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Cognitive Rehabilitation for Attention and Memory in people with Multiple Sclerosis (MS)

Submission date
14/08/2014

Recruitment status
No longer recruiting

Registration date
14/08/2014

Overall study status
Completed

Last Edited
15/01/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many people with multiple sclerosis (MS) experience problems with attention, concentration and memory. They may be offered advice on how to cope with these problems. Cognitive rehabilitation is a structured approach to deal with these problems. The aim of this study is to compare group cognitive rehabilitation programme with usual care. We will look at the usefulness of the rehabilitation in reducing memory and attention problems and what it would cost to deliver this programme in the NHS.

Who can participate?
Adults aged 18-70 years with MS.

What does the study involve?
Participants will be in the study on average 16 months from consent to end of follow-up. There will be an initial assessment to find out whether the participant fulfils all the criteria to take part in the study. The second visit will record baseline details and the participants availability to attend group sessions. When enough participants have been enrolled, each participant will be randomly allocated to receive either group cognitive rehabilitation sessions plus usual care or usual care only. Participants allocated to the usual care group will not have to do anything else until their 6 month follow-up appointment. Participants allocated to the cognitive rehabilitation group will be invited to attend 10 therapy sessions lasting about 1.5 hours, which will take place over about 10 weeks and are led by an assistant psychologist. All participants will have follow-up visits at 6 and 12 months. These will include assessments and completion of questionnaires.

What are the possible benefits and risks of participating?
We do not know whether taking part in the study will help but we expect that some people will find the intervention helps them cope with memory and attention problems. However, the information we get from this study may help us to treat people with MS and attention and memory problems better in future. There are no particular risks involved in taking part in this study.

Where is the study run from?
Four centres in the UK, based in Nottingham, Sheffield, Liverpool and Birmingham. Updated 22

/06/2017: Five centres in the UK, based in
Nottingham, Sheffield, Liverpool, Bristol and South Tees.

When is the study starting and how long is it expected to run for?
The study starts in September 2014 and is expected to run until August 2018.

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

Who is the main contact?
Prof Nadina Lincoln
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17196

Study information

Scientific Title
Cognitive Rehabilitation for Attention and Memory for people with Multiple Sclerosis (CRAMMS): a pragmatic randomised controlled trial

Acronym
CRAMMS

Study objectives
The overall aim is to assess the clinical and cost-effectiveness of cognitive rehabilitation for attention and memory problems in people with multiple sclerosis. The research aims to determine whether attending group cognitive rehabilitation programmes (the intervention) in addition to usual care, is associated with reduced impact of multiple sclerosis on quality of life when compared to usual care alone (control).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands South Birmingham, 01/09/2014, ref. 14/WM/1083

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Neurological disorders; Subtopic: Neurological (all Subtopics); Disease: Multiple Sclerosis

Interventions
Participants will be individually randomised (6:5) to allow for clustering in intervention arm to intervention or control, stratified by recruitment site and minimised by MS-type (relapsing-remitting or progressive) and gender. The randomisation will take place once there are 9-11 individuals who have consented and who are able to attend the same therapy group (location, day of the week and time of day) should they be randomised to receive it.
The intervention is Cognitive rehabilitation, offered in addition to usual clinical care. The rehabilitation is delivered to groups of 4-6 participants for 10 weekly sessions. The programme will be tailored to each patients cognitive status while maintaining a systematic approach to attention and memory by following a treatment manual.
The control group participants will receive their usual clinical care, which may include information on cognitive problems but not cognitive rehabilitation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Psychological impact of MS; Timepoint(s): 12 months

Secondary outcome measures
1. Memory problems in everyday life; Timepoint(s): 6 and 12 months
2. Mood; Timepoint(s): 6 and 12 months
3. Fatigue; Timepoint(s): 6 and 12 months
4. Carer strain; Timepoint(s): 6 and 12 months
5. Quality of Life; Timepoint(s): 6 and 12 months
6. Attention and memory abilities; Timepoint(s): 6 and 12 months
7. Physical impact of MS; Timepoint(s): 6 and 12 months
8. Cost-effectiveness; Timepoint(s): 6 and 12 months
9. Employment status; Timepoint(s): 6 and 12 months
10. Number of reported relapses in the previous six months; Timepoint(s): 6 and 12 months
11. Disability; Timepoint(s): 6 and 12 months

Overall study start date
01/09/2014

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Are 18 or over and under 70 years of age. The lower age limit is because MS is usually diagnosed in adulthood and treatment strategies tend to be different for children. People aged 70 and over may start to encounter age-related cognitive problems, which may confound the effects of cognitive problem due to MS. Also, most tests are standardised on this adult age group.
2. Have relapsing or progressive MS, diagnosed at least 3 months prior to the baseline assessment contact with the study team, to allow for adjustment to diagnosis. Report having cognitive problems as determined by a cut-off score of >27 on the patient version of the Multiple Sclerosis Neuropsychological Screening Questionnaire (MSNQ). This cut-off is based on previous research and is two standard deviations below the mean for healthy participants.
3. Have cognitive deficits, defined as performance below the 25th percentile on the Brief Repeatable Battery of Neuropsychological Tests (BRBN).
4. Are able to travel to one of the centres and attend group sessions.
5. Are able to speak English sufficiently to complete the cognitive assessments and take part in group sessions.
6. Give informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment
449

Key exclusion criteria
1. Vision or hearing problems, such that they are unable to complete the cognitive assessments, judged by assessor.
2. Have concurrent severe medical or psychiatric conditions which would prevent participants from engaging in treatment, if allocated.
3. Are involved in other psychological intervention trials.

Date of first enrolment
01/09/2014

Date of final enrolment
23/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Rehabilitation & Ageing
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details

Research and Graduate Services
Kings Meadow Campus, Lenton Lane
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from nadina.lincoln@nottingham.ac.uk

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/12/2015		Yes	No
Results article	results	01/01/2020	15/01/2020	Yes	No
HRA research summary			28/06/2023	No	No