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Neuropsychological evaluation and rehabilitation in multiple sclerosis – feasibility study

Submission date
01/02/2021

Recruitment status
No longer recruiting

Registration date
09/02/2021

Overall study status
Completed

Last Edited
21/08/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[X] 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. This study 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 implement the pathway in three test sites to explore the feasibility of a larger trial, and further refine the pathway.

Who can participate?
Part 1: Patients aged 18 years or over with MS
Part 2: Patients aged 18 years or over with MS who received cognitive screening and have mild or moderate cognitive problems (Part 1)
Part 3: Patients with MS who participated in Part 2; assistant psychologists/research nurses /assistant occupational therapists delivering the NEuRoMS intervention to patients with MS in Part 2; health professionals (e.g., neurologists, MS nurse specialists, psychologists, occupational therapists) delivering the NEuRoMS screening and management pathway to people with MS.

What does the study involve?
Using a mix of different approaches the researchers will:
Part 1: Observe how cognitive screening is integrated within routine clinical practice and determine the frequency and extent of cognitive problems in patients with MS.
Part 2. Recruit up to 80 patients with mild or moderate cognitive problems, who will be randomly allocated to receive either an intervention or usual care (control group). The brief therapist-led intervention provides information and strategies to help people cope with their cognitive problems. The researchers will evaluate if the way they plan to do the study is feasible.
Part 3. Conduct interviews with people with multiple sclerosis and clinicians involved in delivering the pathway to understand their experiences and identify potential barriers and revisions.

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 means that they may help people with MS in the future. The information from this study will help the researchers decide how to develop this screening and management pathway 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 cognitive management programme (including the feedback interviews), the clinician or interviewer will be there to talk to through these concerns. Participants will have their contact information in case they feel upset after the session for reasons associated with participation. The screening, cognitive management sessions, interviews 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 be available at a specific time during the day to attend the cognitive management sessions or interviews. These will be arranged at a time and date that is suitable for participants and 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 September 2023

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)
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Additional identifiers

Integrated Research Application System (IRAS)
287115

Central Portfolio Management System (CPMS)
47750

Study information

Scientific Title
Neuropsychological Evaluation and Rehabilitation in Multiple Sclerosis (NEuRoMS): multicentre feasibility randomised controlled trial and fidelity evaluation (Phase 2: Work Package 3 feasibility study)

Acronym
NEuRoMS

Study objectives
Current hypothesis as of 19/06/2023:

The primary objective of the study is to assess the feasibility of conducting a definitive randomised controlled trial (RCT) to investigate the clinical and cost-effectiveness of the NEuRoMS intervention in reducing the impact of cognitive problems in daily life amongst people with MS, and the acceptability of the intervention.

The specific secondary objectives of the feasibility study, mapped onto different parts of the study, are to:

Part 1 – testing the cognitive screening pathway:
1. Explore how the NEuRoMS cognitive screening and management pathway is integrated within routine clinical practice
2. Refine cognitive screening pathway by evaluating online cognitive screening and usage data and the observations of clinicians/intervention providers
3. Assess the suitability of online cognitive screening measures (SST and/or WCT) for capturing cognitive deficits according to the refined cognitive deficit categories
4. Assess the frequency of 'within normal range', 'mild cognitive problems', 'moderate cognitive problems', and 'severe cognitive problems', and thus, the size of the target population (potentially eligible participants for a future definitive RCT) based on the SST and/or WCT.

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
1. Identify the necessary parameters and tools to undertake a clinical and cost-effectiveness analysis in a future definitive trial
2. Assess acceptability of data collection tools, processes, data completeness and follow-up rates, and determine the suitability of outcome measures
3. Identify factors that may affect the running of the definitive trial, including barriers and facilitators to recruitment, retention, and delivery of the intervention
4. Evaluate the feasibility and acceptability of the NEuRoMS intervention
5. Evaluate and optimise intervention usage and acceptability
6. Explore ways to assess (type and extent) and minimise contamination
7. Develop and assess intervention fidelity tools (e.g., coding frame for audio/video analysis of intervention delivery)
8. Develop a framework for cost-effectiveness analyses
9. Characterise 'usual care' in the different sites

Part 3 – interviews:
1. Gather detailed qualitative feedback interviews on the pathway, intervention and study procedures to assess their feasibility and acceptability
2. Understand the barriers, facilitators and broader context for delivering and receiving screening and management pathway
3. Improve understanding of how the NEuRoMS screening and management pathway is integrated within routine clinical practice
4. Improve understanding of how the NEuRoMS intervention programme is experienced by those who deliver and receive it
5. Evaluate and refine staff training package for cognitive screening and management pathway
6. Refine the programme theory (and logic model) for the newly developed screening pathway and NEuRoMS intervention programme, embedding it in clinical practice

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Previous hypothesis as of 21/07/2022:

The primary objective of the study is to assess the feasibility of conducting a definitive randomised controlled trial (RCT) to investigate the clinical and cost-effectiveness of the NEuRoMS intervention in reducing the impact of cognitive problems in daily life amongst people with MS, and the acceptability of the intervention.

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3. Assess the suitability of online cognitive screening measures (SST and/or WCT) for capturing cognitive deficits according to the refined cognitive deficit categories
4. Assess the frequency and extent of no cognitive deficits, mild cognitive deficits, moderate cognitive deficits and severe cognitive deficits, and thus, the size of the target population (potentially eligible participants for a future definitive RCT) based on the SST and/or WCT

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
1. Identify the necessary parameters and tools to undertake a clinical and cost-effectiveness analysis in a future definitive trial
2. Assess acceptability of data collection tools, processes, data completeness and follow-up rates, and determine the suitability of outcome measures
3. Identify factors that may affect the running of the definitive trial, including barriers and facilitators to recruitment, retention, and delivery of the intervention
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Previous hypothesis as of 06/04/2022:

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Part 1 – testing the cognitive screening pathway:
1. Explore how the NEuRoMS cognitive screening and management pathway is integrated within routine clinical practice
2. Refine cognitive screening pathway by evaluating online cognitive screening and usage data and the observations of clinicians/intervention providers
3. Assess the suitability of online cognitive screening measures (SST and/or eStroop Task) for capturing cognitive deficits according to the refined cognitive deficit categories
4. Assess the frequency and extent of no cognitive deficits, mild cognitive deficits, and moderate-severe cognitive deficits, and thus, the size of the target population (potentially eligible participants for a future definitive RCT) based on the SST and/or eStroop Task

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
1. Identify the necessary parameters and tools to undertake a clinical and cost-effectiveness analysis in a future definitive trial
2. Assess acceptability of data collection tools, processes, data completeness and follow-up rates, and determine the suitability of outcome measures
3. Identify factors that may affect the running of the definitive trial, including barriers and facilitators to recruitment, retention, and delivery of the intervention
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Previous study hypothesis as of 27/10/2021:
The primary objective of the study is to assess the feasibility of conducting a definitive randomised controlled trial (RCT) to investigate the clinical and cost-effectiveness of the

NEuRoMS intervention in reducing the impact of cognitive problems in daily life amongst people with MS, and the acceptability of the intervention.

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Part 1 – testing the cognitive screening pathway:
1. Explore how the NEuRoMS cognitive screening and management pathway is integrated within routine clinical practice
2. Refine cognitive screening pathway by evaluating online cognitive screening and usage data and the observations of clinicians/intervention providers
3. Assess the suitability of online cognitive screening measures (SDMT and Stroop Test) for capturing cognitive deficits according to the refined cognitive deficit categories
4. Assess the frequency and extent of no cognitive deficits, mild cognitive deficits, and moderate-severe cognitive deficits, and thus, the size of the target population (potentially eligible participants for a future definitive RCT) based on the SDMT and/or Stroop test

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
1. Identify the necessary parameters and tools to undertake a clinical and cost-effectiveness analysis in a future definitive trial
2. Assess acceptability of data collection tools, processes, data completeness and follow-up rates, and determine the suitability of outcome measures
3. Identify factors that may affect the running of the definitive trial, including barriers and facilitators to recruitment, retention, and delivery of the intervention
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4. Assess the frequency and extent of no cognitive deficits, mild cognitive deficits, and moderate-severe cognitive deficits, and thus, the size of the target population (potentially eligible participants for a future definitive RCT) based on the SDMT and Stroop test

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
1. Identify the necessary parameters and tools to undertake a clinical and cost-effectiveness analysis in a future definitive trial
2. Assess acceptability of data collection tools, processes, data completeness and follow-up rates, and determine the suitability of outcome measures
3. Identify factors that may affect the running of the definitive trial, including barriers and facilitators to recruitment, retention, and delivery of the intervention
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6. Refine the programme theory (and logic model) for the newly developed screening pathway and NEuRoMS intervention programme, embedding it in clinical practice

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2021, North West – Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048384, +44 (0) 207 104 8068; gmwest.rec@hra.nhs.uk), REC ref: 20/NW/0454

Study design

Randomized; Both Interventional and Observational; Design type: Treatment, Screening, Process of Care, Psychological & Behavioural, Complex Intervention, Management of Care, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current intervention as of 21/07/2022:
Patients with mild or moderate cognitive problems will be randomly allocated to receive either an intervention plus usual care or usual care only (control group).

The NEuRoMS cognitive management 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). 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. The intervention will be delivered by a trained therapist (Assistant Psychologist, Research Nurse, or Assistant Occupational Therapist), under the supervision of a clinical psychologist or Occupational Therapist). Face-to-face (dependent on Government and NHS COVID-19 advice), videoconferencing and telephone delivery options will be available. The duration of the intervention will be up to 4 hours spread across up to 6 sessions. The researchers anticipate these sessions to occur over a 2-month period, based on patient availability.

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Previous intervention:
Patients with mild cognitive problems will be randomly allocated to receive either an intervention plus usual care or usual care only (control group).

The NEuRoMS cognitive management 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). 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. The intervention will be delivered by a trained therapist (Assistant Psychologist, Research Nurse, or Assistant Occupational Therapist), under the supervision of a clinical psychologist or Occupational Therapist). Face-to-face (dependent on Government and NHS COVID-19 advice), videoconferencing and telephone delivery options will be available. The duration of the intervention will be up to 4 hours spread across up to 6 sessions. The researchers anticipate these sessions to occur over a 2-month period, based on patient availability.

Intervention Type

Behavioural

Primary outcome(s)

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
1. Feasibility and suitability of trial procedures based on response rates, trial uptake and the number of dropouts; measured throughout data collection period
2. Feasibility of recruitment: measured throughout the data collection period, as assessed by:
2.1. Appropriateness of eligibility criteria – the number of those referred to the trial who meet the eligibility criteria and the number of those eligible who expressed interest in the trial
2.2. Success of recruitment strategy – recruitment rate recorded as the number of eligible patients who consent to participate in the trial within the trial recruitment period, and the number of patients who decline to participate (including reasons for non-participation)
2.3. Retention rates assessed as the number of participants who consent to participate that remain in the trial by 6-month follow-up
3. Appropriateness of self-report clinical and health economics measures at three data collection time points (baseline, 3-month and 6-month follow-up), as assessed by: completion rates, rate of return of online/postal questionnaires, level of missing data and completeness of measures, number of participants requiring reminders and extra telephone support to complete the measures and content of contacts between service providers/researchers and patient participants
4. Patient preference for different versions/formats of the outcome data collection tools, measured at three time points (baseline, 3-month and 6-month follow-up), as assessed by: the number completed via paper/online/telephone, the number and types of reminders participants required to complete the tools, data completeness (the number of missing data), the number of participants who complete 3-month and 6-month follow-up measures.
5. Fidelity of the intervention, measured throughout data collection period, as assessed by:
5.1. The accuracy of intervention delivery recording and quality of intervention delivery, through intervention record forms, audio-/video-recordings of intervention sessions, and case notes of interventions
5.2. Contextual and process issues related to intervention delivery, assessed by a review of clinical notes, intervention record forms, audio-/video-recordings of intervention sessions, and through monthly supervision and mentoring sessions with the NEuRoMS therapists and the interviews (Part 3)
6. Documentation of usual care and contamination, measured throughout the data collection period, as assessed by:
6.1 Record of cognitive management/support provided (if any) by the clinical team as routine care and as part of the screening management pathway; assessed by a review of clinical notes and resource use questionnaires, and through monthly teleconferences/videoconferences with clinicians, monthly supervision and mentoring sessions with the NEuRoMS therapists and the Part 3 interviews.
6.2. Records of potential sources of contamination to determine the extent to which participants in the control group received the NEuRoMS intervention, assessed by a review of clinical notes and resource use questionnaire, and through monthly supervision and mentoring sessions with the NEuRoMS therapists and the Part 3 interviews.

Key secondary outcome(s))

Current secondary outcome measures as of 21/07/2022:
Part 1 – testing the cognitive screening pathway:
1. Feasibility of the cognitive screening pathway procedures, measured during screening and throughout Part 1 data collection period, assessed as:
1.1. Number of patients who complete the screening in different settings (online at home, online

in-clinic)
1.2. Number of patients who use different devices to complete the screening (e.g., tablet, mobile phone, laptop)
1.3. Time taken to complete the screening (in minutes)
1.4. Number of patients who require reminders and extra support (telephone/in-clinic) to complete the screening
1.5. Number and content of contacts between service providers and patient-participants.
2. Patient scores from the cognitive screening measures: a version of the Stroop task (Word Colour Task; WCT) and/or a version of the Symbol Digit Modalities Test (Symbol Substitution Task; SST), and three measures from the Multiple Sclerosis Quality of Life Inventory for self-reported cognitive problems, fatigue and mental health, measured during screening as part of usual care.

Part 2 - patient-centred outcomes:
In addition to feasibility outcomes (primary outcomes), the following measures will also be used to capture information about the patient at baseline and to assess outcomes at 3- and 6-months after randomisation:
1. Cognitive impairment is assessed using the Perceived Deficits Questionnaire at baseline, 3-month, and 6-month follow-up
2. Quality of life is assessed using the Multiple Sclerosis Impact Scale (MSIS-29) and EQ-5D-5L at baseline, 3-month, and 6-month follow-up
3. Mood is assessed using the Patient Health Questionnaire-9, Generalized Anxiety Disorder-7 scale, and Whooley Questions for depression screening at baseline, 3-month, and 6-month follow-up
4. Functional ability is assessed using the Nottingham Extended Activities of Daily Living Scale at baseline, 3-month, and 6-month follow-up
5. Self-efficacy is assessed using the Multiple Sclerosis Self-efficacy Scale (MSSE) at baseline, 3-month, and 6-month follow-up
6. Resource/Service use is assessed based on a measure used in other MS trials, adapted for use in the NEuRoMS project, at baseline, 3-month, and 6-month follow-up
7. Work-related issues are assessed using the Multiple Sclerosis Work Difficulties Questionnaire (Short form) at baseline, 3-month and 6-month follow-up
8. The extent to which work and medication adherence have been impacted by cognitive problems is assessed using two single questions at baseline, 3-month and 6-month follow-up.
9. Capability and wellbeing for health economics evaluation is assessed using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3-month and 6-month follow-up.

Part 3 – interviews:
1. Feasibility and acceptability of trial procedures through qualitative data; patients' willingness to be randomised; patients' views on trial recruitment and retention strategies, preferences, barriers and facilitators to trial recruitment and retention; importance and acceptability of outcome measures; measured at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers.
2. Operational issues in the delivery of cognitive screening and management pathway; contextual factors which influence intervention and pathway delivery, including mechanisms which influence its affect and outcomes; behavioural elements of the intervention, essential resources needed, and barriers to screening and intervention delivery; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
3. Patient, intervention provider and clinician experiences of cognitive screening and management pathway; factors facilitating or hindering engagement with the pathway;

mechanisms considered important in determining key outcomes; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
4. Intervention providers' readiness to deliver NEuRoMS intervention following training; potential contamination issues; potential improvements to training; measured throughout data collection and at interviews with intervention providers.

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Previous secondary outcome measures as of 06/04/2022:
Part 1 – testing the cognitive screening pathway:
1. Feasibility of the cognitive screening pathway procedures, measured during screening and throughout Part 1 data collection period, assessed as:
1.1. Number of patients who complete the screening in different settings (online at home, online in-clinic)
1.2. Number of patients who use different devices to complete the screening (e.g., tablet, mobile phone, laptop)
1.3. Time taken to complete the screening (in minutes)
1.4. Number of patients who require reminders and extra support (telephone/in-clinic) to complete the screening
1.5. Number and content of contacts between service providers and patient-participants.
2. Patient scores from the cognitive screening measures: a version of the Stroop task (eStroop Task) and/or a version of the Symbol Digit Modalities Test (Symbol Substitution Task; SST), and three measures from the Multiple Sclerosis Quality of Life Inventory for self-reported cognitive problems, fatigue and mental health, measured during screening as part of usual care.

Part 2 - patient-centred outcomes:
In addition to feasibility outcomes (primary outcomes), the following measures will also be used to capture information about the patient at baseline and to assess outcomes at 3- and 6-months after randomisation:
1. Cognitive impairment is assessed using the Perceived Deficits Questionnaire at baseline, 3-month, and 6-month follow-up
2. Quality of life is assessed using the Multiple Sclerosis Impact Scale (MSIS-29) and EQ-5D-5L at baseline, 3-month, and 6-month follow-up
3. Mood is assessed using the Patient Health Questionnaire-9, Generalized Anxiety Disorder-7 scale, and Whooley Questions for depression screening at baseline, 3-month, and 6-month follow-up
4. Functional ability is assessed using the Nottingham Extended Activities of Daily Living Scale at baseline, 3-month, and 6-month follow-up
5. Self-efficacy is assessed using the Multiple Sclerosis Self-efficacy Scale (MSSE) at baseline, 3-month, and 6-month follow-up
6. Resource/Service use is assessed based on a measure used in other MS trials, adapted for use in the NEuRoMS project, at baseline, 3-month, and 6-month follow-up
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1. Feasibility and acceptability of trial procedures through qualitative data; patients' willingness to be randomised; patients' views on trial recruitment and retention strategies, preferences, barriers and facilitators to trial recruitment and retention; importance and acceptability of outcome measures; measured at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers.
2. Operational issues in the delivery of cognitive screening and management pathway; contextual factors which influence intervention and pathway delivery, including mechanisms which influence its affect and outcomes; behavioural elements of the intervention, essential resources needed, and barriers to screening and intervention delivery; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
3. Patient, intervention provider and clinician experiences of cognitive screening and management pathway; factors facilitating or hindering engagement with the pathway; mechanisms considered important in determining key outcomes; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
4. Intervention providers' readiness to deliver NEuRoMS intervention following training; potential contamination issues; potential improvements to training; measured throughout data collection and at interviews with intervention providers.

Previous secondary outcome measures as of 27/10/2021:
Part 1 – testing the cognitive screening pathway:
1. Feasibility of the cognitive screening pathway procedures, measured during screening and throughout Part 1 data collection period, assessed as:
1.1. Number of patients who complete the screening in different settings (online at home, online in-clinic)
1.2. Number of patients who use different devices to complete the screening (e.g., tablet, mobile phone, laptop)
1.3. Time taken to complete the screening (in minutes)
1.4. Number of patients who require reminders and extra support (telephone/in-clinic) to complete the screening
1.5. Number and content of contacts between service providers and patient-participants.
2. Patient scores from the cognitive screening measures: a version of the Stroop task and the Symbol Digit Modalities Test, and three measures from the Multiple Sclerosis Quality of Life Inventory for self-reported cognitive problems, fatigue and mental health, measured during screening as part of usual care

Part 2 - patient-centred outcomes:
In addition to feasibility outcomes (primary outcomes), the following measures will also be used to capture information about the patient at baseline and to assess outcomes at 3- and 6-months after randomisation:
1. Cognitive impairment is assessed using the Perceived Deficits Questionnaire at baseline, 3-month, and 6-month follow-up
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5. Self-efficacy is assessed using the Multiple Sclerosis Self-efficacy Scale (MSSE) at baseline, 3-month, and 6-month follow-up
6. Resource/Service use is assessed based on a measure used in other MS trials, adapted for use in the NEuRoMS project, at baseline, 3-month, and 6-month follow-up
7. Work-related issues are assessed using the Multiple Sclerosis Work Difficulties Questionnaire (Short form) at baseline, 3-month and 6-month follow-up
8. The extent to which work and medication adherence have been impacted by cognitive problems is assessed using two single questions at baseline, 3-month and 6-month follow-up.
9. Capability and wellbeing for health economics evaluation is assessed using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3-month and 6-month follow-up.

Part 3 – interviews:
1. Feasibility and acceptability of trial procedures through qualitative data; patients' willingness to be randomised; patients' views on trial recruitment and retention strategies, preferences, barriers and facilitators to trial recruitment and retention; importance and acceptability of outcome measures; measured at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers.
2. Operational issues in the delivery of cognitive screening and management pathway; contextual factors which influence intervention and pathway delivery, including mechanisms which influence its affect and outcomes; behavioural elements of the intervention, essential resources needed, and barriers to screening and intervention delivery; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
3. Patient, intervention provider and clinician experiences of cognitive screening and management pathway; factors facilitating or hindering engagement with the pathway; mechanisms considered important in determining key outcomes; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
4. Intervention providers' readiness to deliver NEuRoMS intervention following training; potential contamination issues; potential improvements to training; measured throughout data collection and at interviews with intervention providers.

Previous secondary outcome measures:
Part 1 – testing the cognitive screening pathway:
1. Feasibility of the cognitive screening pathway procedures, measured during screening and throughout Part 1 data collection period, assessed as:
1.1. Number of patients who complete the screening in different settings (online at home, online in-clinic)
1.2. Number of patients who use different devices to complete the screening (e.g., tablet, mobile phone, laptop)
1.3. Time taken to complete the screening (in minutes)
1.4. Number of patients who require reminders and extra support (telephone/in-clinic) to complete the screening
1.5. Number and content of contacts between service providers and patient-participants.
2. Patient scores from the cognitive screening measures: a version of the Stroop task and the

Symbol Digit Modalities Test, and three measures from the Multiple Sclerosis Quality of Life Inventory for self-reported cognitive problems, fatigue and mental health, measured during screening as part of usual care

Part 2 - patient-centred outcomes:
In addition to feasibility outcomes (primary outcomes), the following measures will also be used to capture information about the patient at baseline and to assess outcomes at 3- and 6-months after randomisation:
1. Cognitive impairment is assessed using the Multiple Sclerosis Neuropsychological Questionnaire (MSNQ) at baseline, 3-month and 6-month follow-up
2. Quality of life is assessed using the Multiple Sclerosis Impact Scale (MSIS-29) and EQ-5D-5L at baseline, 3-month and 6-month follow-up
3. Mood is assessed using the Patient Health Questionnaire-9 and Generalized Anxiety Disorder-7 scale at baseline, 3-month and 6-month follow-up
4. Functional ability is assessed using the Nottingham Extended Activities of Daily Living Scale at baseline, 3-month and 6-month follow-up
5. Self-efficacy is assessed using the Multiple Sclerosis Self-efficacy Scale (MSSE) at baseline, 3-month and 6-month follow-up
6. Resource use is assessed based on a measure used in other MS trials at baseline, 3-month and 6-month follow-up
7. Work-related issues are assessed using the Multiple Sclerosis Work Difficulties Questionnaire at baseline, 3-month and 6-month follow-up
8. Improved disease-modifying therapy (DMT) adherence (defined as not missing a treatment within the last 4-weeks) is assessed using four patient-reported outcomes used in the Global Adherence Project and an ongoing PCORI-funded international study DELIVER-MS, at baseline, 3-month and 6-month follow-up
9. The extent to which work and DMT adherence have been impacted by cognitive problems is assessed using two single questions at baseline, 3-month and 6-month follow-up.
10. Capability and wellbeing for health economics evaluation is assessed using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3-month and 6-month follow-up.

