

APPLE-Tree programme for dementia prevention

Submission date 31/10/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/11/2019	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning. The study will test a prevention programme to lower older people's chances of getting dementia. The half of older people (aged 60+) who have problems with "cognition" (memory, orientation and other thinking) have more chance of getting dementia, so we will design an approach that works for them.

The programme will help older people make changes that can prevent dementia. These are:

1. Being more socially and mentally active
2. Eating more healthily
3. Being more physically active
4. Looking after their mental and physical health
5. Stopping smoking
6. Reducing alcohol.

Who can participate?

People aged over 60 years who show signs of cognitive decline (but not have not developed dementia)

What does the study involve?

The programme will be 10 group sessions over 6 months. We will offer individual sessions for people who cannot come to groups. Two facilitators will lead the groups. They will be trained and supervised by an experienced psychologist to keep to a manual so the programme is delivered in the same way each time. Groups will take place in a range of places to be accessible to all. We will ask people taking part to complete questionnaires, including a memory test and give a voluntary blood sample, before the programme starts and 6 and 24 months later. We will interview around 50 people taking part (including those who drop out) or running the groups to hear what went well and what could be better.

What are the possible benefits and risks of participating?

Benefits: There are no immediate benefits of taking part as we do not know if the intervention we are testing is effective. It will be explained to participants they are contributing to the development of a service that may help people with memory problems prevent.

Risks: We do not consider the study to be high risk. It is possible that intervention sessions may induce anxiety or worry in participants. Where this occurs, we will offer a range of mitigation strategies including asking participants if they wish to leave the group session (or terminate an individual session) and offering them the option to take a break during the session or to move on to another topic

Where is the study run from?

1. UCL Division of Psychiatry
2. Camden & Islington NHS Foundation Trust
3. North East London NHS Foundation Trust
4. Essex Partnership University NHS Foundation Trust

When is the study starting and how long is it expected to run for?

July 2020 to August 2024

Who is funding the study?

Economic and Social Research Council (ESRC), UK

Who is the main contact?

Dr Michaela Poppe (public)

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Dr Claudia Cooper (scientific)

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Study website

<https://www.ucl.ac.uk/psychiatry/research/mental-health-neuroscience-department/projects/apple-tree-study>

Contact information

Type(s)

Public

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

EDGE 127266

Study information**Scientific Title**

The APPLE Tree programme: Active Prevention in People at risk of dementia through Lifestyle, bEhaviour change and Technology to build REsiliEnce

Acronym

APPLE-Tree

Study objectives

The study objectives are the following:

Primary: To conduct a randomised controlled trial to evaluate the clinical effectiveness (in terms of reducing cognitive decline) of the APPLE-Tree intervention in individuals at high risk of dementia with Mild Cognitive Impairment (MCI) or Subjective Cognitive Decline (SCD) at 24-month follow-up.

Secondary: (RCT): To evaluate the cost-effectiveness of the APPLE-Tree intervention in individuals with MCI or SCD at 24-month follow-up. To investigate

Process evaluation: To explore how the intervention was implemented (to include fidelity, dose and reach) and any mechanisms of impact which produce behavioural and lifestyle changes during and beyond the facilitated sessions.

Implementation Phase: To explore what factors may determine decisions of NHS and third sector organisations not taking part in the trial, regarding whether they decide to adopt the new intervention if it is demonstrated to be clinically effective and cost-effective.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/02/2020, London - Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; + 44 (0)207 104 8086; camdenandkingscross.rec@hra.nhs.uk), ref: 20/LO/0034

Study design

Interventional randomized single-blind multi-site randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Older adults at high dementia risk with

Interventions

The study is interventional. It is an individually randomised single-blind multi-site randomised controlled trial. Participant's will be individually randomised using a web-based system (sealed envelope) with randomisation blocked and stratified by site. Participants will be randomised after baseline interviews in a ratio of 1:1 to the APPLE-Tree intervention versus control. The control group receives usual care plus written information about dementia prevention, including the behavioural change targets, with signposting information. Study participants will not be blind to treatment allocation. The researcher delivering the intervention will be different from the researcher conducting the follow-up assessments for each participant to enable masking of Research assistants during outcome assessments.

An intervention will be created that targets key risk factors in older people at high dementia risk: cardiometabolic dysfunction (diabetes and cardiovascular risks), physical inactivity, social isolation, mental illness, alcohol and smoking. This is to find out whether a lower intensity, personally tailored intervention that targets older people with subjective memory decline, is flexible in delivery format (with individual sessions for those unable or unwilling to attend groups) and informed by best available behaviour change techniques, can effectively reduce cognitive decline.

The programme will be 10 group sessions over six months. Individual sessions will be offered for people who cannot come to groups. Two facilitators will lead the groups. They will be trained and supervised by an experienced psychologist to keep to a manual so the programme is delivered in the same way each time. Groups will take place in a range of places to be accessible to all. People taking part will be asked to complete questionnaires, including a memory test and give a voluntary blood sample, before the programme starts and 6 and 24 months later. Around 50 people taking part (including those who drop out) or running the groups will be interviewed to hear what went well and what could be better

Intervention Type

Behavioural

Primary outcome measure

Cognition, using the modified Neuropsychological Test Battery (mNTB) composite z score at baseline, 12 months and 24 months

Secondary outcome measures

At baseline, 12 months and 24 months:

1. Health and social care costs, measured using the Client Service Receipt Inventory (CSRI)
2. Quality of life, measured using the EQ-5D-5L
3. Functional Assessment Questionnaire, to measure activities of daily living
4. Neuropsychiatric Inventory to measure neuropsychiatric symptoms will be completed with an informant
5. Hospital Anxiety and Depression Scale
6. Measures of behaviour change:
 - 6.1. Mediterranean Diet Score: to assess consumption of Mediterranean diet elements; e.g., olive oil, wine, fruits, legumes and whole-grain intake. Low consumption of meat, coffee, commercial sweets and fizzy drinks is reverse scored. Higher scores indicate greater dietary adherence
 - 6.2. AUDIT (Alcohol Use Disorders Identification Tool)
 - 6.3. Smoking status
 - 6.4. Measures of primary support-network size, life events and the revised UCLA loneliness scale
7. Mobility limitations and physical functioning using the Short Physical Performance Battery (standing balance test, timed sit-to stand test, 4-m comfortable walking time); and blood pressure, weight and Body Mass Index (BMI), and hip and waist circumference
8. Physical activity over one week (after baseline assessment), using wearable sensors; and download cognitive training use from the website.
9. Blood indices: red blood cell fatty acid and vitamin C to evaluate dietary compliance. We will measure cardiovascular and cognitive biomarkers of risk including plasma total, LDL and HDL-cholesterol, triglycerides, glucose, HBA1c, BDNF (marker of neuronal function) and insulin. The Global Screening Array (Illumina) will be used to generate genome-wide genotype data for each participant and derive Alzheimer's disease polygenic risk scores

Overall study start date

01/01/2019

Completion date

31/12/2027

Eligibility

Key inclusion criteria

1. Age 60+ years
2. Cognitive Change Index score >16 indicating subjective cognitive impairment
3. Quick MCI score within educational and age normal range for MCI or SCD; CAIDE Dementia Risk Score ≥ 6 points (modifiable risk factors)
4. No dementia diagnosis
5. Functional Assessment Questionnaire score <9 (no significant impairment)
6. A relative, friend or professional in at least monthly contact who is able and willing to act as an informant

Participant type(s)

Patient

Age group

Adult

Lower age limit

60 Years

Sex

Both

Target number of participants

704

Total final enrolment

748

Key exclusion criteria

1. AUDIT (Alcohol Use Disorders Identification Tool) score of 8+ (hazardous or harmful use of use of alcohol)
2. Primary neurodegenerative disease
3. Terminal condition which precludes carrying out the intervention
4. Lacking the capacity to consent to take part at baseline
5. We will exclude participants who have scheduled, regular sessions with one of the group facilitators
6. Unable to understand spoken English sufficiently to participate in the intervention.

Date of first enrolment

01/07/2020

Date of final enrolment

31/12/2022

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Camden & Islington NHS Foundation Trust**

Camden Memory Service

The Peckwater Centre

6 Peckwater Street

London

United Kingdom

NW5 2TX

Study participating centre**North East London NHS Foundation Trust**

IAPT/Research & Development Department

1st Floor Maggie Lilley Suite

Goodmayes Hospital

Barley Lane

Ilford

United Kingdom

IG3 8XJ

Study participating centre**Essex Partnership University NHS Foundation Trust**

St. Margaret's Hospital

The Plain

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CM16 6TN

Sponsor information**Organisation**

UCL Joint Research Office

Sponsor details

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Sponsor type

University/education

Website

<https://www.ucl.ac.uk/joint-research-office/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Research council

Funder Name

Economic and Social Research Council

Alternative Name(s)

ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

We will disseminate our findings in a peer reviewed journal and at an international conference. We will present findings in appropriate local forums for health and social care professionals; participants who have indicated they are interested in the results will be sent a summary of the findings. Our publication policy is as follows:

Authorship for any paper or conference abstract will be agreed by completion of the first draft. To be considered for publication it will be expected that authors have contributed to each of the following:

- a. Conception and design of the study, or acquisition of data, or analysis and interpretation of data;
- b. Drafting the article or revising it critically for important intellectual content;
- c. Final approval of the version submitted.

The study co-applicants have all contributed to the conception and design of the study, thereby meeting criteria (a).
We will discuss the most useful form in which to disseminate our findings within the APPLE-Tree Project Management Groups.
All conference posters and presentations should acknowledge the Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR) as the funder.

Intention to publish date

31/08/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/07/2022	27/07/2022	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	Qualitative survey, regarding how the Covid pandemic impacted their lifestyle and wellbeing in areas relevant to dementia risk	13/06/2025	16/06/2025	Yes	No