

Evaluation of exercise on individuals with dementia and their carers

Submission date 22/04/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 26/05/2009	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 28/08/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.evidem.org.uk/projects/evidem-e>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled evaluation of exercise as a therapy for the behavioural and psychological symptoms of dementia

Acronym

EVIDEM-E

Study objectives

The introduction of a tailored exercise programme will significantly reduce behavioural and psychological symptoms of dementia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West London R&D Consortium, submission planned for June 2009 (as of 22/04/2009).

Study design

Pragmatic single-blind randomised single-centre trial

Primary study design

Interventional

Secondary study design

Single-centre

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Behavioural and psychological symptoms of dementia

Interventions

A 6-week supervised incremental course of walking outside, at a pace and distance to suit the participant and carer for at least 5 days per week. Walking is a useful exercise which is considered acceptable by participants, and is easily delivered and measured (in terms of time and distance) but rarely incorporated in a daily routine. A physiotherapist or exercise therapist will oversee the delivery of the exercise programme. The sustainability of this intervention will

be assessed by evaluating adherence and impact during an unsupervised interval (weeks 6-12) and by further telephone contact at 6 months.

Control group: No exercise training

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Behavioural and psychological symptoms measured by NPI at baseline, week 6 and 12.

Secondary outcome measures

1. Participants' mental health (General Health Questionnaire) at baseline, week 6 and 12
2. Participants' quality of life (DemQOL-Proxy) at baseline, week 6 and 12
3. Caregivers' burden of caring (short Zarit Caregiver Burden Inventory) at baseline, week 6 and 12
4. Participants' level of physical activity and compliance with the intervention (diaries and heart rate monitors, to be completed by the participant and their carer)
5. Participants' and carers' views about the intervention (Diaries and semi-structured questionnaires to be carried out after the trial)
6. Mortality and domiciliary status at 6 months

Overall study start date

01/08/2009

Completion date

30/04/2011

Eligibility

Key inclusion criteria

1. Both males and females, no age limits
2. Diagnosis of:
 - 2.1. Dementia in primary or secondary care OR
 - 2.2. Suspected dementia confirmed by the researcher to ensure the International Classification of Diseases 10th Revision (ICD-10) research criteria for dementia (DCR-10) are met
3. Presence of a carer (professional, friend or family member, who does not necessarily have to live with the participant)
4. Neuropsychiatric Inventory (NPI) score in any one sub-set except only hallucination or delusion more than or equal to 2 in severity and more than or equal to 2 in frequency
5. Consent of participant, or in the case of an individual who is not capable of giving informed consent, the assent of the participant with agreement of carer
6. Consent of carer

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

145

Key exclusion criteria

1. Cardio-respiratory condition, neurological or musculo-skeletal condition of a degree that prevents participation to even the modified exercise regime unsafe or not possible
2. A score of three or more assessed using the Falls Risk Assessment Tool or less than one minute as assessed by the Timed Unsupported Steady Stand test
3. Uncontrolled medical problems, which the GP considers would exclude participants from undertaking the exercise programme; for example, acute systemic illness such as pneumonia, poorly controlled angina, acute rheumatoid arthritis, unstable or acute heart failure
4. Sensory impairment to an extent that prevents dyad facilitated exercise
5. Participant or carer dissent to engage in the exercise programme
6. Acute confusional state

Date of first enrolment

01/08/2009

Date of final enrolment

30/04/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Central and North West London NHS Foundation Trust

London

United Kingdom

NW1 7QY

Sponsor information**Organisation**

Central and North West London NHS Foundation Trust (UK)

Sponsor details

Greater London House
Hampstead Road
London
England
United Kingdom
NW1 7QY

Sponsor type

Hospital/treatment centre

Website

<http://www.cnwl.nhs.uk>

ROR

<https://ror.org/05drfg619>

Funder(s)

Funder type

Government

Funder Name

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Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/05/2010		Yes	No
Results article	results	01/08/2014		Yes	No

Results article	results	01/04/2015	Yes	No
Results article	cost-effectiveness results	01/06/2016	Yes	No