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Trialling the Active Brains programme to reduce cognitive impairment in older age groups

Submission date	Recruitment status	[X] Prospectively registered
14/04/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
28/04/2020	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/11/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

The researchers have made a new website called 'Active Brains' which aims to help older adults to look after their brain and body health. The aim is to help prevent problems with things like remembering, concentrating or reasoning (known as cognitive decline). The website will help older adults to make simple changes such as getting more active, playing brain training games and finding ways to eat more healthily. This study will test how well the website works in two groups of people: older adults with signs of cognitive decline, and older adults without any cognitive decline.

Who can participate?

Men and women aged 60 -85 registered with participating GP surgeries, with access to the internet and who do not have dementia

What does the study involve?

Participants will be randomly put into one of three study groups: care as they usually receive it from their GP practice, or the Active Brains website, or the Active Brains website plus a bit of support from a trained person (over the phone or by email). The study will last for 5 years. At the end of the first year the researchers will compare people's thinking (cognitive) skills in each of the three study groups. After 5 years they will compare the three study groups again and also check how many of the people in each study group went on to be diagnosed with dementia.

What are the possible benefits and risks of participating?

There is no direct benefit but taking part in the study and using Active Brains might improve participants' memory and thinking skills and general well-being. In the researchers' other studies, people have enjoyed taking part and learning new things. A while after the study has finished the researchers will tell everyone who took part what the study found out. If Active Brains is shown to be helpful for people's memory and thinking skills, then the study team will try to make it available for everyone to use. If this is the case, participants of the study will be advised how they can access Active Brains. The main disadvantage of taking part is that it will take up some of the participants' time. It will take about 30 minutes to fill in the questionnaires. Participants will be asked to complete these questions every year.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
January 2018 to June 2029

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
273507

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44571, IRAS 273507

Study information

Scientific Title
Trialling the Active Brains programme to reduce cognitive impairment in older age groups: a randomised controlled trial

Study objectives
The trialists have made a new website called ‘Active Brains’ which aims to help older adults to look after their brain and body health, to help to reduce cognitive decline and dementia. The website will help older adults to make simple changes such as getting more active, playing brain training games and finding ways to eat more healthily.

This study will test whether the ‘Active Brains’ programme reduces cognitive decline among older age adults both with and without cognitive decline, compared to standard care.

It will also test whether the Active Brains programme with additional brief telephone support from a trained facilitator reduces cognitive decline among older age adults both with and without cognitive decline, compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2020, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), REC ref: 20/YH/0018

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

Primary study design

Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Cognitive decline

Interventions
Fully powered, definitive trials will test the effectiveness and cost-effectiveness of both the standalone Active Brains digital intervention and the Active Brains digital intervention plus support from a central facilitator to see if either of these interventions can maintain cognitive function and prevent cognitive decline (compared with usual care), in two groups of people:
1. Older people who currently show signs of MCI or AACD
2. Older people who do not show any signs of cognitive decline

Participants will be randomly allocated to one of three study groups:
1. Usual care
2. Access to the Active Brains website
3. Access to the Active Brains website with flexible human support from a central support facilitator

There are therefore two parallel trials with the same trial interventions: in one trial the researchers will be recruiting a group of patients with cognitive decline and in the second trial a group without cognitive decline.

Consent will be collected online, following consent participants will complete online screening to check eligibility. Participants will complete the online cognitive assessment screening. Online screening comprises cognitive assessment (Baddeley verbal reasoning task), self-reported leisure-time physical activity, dementia/cognitive status questions and participation in other research studies.

Those meeting the threshold for cognitive impairment (see eligibility criteria) will be recruited to the cognitively impaired trial. Those not meeting this threshold will be recruited into the trial for those not cognitively impaired. Once a minimum of 10,515 participants have been recruited into this trial (or 10,940 in the cognitively impaired trial - whichever comes first), further participants without signs of impairment (or with signs of impairment if this trial reaches recruitment target first) will be given the opportunity to participate in a non-randomised cohort study which will provide the same digital intervention as in the full trial, with online self-completion of follow up only (the researchers won’t do a notes review or provide additional support from a centralised facilitator to this group).

The Active Brains Intervention
Those participants randomised to the intervention groups will be given access to The Active Brains digital intervention. For the first 7 months, users will be given access to the Active Brains "starter section" which provides support for users to initiate changes to their lifestyle in line with the intervention's recommendations;increasing levels of activity; brain training; healthy eating.

After 7 months users will be directed to access to The Active Brains Booster section. This content will include access to all content from the Starter Section, as well as advice on a

'maintenance' schedule for brain training, and centralised links to external resources for additional support and to extend their progress with the behavioural changes made.

Central Facilitator Support
Patients in the group receiving support from a central facilitator (in addition to the website) will be offered a brief (10-minute) telephone support call 2 weeks after they begin the study. In this support call they will discuss the cognitive/lifestyle changes that they are choosing to try. Patients will be offered two more support contacts by phone (up to 10 minutes) or email to support them in making behavioural changes.

For patients who feel the need, up to seven further email or phone contacts can be arranged. In the feasibility study, only one participant requested additional contact beyond the three initial calls (n = 120 in support arm). In previous studies only around 10-15% of patients have required this further support.

Usual care
Those participants randomised to the usual care group will receive usual care from their GP practice, plus brief online advice about getting more active, improving diet and staying mentally active.

Follow up
Participants in both the randomised trials and cohort study will be followed-up every 12 months for the 5-year duration of the study. At years 1 and 5, participants will be asked to complete a full set of follow-up measures. In years 2, 3 and 4 participants will only be requested to complete a subset comprising the most important outcome measures.

Intervention Type
Other

Primary outcome(s)
1. Cognitive performance (verbal reasoning) measured using online version of the Baddeley Verbal Reasoning task at baseline and 1, 2, 3, 4 and 5 years
2. Dementia diagnosis, determined by data collected from patient notes review at 5 years

Funding for five-year follow-up is contingent on evidence of effectiveness in changing behaviour and improving cognition at 1 year

Key secondary outcome(s))
1. Ability to perform activities of daily living measured using Instrumental Activities of Daily Living scale (the key secondary outcome) at baseline and years 1, 2, 3, 4 and 5
2. Secondary cognitive outcomes measured at baseline and years 1, 2, 3, 4, and 5:
2.1. Spatial working memory measured using the self-ordered search test
2.2. Digit vigilance (attention) measured using a version of the 'digit span' task
2.3. Verbal short-term memory (VSTM) measured through the paired associates learning (PAL)
3. Patient enablement measured using modified Patient Enablement scale at years 1 and 5
4. Depression measured using the short form of the Brief Geriatric Depression Scale at baseline and year 1
5. Significant cognitive decline:
5.1. Diagnosis of dementia (among cognitively impaired participants defined at baseline): evidence from cognitive testing, notes review, and using Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (short form) as necessary; at 5 years there will be input from a

consensus panel
5.2. Cognitive impairment (among non-cognitively impaired individuals): the researchers will document those who become cognitively impaired (defined as above, including MCI and AACD)
6. Mortality collected from note reviews at year 1 and year 5
7. Health-related quality of life measured using EQ5D (and proxy versions of EQ5D if necessary) at baseline and years 1, 2, 3, 4 and 5, SWEMWBS -7 item at baseline and years 1 and 5, and SF-12 at baseline and years 1 and 5
8. Diet quality/dietary behaviour measured using brief validated food frequency questionnaire at baseline and years 1, 2, 3, 4, 5
9. Physical activity behaviour measured by IPAQ plus additional items about strength and balance at baseline and years 1, 2, 3, 4, 5

Other measures:
Resource usage for the health economic analysis (medication, consultations, hospitalisation, A&E attendance, outpatient visits) extracted through notes review and health, medication and work status items at baseline years 1 and 5

Implementation assessment:
1. Web usage: with informed consent, the researchers will analyse all website usage, which is unobtrusively automatically collected by the online systems, including time spent on each page and entries (e.g. goal setting and goal-related progress in all behaviours)
2. Self-reported behaviours and their expected determinants:
2.1. Self-efficacy for exercise measured by Self-efficacy for exercise scale at baseline, year 1 and 5
2.2. Perceived social support measured by mMOS Social Support Survey – 8 item at baseline, year 1 and 5
2.3. Perceived social support to be physically active measured by Social Support for Exercise scale at year 1 and 5
2.4. Motivation to be active measured by Locus of Causation in Exercise at baseline, year 1 and 5
2.5. Pedometer use/purchase measured by two single items about whether these behaviours have occurred at year 1 and 5
2.6. Perceived ease of use of intervention measured by Technology Acceptance Model Perceived Ease of Use scale at year 1 and 5
2.7. Difficulties with adhering to recommendations measured by Problematic Experiences of Therapy Scale at year 1 and 5
3. Qualitative process studies of 12-18 patients from each study arm

Completion date
12/06/2029

Eligibility

Key inclusion criteria
Individuals with signs of cognitive decline:
1. Aged between 60 and 85 years old.
2. Cognitive impairment defined as 1 SD below the norm on the Baddeley reasoning test. The researchers will also explore the impact in subgroups defined by combinations of impairment in Baddeley reasoning, IADL and memory. Key subgroups are MCI, which will be defined as 1.5 SD below the norm in a non-memory cognitive domain plus memory impairment, and AACD defined as 1 SD below the norm for the Baddeley reasoning test and IADL
3. Willing and able to access the internet

Individuals without signs of cognitive decline:
1. Aged between 60 and 85 years old
2. Normal cognitive function (i.e. do not meet criteria for cognitive impairment as defined above)
3. Willing and able to access the internet

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 years

Upper age limit
85 years

Sex
All

Total final enrolment
24324

Key exclusion criteria
1. Existing diagnosis of dementia at baseline
2. Report high levels of leisure time physical activity already (i.e. score 30 or more on the Godin Leisure Time Exercise Questionnaire (counting moderate or vigorous physical activity only))
3. Terminally ill/ in receipt of palliative care
4. Seriously mentally ill (e.g. major uncontrolled depression, schizophrenia)

Date of first enrolment
01/06/2020

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
NIHR CRN: North East and North Cumbria
-
United Kingdom
NE3 3HD

Study participating centre
NIHR CRN: North West Coast
United Kingdom
L7 8XP

Study participating centre
NIHR CRN: Yorkshire and Humber
United Kingdom
S10 2SB

Study participating centre
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M13 9WL

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BS1 2NT

Study participating centre

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OX3 9DU

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NR1 1QQ

Study participating centre
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Study participating centre
NIHR CRN: Wessex
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Sponsor information

Organisation
University of Southampton

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20014

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 non-publically available repository.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 9	23/09/2024	19/11/2024	No	No
Statistical Analysis Plan	version 1	31/10/2024	19/11/2024	No	No