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Can mindfulness and lifestyle interventions improve the memory and mental function in people who are starting to notice a decline in their memory and thinking abilities?

Submission date
26/01/2019

Recruitment status
No longer recruiting

Registration date
21/02/2019

Overall study status
Completed

Last Edited
21/02/2019

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
At present there is little to offer to people who are concerned about their memory and thinking abilities, in terms of support or treatment. This is because these people do not have serious problems with daily living and do not have any formal diagnosis. Even if they visit a specialist, they will usually be discharged without any further recommendations. However, this lack of support might leave them feeling confused and anxious. The aim of this study is to develop a new online course and test it against already available courses to examine whether these would be effective interventions for people who are worried about their memory. We also aim to describe the characteristics of these people and assess how these characteristics might be related to the risk of future memory problems.

Who can participate?
Adults over the age of 45 who are concerned about their memory.

What does the study involve?
We are asking participants to attend three visits at Southmead Hospital, in Bristol (baseline, 6 weeks later and 6 months later). During these visits the examiners will give them some pen-and-paper tests to assess their memory and thinking abilities and their quality of life. The participants will be divided into three groups. Two of the groups involve an online course where participants are asked to watch some video presentations for 4 weeks. One of the courses aims to inform them about relaxation and stress relief techniques (mindfulness meditation) while the other one is about lifestyle factors that could make our brains healthier (like diet and exercise). The third is a control group where participants will just wait until the next visit. We are also asking participants to give an optional blood sample, but this is not a requirement for entering the study. The blood sample will help us see if some people are at higher risk of memory lapses.

What are the possible benefits and risks of participating?
Through this study, participants will have the chance to participate in an educational course that

could possibly improve their quality of life. Regarding the risks, there is a potential for upset, because of the questionnaire's sensitive nature. In the unlikely event that someone feels uncomfortable with the tests, they can discuss this with the examiner and/or withdraw at any point without giving any reason. The study also involves an optional blood sample. The physical risks of giving this blood sample are the same as any blood sample taken from a vein. Participants may experience minor bruising or irritation.

Where is the study run from?
The DECODE study is part of a PhD degree (University of Bristol) and is taking place in Bristol. All visits are taking place at Southmead Hospital, North Bristol NHS Trust, where the researchers are based.

When is the study starting and how long is it expected to run for?
September 2015 to September 2019.

Who is funding the study?
The study is funded by BRACE, a regional charity that supports researchers in South West England and South Wales.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
201727

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2662, IRAS 201727

Study information

Scientific Title
Development and evaluation of interventions in people with subjective cognitive decline

Acronym
DECODE

Study objectives
Two non-pharmacological interventions (Mindfulness course and Lifestyle factors intervention) will improve the memory/thinking abilities and well-being of people with memory concerns who do not have any diagnosis of dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2017, South West - Central Bristol Research Ethics Committee (Whitefriars Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; nrescommittee.southwest-bristol@nhs.net; +44 (0)207 104 8028), ref: 16/SW/0328

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subjective cognitive decline (SCD)

Interventions
At present there is little to offer to people with Subjective Cognitive Decline because most services focus on the treatment of people who have already received a diagnosis of dementia. In this study we aim to evaluate the effectiveness of two non-pharmacological interventions on people with Subjective Cognitive Decline. The first one is an online course of Mindfulness which is already commercially available, while the second one is a Lifestyle factors intervention that has been specifically designed for the purposes of this study.

The two interventions are going to be tested against a Control group and against each other. All participants will be randomly assigned to one of the three groups and the researcher who is doing the testing will be blinded to the participants' group.

The Mindfulness course is delivered online and has a duration of 4 weeks. Participants in this group are invited to learn the main techniques of mindfulness meditation and are encouraged to practice on a daily basis. The course includes audio and video presentations led by two qualified instructors. More information can be found on www.bemindfulonline.com

The Lifestyle factors intervention has been designed for the purposes of this research study and similarly to the Mindfulness course, lasts for 4 weeks and is delivered online. Each week the participants in this group are presented with a new factor (exercise, diet, mental stimulation and social engagement) that could possibly improve their brain health. The information is provided through video presentations and participants are encouraged to exercise, follow a healthy diet and engage in social and mentally stimulating activities. For more information and to get access to the website, please contact the researchers.

All participants are asked to attend three visits: baseline, visit 2 (right after the end of the intervention) and visit 3 (6 months after visit 2). During these visits participants go through (pen and paper) tests that measure their cognitive function and questionnaires that measure psychological factors. Most of the tests are repeated during all visits in order to examine any difference between the three groups over time.

Moreover, participants are asked to fill in a questionnaire about their daily habits (diet, exercise, activities), for 1 week before starting the intervention, one week after finishing it (or 4 weeks later for the control group) and finally, for 1 week before their last appointment.

Intervention Type
Behavioural

Primary outcome(s)
1. Cognitive impairment assessed using the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005) at baseline
2. Likelihood of memory malingering assessed using the Test of Memory Malingering (TOMM; Tombaugh, 1997) at baseline
3. Cognitive reserve assessed using the Cognitive Reserve Index Questionnaire (CRIq; Nucci, Mapelli, & Mondini, 2012) at baseline
4. Letter verbal fluency (retrieval ability, executive functioning and semantic knowledge) at baseline, 6 weeks and 6 months. Participants are given three different letters of the alphabet and are asked to generate as many words as they can that begin with these letters in 1 minute.
5. Semantic category verbal fluency (retrieval ability, executive functioning and semantic knowledge) at baseline, 6 weeks and 6 months. Participants are given a category (articles of clothing, animals, fruit and vegetables) and asked to say as many words as possible that belong to these categories in 1 minute.
6. short-term memory, learning, recognition and proactive interference assessed using the Rey Auditory Verbal Learning Test (Lezak, 1976, 1983) with the alternate versions of Geffen (Geffen, Butterworth, & Geffen, 1994) and Majdan (Majdan, Sziklas, & Jones-Gotman, 1996) at baseline, 6 weeks and 6 months
7. Working memory assessed using the N-back test on a university laptop (based on Verhaeghen & Basak, 2005) at baseline, 6 weeks and 6 months
8. Mental flexibility, attention and task switching assessed using the Trail Making Test parts A and B (Reitan, 1955) at baseline, 6 weeks and 6 months
9. Functional memory assessed using the 10-item Functional Memory Disorder Questionnaire (Schmidtke & Metternich, 2009)
10. Health anxiety assessed using the Health Anxiety Inventory (Salkovskis, Rimes, Warwick, &

Clark, 2002) at baseline, 6 weeks and 6 months
11. Mindfulness assessed using the Five Facets Mindfulness Questionnaire (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) at baseline, 6 weeks and 6 months
12. Readiness to change assessed using questions based on Prochaska, Norcross, & DiClemente's change model (1994) at baseline, 6 weeks and 6 months
13. Mental health assessed using the Depression Anxiety and Stress Scale (DASS) 21-item version (Henry & Crawford, 2005; Norton, 2007) at baseline, 6 weeks and 6 months
14. Mental wellbeing assessed using the WHO Five Well-Being Index (Bech, Olsen Kjoller, & Rasmussen, 2003) at baseline, 6 weeks and 6 months

Key secondary outcome(s))
1. Background information including age, gender, area of living, smoking (never, ex, current), alcohol use, physical activity level, height and weight, years of education, meditation, question about health concerns behaviour ("Have you sought help about your memory prior to coming here?" and "How many times have you seen your GP in the past year?"), medications (if any), family history of Alzheimer's or other form of dementia and medical history (depression/anxiety /cholesterol/diabetes/stroke/TIA/heart disease/other neurological condition/other psychiatric condition/any other medical condition) assessed using a questionnaire at baseline
2. Daily activities (including sleep, eating/drinking habits, exercise, meditation, alcohol use, smoking, mentally stimulating and socially engaging activities) assessed using questionnaires at baseline, 6 weeks and 6 months
3. ApoE genotype assessed using DNA analysis from a blood sample taken at baseline

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Has expressed concern about cognitive decline (subjective cognitive decline) and has answered "yes" to the following question: "Are you concerned or worried that you are experiencing significant decline in your thinking abilities, more than just normal ageing?"
2. Aged over 45 years
3. In the opinion of the investigator, is capable of understanding and complying with protocol requirements
4. In the opinion of the investigator, is able to physically perform the cognitive tests and is fluent in the language that tests will be administered.

The study also includes a small sample of people with Functional Cognitive Disorder (FCD). These patients are recruited through our Memory Clinic and have already received this diagnosis.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. Has a current diagnosis or history of any type of cognitive impairment or dementia, or has a current diagnosis of neurological/psychiatric disorder or any other diagnosis that significantly affects cognitive performance (including substance abuse)
2. Incapable of doing a brisk walk
3. Has been exposed to the cognitive tests performed in this study within 6 months prior to the baseline assessment
4. Score on MoCA test is <20. An individual with a MoCA score this low may have significant cognitive decline (Larner, 2012) and should be referred to their GP.
5. Knows his or her own ApoE genotype/phenotype
6. Cannot adequately understand verbal explanations or written information given in English

Date of first enrolment
24/01/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
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BS10 5NB

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
BRACE

Alternative Name(s)
Alzheimer's Brace, BRACE Alzheimer's Research, BRACE Dementia Research

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

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