ISRCTN15746123 https://doi.org/10.1186/ISRCTN15746123

Practical management of behavioural impairment in motor neurone disease: MiNDToolkit feasibility study

Submission date
17/05/2021

Recruitment status
No longer recruiting

Registration date
26/05/2021

Overall study status
Completed

Last Edited
25/09/2024

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
Motor neurone disease (MND) is an uncommon condition that affects the brain and nerves. It causes weakness that gets worse over time.
MND is now recognised as a multi-system disorder, affecting also people's behaviours and cognitive abilities - referred to as 'non-motor symptoms'. This usually occurs in up to 50% of people diagnosed with MND. Clinical assessments have been developed to support identification of these non-motor symptoms, but appropriate support to manage these symptoms are lacking.
This study aims to test the feasibility (can this be done?) of a new psychoeducational intervention for carers, delivered via a bespoke online platform, with optional support from healthcare professionals.

Who can participate?
Carers of people with Motor Neurone disease - family carer/relative/live-in professional carer, who present with additional behavioural impairments.

What does the study involve?
Carers (participants) complete online screening assessments to verify they are eligible to the study. Next, carers complete baseline assessments, also online. Once these assessments are complete, carers are randomly assigned to the MiNDToolkit intervention or control group. Carers in the intervention group will access the online intervention for 3 months. Healthcare professionals involved in the care of their person with MND may also support the intervention delivery. At the end of the 3-month period, carers complete a follow-up assessment, similar to the baseline assessment. They are then offered to continue using the MiNDToolkit for another 3 months, if they wish to.
Carers in the control group will not access the intervention for the initial 3 months. After this period, carers complete a follow-up assessment, similar to the baseline assessment. They are then offered to start using the MiNDToolkit for 3 months, if they wish to.

What are the possible benefits and risks of participating?
Benefits include access to novel tailored resources for the management of behavioural symptoms, which are currently not available for carers in the UK or other countries.
Risks include distress from completing questionnaires about carers' own health and the person with MND.

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

When is the study starting and how long it is expected to run for?
July 2020 to March 2023

Who is funding the study?
The Motor Neurone Disease Association (UK)

Who is the main contact?
Prof. Eneida Mioshi, e.mioshi@uea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Eneida Mioshi

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Additional identifiers

Integrated Research Application System (IRAS)
260290

Central Portfolio Management System (CPMS)
41888

Protocol serial number
Grant Codes: Mioshi/May16/934-794

Study information

Scientific Title
Practical management of behavioural impairment in Motor Neurone Disease: MiNDToolkit for carers feasibility study

Acronym
MiNDToolkit

Study objectives
Carers of people with Motor Neurone Disease presenting with behavioural symptoms require additional support to manage these non-motor symptoms. A novel online psychoeducational intervention, the MiNDToolkit, may be useful in supporting carers dealing with these non-motor symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2021, London Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44(0)207 104 8061; queensquare.rec@hra.nhs.uk), ref: 19/LO/0692

Primary study design
Interventional

Study design
Interventional pilot open-label randomized controlled design feasibility study

Study type(s)
Other

Health condition(s) or problem(s) studied
Motor neurone disease with behavioural symptoms

Interventions
The new online intervention comprises modules that:
(1) target symptoms identified in the screening/baseline assessments;
(2) suggest which strategies the person with MND and carer would benefit from;
(3) utilise these techniques during each week.
In addition, (4) if the HCP of the person with MND has also been trained, they will demonstrate those techniques for the carers during consultations.

Each week, the carer will be given modules with information on behavioural symptoms as well as strategies to apply, tailored to the issues identified during the screening/baseline assessments.

It is expected that the carer will apply these techniques in their daily routine after the modules for a week. At any following MND consultation with a HCP trained in the MiNDToolkit, a review

of strategies utilised will be recorded and the HCP will discuss with the carer what may have worked or not, and examples of context. The healthcare professionals will then record this information on the MiNDToolkit online platform.

The intervention period is 3 months.

Participants in the control group will be offered the opportunity to use the MiNDToolkit after the follow-up assessment. Participants in the intervention group will be offered the opportunity to continue using the MiNDToolkit for an additional three months, after the follow-up assessment.

Randomisation:
When a consented participant has completed the screening and pre-intervention assessment, the trial manager will receive an automatic email notification that a participant is ready for randomisation. They will contact (by email or phone) the CTU data management team which holds a randomisation list generated by the study statistician and held on secure CTU servers. Randomisation is simple 1:1 randomisation to either intervention or control arm with no stratification or minimisation. The next allocation on the randomisation list will be communicated to the trial manager who will log this on the platform. The platform sends a text and/or email notification to the participant informing them of their allocation and the next steps in the study processes, e.g. access to the online modules if in the intervention arm or the next follow up survey in the control arm.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility of the MiNDToolkit online intervention in MND Specialist Settings measured using:
1. Recruitment, eligibility, and attrition: Numbers of potentially eligible patients who meet the inclusion criteria, Number of participants subsequently recruited into the study, rates and reasons for refusal, numbers ineligible, reasons for ineligibility, attrition rate, and reasons for withdrawing throughout the study. Timepoint: During the trial recruitment phase
2. Resources needed to complete the online MiNDToolkit: length of time carers spend on modules per week, length of time required for HCPs to provide online and 'face-to face' (e.g. could be via online appointments) feedback per participant, and the amount and nature of feedback provided
3. Carer adherence to MiNDToolkit: records of access and engagement with online MiNDToolkit (number of modules accessed; how long; contacts with HCPs). Timepoint: During the intervention phase and post-intervention phase
4. Carer acceptability: aspects of the MiNDToolkit that carers found helpful and unhelpful, satisfaction with the intervention and HCP interactions, and reasons for withdrawing from the MiNDToolkit. Timepoint: During the intervention phase and post-intervention phase
5. Therapist acceptability: satisfaction with training and supervision evaluated through qualitative interviews at the end of the study, and intervention fidelity monitored through their online notes, entered directly in the platform, and weekly drop in sessions offered

Key secondary outcome(s)
Current secondary outcome measures as of 26/11/2021:
Measured at baseline, and post-intervention at 3 months.
1. Severity of depression for the carer measured using The Patient Health Questionnaire 9 (PHQ-9)

2. Generalized anxiety disorder for the carer measured using The Generalized Anxiety Disorder Questionnaire 7 (GAD-7)
3. Services and supports currently being utilised by the patient measured using The Adapted Client Service Receipt Inventory (CSRI)
4. Caring experience measured using The Carer Experience Scale (CES)
5. Wellbeing for the carer measured using ICEpop CAPability measure for Adults (ICECAP-A)
6. Psychological flexibility via the Acceptance and Action Questionnaire (AAQ)

Previous secondary outcome measures:
Measured at baseline, and post-intervention at 3 months.
1. Severity of depression for the carer measured using The Patient Health Questionnaire 9 (PHQ-9)
2. Generalized anxiety disorder for the carer measured using The Generalized Anxiety Disorder Questionnaire 7 (GAD-7)
3. Services and supports currently being utilised by the patient measured using The Adapted Client Service Receipt Inventory (CSRI)
4. Caring experience measured using The Carer Experience Scale (CES)
5. Wellbeing for the carer measured using ICEpop CAPability measure for Adults (ICECAP-A)

Completion date
30/03/2023

Eligibility

Key inclusion criteria
Participants will be family carers, relatives, or live-in professional carers of:
1. Patients with a diagnosis of MND with cognitive impairment or behavioural impairment, based on Strong et al. (2017) diagnostic criteria, or
2. Patients with a diagnosis of MND-FTD based on Strong et al. (2017) diagnostic criteria;
3. Carers will have at least 14 hours of contact with the person with MND per week and be willing to participate in research activities. Carers must be aged 18 years or over

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
55

Key exclusion criteria
Inability to read or communicate in English (with or without support)

Date of first enrolment
01/07/2021

Date of final enrolment
16/12/2022

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
West Pottergate Medical Centre
Norfolk Community Health and Care NHS Trust
Research Office, Ground Floor
Earlham Road
Norwich
United Kingdom
NR2 4BX

Study participating centre
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre

Huddersfield Royal Infirmary
Acre Street
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
Leicestershire and Rutland Hospice
Groby Road
Leicester
United Kingdom
LE3 9QE

Study participating centre
Marie Curie Cardiff and Vale Hospice
Bridgeman Road
Penarth
United Kingdom
CF64 3YR

Study participating centre
Prince Philip Hospital
Bryngwynmawr
Dafen
Llanelli
United Kingdom
SA14 8QF

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
West Suffolk Hospital
Hardwick Lane

Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Charity

Funder Name
Motor Neurone Disease Association

Alternative Name(s)
MND Association, Motor neurone disease (MND), Mndassos, MNDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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 as this is a feasibility study, which does not aim to evaluate the efficacy of the intervention.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/05/2024	25/09/2024	Yes	No
Results article	Process evaluation	15/05/2024	25/09/2024	Yes	No
Basic results			25/09/2024	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 9	06/02/2023	06/07/2023	No	No
Statistical Analysis Plan	version 1.0		06/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes