Dementia And Physical Activity (DAPA) trial of moderate to high intensity exercise training for people with dementia: randomised controlled trial

Sarah E Lamb,[1,2] Bart Sheehan,[3] Nicky Atherton,[3] Vivien Nichols,[2] Helen Collins,[4] Dipesh Mistry,[2] Sukhdeep Dosanjh,[2] Anne Marie Slowther,[5] Iftekhar Khan,[2] Stavros Petrou,[2] Ranjit Lall,[2] on behalf of the DAPA Trial Investigators

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RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Dementia and exercise	RCT	329	+	+	?	+

Characteristics of studies

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Population	1. Participants People with dementia were eligible if they had a clinically confirmed diagnosis of dementia in accordance with the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) 7 and a standardised mini mental state examination score (sMMSE) 8 of greater than 10, were able to sit on a chair and walk 10 feet (3.05 m) without assistance, and lived in the community either alone or with others. 2. We designed and tested an intervention that targeted known mechanistic pathways in vascular and Alzheimer's type dementia and which, if found effective, could be scaled for use within the UK National Health Service.
Intervention	1. We compared the effect on cognitive impairment at 12 months of a combination of a moderate to high intensity aerobic and strength exercise training programme in addition to usual care compared with usual care alone in people with mild to moderate dementia. 2. INTERVENTIONS Usual care plus four months of supervised exercise and support for ongoing physical activity, or usual care only.
Outcomes	1. The primary outcome was score on the Alzheimer's disease assessment scale-cognitive subscale (ADAS-cog) at 12 months. 2. Secondary outcomes included activities of daily living, neuropsychiatric symptoms, health related quality of life, and carer quality of life and burden.

3. Secondary outcomes at six and 12 months after randomisation were measured using the Bristol activity of daily living index 14 (scored 0 to 60, higher scores indicate worse impairment, carer rated), neuropsychiatric index 15 (scored 0 to 144, higher scores indicate worse behavioural symptoms, carer rated), the three level version of the EQ-5D quality of life measure 16 (scored 0 to 1, higher scores indicate better quality of life), the quality of life Alzheimer's disease scale 17 (scored 13 to 52, higher scores indicate better quality of life), ADAScog subscale at six months, and ADAS praxis, memory, and language subscales 13 at six and 12 months (praxis scored 0-10, memory scored 0-35, language scored 0-25, higher scores indicate worse impairment).

Bias	Judgement	Support for judgement
Random sequence generation	low	1. An independent statistician used a computerised random number generator for the allocation sequence, then a central telephone registration and randomisation service implemented the sequence. 2. Random allocation was 2:1 in favour of the exercise arm. 3. At each time point we measured carer burden with the Zarit burden interview 19 (scored 0 to 88, higher scores indicate greater stress) and carer health related quality of life using the EQ-5D-3L. Randomisation and masking An independent telephone randomisation system assigned participants to exercise training or usual care in a 2:1 ratio.
Allocation concealment	low	1. An independent statistician used a computerised random number generator for the allocation sequence, then a central telephone registration and randomisation service implemented the sequence. 2. If the allocation was revealed, we assigned a different interviewer to complete the next follow-up. 3. If they could not attend these dates, then we delayed their enrolment, baseline assessment, and randomisation until the next cycle of exercise interventions became available.
Blinding of participants and personnel	high/unclear	1. Researchers unaware of treatment assignment undertook all baseline and follow-up interviews in the participants' home. 2. Researchers who undertook data entry and cleaning were unaware of treatment allocation. 3. At 12 months, interviewers reported that they knew the treatment assignment in 11/132 cases (8%) in Strengths and limitations of this study
Blinding of outcome assessment	low	1. At the end of the study, people with dementia and carers were invited to a joint feedback day with research and clinical staff, and they contributed actively to discussions about the results and interpretation. 2. At each time point we measured carer burden with the Zarit burden interview 19 (scored 0 to 88, higher scores indicate greater stress) and carer health related quality of life using the EQ-5D-3L. Randomisation and masking An independent telephone randomisation system assigned participants to exercise training or usual care in a 2:1 ratio. 3. An independent statistician used a computerised random number generator for the allocation sequence, then a central telephone registration and randomisation service implemented the sequence.