 had the highest referral rate, referring 28% (n=99) of the total referrals, with a conversion rate of 28%. NHS Trusts 3 had the lowest trust referral rate, referring 9% (n=31) of the total referrals, but had the highest conversion rate of 48%. The face-to-face recruitment approaches used in NHS Trust 2 and 3 had a higher conversion rate than the database approach used in NHS Trust 1. While the highest number of consenting dyads came from NHS Trust 2 (n=34), we evaluated recruitment based on rate of consented dyads rather than number to identify the most efficient strategy. The highest number of referrals to consenting participants came from NHS Trust 3, this approach was the most resource intensive as NHS staff spent 30 minutes with each patient and carer dyad talking to them about the study.

### ***Estimated cost for each NHS Trust for time spent on recruitment activity***

Given that the recruitment approaches used in NHS Trust 2 and 3 had the highest conversion rates, cost effectiveness of these approaches were compared. NHS Trust 2 referred

Locality	1			2					3			Not specified	Total
Source of recruitment	NHS Trust 1 (+ Join Dementia Research)	GP PIC <sup>1</sup>	Publicity / Self-referral	NHS Trust <sup>2</sup>	Join dementia research	Memory Support and Advisory Service	GP PIC <sup>1</sup>	Publicity / Self-referral	NHS Trust 3 (+ Join Dementia Research)	GP PIC <sup>1</sup>	Publicity / Self-referral	Other	
Number of referrals (%)	65 (18.1)	11 (3.1)	5 (1.4)	99 (27.6)	67 (18.7)	3 (0.8)	18 (5)	43 (12)	31 (8.6)	8 (2.2)	6 (1.7)	3 (0.8)	<b>359 (100)</b>
Number could not be contacted for assessment of initial eligibility (%)	8 (17.8)	2 (4.4)	1 (2.2)	12 (26.7)	14 (31.1)	1 (2.2)	1 (2.2)	3 (6.7)	2 (4.4)	0 (0)	0 (0)	1 (2.2)	<b>45 (100)</b>
Number assessed for initial eligibility (%)	57 (18.2)	9 (2.9)	4 (1.3)	87 (27.7)	53 (16.9)	2 (0.6)	17 (5.4)	40 (12.7)	29 (9.2)	8 (2.5)	6 (1.9)	2 (0.6)	<b>314 (100)</b>
Number ineligible at screening or declined (%)	51 (23.5)	6 (2.8)	3 (1.4)	58 (26.7)	46 (21.2)	0 (0)	8 (3.7)	22 (10.1)	13 (6)	6 (2.8)	3 (1.4)	1 (0.5)	<b>217 (100)</b>
Number initially eligible and willing (%)	6 (6.2)	3 (3.1)	1 (1)	29 (29.9)	7 (7.2)	2 (2.1)	9 (9.3)	18 (18.6)	16 (16.5)	2 (2.1)	3 (3.1)	1 (1)	<b>97 (100)</b>
Number ineligible at home visit (5)	2 (22.2)	1 (11.1)	1 (11.1)	1 (11.1)	1 (11.1)	0 (0)	0 (0)	3 (33.3)	0 (0)	0 (0)	0 (0)	0 (0)	<b>9 (100)</b>
Number not willing to take part - at home visit (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	<b>2 (100)</b>
Number consented and recruited (%)	4 (4.7)	2 (2.3)	0 (0)	28 (32.6)	6 (7)	2 (2.3)	8 (9.3)	14 (16.3)	16 (18.6)	2 (2.3)	3 (3.5)	1 (1.2)	<b>86 (100)</b>
Number withdrew before randomisation (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	<b>1 (100)</b>
Number randomised into study (%)	4 (4.7)	2 (2.4)	0 (0)	28 (32.9)	6 (7.1)	2 (2.4)	8 (9.4)	14 (16.5)	15 (17.6)	2 (2.4)	3 (3.5)	1 (1.2)	<b>85 (100)</b>
Conversion rates <sup>2</sup> %	6.1	18.2	0	28.3	9	66.7	44.4	32.6	48.3	25	50	33.3	<b>n/a</b>

<sup>1</sup>General Practitioner Participant Identification Centre.

<sup>2</sup>Number randomised into study / number of referrals x 100.

