ISRCTN17060879 https://doi.org/10.1186/ISRCTN17060879

A blended app and coach support programme to improve brain health

Submission date
21/11/2024

Recruitment status
Recruiting

Registration date
03/03/2025

Overall study status
Ongoing

Last Edited
21/05/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
The prevalence of dementia in the UK is increasing. The risk is known to be greater in people from underprivileged and ethnic minority backgrounds. Our research with the Lancet Commission previously identified 10 risk factors associated with dementia, that can potentially be changed. These are: less education, hypertension, hearing impairment, smoking, social isolation, obesity, depression, physical inactivity, diabetes, and excessive alcohol use. Research programmes targeting those individuals who are at greatest risk and where a positive difference could be made, are now needed. We have developed a personalised program for individuals consisting of a digital app along with coaching support, to address these 10 dementia risk factors, targeting those in ethnic minority and lower socio-economic groups. We will test the program in a pilot study to see if it is feasible and acceptable. If the results are positive, we will undertake a full randomised controlled trial to determine the effectiveness and cost-effectiveness of the ENHANCE intervention.

Who can participate?
Participants aged 60 to 80 years, living in the community (not care home) and who are registered with a GP practice.

What does the study involve?
Participants will be recruited through primary and secondary care and will be invited to attend an assessment meeting at the GP practice or secondary care clinic site. Questionnaires and clinical measures will be collected on each of the risk factors ENHANCE aims to address. If the assessment shows a participant has 3 or more risk factors, they will be randomised to either the study arm (to receive the ENHANCE app and coaching support) or the control arm (to receive Care-As-Usual). Participants in the study arm will be invited to use the app for 3 months (feasibility trial) or 6 months (Full randomised controlled trial). In the feasibility trial, participants will attend a 3-month follow-up assessment meeting and the same measures will be collected as at baseline. In the randomised controlled trial, participants will attend 6- and 12-month follow-up assessment meetings with the same measures will be collected as at baseline. Feasibility study participants will receive 3 months of support from a coach participants in the randomised controlled trial will have a coach for 6 months. ENHANCE coaches will encourage behaviour change and active engagement with the app. We will conduct qualitative follow-up interviews

with study participants and practitioners to obtain feedback on the intervention and their thoughts on participating in the study.

What are the possible benefits and risks of participating?
Participants may find the ENHANCE app helpful in the management of various health-related behaviours. They will also be contributing to the development of a new smartphone app that has the potential to improve health and reduce cognitive decline. A personal health coach will be there to support them in making positive lifestyle changes. By providing feedback on using the app, participants can contribute to further research, which may help to improve the app and support people to manage their health.
The risk to study participants taking part in the research is considered low. Participants may find some assessment procedures time-consuming or may find the app irritating to use. We will try to minimise the time needed to deliver assessments and the coach will have regular contact with participants to support app use.

Where is the study run from?
The study is being run from the Division of Psychiatry, University College London. The sponsor of this research is North London NHS Foundation Trust. The research is being managed by the Priment Clinical Trials Unit, University College London.

When is the study starting and how long is it expected to run for?
November 2023 to December 2028

Who is funding the study?
The ENHANCE Programme is funded by the NIHR under the Programme Grants for Applied Research (PGfAR) stream - NIHR203670

Who is the main contact?
Prof. Sergi Costafreda-Gonzalez, s.costafreda@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr James Jamison

ORCID ID
https://orcid.org/0000-0002-6452-0561

Contact details
Division of Psychiatry
University College London
4th Floor, Maple House
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
+44 (0)2031085740
james.jamison@ucl.ac.uk

Type(s)
Principal investigator

Contact name
Prof Sergi Costafreda-Gonzalez

ORCID ID
https://orcid.org/0000-0001-6914-086X

Contact details
Division of Psychiatry
University College London
4th Floor, Maple House
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
+44 (0)20 7679 9059
s.costafreda@ucl.ac.uk

Type(s)
Scientific

Contact name
Prof Gill Livingston

ORCID ID
https://orcid.org/0000-0001-6741-5516

Contact details
Division of Psychiatry
University College London
4th Floor, Maple House
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
+44 (0)20 7679 9435
g.livingston@ucl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
334260

Central Portfolio Management System (CPMS)
62622

National Institute for Health and Care Research (NIHR)
203670

Study information

Scientific Title
TailorEd iNtervention for brain HeAlth aNd Cognitive Enrichment (ENHANCE) for underserved people at higher risk of dementia in the UK

Acronym
ENHANCE

Study objectives
We hypothesise that the ENHANCE intervention—a blended eHealth multidomain program combining an app with individualised coaching—will be feasible and acceptable, and that, when compared to Care As Usual (CAU) in a randomised controlled trial (RCT), it will reduce cognitive decline, and will be cost-effective and implementable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2024, West of Scotland 5 REC Committee (Ward 11, Dykebar Hospital, Paisley, Glasgow, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/0077

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Study type(s)
Prevention

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

Interventions
Intervention Arm (Feasibility Trial):
Participants with at least three dementia risk factors as specified in the eligibility criteria, are randomised (2:1; n = 40) to receive a 12-week ENHANCE intervention. This includes a prototype app that delivers weekly activities focused on selected risk factors and personalised support from a coach. The coach meets the participant face-to-face for onboarding, provides necessary equipment (e.g., BP monitor, pedometer), is available for problem-solving through messaging, and conducts fortnightly coaching sessions personalised to their risk factor profile and preferences in which risk factors to address and in which order.

Control Arm (Feasibility Trial):
Participants randomised to Care As Usual (CAU; n = 20), receive a letter containing their risk profile and encouragement to share this with their GP practice for follow-up, without additional coaching or app support.

Intervention Arm (Main RCT):
Following the finalisation of the intervention after the feasibility trial, participants with at least three dementia risk factors are randomised (1:1; n = 294) to receive the intervention over 12 months. Baseline assessments—including questionnaires, clinical evaluations, blood sample analysis, and measurement of the 10 specified risk factors—are completed prior to randomisation. The intervention setup visit mirrors that of the feasibility trial, with a face-to-face onboarding meeting, provision of necessary equipment (e.g., BP monitor, pedometer), and app setup. The app delivers weekly activities tailored to the participant's selected risk factors, with the first 6 months supported by personalised, fortnightly coaching sessions. After 6 months, participants are encouraged to continue using the app independently.

Control Arm (Main RCT):
Participants randomised to Care As Usual (CAU; n = 294) receive a letter containing their risk profile along with encouragement to share this with their GP practice for follow-up, without additional coaching or app support.

Implementation Study:
Implementation work will run throughout the study, guided by the Consolidated Framework for Implementation Research (CFIR) in qualitative interviews. In addition, a single-arm qualitative study will recruit 30 participants in a non-randomised phase after RCT recruitment concludes, exploring facilitators, barriers, and sustainability issues from the perspectives of both intervention deliverers (coaches, supervisors) and end users. This work aims to clarify current beliefs, expectations, and the adaptability of the intervention to inform future scalability and real-world implementation.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility trial outcome measures:
1. Sociodemographic measures: deprivation- measured using the Index of Multiple Deprivation (IMD) of the participant postcode, ethnicity as per ONS classification, age and gender, and education, questionnaire at baseline
2. Recruitment, acceptability of trial randomisation, intervention adherence, attrition: data log at 3 months
3. Availability of a designated practice nurse, health care assistant or CRN research delivery staff within participating GP practices: data log at baseline
4. Primary and secondary outcomes completion:
4.1. Cognition (80% follow-up): NIH Toolbox at 3 months
4.2. Use of app: data log at 3 months
4.3. BP (measured using blood pressure monitor): baseline and 3 months
4.4. BMI: (measurement of height and weight): baseline and 3 months
4.5. HbA1c(blood test):baseline and 3 months
4.6. Dementia Risk Score (PHQ-9): baseline and 3 months
4.7. Use of hearing devices: data log at 3 months
4.8. Social contact (Lubben Social Network Scale): questionnaire at baseline and 3 months

4.9. Quality of life (EQ-5D-5L): questionnaire at baseline and 3 months
4.10. Resource use (Client Service Receipt Inventory - CSRI): questionnaire at baseline and 3 months
5. Process evaluation: think-aloud interviews, individual interviews and if needed, focus groups, considering active elements, acceptability: Qualitative work at 3 months
6. The number of people identified as potentially eligible from GP lists: data log at baseline
7. The number of people who have been sent an invite to participate: data log at baseline
8. Number who agreed to contact about participation by responding to the invitation from the practice: data log at baseline
9. Number consenting to be included in the study: data log at baseline
10. Number recruited who meet eligibility criteria after baseline assessment: data log at baseline
11. Number randomised after baseline assessment from those eligible: data log at baseline
12. From those randomised, the number and proportion of people from deprived backgrounds (postcode in lower 4 deciles of the Index of Multiple Deprivation): data log at baseline
13. From those randomised, the number and proportion of people with formal education ending before 14 years of age: questionnaire at baseline
14. From those randomised, the number and proportion of people from minority ethnic backgrounds, measured according to Office for National Statistics guidance: questionnaire at baseline
15. The number and proportion randomised to the intervention arm who start the intervention (at least one intervention coaching session): data log at baseline
16. The number and proportion of participants randomised to the intervention arm who are adherent to the intervention, operationalised as logging into the intervention at least once a week, for at least two-thirds of weeks: data log at 3 months
17. The number and proportion of participants, by arm, who remain in the study until the final follow-up:
data log at 3 months
18. The number and proportion of participants, by arm, completing the envisaged primary outcome (NIH Toolbox) and each outcome measure at baseline and 3 months follow-up: questionnaire at baseline and 3 months
19. The intervention's acceptability assessed during the process evaluation: data log at 3 months
20. The costs of delivering the intervention: data log at 3 months
21. Barriers and facilitators of using the prototype ENHANCE App as determined by qualitative interviews: Qualitative work at 3 months

Randomised controlled trial:
Between randomisation group differences at 12 months in individual Z-scores of the NIH Toolbox, comprising of 4 subtests: Pattern Comparison, Flanker, Picture Sequence, and Dimensional Card Sorting.

Key secondary outcome(s)

Randomised controlled trial:
1. Changes in each one of the NIH Toolbox four cognitive tests (Pattern Comparison, Flanker, Picture Sequence, Dimensional Card Sorting)
2. Between group change in dementia risk factors at follow-up:
2.1. Systolic/diastolic blood pressure measured using BP monitor at baseline, 6 months and 12 months
2.2. BMI (measurement of height and weight) at baseline, 6 months and 12 months
2.3. HBA1c (blood test) at baseline, 6 months and 12 months
2.4. Self-reported smoking (cigarettes/week) questionnaire at baseline, 6 months and 12 months
2.6. Self-reported alcohol use (units/week measured using the Audit-C) questionnaire at

baseline, 6 months and 12 months.
2.7. Hearing device use: self-reported yes/no use and if a user, self-reported daily use (in hours): Measured using 1 item of the International Outcome Inventory for Hearing Aids (IOI-HA) "Over the past 2 weeks, estimate the average daily duration of hearing aid use": questionnaire at baseline
2.8. Hearing disability: change in self-reported hearing disability (when using hearing devices, if hearing device user), measured by validated Hearing Handicap Inventory for the Elderly – Screening version (HHIE-S) questionnaire at baseline, 6 months and 12 months.
2.9. Social contact: self-reported weekly contact using the 6-item Lubben Social Network Scale questionnaire at baseline, 6 months and 12 months
2.10. Mood: PHQ-9 questionnaire at baseline, 6 months and 12 months
2.11. Engagement in weekly physical activities measured by validated Rapid Assessment of Physical Activity (RAPA) questionnaire at baseline, 6 months and 12 months
2.12. Composite dementia risk score using an adapted LIBRA score, incorporating all 10 risk factors of interest and modified from risk scores found to be sensitive and responsive for use as surrogate outcomes in dementia prevention trials: questionnaire at baseline, 6 months and 12 months
3. App login (system usage) data on engagement: data log at 6 months and 12 months:
3.1. Number, frequency, and duration of participant logs into the app, per week, over the 24 weeks of the intervention: data log at 6 months and 12 months
3.2. Number, frequency, and duration of logs in each risk-specific component and in cognitive training activities
4. EuroQol EQ-5D-5L, a preference-based measure of health-related quality of life for calculation of quality-adjusted life years (QALYs): Questionnaire at baseline 6 months and 12 months
5. Adapted version of the Client Service Receipt Inventory (CSRI) questionnaire at baseline 6 months and 12 months

