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The Active Brains study - feasibility trial

Submission date	Recruitment status	[X] Prospectively registered
30/07/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/08/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Plain English summary as of 21/09/2018:
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 to prevent 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. The aim of this study is to test how easy to use and helpful the website is. It will also test how easy and useful the study procedures are for the larger main trial. If no significant changes are made in the study intervention or outcome measures the feasibility study will progress to the main trial and the data from the feasibility study can also be used in the analysis of the main trial. If there is evidence of the effectiveness of the interventions at 1 year funding will be released to follow-up participants for 5 years.

Who can participate?
Older adults (aged between 60 and 85) who have problems remembering or concentrating (known as cognitive decline), and older adults without any of these problems

What does the study involve?
Both groups of people are randomly allocated into one of three groups to receive either: 1) care as they usually receive it from their GP practice, or 2) access to the Active Brains website, or 3) access to the Active Brains website plus a bit of support from a trained person (over the phone or by email).

What are the possible benefits and risks of participating?
The findings of this study will be used to spot any changes which are important to make to the website, the support (in the third group) or the study procedures. Any changes will be made before the main trial. There is no direct benefit to participants but taking part in the study and using Active Brains might improve memory and thinking skills and general well-being. In other studies, people have enjoyed taking part and learning new things. The main disadvantage of taking part is that it will take up time. It will take about 30 minutes to fill in the questions and the participant will be asked to complete these questions twice: at the start of study and again after about a year.

Where is the study run from?
1. University of Southampton (UK)
2. Primary care practices within Wessex CRN (UK) with other centres joining for the main trial

When is the study starting and how long is it expected to run for?
January 2018 to March 2020 and if the main trial proceeds to September 2026

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

Who is the main contact?
Ms Joanne Kelly
jk1@soton.ac.uk

Previous plain English summary:
Background and study aims
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Who is the main contact?
Ms Joanne Kelly
jk1@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Joanne Kelly

ORCID ID
https://orcid.org/0000-0001-7690-6763

Contact details
Primary Care and Population Sciences
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST
+44 (0)2380 591751
jk1@soton.ac.uk

Additional identifiers

Central Portfolio Management System (CPMS)
38420

Study information

Scientific Title
REducing and preventing COgnitive impairment iN older age groups (the RECON Programme) feasibility trial

Acronym
RECON

Study objectives
Hypothesis as of 21/09/2018:
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 prevent 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 research project will test how easy to use and helpful the website is. It will also test how easy and useful the study procedures are for the main trial. The main trial will test whether internet-supported healthy behaviour/cognitive exercises reduce cognitive decline among older age adults.

Previous hypothesis:
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 prevent 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 research project will test how easy to use and helpful the website is. It will also test how easy and useful the study procedures are for the main trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester South Research Ethics Committee, 20/06/2018, ref: 18/NW /0341

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Screening, Process of Care, Psychological & Behavioural, Other, Qualitative

Study type(s)
Treatment

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

Interventions
Intervention as of 21/09/2018
This feasibility trial will be used to examine the study and intervention procedures, to ensure that they are acceptable and feasible, in order to check that the future planned RCT can be carried out successfully. The future planned fully powered definitive trial will test the effectiveness and cost-effectiveness of both Active Brains and Active Brains plus support from a central facilitator, to see if either of these interventions can maintain cognitive function and prevent cognitive decline in 1) individuals with cognitive impairment but particularly people who currently show signs of Mild Cognitive Impairment (MCI) or Age Associated Cognitive Decline (AACD), and 2) people who do not show any signs of cognitive decline. The findings of the feasibility study may be used to make modifications to the study or intervention procedures to ensure the success of the definitive trial.

In both the feasibility and fully powered trials, patients will be randomly allocated to one of three 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

The trialists will recruit a cohort of patients with cognitive decline and a cohort without cognitive decline.
1. In patients with cognitive decline they will recruit a minimum of 60 patients to each of the three groups, approximately half of these patients will have MCI and half will have AACD.

2. In patients without cognitive decline they will recruit a minimum of 60 patients to each of the three groups.
This means the total sample size across both cohorts will be a minimum of 360 participants.

We will explore a range of recruitment strategies to see which are most feasible and effective to carry forward into the main trial. Participants will be recruited via Primary Care, and possibly through charity databases (DPUK, JDR) or media campaigns.

Primary Care recruitment will involve practice staff inviting patients from practice lists (GPs will screen practice lists to avoid inviting those who have an existing diagnosis of dementia, are terminally ill or seriously mentally ill). Participants information sheets, reply slips (for those not interested to inform us why) and a 'getting started' card with instructions on how to start the log on to the website to start the study, will be sent from GP Practices via Docmail. Participants can also contact the research team directly if they have any questions. GP practices will be asked to provide demographic data (gender, age and postcode - to help us establish level of deprivation) for all participants who are invited to the study. We will compare the demographics of those invited who do not participate to recruited participants to examine any differences between these two groups. This will help us to assess the likely generalisability of our findings.

We aim to explore the possibility of recruiting participants via invitation through DPUK (including the established Biobank and PROTECT research cohorts) and JDR (a public facing web portal for matching patients and public to relevant studies), but this may not prove feasible..

We may also explore the option of using media campaigns to promote the study e.g. advertising our study poster through dementia charities, in newspapers/magazines or social media that the target groups are likely to read, or through discussions of the study on radio or TV. Participants will be given a link to the study website where they can view the participant information sheet, complete online consent and screening and (if eligible) start the study.

Feasibility trial
Planned Sample Size: 360; UK Sample Size: 360

Main trial
Cognitively impaired individuals
Planned Sample Size: 2805 with follow-up data in each subgroup; UK 2805 with follow-up data in each subgroup
Non-Cognitively impaired individuals
Planned Sample Size: 6309 with follow-up data; UK 6309 with follow-up data

Cognitively impaired participants
Cognitive decline:
A range of scenarios were tabulated. To find a difference of 0.15 SMD in any pairwise comparison between intervention and control for 90% power and alpha=0.05 we estimated would require 935 per group with MCI having follow-up data (i.e. 2805 for three groups), and the same number for AACD. The planned sample size will be finalised at the end of the feasibility study.

Development of dementia.
We calculated that 1094 individuals with complete outcomes per group will be needed to detect a 5% progression to dementia per annum, and a similar number with AACD. Assuming a lower progression rate, for MCI/AACD combined the above sample provides 80% power to detect a 3% progression rate.

Non-cognitively impaired participants
We estimate that for an SMD of 0.1 with 90% power for an alpha of 0.05 2103 individuals with follow-up data are needed in each group

Patients will be randomised online using the study software. They will have an equal chance of being in each of the three groups. Once randomised, participants will be informed of their group allocation (they will also be emailed this information). If participants are in one of the treatment arms they will be taken directly to Active Brains to begin the intervention. These participants can then use Active Brains as much as they would like to over the course of the study. The central facilitator will be notified by email when a participant is randomised to the support arm of the trial, so that they know to expect to provide support to the participant in the coming weeks.

Consent will be collected online (a method we have used successfully in our PRIMIT and CLASP trials). Following consent participants will complete online screening to check that they meet the above eligibility criteria for the study. Those who are ineligible based on the screening measures will receive immediate feedback which thanks them for their time, advises that they are not eligible and explains the reason for this (e.g. that they are already very highly physically active).

Should participants' scores on the online cognitive assessment screening tools meet the threshold for cognitive impairment (1 SD below normal scores for verbal reasoning) , they will be advised that slightly lower scores on formal tests like these, whilst within normal limits of performance, might indicate a risk for difficulties with memory in the future. For these individuals it will be stressed that these scores certainly do not indicate a diagnosis or a definite problem and that, if concerned, they could consider seeing their GP for further advice. The acceptability of this wording was tested in the recent qualitative development work and amended according to participant feedback.

Those whose scores do not meet the threshold for cognitive impairment will not be excluded, as we are also aiming to recruit a group of a minimum of 180 patients who do not show signs of cognitive decline. Thus the sample will be stratified by cognitive impairment i.e. in effect a feasibility trial is proposed for cognitively impaired individuals, and a similar sized trial for non-cognitively impaired individuals; the same stratification will be used in the main trial. However, given that there is likely to be a far greater number of individuals whose scores don't meet the cognitive decline threshold, not all will be required to participate in the randomised feasibility trial. Once we have recruited a minimum of 180 people who do not show signs of cognitive impairment, further participants without signs of cognitive impairment will not be included in this randomised feasibility trial. Instead, they will be given the opportunity to participate in a non-randomised cohort study which will use the same processes as the feasibility trial: specifically these participants will complete the same baseline and follow up measures as randomised participants (at the same time points) but will all be given access to the Active Brains website (without support from the centralised facilitator). The same process will be used in the main trial. After initial screening indicates that these participants are eligible, and that they are not needed for the feasibility trial, these participants will be shown a different participant information sheet for a cohort study online and will complete a slightly different consent form. This procedure could be beneficial for participants without signs of cognitive impairment who will get access to the Active Brains intervention and will enable us to examine how the intervention might be implemented outside of a randomised trial (which will be more similar to the effects one might expect if implementing in clinical practice).

Within the first section of Active Brains, three primary modules will become available to users sequentially. Within these modules, users will have access to: information addressing common concerns, instruction about recommended activities, facilities to set and review goals about their chosen activities, tailored motivational feedback about their progress, and reminder emails to motivate them to continue with their activities and to revisit intervention content as appropriate.

After six months, it is expected that the primary needs of intervention users will be somewhat different. It is likely that, with support from the Active Brains Starter Sessions, the recommended activities that users have chosen to engage with will have become more habitual behaviours. These users are, therefore, expected to have less need to rely on the intervention content so extensively. Accordingly, at this stage, users will be directed to access the Active Brains Maintenance Phase. On initial login to this section, users will be provided with a tailored summary of their progress and engagement with the Starter Session content. Based on this, they will receive tailored suggestions about content they may wish to view. This content will include summarised versions of key content from the starter sessions and links to additional resources for additional support and to extend their progress with the behavioural changes made.

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 (which we anticipate will be up to 10 minutes but the length of facilitation may be modified in the feasibility study) and/or email to support them in making behavioural changes. For patients who feel the need, up to 7 further email or phone contacts can be arranged. In our previous studies only around 10-15% of patients have required this further support.

The comparison group will receive usual care from their GP practice, plus brief online advice about getting more active, improving diet and staying mentally active.

Participants in both the feasibility trial and cohort study will receive 3 automated email reminders to complete follow-up measures. After this we will contact participants in the feasibility trial by post then, or if unsuccessful, by phone to ask them to complete the most important outcome measures (verbal reasoning), Instrumental Activities of Daily Living, quality of life with the EQ5D and the IQCODE (in cases where the participant shows a decline in cognitive ability). We will also send these participants a £10 Amazon or high street stores gift voucher to explore whether this helps to enhance follow up rates (this will inform whether we need to provide gift vouchers at follow up within the later planned fully powered trial). The verbal reasoning task cannot be completed by phone, so if phone calls are required then they will be used to prompt/support (as required) the participant to complete this task online/by post or to ascertain that the participant is no longer able to complete these measure (e.g. in the case of cognitive decline). All of the participants will be contacted to complete follow-up measures, whether or not they have used the website. If the participant indicates that they would not be willing to complete any further measures at any point then no further contact will be made regarding the follow-ups.

There will be two qualitative process studies, one with participants and one with central support facilitators. Interviews in both these studies may be carried out anytime between 2-12 months after participants begin the study. Both of these studies will allow assessment of the

acceptability and feasibility of the intervention and highlight any modifications to the intervention or study procedures which might be required prior to embarking on the later planned fully powered trial.

The trialists will interview 12-18 participants from each of the intervention arms, employing purposive sampling to ensure a diverse range of participants in terms of demographic and clinical profiles, as well as website usage. Participants will have consented to be contacted by the research team throughout the study. Participants will be invited to participate by the research team (phone, email or by post) and asked if they would be willing to take part in an interview (by telephone or face-to-face in a place of their choosing, e.g. GP surgery, university, own home). Participants will complete a separate consent form (online) prior to taking part in an interview. During the interview, open-ended questions will be used to explore participants' perceptions of the study, the website (if in one of the intervention groups) and the support they received from the central facilitator (if in the support group). Participants in the control group will be asked about the brief advice they were given at baseline.

The second sub-study will use face-to-face or telephone interviews to explore central support facilitators' views of the study procedures, the website, the training they were provided with and the support that they provided to patients (including perceptions of the CARE approach).

Data from both qualitative process studies will be analysed using inductive thematic analysis with inter-rater agreement reached between team members. The findings will be discussed and interpretations agreed between the co-investigators (including PPI representatives).
There will also be both quantitative and qualitative process analyses for the main trial should the feasibility study progress to a full trial.

Previous intervention:
This feasibility trial will be used to examine the study and intervention procedures, to ensure that they are acceptable and feasible, in order to check that the future planned RCT can be carried out successfully. The future planned fully powered definitive trial will test the effectiveness and cost-effectiveness of both Active Brains and Active Brains plus support from a central facilitator, to see if either of these interventions can maintain cognitive function and prevent cognitive decline in two cohorts: 1) people who currently show signs of MCI or AACD, 2) people who do not show any signs of cognitive decline. The findings of the feasibility study may be used to make modifications to the study or intervention procedures to ensure the success of the definitive trial.

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We aim to recruit participants via invitation through DPUK (including the established Biobank and PROTECT research cohorts) and JDR (a public facing web portal for matching patients and public to relevant studies). These databases include patients with and without cognitive decline. Individuals registered with DPUK and JDR who are not currently listed on these databases as having a diagnosis of dementia will be emailed an invitation letter, with a link to a website where they can view the participant information sheet, complete online consent and screening and (if eligible) start the study.

We will also explore the option of using media campaigns to promote the study e.g. advertising our study poster through dementia charities, in newspapers/magazines or social media that the target groups are likely to read, or through discussions of the study on radio or TV. Participants will be given a link to the study website where they can view the participant information sheet, complete online consent and screening and (if eligible) start the study.

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Those whose scores do not meet the threshold for MCI/AACD will not be excluded, as we are also aiming to recruit a group of 180 patients who do not show signs of cognitive decline. However, given that there is likely to be a far greater number of individuals whose scores don't meet the MCI/AACD threshold, not all will be required to participate in the randomised feasibility trial. Once we have recruited 180 people who do not show signs of MCI/AACD, further participants without signs of MCI or AACD will not be included in this randomised feasibility trial. Instead, they will be given the opportunity to participate in a non-randomised cohort study which will use the same processes as the feasibility trial: specifically these participants will complete the same baseline and follow up measures as randomised participants (at the same time points) but will all be given access to the Active Brains website (without support from the centralised facilitator). After initial screening indicates that these participants are eligible, and that they are not needed for the feasibility trial, these participants will be shown a different participant information sheet for a cohort study online and will complete a slightly different consent form . This procedure could be beneficial for participants without signs of MCI or AACD who will get access to the Active Brains intervention and will enable us to examine how the intervention might be implemented outside of a randomised trial (which will be more similar to the effects one might expect if implementing in clinical practice).

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The comparison group will receive usual care from their GP practice, plus brief online advice about getting more active, improving diet and staying mentally active.

Participants in both the feasibility trial and cohort study will receive 3 automated email reminders to complete follow-up measures. After this we will contact participants in the feasibility trial by post then, or if unsuccessful, by phone to ask them to complete the most important outcome measures (verbal reasoning), Instrumental Activities of Daily Living, quality

of life with the EQ5D and the IQCODE (in cases where the participant shows a decline in cognitive ability). We will also send these participants a £10 Amazon or high street stores gift voucher to explore whether this helps to enhance follow up rates (this will inform whether we need to provide gift vouchers at follow up within the later planned fully powered trial). The verbal reasoning task cannot be completed by phone, so if phone calls are required then they will be used to prompt/support (as required) the participant to complete this task online/by post or to ascertain that the participant is no longer able to complete these measure (e.g. in the case of cognitive decline). All of the participants will be contacted to complete follow-up measures, whether or not they have used the website. If the participant indicates that they would not be willing to complete any further measures at any point then no further contact will be made regarding the follow-ups.

There will be two qualitative process studies, one with participants and one with central support facilitators. Interviews in both these studies may be carried out anytime between 2-12 months after participants begin the study. Both of these studies will allow assessment of the acceptability and feasibility of the intervention and highlight any modifications to the intervention or study procedures which might be required prior to embarking on the later planned fully powered trial.

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The second sub-study will use face-to-face or telephone interviews to explore central support facilitators' views of the study procedures, the website, the training they were provided with and the support that they provided to patients (including perceptions of the CARE approach).

Data from both qualitative process studies will be analysed using inductive thematic analysis with inter-rater agreement reached between team members. The findings will be discussed and interpretations agreed between the co-investigators (including PPI representatives).

Intervention Type
Other

Primary outcome(s)
Primary outcome measure as of 21/09/2018:
Feasibility study
1. The ability to collect clinical outcome and notes review data, built around the stop/go criteria for the trial: the main trial will proceed if 80% of the clinical outcome and notes review data are available for analysis. If the figures are 70-80% the trialists will discuss with the steering committee their plans for appropriate mechanisms to increase response rate. If much less than

70% of the data is available, in negotiation with the funder they will consider not proceeding to the main trial unless there is a clear and plausible plan to increase response rates/reduce missing data.

Main trial
1. Verbal reasoning (measured using the simple Baddeley reasoning test)

Previous primary outcome measure:
The ability to collect clinical outcome and notes review data, built around the stop/go criteria for the trial: the main trial will proceed if 80% of the clinical outcome and notes review data are available for analysis. If the figures are 70-80% the trialists will discuss with the steering committee their plans for appropriate mechanisms to increase response rate. If much less than 70% of the data is available, in negotiation with the funder they will consider not proceeding to the main trial unless there is a clear and plausible plan to increase response rates/reduce missing data.

Key secondary outcome(s)

Secondary outcome measures as of 21/09/2018:
Feasibility study
Feasibility in terms of:
1. Suitability of recruitment screening methods
2. Acceptability of all trial procedures, including recruitment strategies, randomisation, study materials, follow-up procedures and notes review
3. Recruitment and attrition rates
4. Acceptability of the digital intervention (assessed by uptake, usage and attrition and qualitative process evaluation)
5. Appropriateness of human support module (uptake, adherence, number of sessions and qualitative process evaluation)
6. Suitability of all outcome measures
7. Health economics analysis – the key resources to be collected, to inform choice of quality of life instruments to be used in the full trial

Main trial (both cognitively impaired and non-impaired participants) at 1 year (and 5 years if funding is released for longer term follow-up):
1.Instrumental Activities of Daily living (the key secondary outcome)
2. Secondary cognitive outcomes: Spatial Working Memory through the self ordered search test; Digit vigilance (attention) through a version of the 'digit span' task; Verbal short-term memory (VSTM) measured through the paired associates learning (PAL)
3. Patient enablement (modified Patient Enablement scale)
4. Brief depression instrument: the short form of the Geriatric Depression Scale
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): we will document those who become cognitively impaired (defined as above, including MCI and AACD)
6. Mortality.
7. Health-related QoL. The feasibility study will determine which of three instruments will be used in the main trial: EQ5D (and proxy versions of EQ5D if necessary); ICE CAP; and the SF 12.
8. Brief validated food frequency, physical activity questionnaires, including the assessment of sedentary time.

Other measures:
1. Resource usage for the Health Economic analysis (medication, consultations, hospitalisation, A&E attendance, outpatient visits) will be extracted through notes review.

Implementation assessment
1. Web usage. With informed consent, we 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 determinants.
3. Qualitative process studies of 12-18 patients from each study arm.

Previous secondary outcome measures:
Feasibility in terms of:
1. Suitability of recruitment screening methods
2. Acceptability of all trial procedures, including recruitment strategies, randomisation, study materials, follow-up procedures and notes review
3. Recruitment and attrition rates
4. Acceptability of the digital intervention (assessed by uptake, usage and attrition and qualitative process evaluation)
5. Appropriateness of human support module (uptake, adherence, number of sessions and qualitative process evaluation)
6. Suitability of all outcome measures
7. Health economics analysis – the key resources to be collected, to inform choice of quality of life instruments to be used in the full trial

Completion date
21/03/2020

Eligibility

Key inclusion criteria
Participant inclusion criteria as of 11/10/2018:
Cognitively impaired participants:
1. Aged between 60 and 85 years old
2. Have cognitive impairment: 1 SD below the norm for the Baddeley reasoning test. We will explore the impact in subgroups defined by combinations of impairment in Baddeley reasoning, IADL and memory. Key subgroups for those with cognitive impairment that are of particular interest are:
2.1. AACD: 1SD below norm for an average of 3 tests for Baddeley reasoning + 1sd below norm for Instrumental activities of Daily Living (IADL)
2.2. MCI: 1.5SD below norm for an average of 3 tests for Baddeley reasoning + 1.5 SD below norm for an average of 3 tests for impaired memory (self-ordered search test)
3. Be willing and able to access the internet

Non-Cognitively impaired participants:
To be eligible for inclusion individuals without signs of cognitive decline will:
1. Be aged between 60 and 85 years old
2. Have normal cognitive function (i.e. do not meet criteria for inclusion in the cognitively impaired trial)
3. Be willing and able to access the internet

Previous participant inclusion criteria:
To be eligible for inclusion, individuals with signs of cognitive decline will:
1. Be aged between 60 and 85 years old
2. Have either MCI (defined as 1.5 SD below the norm in a non-memory cognitive domain plus memory impairment or AACD (defined as 1 SD below the norm for the Baddeley reasoning test)
3. Be willing and able to access the internet

To be eligible for inclusion individuals without signs of cognitive decline will:
1. Be aged between 60 and 85 years old
2. Have normal cognitive function (i.e. do not meet criteria for MCI or AACD)
3. Be willing and able to access the internet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 Years

Upper age limit
85 Years

Sex
All

Key exclusion criteria
1. Have an existing diagnosis of dementia
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. Do not have access to the internet

Individuals without signs of cognitive decline will be excluded if:
1. In full time employment (or are fully retired)
2. Have an existing diagnosis of dementia
3. 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))
4. Do not have access to the internet

Date of first enrolment
01/09/2018

Date of final enrolment
14/01/2019

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Southampton
United Kingdom
-

Study participating centre
Primary care practices within Wessex CRN (not yet confirmed)
United Kingdom
-

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

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 are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/09/2022	06/09/2023	Yes	No
Protocol article	protocol	20/11/2020	23/11/2020	Yes	No
HRA research summary			28/06/2023	No	No