**Table 2.** Dyads from referral to randomisation by locality (number and percentage).

99 dyads, with 28 consenting to participate. The approach used by NHS Trust 2 took approximately 5 minutes per consenting participant with a total staff cost of £84, which equated to £3 per consenting participant. NHS Trust 3 referred 31 dyads, with 16 consenting to participate. The approach used by NHS Trust 3 took approximately 30 minutes per consenting participant with a total staff cost of £288, which equated to £18 per consenting participant. The approach used by NHS Trust 2 was therefore £15 cheaper per consented participant than NHS Trust 3.

### **Retention rates and estimated costs**

Of the 85 dyads that were randomised into the trial, 42 were in the intervention group and 43 in the control group (Figure 1). In the intervention group the retention rate was 86% (n=36/42). Six dyads were lost at the 6-month follow up. Five dyads did not withdraw, but discontinued participation in the intervention (agreed to still provide data). Specific reasons for attrition from the intervention group were: clash with other commitments (n=1), worsening or other health problems (n=2), study burdensome or no longer interested (n=2), and unknown (n=1). In the control group the retention rate was 81% (35/43). Seven dyads withdrew at the follow up stage with an additional dyad withdrawing the person with dementia (as they moved to residential care) but not the carer who continued to provide data. Specific reasons for attrition from the control group were: no longer interested in study (n=5), worsening health problems (n=1), and death (n=1). The researcher undertaking the weekly telephone calls was a postgraduate student. They made an estimated 2210 weekly telephone calls (85 dyads x 26 weeks) at an estimated average of 5 minutes per call costing £1,347 (£7.28 per hour x 185 hours). In addition, the £50 incentive for each dyad at the end of the study in the control arm cost £1,800 (36 x £50). This equated to a total cost of £3,147 (£1,347 + £1,800) or £37 per dyad (£3,147 / 85 dyads).

## **Discussion**

The aim of this paper was to examine the data from the TAI CHI for people with dementia (TACIT) trial<sup>13</sup> to identify effective recruitment and retention strategies for exercise trials for people with dementia and informal carers. Many previous trials only report on what happens to participants that complete the study<sup>3</sup>. Knowledge and understanding about recruitment and retention strategies used throughout a trial, as presented in this paper, contributes new evidence that is vital in improving future trial design, participant experience and educating researchers in what works<sup>5,10</sup>. Like many before, this trial did not recruit adequate participants within the planned timeframe<sup>1-4</sup>. The choice to be led by the NHS Trusts in their different abilities to recruit offered greater potential for staff to recruit into the trial. The research team also attempted different strategies for recruitment to exhaust the potential opportunities for reaching the target patient group. The results show that

each of the five recruitment strategies had varying success rates. From referral to randomisation, our most successful recruitment strategy was through NHS Trusts. The highest referral to randomisation rate was NHS Trust 3 (research nurses spending approximately 30 minutes with eligible patients at their 6-month review meeting, once the clinician had introduced them, or if short of time at a later home visit); followed by NHS Trust 2 (nurses and doctors spending approximately five minutes with eligible patients at end of routine clinics and review appointments). While NHS Trust 3 had a higher conversation rate, the cost per consented participant of this more resource-intensive approach was double that of NHS Trust 2. Recruitment is a core part of a research nurse's role and so they may have been more motivated and skilled in their recruitment and have more knowledge of research than nurses and doctors generally. All NHS staff involved in recruitment had the same site visit and materials about the study, yet research nurses may have had more time to read the information. Therefore, the background of research nurses as well as increased time spent with patients may have facilitated their higher conversion rate into the trial.

The largest number of self referrals were from locality 2. This may have been because it was geographically closest to the research team and so they were able to visit more support groups using existing contacts. From referral to randomisation, our least successful recruitment strategy was inviting eligible participants identified through the Join Dementia Research database. We note though that our data may be negatively skewed as it was not possible to determine how many of the NHS Trust referrals in localities 1 and 3 were from the Join Dementia Research database. The recruitment strategy with the lowest number of referrals was inviting eligible participants through the Memory Support and Advisory Service database.

Retention rates were similar in both the intervention and control group and resulting attrition rates were 14% and 19% respectively. Participants were encouraged to attend all Tai Chi classes and home-based sessions. Data collection was however flexible if participants missed a week due to being unwell or other personal reasons<sup>14,17,18</sup>. Telephoning each dyad weekly to collect data and maintain a close connection with participants and provide regular study updates may have been equally beneficial for both intervention and control groups. At an estimated cost of only £37 per dyad, this may be a cost-effective retention strategy for exercise trials involving people with dementia and carers, in addition to being effective in supporting retention of older people in clinical research as previously identified<sup>6</sup>.

### **Effectiveness of recruitment and retention strategies**

The recruitment rate from referral to randomisation for this trial was 24% (n=85/359). Our recruitment rate was higher than other comparable studies (17%, n= 210/1264<sup>14</sup>; 10%, n=19/181<sup>17</sup>). Yet, lower than

previously outlined in reviews focused on (i) strategies to improve recruitment and retention of older adults in trials (3–68% (median 41%, 32 studies)<sup>26</sup> and (ii) fall prevention trials involving community-dwelling older people based on willingness to accept an invitation to participate (64–82%, median=71%, n=78)<sup>7</sup>. This indicates that the recruitment of people with dementia is more challenging than recruiting older people from the general population, which concurs with previous studies<sup>14–18</sup>. One reason for our higher recruitment rates may be our uses of several different recruitment strategies, instead of relying on one approach like a targeted mail out as others have<sup>14,17</sup>. Though, an exercise trial recruiting older adults at high risk of mobility disability<sup>4</sup> has found a targeted mail out through GP's to be a successful approach. Our results show that use of recruitment strategies that support relationship building such as NHS staff spending time, or R&D having more detailed discussions, with potential participants to ensure they understand the requirements of the study and have an opportunity to ask questions could be important when recruiting people with dementia and carers into exercise trials.

In our study, from dyads referred to the study at the screening stage, the main reasons for non-enrolment into the trial were either ineligibility, declining participation, or inability to make contact. After receiving a home visit, few dyads were ineligible, and one dyad had to be withdrawn before randomisation because no other dyads were recruited to the class cohort in their locality. Mackintosh & Sheppard<sup>18</sup> reported fewer older adults being excluded after referral stage although stating similar reasons: ineligibility as they had not adhered to the wider programme the study was part of; and declining participation. Yao et al<sup>17</sup> reported more being excluded after referral stage for the following reasons: not community-dwelling, further than 1 hour drive, time constraints, health deteriorated, phone not working, moved out of town, do not feel up to exercise, not wanting to take part in programme, not interested or doing other exercise, would consider at a later date. It was not possible to draw comparisons with Pitkala et al<sup>14</sup> as this information was not reported.

The retention rates for this study were similar for the intervention group (86% or n=36/42) and control group (81% or 35/43). This falls within the parameters outlined in a previous systematic review<sup>26</sup> focused on strategies to improve recruitment and retention of older adults in trials that suggests retention were wide ranging from 19–95% (median 49%, based on 32 studies). Similar retention rates have been reported in a small pilot study by Yao et al<sup>17</sup> (86% n=19/22) and larger trials over several months by Pitkala et al<sup>14</sup> (77% n=161/210), and a much lower retention rate in a pre- and post-study by Mackintosh & Sheppard<sup>18</sup> (50% n= 32/64). None of these studies specifically outlined their retention strategies or costs so it not possible to assess our study in relation to others. Future

studies should record more detailed retention information to enable comparisons.

A previous review suggests that attrition of older people in falls prevention interventions is on average 9–11 percent<sup>7</sup>. The attrition rate for this study was higher at 16% (n=14/85), and main reasons were: clash with other commitments, worsening or other health problems, study burdensome or no longer interested, not enjoying Tai Chi, and death. This corresponds with the findings of the Forsat et al<sup>6</sup> review. Our attrition rate is like another fall prevention exercise trial (23% or n=49/210<sup>14</sup>), although this was after 12 months. This trial also reported higher rates of participants moving to residential care (n=8) and death (n=17), compared with our study which only reported one death. Mackintosh & Sheppard<sup>18</sup> had a higher attrition rate (50%, n=32/64) and reported higher rates of moving to residential care (n=11) and death (n=7). Yao et al<sup>17</sup> reporting on a smaller cohort of 22 participants, reported lower attrition rates (14%, n=19/22) but with similar reasons for attrition to our study: withdrew, other health problems, lost at follow up. The results of this study and other comparable studies suggests that retention rates of people with dementia in exercise-based fall prevention intervention studies is slightly lower than that of older people from the general population.

### ***Limitations and suggestions for further research***

The main limitations of this study are that it was not always possible to report the data by recruitment strategy for every locality, because of how the data was provided to the research team. The approach taken in some localities meant they used a mixture of strategies and as such reported the statistics together. In addition, we are unable to report on whether word of mouth and snowballing techniques (i.e. sharing information about the study between friends and relatives) also led to self-referrals. The sample size was smaller than originally intended (half the intended sample size) and this may have limited our analysis and increased the risk of bias. The approach we used to evaluate cost-effectiveness used reported averages rather than detailed data from each patient and staff member. Future studies could collect more detailed data on how many patients were approached, the time taken with potential participants, and the specific salaries of staff involved to give more accurate figures. Moreover, detailed data could also be collected about self-referral activities and costs involved, including research team time and specific salaries to include in cost-effectiveness evaluations. Further research reporting on recruitment and retention strategies in exercise and fall prevention trials involving people with dementia, and trials more generally, should consider and identify in the trial design appropriate ways to capture such data consistently. Sharing what works in published articles is beneficial for others designing similar intervention studies.

## **Implications for future exercise or fall prevention trials involving people with dementia**

Key questions to guide the recruitment strategies of health trials with older people have been identified<sup>27</sup>. There is a need for those designing future interventions studies involving people with dementia to consider and identify potential recruitment and retention strategies early in the development process. This could involve drawing on lessons learnt from previous studies, as well as discussing with recruiting organisations, staff and experts by experience (such as Patient and Public Involvement groups) the potential merit of different approaches to identify what might work best for the specific study. Consideration should be given to approaches that enable those who are recruiting participants with dementia and carers appropriate time to build rapport and engage trust<sup>4</sup>. Once refined those involved may also wish to test the chosen strategies in pilot phases of studies to work out the cost and ensure they are cost-effective. Our data also suggests that while retention and attrition may not be more challenging with people with dementia, recruitment may be lower in dementia trials than in the general older adult population.

## **Conclusions**

This paper demonstrates the need for those involved in exercise trials with people with dementia and carers to adopt relationship-based recruitment and retention strategies that ensure research teams and/or clinicians have adequate time to discuss the study and participation commitments. Our results demonstrated that the most effective recruitment strategies were based upon NHS staff spending time, or R&D staff having more detailed discussions, with potential participants building a relationship with them and ensuring that they understood the requirements of the study. Retention was also supported with a similar personal touch of weekly telephone calls to collect data and check in with the participants. This person-centred approach could be important when recruiting people with dementia and carers into exercise trials. People with dementia and carers may require additional time to process the information before deciding whether to participate. The time recruiting staff need for each referral and to keep in contact with participants throughout the trial should not be underestimated, and must be considered in the design and costings of future intervention studies aiming to recruit and retain people with dementia and carers. To develop the wider evidence base and support those involved in intervention studies, there is a need for more trials involving people with dementia and carers to report detailed information on the success and failure of recruitment and retention strategies.

### **Funding**

*This work was supported by a National Institute for Health Research (NIHR) Career Development Fellowship Award to SRN (chief investigator). This paper presents independent*

*research funded by the NIHR's Career Development Fellowship Programme (grant number CDF-2015-08-030).*

### **Disclaimer**

*The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. During the peer-review and interview process the chief investigator received critical comment on the proposal. However, the funder had no influence on the trial, including: trial design; data collection, analysis, and interpretation; manuscript writing; and dissemination of results including the decision to submit the article. The chief investigator had final decision on these matters.*

### **Acknowledgements**

*The authors acknowledge colleagues from the TACIT Trial, from which the data for this paper was drawn. In particular, the authors acknowledge Chris Hayward, Wendy Ingram, and Jeanette Sanders (Peninsula Clinical Trials Unit, University of Plymouth), Peter Thomas, Sarah Thomas, and Helen Allen (Bournemouth University Clinical Research Unit, Bournemouth University), Michael Vassallo (Centre of Postgraduate Medical Research and Education, Bournemouth University), James Raftery (Faculty of Medicine, University of Southampton), and Iram Bibi and Yolanda Barrado-Martín (Department of Psychology and Ageing & Dementia Research Centre, Bournemouth University). The authors acknowledge Southern Health NHS Foundation Trust for sponsorship of the trial.*

*The authors acknowledge the assistance of our public and patient involvement group on our approach to recruitment and data collection. The authors thank the Alzheimer's Society for their assistance with publicizing the study, and the support of the National Institute for Health Research Clinical Research Network (NIHR CRN). The authors thank the General Practice surgeries in Wessex that assisted with recruitment, and the three main recruitment sites: Memory Assessment Research Centre, Southern Health NHS Foundation Trust (Principal Investigator: Brady McFarlane), Memory Assessment Service, Dorset HealthCare University NHS Foundation Trust (Principal Investigator: Kathy Sheret and then Claire Bradbury), and Research and Improvement Team and Older People's Mental Health Service, Solent NHS Trust (Principal Investigator: Sharon Simpson). We also thank the Trial Steering Committee for their expert input (Independent Chair: Frances Healey, NHS Improvement).*

### **References**

1. Kearney A, Harman N, Rosala-Hallas A, Beecher C, Blazeby J, Bower P, Clarke M, Cragg W, Dune S, Gardner H, et al. Development of an online resource for recruitment research in clinical trials to organise and map current literature. *Clinical Trials* 2018; 15(6): 533–542.
2. Krusche A, Rudolf von Rohr I, Muse K, Duggan D, Crane C, Williams J. An evaluation of the effectiveness of recruitment methods: The

- staying well after depression randomized controlled trial. *Clinical Trials* 2014; 11:141–149.
3. Toerien M, Brookes S, Metcalfe C, de Salis I, Tomlin Z, Peters T, Sterne J, Donovan J. A review of reporting of participant recruitment and retention in RCTs in six major journals. *Trials* 2009; 10(1):52.
  4. Withall J, Greaves CJ, Thompson JL, de Koning JL, Bollen JC, Moorlock SJ, Fox KR, Western MJ, Snowsill T, Medina-Lara A, et al. The Tribulations of Trials: Lessons Learnt Recruiting 777 Older Adults Into REtirement in ACTion (REACT), a Trial of a Community Group-Based Active Aging Intervention Targeting Mobility Disability. *J Gerontol A Biol Sci Med Sci* 2020; 13:75(12):2387–2395.
  5. Campbell M, Snowdon C, Francis D, Elbourne D, McDonald A, Knight R, et al. Recruitment to randomised trials: strategies for trial enrolment and participation study: The STEPS study. *Technol Assess* 2007; 11(48):iii, ix-105.
  6. Forsat ND, Palmowski A, Palmowski Y, Boers M, Buttgerit F. Recruitment and Retention of Older People in Clinical Research: A Systematic Literature Review. *Journal of the American Geriatrics Society* 2020; 68(12):2955–2963.
  7. Nyman SR & Victor C. Older people's participation in and engagement with falls prevention interventions in community settings: an augment to the Cochrane systematic review. *Age and Ageing* 2012; 41(1):16–23.
  8. Jancey J, Lee A, Howat P, Clarke A, Wang K, Shilton T. Reducing Attrition in Physical Activity Programs for Older Adults. *Journal of Aging and Physical Activity* 2007; 15:152–165.
  9. Miller E, Nowson C, Dunstan D, Kerr D, Solah V, Menzies D, Daly R. Recruitment of older adults with type 2 diabetes into a community-based exercise and nutrition randomised controlled trial. *Trials* 2016; 17:467.
  10. Di Lorito C, Bosco A, Booth V, Goldberg S, Harwood R, Van der Wardt V. Adherence to exercise interventions in older people with mild cognitive impairment and dementia: A systematic review and meta-analysis. *Prev Med Rep* 2020; 19:101139.
  11. Sherrington C, Fairhall NJ, Wallbank GK, Tiedemann A, Michaleff ZA, Howard K, Clemson L, Hopewell S, Lamb SE. Exercise for preventing falls in older people living in the community. *Cochrane Database of Systematic Reviews* 2019; 1:CDO12424.
  12. Burton E, Cavalheri V, Adams R, Browne C, Boverly-Spencer P, Fenton A, Campbell B, et al. 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* 2015; 10:421–434.
  13. Nyman SR, Ingram W, Sanders J, Thomas PW, Thomas S, Vassallo M, Rafferty J, Bibi I, Barrado-Martín Y. Randomised controlled trial of the effect of tai chi on postural balance of people with dementia. *Clinical Interventions in Aging* 2019; 14:2017–2029.
  14. Pitkälä KH, Pöysti MM, Laakkonen M-L, Tilvis RS, Savikko N, Kautiainen H, Strandberg T. Effects of the Finnish Alzheimer Disease Exercise Trial (FINALEX): A Randomized Controlled Trial. *JAMA Internal Medicine* 2013; 173(10):894–901.
  15. Suttanon P, Hill K, Said C, Williams S, Byrne K, LoGiudice D, Lautenschlager N, Dodd K. Feasibility, safety, and preliminary evidence of the effectiveness of a home-based exercise programme for older people with Alzheimer's disease: a pilot randomized controlled trial. *Clin Rehabil* 2013; 27(5):427–438.
  16. Wesson J, Clemson L, Brodaty H, et al. A feasibility study and pilot randomised trial of a tailored prevention program to reduce falls in older people with mild dementia. *BMC Geriatrics* 2013; 13:e89.
  17. Yao L, Giordani BJ, Algase DL, You M, Alexander NB. Fall Risk-Relevant Functional Mobility Outcomes in Dementia Following Dyadic Tai Chi Exercise. *Western Journal of Nursing Research* 2013; 35(3):281–296.
  18. Mackintosh SF, Sheppard LA. A Pilot Falls-prevention Programme for Older People with Dementia from A Predominantly Italian Background. *Hong Kong Physiotherapy Journal* 2005; 23(1):20–26.
  19. Barrado-Martín Y, Heward M, Polman R, Nyman SR. Acceptability of a dyadic Tai Chi intervention for older people living with dementia and their informal carers. *Journal of Aging and Physical Activity* 2019; 27(2):166–183.
  20. Nyman SR, Hayward C, Ingram W, Sanders J, Thomas P, Thomas S, Vassallo M, Rafferty J, Bibi I, Barrado-Martín Y. 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: protocol for The TACIT Trial (TAi Chi for people with demenTia). *BMC Geriatrics* 2018; 18:e263.
  21. Hsieh S, McGrory S, Leslie F, Dawson K, Ahmed S, Butler C. The mini addenbrooke's cognitive examination: a new assessment tool for dementia. *Dement Geriatr Cogn Disord* 2015; 39(1):1–11.
  22. Census, 2011, <https://www.ons.gov.uk/census/2011census/2011censusdata>. Accessed 7th June 2021.
  23. Adamczewska N, Vassallo M, Thomas P, Thomas S, Barrado-Martín Y, Nyman SR. Feasibility and Accuracy of Different Methods for Collecting Data on Falls Among Older People With Dementia. *Alzheimer Disease & Associated Disorders* 2020; 34(4):362–365.
  24. Fox-Rushby J, Cairns J. Efficiency and economic evaluation. In J. Fox-Rushby & J. Cairns (Eds.). *Economic evaluation* 2005; 7–18. Maidenhead: Open University Press.
  25. NIHR. Schedule of Events Cost Attribution Template (SoECAT) guidance. <https://www.nihr.ac.uk/documents/schedule-of-events-cost-attribution-template-soecat-guidance/23214>. 2019, accessed 19/04/2021.
  26. Lacey R, Wilkie R, Wynne-Jones G, Jordan J, Wersocki E, McBeth J. Evidence for strategies that improve recruitment and retention of adults aged 65 years and over in randomised trials and observational studies: a systematic review. *Age and Ageing* 2017; 46(6):895–903.
  27. Houghton C, Dowling M, Meskill P, Hunter A, Gardner H, Conway A, Treweek S, Sutcliffe K, Noyes J, Devane D, et al. Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis. *Cochrane Database Syst Rev*. 2020; 10(10):MR000045.