Part 3 – interviews:
1. Feasibility and acceptability of trial procedures through qualitative data; patients' willingness to be randomised; patients' views on trial recruitment and retention strategies, preferences, barriers and facilitators to trial recruitment and retention; importance and acceptability of outcome measures; measured at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers.
2. Operational issues in the delivery of cognitive screening and management pathway; contextual factors which influence intervention and pathway delivery, including mechanisms which influence its affect and outcomes; behavioural elements of the intervention, essential resources needed, and barriers to screening and intervention delivery; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.
3. Patient, intervention provider and clinician experiences of cognitive screening and management pathway; factors facilitating or hindering engagement with the pathway; mechanisms considered important in determining key outcomes; measured throughout data collection by reviewing notes from monthly teleconferences/videoconferences with clinicians and supervision sessions with intervention providers, and at 3-month interviews and 6-month interviews with patients, and interviews with intervention providers and clinicians.

4. Intervention providers' readiness to deliver NEuRoMS intervention following training; potential contamination issues; potential improvements to training; measured throughout data collection and at interviews with intervention providers.

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/07/2022:

All individuals:
Able and willing to give consent and able to communicate in English. Participant information sheets can be provided in Welsh upon request but the standardised materials and tests to be used require communication in English since these have not yet been developed for other languages.

Part 1 – testing the cognitive screening pathway:
People with MS:
1. Diagnosis of MS
2. Aged 18 years or above

Part 2 – acceptability, feasibility RCT and fidelity evaluation:
People with MS:
1. Diagnosis of MS
2. Received cognitive screening and mild or moderate cognitive problems identified (Part 1)
3. Aged 18 years or above

Part 3 – interviews:
1. People with MS:
1.1. People with MS participated in Part 2
2. Intervention providers:
2.1. Assistant Psychologist/Research Nurses/Assistant Occupational Therapist delivering the NEuRoMS intervention to people with MS in Part 2
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

Previous inclusion criteria:

All individuals:
Able and willing to give consent and able to communicate in English. Participant information sheets can be provided in Welsh upon request but the standardised materials and tests to be used require communication in English since these have not yet been developed for other languages.

Part 1 – testing the cognitive screening pathway:
People with MS:
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People with MS:
1. Diagnosis of MS
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Part 3 – interviews:
1. People with MS:
1.1. People with MS participated in Part 2
2. Intervention providers:
2.1. Assistant Psychologist/Research Nurses/Assistant Occupational Therapist delivering the NEuRoMS intervention to people with MS in Part 2
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

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
2354

Key exclusion criteria
Part 2 participants only:
1. Currently receiving neuropsychological intervention for cognitive problems
2. Received NEuRoMS intervention during WP2ii

All participants:
1. Does not have the mental capacity to consent to take part in the study

Date of first enrolment
01/04/2022

Date of final enrolment

31/08/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

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

Study participating centre
University Hospital of Wales
Cardiff and Vale University Health Board
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 (NIHR) - 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 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?
Protocol article		11/06/2022	13/06/2022	Yes	No
Basic results		21/08/2024	21/08/2024	No	No
Statistical Analysis Plan	version 1	18/07/2023	22/08/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes