ISRCTN14208138 https://doi.org/10.1186/ISRCTN14208138

A study exploring the feasibility of delivering, evaluating, and implementing a new self-management programme for people with neuromuscular diseases

Submission date
14/06/2021

Recruitment status
No longer recruiting

Registration date
18/08/2021

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Supported self-management is part of the 'NHS Long-term Plan's' commitment to make personalised care 'business as usual' across the health and care system. Research has shown that self-management programmes can support people with long-term conditions to problem solve, set goals, and take action. The focus is on living well with a condition, not just the medical needs. Self-management support has been shown to be effective in other neurological diseases, but there is very little research into specific programmes for people living with a neuromuscular condition.
Bridges is a social enterprise that works with teams from health, social care and the third sector, to help them deliver self-management support to people with chronic health conditions. Bridges have recently worked with people with neuromuscular conditions to produce a support programme that is tailored specifically to their needs. This new programme needs to be evaluated, which is why this study is taking place. We will also be investigating how the Bridges programme can be effectively introduced into the clinical service at the Queen Square Centre for Neuromuscular diseases.

Who can participate?
Anyone over the age of 18 who is a patient at the Queen Square Centre for Neuromuscular Diseases and has a confirmed diagnosis of neuromuscular disease from a consultant neurologist at the centre.

What does the study involve?
1. If participants consent to take part, they will be asked to fill in a selection of questionnaires asking about their experience of living with a neuromuscular condition. This will either be done remotely or face-to-face depending on preference.
2. Fairly soon after this, they will attend a routine appointment with one of the health care professionals at Queen Square (this could be a nurse, a physiotherapist, or an occupational therapist). This professional will have been trained in the 'Bridges self-management approach'

and will work with them to find new ways to build knowledge, skills and confidence. Hopefully, this will help them to manage living with their condition.
3. Directly after the session they will be asked to complete some more questionnaires.
4. Three months later, they will be asked to complete the questionnaires one final time.

What are the possible benefits and risks of participating?
Possible benefits: Bridges training helps health professionals to adapt their approaches to working with people, and work in a personalised way based on 'what matters' to the person. It enables them to use techniques to support people to build knowledge, skills and confidence. People with other neurological conditions have found this to be very helpful. This study may help us improve the advice and treatment given to patients with neuromuscular diseases in the future and help us with future research. Some people may enjoy the opportunity to share from their experience and take part in a research project.
Possible risks: It is very unlikely that taking part will cause harm, but some people might find it upsetting to talk about their experiences of living with the condition that they have. If this happens, we will offer to refer to counselling services.

Where is the study run from?
The Queen Square Centre for Neuromuscular diseases which is part of University College London Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to October 2022

Who is funding the study?
Muscular Dystrophy UK.

Who is the main contact?
Mr Louie Lee, louie.lee@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Louie Lee

ORCID ID
https://orcid.org/0000-0001-8805-6188

Contact details
Centre for Neuromuscular Diseases
Box 102
National Hospital for Neurology and Neurosurgery Queen Square
London
United Kingdom
WC1N 3BG
+44 (0)2031086301
Louie.lee@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282646

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49134, IRAS 282646

Study information

Scientific Title
ADAPT NMD: a hybrid II study of the feasibility and implementation of a self-management programme for people with neuromuscular diseases

Acronym
ADAPT-NMD

Study objectives
To test feasibility and implementation of a self-management programme for people with neuromuscular diseases

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048 088; bradfordleeds.rec@hra.nhs.uk), ref: 21/TH/0092

Study design
Non-randomized; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neuromuscular diseases

Interventions

The intervention will be delivered in a one-off session as part of routine therapy and nursing appointments. The intervention is designed to be woven into routine clinical appointments, it is therefore not expected that delivering NM Bridges will have any adverse effect on the time it takes to deliver appointments, the care that participants receive, or the workload of clinicians. The funding for this study includes funding for staff at the CNMD to receive a 2 day training course in the Bridges Self-Management approach.

Participant journey through trial:
1. Participant invited by clinical team from the clinics at Queens Square Centre for Neuromuscular diseases and provided with participant information sheet
2. If interested, a member of the research team will take informed consent. This will be either be done face to face or remotely, depending on the current recommendations from UCL/UCLH regarding COVID-19.
3. Baseline outcome measures will then be completed remotely. They are to be completed post registration and providing of informed consent but before the routine therapy or nursing appointment in which the intervention is delivered
4. Routine therapy or nursing appointment takes place. NM Bridges intervention delivered as part of the appointment either face-to-face or remotely depending on recommendations to researchers regarding COVID-19.
5. Immediately post-appointment: Participant repeats outcome measures (remotely or face-to-face, depending on COVID-19).
6. After 3 months, outcome measures are repeated for the final time
7. 3-months post intervention participants will be recruited for semi-structured interviews to explore their experiences of receiving NM Bridges.

Centre staff will be interviewed at the end of the intervention phase of the study to identify the experience of delivering NM Bridges as part of the clinical service: benefits, challenges, suggestions for streamlining delivery, translation to other areas and environments.

Fidelity of the NM Bridges SMP will be assessed through a mixture of session observation, a fidelity checklist, and educational meetings. A selection of the intervention sessions will be video recorded and reviewed by the research team, who will evaluate the session against pre-agreed fidelity markers. Participants can choose not to be recorded if they do not want to.

Participant interviews will take place in a location of their choice, including the option of remote interviews.

Participants will be in the trial for 4 months.

A patient and public involvement group has been consulted on the design of this trial and have reviewed the study documents.

During the the trial, an implementation strategy will be employed. The main components of this strategy will be:
1. 'Bridges champion/s' actively promoting uptake of the intervention.
2. Educational meetings to discuss barriers and
facilitators to uptake and problem solve and issues.
3. Educational materials and academic detailing to increase 'buy-in' from clinicians.
4. email reminders about using the Bridges approach in sessions and reminders about intervention components

Intervention Type

Behavioural

Primary outcome(s)
1. Feasibility of delivery of the NM Bridges intervention:
1.1. The acceptability of NM Bridges (to clinicians and participants) when delivered in one-off interactions, measured using qualitative interview data and administrative data 3 months after the final participant is recruited
1.2. The demand for NM Bridges within the service, measured using qualitative interview data and administrative data 3 months after the final participant is recruited
2. Feasibility of evaluation:
2.1. The acceptability and performance of candidate outcome measures, measured using quantitative analysis of the documented study outcome measures and qualitative interview data at baseline, directly after the intervention and 3 months post-intervention
2.2. Participant recruitment and retention measured using administrative data throughout the duration of the study
3. Feasibility of implementation:
3.1. The fidelity of the implementation process measured using qualitative interview data and session observation throughout the duration of the study
3.2. Intervention fidelity measured using a fidelity checklist, a sample of video-recorded clinical sessions score using a fidelity checklist, throughout the duration of the study
3.3. The acceptability of the implementation strategy package to clinicians at the specialist centre, measured using qualitative interview data and administrative data 3 months after the final participant is recruited
3.4. Barriers and facilitators to the implementation strategy package, measured using qualitative interview data and administrative data 3 months after the final participant is recruited
3.5. The appropriateness and practicability of the implementation strategy package to the specialist clinical service, measured using
qualitative interview data and administrative data 3 months after the final participant is recruited
3.6. The effect of the implementation strategy package on adoption, measured using qualitative interview data and administrative data 3 months after the final participant is recruited

Key secondary outcome(s))
1. Health-related quality of life will be measured using the EQ-5d,
2. Self-efficacy will be measured using the General Self-Efficacy Scale (GSES)
3. Mood will be measured using the General Health Questionnaire (GHQ)
4. Participation will be measured using the the Oxford Participation and Activities Questionnaire (Ox-PAQ)
5. A profile of the broad impacts of the intervention will be measured through the Health Education Impact Questionnaire (heiQ).
6. The person-centredness of the intervention will be measured through the Client-Centred Care Questionnaire (CCCQ) and the Patient Assessment of Care for Chronic Conditions (PACIC)
Outcome measures will be collected at baseline, immediately after patients receive the intervention and 3 months post intervention.

Completion date
30/10/2022

Eligibility

Key inclusion criteria

1. New referral to the centre for neuromuscular diseases or any patient who is within 4 weeks of commencing treatment
2. Clinical diagnosis of neuromuscular disease (i.e a disease affecting either the anterior horn cell, peripheral nerves, neuromuscular junction or muscle tissue) from a consultant neurologist at the centre for neuromuscular diseases
3. Ability to follow a two-stage command
4. Over 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients aged <18 years
2. Patients that do not attend clinics at Queen Square Centre for Neuromuscular Diseases or University College London Hospital
3. Patients that do not have the capacity to provide informed consent
4. Patients have competing comorbidities influencing their rehabilitation, e.g. malignant cancer
5. Patients have significant issues with their readiness to participate as judged by the clinical team, e.g. illness of a carer
6. Do not require multidisciplinary rehabilitation
7. Hearing and visual impairments precluding their ability to fully participate in NM Bridges

Date of first enrolment
22/09/2021

Date of final enrolment
30/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University College London Hospital
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Muscular Dystrophy UK; Grant Codes: 18GRO-PS48-0122-1

Alternative Name(s)
Muscular Dystrophy UK London, Muscular Dystrophy Group, Muscular Dystrophy Campaign, MDUK

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 current data sharing plans for this study are unknown and will be 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		09/01/2023	10/01/2023	Yes	No
Participant information sheet	version 2	04/05/2021	13/08/2021	No	Yes