

## **Methods**

### *Design*

This paper used data from the TACIT trial (TAi Chi for people with dementia); a randomised, assessor-blind, two-arm, parallel group, superiority trial investigating the effectiveness of Tai Chi to improve postural balance among community-dwelling people with dementia (blinded for review). The study was registered on ClinicalTrials.gov (ID: blinded for review) and the protocol has been published (blinded for review). The trial was approved by the xxxx Research Ethics Committee 4 (reference: blinded for review) and the Health Research Authority (xx project ID: blinded for review).

### *Setting*

The study was conducted in three locations across the South of England. Participants enrolled in the trial were recruited via various sources such as National Health Service memory clinics, local charities and self-referral. The control group received usual care, while the intervention group received usual care plus a Tai Chi exercise intervention for 20 weeks. Irrespective of the random group allocation, all participants provided data at baseline and at a six-month follow-up in the same way. Details are described elsewhere (blinded for review).

### *Participants*

We recruited dyads into the study, comprising a person with dementia and a carer. For the secondary analysis reported here, we only included dyads who were married. For the study overall, people with dementia who were eligible were: aged 18 or above, community-dwelling, had a diagnosis of a dementia (indicated on their medical record held by the NHS or general practitioner [GP]), physically able to do standing Tai Chi, and willing to attend weekly Tai Chi classes. Several exclusion criteria were applied: living in a care home; in

receipt of palliative care; severe dementia (score of 0-9 on the Mini Addenbrooke's Cognitive Examination <sup>1</sup>), had Lewy body dementia or dementia with Parkinson's disease, severe sensory impairment; already currently practising or were practising within the past 6 months Tai Chi or similar exercise on average once a week or more (Qi Gong, yoga, or Pilates); under the care of or 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. Carers had to be: able to commit to supporting the person with dementia with data collection throughout the trial and in the intervention components if allocated to the intervention group, physically 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.

### *Measures*

At baseline and the six-month follow-up, all data were collected in a home visit to both the person with dementia and carer together. A researcher was trained to conduct the data collection in a uniform manner at both baseline and follow-up and was blind to randomisation group; at follow-up dyads were asked not to reveal their group allocation and to conceal identifying items from the researcher (e.g. Tai Chi materials). At baseline, after both dyad members gave written informed consent, the person with dementia provided information by structured interview. This began with the Mini Addenbrooke's Cognitive Examination to assess global cognitive functioning to confirm eligibility <sup>1</sup>. The sum score of the 5-items was used (minimum to maximum possible scores of 0 - 30 with higher scores indicating greater cognitive function). The person with dementia then provided demographic data and completed further scales by structured interview.

People with dementia completed a measure of quality of life, the ICEpop CAPability measure for Older people (ICECAP-O) <sup>2</sup>. This 5-item scale produces a sum score that is then assigned weights (minimum to maximum possible scores of 0 – 1, with a higher score indicating greater capability). This measure of quality of life was chosen as it uses a broader scope of attributes identified by older people as important to quality of life (attachment, security, role, enjoyment, and control) <sup>2</sup>, and thus was more likely to be sensitive to psychological changes than a health-related measure of quality of life. Nonetheless, scores on the ICECAP-O have previously been associated with fall risk, general balance and mobility, and sensitive to cognitive status <sup>3</sup>. It is also a measure recommended in guidelines on economic evaluation of fall prevention interventions <sup>4</sup>. In addition, we have found the ICECAP-O to be a valid and reliable measure for use directly with people with dementia, with data supporting its convergent validity, discriminant validity, sensitivity to change, adequate factorial structure (blinded for review) and retest reliability (blinded for review).

Carers also provided demographic data by structured interview. They were then asked to self-complete the same ICECAP-O measure of quality of life and a measure of carer burden by hand away from the researcher and person with dementia. This was to promote honest reporting by carers without concern of their partner's reaction to their scores. Carer burden was assessed using the Zarit Burden Interview (short-form) <sup>5</sup>. The sum score of this 12-item scale was used (minimum to maximum possible scores of 0 – 48 with higher scores indicating greater burden). It is the most commonly used tool for carer burden <sup>6</sup>, and is shorter but just as reliable and valid as the full-length version <sup>5 6</sup>.

### *Statistical analysis*

All analyses were conducted using IBM SPSS Statistics 25. Given the non-normal distribution of scores, before analyses were conducted, each variable except for baseline carer

burden and follow-up M-ACE was transformed using the fractional rank and inverse distribution functions method.<sup>7</sup> The relationships between the variables at baseline and follow-up were then tested using bivariate Pearson correlations. The correlations were undertaken to explore the associations between people with dementia's quality of life and their spousal carers' quality of life and carer burden. Significant variables were then selected for entry into multiple linear regressions to test whether people with dementia's quality of life could predict carer burden. Baseline variables that were significantly associated with carer burden at baseline at  $p < 0.10$  were selected to be entered into a multiple regression to predict baseline carer burden. Similarly, baseline and follow-up variables that were significantly associated with carer burden at follow-up at  $p < 0.10$  were selected to be entered into a multiple regression to predict carer burden at follow-up. A  $p$  value of  $p < 0.10$  was used as a more inclusive approach to ensure the key potential predictor variables were entered into the multiple regression. Six statistical assumptions for conducting multiple linear regressions were checked and all of them were met. These were as follows:

1. The relationships between the independent variables and the dependent variable were linear; checked via scatterplot.
2. There was no multicollinearity in the data; the independent variables were not too correlated (Pearson's  $r = \leq 0.8$ ).
3. The values of the residuals were independent; checked via The Durbin-Watson statistic.
4. The variance of the residuals were similar; checked via scatterplot.
5. The values of the residuals were normally distributed; checked via visual inspection of the P-P plot that the dots were close to the line.
6. There were no influential cases biasing the model; no outliers were identified.

An important consideration for our analysis was that the data were from a randomised controlled trial. This meant that the data at follow-up could have been influenced by whether participants had been randomised to the intervention group (usual care plus Tai Chi) or control group (usual care only). To account for this, we included the variable of trial arm (intervention vs. control group) in the bivariate correlational analysis. If found to be significant ( $p < 0.10$ ), we would then control for this variable by including it in the multiple linear regressions.

## References

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