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Testing a new brain training treatment (called 'SMART') for people with mild cognitive impairment

Submission date
05/01/2023

Recruitment status
No longer recruiting

Registration date
25/01/2023

Overall study status
Completed

Last Edited
25/01/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mild cognitive impairment (MCI) is a condition where people experience memory and thinking problems. There is a need for treatments to address these problems and improve quality of life. A new 'brain training' treatment has been developed to help people with MCI who have problems with thinking skills. This study aims to test whether this training (known as the SMART programme) is acceptable to people with MCI. It will also assess whether we can do a larger study to test whether SMART improves thinking skills in people with MCI.

Who can participate?
People who have been diagnosed with MCI and are experiencing problems with their thinking skills

What does the study involve?
Participants will be asked to do some tests of thinking skills and fill in some forms about their problems with thinking, mood, and health. Participants will then be put into three groups by chance:
Group 1: Receives the online SMART treatment in addition to their usual care (often informational support). SMART treatment involves doing a series of puzzles. These puzzles are designed to train key skills that support thinking and new learning.
Group 2: Receives a different online brain training treatment in addition to their usual care. This brain training treatment involves doing a series of puzzle games that have shown promise in previous research.
Group 3: Receives usual care alone.
Three and six months later, participants again complete the tests and forms that they did before treatment. Researchers will also interview some patients about how they found the study and the treatment received.

What are the possible benefits and risks of participating?
The researchers cannot promise the study will help individual participants but the information they get from this study will help them to decide whether they should develop the SMART

programme for future use by people with MCI. Those taking part in this study may ultimately help to improve treatment options for people with MCI.
Participating will take time and may therefore be inconvenient. The SMART programme may be challenging and difficult to understand at first. Participants can stop at any time if they do not wish to continue.

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

When is the study starting and how long is it expected to run for?
December 2021 to May 2024

Who is funding the study?
National Institute of Health Research (NIHR) Research for Patient Benefit Programme (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)
311736

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54220, IRAS 311736

Study information

Scientific Title
Strengthening Mental Abilities with Relational Training (SMART) for Mild Cognitive Impairment (MCI): a feasibility trial

Acronym
SMART MCI

Study objectives
Primarily, the aim of this study is to assess the acceptability and feasibility of the SMART programme as a prospective intervention for improving cognitive functioning in people with MCI. Specifically, the study will assess:
1. Acceptability and feasibility of the intervention, delivery format, inclusion/exclusion criteria, baseline and outcome measures, randomisation protocol, and study procedures
2. Participant recruitment and retention rates
3. Signal of efficacy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2022, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048306; gmeast.rec@hra.nhs.uk), ref: 22/NW/0335

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild cognitive impairment

Interventions
Participants will be individually randomised at baseline (after consent) in unequal proportions to one of three groups (2:1:1 ratio) using block randomisation (block size 4). Randomisation will be computer generated via the electronic trial database in Castor EDC (Castor Electronic Data Capture, available at: https://castoredc.com).

Group 1: SMART training programme
Participants in the intervention (SMART training) group will be asked to use the online training programme for 12 weeks and encouraged to use it for at least one 30-minute session per week (recommended minimum) and up to three 30-minute sessions per week (recommended

maximum). They will receive phone/video calls from a researcher to support their use of the programme (weekly or as needed). Participants in this group will also receive treatment as usual (described under Group 3, below).

Group 2: Active control training
Participants in the active control group (other brain training) will be asked to use the online training for 12 weeks and encouraged to use it for at least one 30-minute session per week (recommended minimum) and up to three 30-minute sessions per week (recommended maximum). They will receive phone/video calls from a researcher to support their use of the programme (weekly or as needed). Participants in this group will also receive treatment as usual (described under Group 3, below).

Group 3: Treatment as usual
Participants in this arm will receive treatment as usual (TAU). Content of TAU for MCI is often informational support (potentially including a one-to-one appointment with an Alzheimer's Society support worker) but there is no standardised model of MCI follow-up or access to cognitive stimulation therapies. Thus, over the 12-week intervention period, participants are likely to receive no more than one appointment with a support worker or clinician (lasting up to 60 minutes).

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome measures in this study relate to the acceptability and feasibility of both the SMART intervention and applied research methods. Primary outcome measures include:
1. Intervention drop-out rate is measured as the proportion of participants in the intervention condition who drop out (complete <6 sessions) over the 3-month intervention period
2. Completion rate for outcome measures is measured as the proportion of missing response data over the 6-month data collection period
3. Recruitment and retention rates are measured in terms of the total number of cases recruited over a 10-month period (as a proportion of eligible referrals) and the proportion retained at 3-month follow-up

Key secondary outcome(s))
The exploratory outcomes are related to the signal of efficacy and indicative estimation of intervention effects (effect sizes and 95% CIs) for the following outcome measures:

Primary outcome measures for exploratory estimation of effects:
1. Subjective cognitive functioning measured using the Quick Dementia Rating System (QDRS) at baseline, 3 months, and 6 months
2. Objective cognitive performance (attention, language, visuospatial/constructional abilities, and immediate and delayed memory) is measured using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) at baseline, 3 months, and 6 months
3. Objective cognitive performance (executive functioning) is measured using the Wisconsin Card Sorting Test (WCST) at baseline, 3 months, and 6 months

Secondary outcome measures for exploratory estimation of effects:
1. Anxiety is measured using the Generalized Anxiety Disorder Scale-7 (GAD-7) at baseline, 3 months, and 6 months
2. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 3

months, and 6 months
3. Participant-identified cognitive problems are measured using the Personal Questionnaire (PQ) at baseline, 3 months, and 6 months
4. Health-related quality of life is measured using the EQ-5D-5L at baseline, 3 months, and 6 months
5. Cognitive impairment-specific health-related quality of life is measured using the Quality of Life in Alzheimer's Disease (QoL-AD) at baseline, 3 months, and 6 months
6. Capability wellbeing is measured using the ICECAP-A at baseline, 3 months, and 6 months

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. Existing diagnosis of MCI or meets screening criteria for MCI (Quick Dementia Rating System score ≥1.5 and Montreal Cognitive Assessment score ≤26)
2. Age 18-89 years (to meet the standardisation criteria of psychometric assessments)
3. Able to read and speak English to the standard necessary for completing assessment and intervention procedures
4. Able and willing to access a computer/tablet/smartphone with an internet connection throughout the study
5. Able and willing to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
89 years

Sex
All

Key exclusion criteria
1. Currently receiving cognitive rehabilitation
2. Previously received SMART training
3. Vision or hearing problems precluding completion of procedures
4. Unable to give informed consent
5. Diagnosis of dementia

Date of first enrolment

08/12/2022

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
Older People & Frailty Division
Witham Court
Fen Lane
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Sponsor information

Organisation
University of Lincoln

ROR
https://ror.org/03yeq9x20

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201990

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes