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Neuropsychological evaluation and rehabilitation in multiple sclerosis – qualitative case study

Submission date
10/02/2021

Recruitment status
No longer recruiting

Registration date
23/02/2021

Overall study status
Completed

Last Edited
18/12/2023

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
Problems with memory, attention, and problem solving (together known as 'cognitive' problems) affect up to 70% of people with multiple sclerosis (MS). These problems are distressing for people with MS, affecting their mood, ability to work, and enjoy social activities. Therefore, treating cognitive problems is a 'top 10' research priority for people with MS. The NEuRoMS (Neuropsychological Evaluation and Rehabilitation in Multiple Sclerosis) project aims to develop a clinical pathway, to routinely assess people with MS for cognitive problems using brief, online tasks (cognitive screening) and provide appropriate support to help them manage these problems. In this smaller study, the researchers will investigate what potential benefits and issues people with MS who undergo neuropsychological screening and rehabilitation intervention encounter, to identify any barriers/facilitators to delivery of the screening and management pathway and the intervention.

Who can participate?
People with MS: aged 18 or over who received neuropsychological screening and mild cognitive problems identified
Related informants: relative, friend or carer supporting a person with MS, aged 18 or over
Clinicians: health professionals (e.g., neurologists, MS nurse specialists, psychologists, occupational therapists) delivering the NEuRoMS screening and management pathway to people with MS
Intervention providers: assistant psychologists or research nurses delivering the intervention to people with MS as part of the study

What does the study involve?
Participants will be identified through MS Clinics at three NHS sites. The current study will recruit ten people with multiple sclerosis who receive a brief online neuropsychological screening and are identified as having mild cognitive problems.
These participants will be offered the NEuRoMS intervention (cognitive management programme) during a discussion of their screening results with a member of their clinical team (MS nurse, neurologist, occupational therapist (OT), or physiotherapist). Upon completion of the

NEuRoMS intervention, a member of the research team will conduct semi-structured interviews with people with multiple sclerosis and their related informants (families/carers/friends). Clinicians and intervention providers involved in delivering the screening and management pathway will also be interviewed. Interviews will mostly be conducted over the phone /videoconferencing.
Data will be analysed to inform: (i) understanding of people with multiple sclerosis' experiences of receiving the intervention, (ii) the refinement of the screening and management pathway, (iii) the revision of programme theory.

What are the possible benefits and risks of participating?
It is not known whether the study will have a direct benefit to participants, but participating may help other people with MS in the future. The information obtained from this study will help the researchers decide how to develop the cognitive screening and management programme further in the hope of providing standardised screening and support for cognitive problems in MS.
When talking about experiences and issues associated with cognitive problems, people may feel upset. This may also cause some concerns about their own cognitive abilities. If this happens during the intervention or interview, the therapist/researcher will be there to talk to through these concerns. Participants will have their contact information in case they feel upset after the session/interview for reasons associated with participation. The interview, intervention sessions and any other aspect of participants' involvement can stop at any time if they do not wish to continue.
A possible disadvantage is that it may inconvenience people to attend a session in person or be available at a specific time during the day. Intervention sessions and interviews will be arranged at a time and date that is suitable for participants, and these can be conducted over the phone or videoconferencing (based on preference).

Where is the study run from?
This is a multicentre study conducted across three NHS sites in the UK with MS outpatient clinics:
1. Nottingham University Hospitals NHS Trust (UK)
2. Cardiff and Vale University Health Board (UK)
3. Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2017 to December 2022

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

Who is the main contact?
Prof. Roshan das Nair (Chief Investigator)
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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)
276903

Protocol serial number
CPMS 44712, IRAS 276903

Study information

Scientific Title

Neuropsychological Evaluation and Rehabilitation in Multiple Sclerosis (NEuRoMS): refining the screening and management pathway in routine clinical practice (Phase 1: Work Package 2ii Qualitative Study)

Acronym
NEuRoMS-WP2ii

Study objectives
The primary objectives of the study are to:
1. To improve understanding of how the NEuRoMS screening and management pathway is integrated within routine clinical practice.
2. To improve understanding of how the NEuRoMs intervention programme is experienced by those who deliver and receive it.

The secondary objectives of the qualitative study are to:
1. Refine the intervention resource book and staff training package.
2. Develop fidelity tools for the definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2020, North West – Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8384, +44 (0)207 104 8068, +44 (0)207 104 8328; gmwest.rec@hra.nhs.uk), REC ref: 20/NW/0081

Study design
Non-randomized; Both Interventional and Observational; Design type: Treatment, Process of Care, Psychological & Behavioural, Complex Intervention, Management of Care, Rehabilitation, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
The newly designed manualised NEuRoMS intervention is multi-faceted, involving various components (i.e., information provision, goal setting), and a range of strategies and techniques (e.g., psychoeducation, compensatory strategies, boosting cognitive reserve), delivered by a trained Research Nurse or Assistant Psychologist (under the supervision of a clinical psychologist). The intervention is person-centred, tailored to the needs and lifestyle of each participant, and aims to help people with MS cope with and manage cognitive problems by establishing strategies that can be maintained once the intervention sessions are finished. Sessions will predominately be delivered remotely via videoconferencing and telephone sessions, however, those who prefer to undertake intervention sessions face-to-face can opt to do so for the first two sessions (dependent on Government and NHS COVID-19 advice). The

duration of the intervention will be up to 4 hours spread across up to six sessions. The researchers anticipate these sessions to occur over a 2-month period, based on patient availability.

Intervention Type
Behavioural

Primary outcome(s)
1. Improved understanding of how the NEuRoMS screening and management pathway is integrated within routine clinical practice (e.g. contextual factors which influence its delivery, those mechanisms which influence its affect and those outcomes which are described by interviewees) through qualitative data; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at interviews with patients and related informants (within approximately 2 weeks of completing the intervention), and at interviews with clinicians and intervention providers (after experiencing different elements of the pathway; 3-8 months post patient recruitment).
2. Improved understanding of how the NEuRoMS intervention programme is experienced by those who deliver and receive it (e.g. behavioural elements of the intervention, essential resources needed for, and barriers to screening and intervention delivery) through qualitative data; measured throughout data collection by reviewing notes from monthly supervision sessions with intervention providers, intervention audio-recordings, and at interviews with patients and related informants (within approximately 2 weeks of completing the intervention) and intervention providers (after experiencing different elements of the intervention; 3-8 months post patient recruitment).

Key secondary outcome(s))
1. Patient, related informant and intervention provider views of the intervention resource book, measured throughout data collection by reviewing notes from monthly supervision sessions with intervention providers, intervention audio-recordings, and at interviews with patients and related informants (within approximately two weeks of completing the intervention) and intervention providers (after experiencing different elements of the intervention; 3-8 months post patient recruitment)
2. Intervention provider views and experiences of the staff training package, measured throughout data collection by reviewing notes from monthly supervision sessions with intervention providers and at interviews with intervention providers (after experiencing different elements of the intervention; 3-8 months post patient recruitment)
3. Appropriateness of fidelity tools measured throughout data collection by reviewing notes from monthly supervision sessions with intervention providers and at interviews with intervention providers (after experiencing different elements of the intervention; 3-8 months post patient recruitment)

Completion date
31/12/2022

Eligibility

Key inclusion criteria

1. People with MS:
1.1. Diagnosis of MS
2.2. Received neuropsychological screening and mild cognitive problems identified (in WP2i IRAS ID: 276570)

2. Related informants:
2.1. Relative or carer supporting a person with MS

3. Clinicians:
3.1. Health professionals (e.g., neurologists, MS nurse specialists, psychologists, occupational therapists) delivering the NEuRoMS screening and management pathway to people with MS

4. Intervention providers:
4.1. Research nurses/assistant psychologists delivering the intervention to people with MS identified above in 1

All individuals:
Aged 18 years or above, able and willing to give informed consent and able to communicate in English

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Do not have the mental capacity to consent to take part in the study
2. Are unable to communicate in English (standardised materials are to be used which have not yet been developed for other groups)

Date of first enrolment
01/05/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Nottingham University Hospitals NHS Trust
The Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Cardiff and Vale University Health Board
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Programme Grant for Applied Research (Ref. No.: RP-PG-0218-20002)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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 due to the nature of the data and confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			18/12/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 7.0	05/07/2022	07/11/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes