

# APPLE-Tree programme for dementia prevention

<b>Submission date</b> 31/10/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/11/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/03/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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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## Contact information

### Type(s)

Public

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

60 years

**Upper age limit**

110 years

**Sex**

All

**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**

United Kingdom

England

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

Camden Memory Service

The Peckwater Centre

6 Peckwater Street

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NW5 2TX

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

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**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

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

## Funder(s)

**Funder type**  
Research council

**Funder Name**  
Economic and Social Research Council

**Alternative Name(s)**  
Social Science Research Council, ESRC, SSRC, UKRI ESRC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

# Results and Publications

## 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?
<a href="#">Results article</a>		20/10/2025	24/10/2025	Yes	No
<a href="#">Protocol article</a>		26/07/2022	27/07/2022	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Other publications</a>	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
<a href="#">Other publications</a>	Ethnographic study examined how participants engaged with active ageing	23/03/2026	31/03/2026	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes