ISRCTN32612072 https://doi.org/10.1186/ISRCTN32612072

Physical activity programmes for community dwelling people with mild to moderate dementia (DAPA - Dementia And Physical Activity)

Submission date
27/07/2011

Recruitment status
No longer recruiting

Registration date
29/07/2011

Overall study status
Completed

Last Edited
12/03/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dementia is a disease characterised by a progressive decline in functional abilities, including memory and the skills to perform activities of daily living. It affects increasing numbers of people in the UK, the largest proportion being people with mild to moderate dementia. Patients with mild or moderate dementia and their carers both want and require treatments that can alleviate burden associated with the progression of dementia but there are relatively few anti - dementia drug treatments available for this group and side effects limit their use. Physical activity has numerous health benefits, but it is currently unclear if physical activity will help to slow the rate of cognitive decline in people with mild or moderate dementia. Our aim is to estimate the effects of a novel exercise/physical activity programme that can be provided through the National Health Service. We will also identify ways in which we can promote continued physical activity after completion of the supervised element of the programme.

Who can participate?
To take part participants must meet the following criteria:
1. Have probable dementia of mild to moderate severity
2. Be able to participate in a structured exercise programme:
a) Able to walk 10 feet without human assistance
b) Have no serious unstable illness (e.g. unstable angina)
3. Live in the community, either alone or with a relative, friend or carer, or in sheltered accommodation.

What does the study involve?
The study is testing the DAPA exercise programme. The trial is made of two groups; one group will remain on their usual care, and their progress is compared to the other group of people who are given the exercise programme as well as their usual care. The group each participant goes into is decided by chance, this will be done by a computer programme. Everyone has an equal chance of receiving the exercise programme.

The DAPA exercise programme will consist of:
1. Exercise classes (approximately 1 hour long) to be held twice a week in a local venue for 4 months. The programme will be delivered by a specially trained physiotherapist supported by an exercise assistant
2. Exercise on stationary exercise bikes and also using weights
3. Exercising will be done at a level to improve aerobic fitness and muscle strength
Everyone taking part in the classes will be encouraged to do at least another hour of exercise a week outside of the classes, according to choice, e.g. walking, swimming, cycling, dancing. Once the 4 months of classes have been completed, everyone will be encouraged to continue exercising regularly at home or in the community for the next 8 months. Everyone who takes part in the study will have short assessments with a researcher which will consist of a series of questions and observations to measure memory, thinking abilities, quality of life, and physical abilities. Assessment will be measured at 0, 6 and 12 months. After the first assessment, participants will be told if they have been selected to take part in the exercise programme. If they have not been selected to take part in the exercise programme they will continue with their usual care.

What are the possible benefits and risks of taking part?
The DAPA exercise programme will be closely supervised by specially trained physiotherapists. We hope the information from this trial will help improve the treatment of people with dementia.

Where is the study run from?
The study is organised from the Warwick Clinical Trials Unit at the University of Warwick. Participants will be referred from primary or secondary care providers, Alzheimer Cafes or can self-refer via the Join Dementia Research (JDR) programme across England.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study between January 2013 and July 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Professor Sarah Lamb
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Study website
http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/critical/dapa/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/80/04

Study information

Scientific Title
Physical activity programmes for community dwelling people with mild to moderate dementia (DAPA - Dementia And Physical Activity): a multi-centre, randomised controlled trial

Acronym
DAPA

Study objectives
Current hypothesis as of 06/01/2015:
To undertake a definitive randomised controlled trial to estimate the effects of an exercise /physical activity intervention that is feasible for delivery within the current constraints of National Health Service delivery. Our objectives are to:
1. Develop a novel evidence-based exercise intervention for delivery to community dwelling populations of people with dementia, supported by the results of a systematic review on the effects of exercise on cognition in people with mild or moderate dementia.
2. Pilot critical procedures for the intervention
3. Complete a definitive, individually randomised controlled trial to estimate the effectiveness of the DAPA programme in addition to usual care on cognitive decline (primary outcome), function and quality of life in people with mild or moderate dementia, and for carers, carer burden.
4. Complete a parallel cost study and conduct an economic analysis from a healthcare and societal perspective
5. Investigate intervention effects in pre-defined sub-groups of gender and dementia severity

Previous hypothesis:
To undertake a definitive randomised controlled trial to estimate the effects of an exercise /physical activity intervention that is feasible for delivery within the current constraints of

National Health Service delivery. Our objectives are to:
1. Refine an existing intervention for delivery to community dwelling populations of people with dementia, including an update/expansion of a systematic review completed as part of the HTA funded Older People's Exercise in Residential Accommodation (OPERA) HTA 06/02/01)) trial and user involvement processes.
2. Pilot critical procedures in the intervention and trial
3. Complete a definitive, individually randomised controlled trial to estimate the effectiveness of the DAPA programme in addition to usual care on cognitive impairment (primary outcome), function and quality of life in people with mild or moderate dementia, and for carers, carer burden.
4. Complete a parallel cost study and conduct an economic analysis from a healthcare and societal perspective
5. Investigate intervention effects in pre-defined sub-groups of gender and dementia severity

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West, 19/01/2012, ref: 11/SW/0232

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please follow the link below to the Study Information section of the trial website for all current information sheets: http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/critical/dapa/resources/

Health condition(s) or problem(s) studied
Dementia

Interventions
Current interventions as of 06/01/2015:
Best practice usual care: All participants will receive care as usual from the clinical service they attend. All of the services participating in our study provide best practice care in accordance with national guidance, including relevant National Institute for Health and Clinical Excellence (NICE) guideline.

Exercise intervention: The exercise intervention will be delivered in a group format, with up to 8 participants in each group. The programme will be provided in two, 1-hour sessions per week for 4 months, supplemented with between-session-at-home exercises of at least one hour per week. Each participant will receive a brief assessment prior to entering the exercise class to determine initial dose. The intervention will be delivered in a secure environment which ensures adequate access and appropriate security. We will train physiotherapists to deliver the intervention, and provide them with specialist expertise to manage people with dementia. Physiotherapists will be supported by an exercise assistant.

Previous interventions:
Best practice usual care: All participants will recieve care as usual from the clinical service they attend. All of the services participating in our study provide best practice care in accordance with national guidance, including relevant National Institute for Health and Clinical Excellence (NICE) guideline.

Exercise intervention: The excercise intervention will be delivered in a group format, with up to 14 participants in each group. The programme will be provided in two, 1-hour sessions per week for 4 months, supplemented with between-session-at-home exercises of at least one hour per week. Each participant will receive a brief assessment prior to entering the exercise class to determine initial dose. The intervention will be delivered in a secure environment, for example day centres where dementia respite care is provided already. This ensures adequate access and appropriate security. We will train physiotherapists to deliver the intervention, as although therapists are more expensive than exercise trainers, they have the specialist expertise to deal with dementia. Physiotherapists will be supported by a technical assisstant as the groups are likely to be challenging to deliver.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 06/01/2015:
The primary outcome measure will be cognition
1. Cognitive function will be measured using the Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog) at 0, 6 and 12 months

Previous primary outcome measures:
The primary outcome measure will be cognition at 0, 6 and 12 months
1. Cognitive function will be measured using the Mini Mental State Examination (MMSE)
2. Function will be measured using the Bristol Activity of Daily Living scale (BADL)

Secondary outcome measures
Current secondary outcome measures as of 06/01/2015:
1. Function: measured using the Bristol Activity of Daily Living scale (BADL) at 0, 6 and 12 months
2. Health-related quality of life: measured using (EuroQol EQ-5D) at 0, 6 and 12 months
3. Dementia quality of life; measured using (QoL-AD) at 0, 6 and 12 months
4. Behavioural symptoms: measured using the Neuropsychiatric Index (NPI) at 0, 6 and 12 months
5. Carer burden: measured using Zarit Burden Interview (ZBI) at 0, 6 and 12 months

Previous secondary outcome measures:
1. Health-related quality of like (EuroQol EQ-5D) at 0, 6 and 12 months
2. Dementia quality of life (Qol-AD) at 0, 6 and 12 months

3. Behavioural symptoms (NPI) at 0, 6 and 12 months
4. Mood (Cornell Scale for Depression in Dementia [CSDD]) at 0, 6 and 12 months
5, Carer burden (Zarit Burden Interview [ZBI]) 0, 6 and 12 months

Overall study start date
19/01/2012

Completion date
14/10/2016

Eligibility

Key inclusion criteria
1. Probable dementia according to Diagnostic and Statistical Manual, Fourth Edition (DSM-IV) criteria:
1.1. Memory impairment with cognitive disturbance in a least one of the following domains - aphasia (language), apraxia (motor activities), agnosia (object recognition) or executive functioning (planning, sequencing, abstracting)
1.2. Functional decline: increasing impairment in functional ability (social, occupational, personal /self-care) related to cognitive deficits
2. Probable dementia of mild to moderate severity (MMSE >10)
3. Are able to participate in a structured exercise program:
3.1. Are able to sit on a chair and walk 10 feet without human assistance
3.2. No serious unstable illness (e.g. unstable angina)
4. Live in the community, either alone or with a relative, friend, or carer, or in sheltered accomodation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
468

Key exclusion criteria
1. People with severe dementia (MMSE <10)
2. People living in residential nursing homes
3. People with acute, unstable or terminal illness which would make participation in the exercise group impractical

Date of first enrolment
09/01/2013

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Coventry and Warwickshire Partnership Trust
Coventry
United Kingdom
CV6 6NY

Study participating centre
Oxford Health NHS Foundation Trust
Oxford
United Kingdom
OX3 7JX

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
Kettering
United Kingdom
NN15 7PW

Study participating centre
Worcestershire Health and Care NHS Trust
Worcester
United Kingdom
WR4 9RW

Study participating centre
Leicestershire Partnership NHS Trust
Leicester
United Kingdom
LE19 1SX

Study participating centre

Solent NHS Trust
Southampton
United Kingdom
SO16 4XE

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Black Country Partnership NHS Foundation Trust
West Bromwich
United Kingdom
B70 9PL

Study participating centre
Greater Manchester West Mental Health NHS Foundation Trust
Prestwich
United Kingdom
M25 3BL

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Devon
United Kingdom
EX2 5DW

Study participating centre
2gether NHS Foundation Trust
Gloucester
United Kingdom
GL1 1LY

Study participating centre

North East London Partnership NHS Foundation Trust
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IG3 8XJ

Sponsor information

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (09/80/04)

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2015		Yes	No
Protocol article	protocol	25/03/2016		Yes	No
Results article	results	01/05/2018		Yes	No
Results article	results	16/05/2018		Yes	No
Results article	results	01/09/2020	12/03/2021	Yes	No