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Age >=60 and <=80 years
2. Living in the community (not admitted to hospital or in a care home)
3. Registered with a GP practice
4. Able and willing to give informed consent
5. Participants should in principle be available for data collection at trial follow-up
6. Has access to a phone (does not have to own a phone but needs access to receive login code)
7. Has >=3 of the following risk factors:
7.1. Untreated or undertreated hypertension at a level increasing dementia risk measured as per NHS recommendations for blood pressure monitoring at a GP surgery (>=140/90 mmHg)
7.2 Untreated or undertreated diabetes mellitus (baseline HbA1c >= 48 mmol/mol)
7.3. Obesity (BMI >30 kg/m^2) in those aged 60-75 years; high BMI will not be considered a risk factor in those over 75 years because the evidence suggests that losing weight after that age may increase dementia risk
7.4. Current smoker (smoking at least 7 cigarettes in the past week)
7.5. Drinking above level increasing dementia risk (>21 U/week)
7.6. Low level of physical activity (RAPA <150 min/week)
7.7. Formal education stopped before age 14
7.8. Depression (PHQ-9->=9)

7.9. Infrequent social contact as measured using the 6-item version of the Lubben Social Network Scale
7.10. Untreated or undertreated hearing loss as determined by the following:
7.10.1. Untreated hearing loss: The participant has never been prescribed hearing aids and a Hearing screening test using the HearWHO app as tested during baseline is positive for hearing loss.
7.10.2. Undertreated hearing loss: The participant has been prescribed hearing aids at some point but is currently using them for less than 1 h per day on average, as determined by the International Outcome Inventory for Hearing Aids (IOI-HA).
7.10.3. If the person has treated hearing loss with current average daily use above 1 h a day they do not meet this criterion. People who have ever been prescribed hearing aids are assumed to have hearing loss and do not need to have their hearing tested.

The inclusion criteria for the main RCT will be refined following the feasibility trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Participants already enrolled in another intervention trial.
2. Dementia - either existing recorded diagnosis, taking acetylcholinesterase inhibitor, memantine or other dementia-specific medication. We will also monitor low cognitive score at baseline in the NIH Toolbox, and scores lower than 2 SD below the mean according to published norms will be discussed with clinical researchers to consider dementia adjudication for exclusion. (When this happens, the clinician making the adjudication will contact the participant to discuss the results and the reasons for exclusion and encourage them to visit their GP about this).
3. Active alcohol (AUDIT-C ≥8) or known substance dependence as identified by the practice team.
4. If question No. 9 on PHQ-9 ≥1, the participant will be excluded from ENHANCE due to suicidal thoughts.
5. Medical conditions preventing trial completion, including end-of-life care as determined by a practice GP, patients on the severe mental illness register, and blindness.
6. If in the opinion of the practitioner taking consent, the person is unable to provide informed consent.
7. Another member of the household has been recruited into the ENHANCE trial.

The inclusion and exclusion criteria for the main RCT will be refined accordingly following the feasibility trial.

Date of first enrolment
28/05/2025

Date of final enrolment
28/02/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Yorkshire Teaching NHS Foundation Trust
Mary Seacole Building
Willerby Hill
Beverley Road
Willerby
United Kingdom
HU10 6ED

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Harry Pitt Building
Earley Gate
Whiteknights Road
University of Reading
Reading
United Kingdom
RG6 7BE

Study participating centre
University College London
Division of Psychiatry
Maple House
4th Floor
149 Tottenham Court Road
London
United Kingdom
W1T 7NF

Sponsor information

Organisation
North London NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes