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APPLE-Tree programme for dementia prevention

Submission date	Recruitment status	[X] Prospectively registered
31/10/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/11/2019	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/06/2025	Mental and Behavioural Disorders	[X] 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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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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Scientific

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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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United Kingdom
CM16 6TN

Sponsor information

Organisation
UCL Joint Research Office

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Gower Street
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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