ISRCTN12655391 https://doi.org/10.1186/ISRCTN12655391

A trial of acceptance and commitment therapy for people with motor neuron disease

Submission date
25/06/2017

Recruitment status
No longer recruiting

Registration date
17/07/2017

Overall study status
Completed

Last Edited
01/08/2025

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
Motor neuron disease (MND) is a rapidly progressive, fatal neurological disease with no known cure. It affects parts of the brain and spinal cord, and results in loss of the ability to move, speak, swallow and breathe. Typical survival is 2-3 years following symptom onset and current drugs only prolong life by 2-3 months. Many people with MND experience distress due to the disease's nature, impact and outlook. Evidence of effective ways of improving psychological health in people with MND is urgently needed, but is lacking. Acceptance and Commitment Therapy (ACT) is a form of talking therapy that helps people learn how to live with difficult emotions, thoughts or bodily sensations, while still doing things that really matter to them. It is helpful in improving psychological health in other conditions including life-limiting illnesses (e.g. cancer) and disabling long-term conditions. However, whether it can help people with MND is unknown. The aims of the study are to find out whether it is possible to adapt ACT for people with MND and to find out whether, along with usual care, it improves their psychological health in comparison to usual care alone.

Who can participate?
Patients aged 18 and over with MND

What does the study involve?
In the first part of the study, people with MND, their carers and MND healthcare professionals take part in four workshops in order to create a treatment programme based on ACT that has been adapted for people with MND. Following this, around 28 people with MND receive up to 8 sessions of adapted ACT face-to-face and via online/DVD video (with support from therapists) plus usual care or usual care alone over 3 months. Face-to-face sessions are delivered at home, in clinics/GP surgeries or via videoconferencing, according to participants' preferences, by therapists in psychology services. All therapists receive training in ACT, as well as regular supervision. The sessions involve working with therapists to learn new skills to help deal with MND and associated symptoms. At the start of the study and then again after 6 months, participants are asked to complete a number of questionnaires including those that assess levels of quality of life, anxiety, depression, functioning, service use and how satisfied they are with the therapy they have received. Carers are asked to complete a number of questionnaires that assess quality of life and carer burden. About 15 people with MND and all therapists are asked to

complete an interview afterwards to further explore how satisfied they are with the therapy they have received or delivered, respectively.
In the second part of the study, around 188 people with MND are randomly allocated to receive either up to 8 sessions of adapted ACT as described above (subject to change based on the results of the first part of the study) plus usual care, or usual care alone. Sessions are delivered as described above. At the start of the study and then again after 6 and 9 months, participants are asked to complete a number of questionnaires including those that assess levels of quality of life, anxiety, depression, functioning, service use, and how satisfied they are with the therapy they have received. Carers are asked to complete a number of questionnaires that assess quality of life and carer burden.

What are the possible benefits and risks of participating?
The main possible benefit is that participants are given access to a new form of talking therapy that is not yet available on the NHS for this condition. The main possible risk is that participants may experience a deterioration in anxiety and/or depression symptoms during the intervention (as it may not be beneficial for them) or distress during the interviews (e.g. when discussing their current difficulties). Participants remain under the care of their MND care team during the study, and will be monitored and referred for further support if necessary.

Where is the study run from?
University College London Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to April 2023

Who is funding the study?
National Institute for Health Research Health Technology Assessment Programme (NIHR_HTA) (UK)

Who is the main contact?
Dr Rebecca Gould
r.gould@ucl.ac.uk

Study website
https://www.ucl.ac.uk/psychiatry/research/mental-health-older-people/projects/commend

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 16/81/01

Study information

Scientific Title
A feasibility study and randomised controlled trial of acceptance and COMmitment therapy for people with Motor nEuroN Disease (COMMEND)

Acronym
COMMEND

Study objectives
The research question is what is the clinical and cost effectiveness of Acceptance and Commitment Therapy (ACT), modified for people with motor neuron disease (MND), plus usual multidisciplinary care in comparison to usual multidisciplinary care alone for improving psychological health in people with MND?

The study objectives are to:
1. Develop and refine a manualised intervention tailored to people with MND
2. Obtain quantitative estimates of the acceptability and feasibility of the intervention and study methods in an open uncontrolled feasibility study
3. Use qualitative approaches to explore the intervention's acceptability and feasibility to people with MND and therapists
4. Evaluate the acceptability and feasibility of participating in a randomised controlled trial (RCT) of ACT through qualitative interviews with people with MND
5. Clarify study design parameters for the RCT
6. Establish the clinical and cost effectiveness of ACT plus usual multidisciplinary care for people with MND compared to usual multidisciplinary care alone in an RCT with an internal pilot phase
7. Collect qualitative data from people with MND and therapists to examine perceived mechanisms of impact and the context in which the intervention is delivered

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Phase 1 approved 12/03/2018, London - Dulwich Research Ethics Committee (Skipton House, 80 London Rd, London, SE1 6LH; +44 (0)20 7972 2561; dulwich.rec@hra.nhs.uk), ref: 18/LO/0227
2. Phase 2 approved 30/04/2019, London - Dulwich Research Ethics Committee (Skipton House, 80 London Rd, London, SE1 6LH; +44 (0)20 7972 2567; dulwich.rec@hra.nhs.uk), ref: 19/LO/0272

Study design
Open uncontrolled feasibility study and multicentre single-blind parallel two-arm randomised controlled trial with an internal pilot phase

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Available from: https://www.ucl.ac.uk/psychiatry/research/mental-health-older-people/projects/commend/get-involved

Health condition(s) or problem(s) studied
Motor neuron disease

Interventions
Phase 1:
A manualised intervention will be developed based on Acceptance and Commitment Therapy (ACT) and adapted for people with motor neuron disease (MND). This will be achieved through a series of four workshops and individual qualitative interviews with people with MND and MND healthcare professionals. These will explore:
1. Facilitators/barriers to engagement in psychotherapy (including potential ways of overcoming barriers)
2. Positive and negative experiences of psychotherapy
3. How best to adapt ACT for people with MND
4. Ways of optimising engagement
5. How best to promote the intervention to people with MND not currently experiencing distress.
Once the intervention has been developed, approximately 28 people with MND will receive up to eight 1:1 sessions of adapted ACT plus usual care, each lasting up to 1 hour, over the course of 3 months. A minimum of four sessions will be face-to-face (delivered within the MND clinic, GP surgery or participant's home or via videoconferencing, as per patient preference and therapist availability) and up to four will be delivered via online videos/DVDs (followed by therapist support via videoconferencing, instant messaging, telephone or email, depending on patient preference). The intervention will involve helping participants to increase psychological flexibility through learning new skills, metaphors, experiential exercises and home practice tasks. These will aim to:

1. Reduce avoidance of difficult or uncomfortable experiences where such behaviour might be a barrier to life enriching activity
2. Reduce the amount of time people are "stuck in their head" ruminating about the past or worrying about the future
3. Reduce the degree to which people are caught up in negative or unhelpful thoughts about themselves, their situation or their identity and roles
4. Identify what really matters to them in their lives
5. Commit to doing personally meaningful activities that support what they value
Sessions will be delivered by Band 7 or Band 8 clinical psychologists or accredited Cognitive Behavioural therapists identified to work with people with MND via clinical psychology, neuropsychology and Improving Access to Psychological Therapies services. All therapists will receive training and fortnightly group supervision in ACT for people with MND. After 6 months, all participants will be followed up by an independent outcome assessor to assess how acceptable and feasible the intervention was. In addition, a sample of 15 participants and all therapists will also be invited to complete individual interviews to further assess acceptability and feasibility. These interviews will explore the perceived benefits and limitations of the intervention, together with any recommendations for revising it.

Phase 2:
The clinical and cost effectiveness of ACT plus usual multidisciplinary care for improving the psychological health of people with MND in comparison to usual multidisciplinary care alone will be established in a multicentre, single-blind, parallel RCT (N = 188). Eligible participants will be randomised using a web-based, centralised randomisation system hosted by the Sheffield Clinical Trials Research Unit. Randomisation will use blocks of varying length, stratified by recruitment site. Allocation concealment will be achieved by requiring participants' details to be entered onto the system before the randomly allocated treatment is revealed. Participants and their GPs will be informed of the allocation by telephone or letter. Participants are randomised to receive either:
1. 8 sessions of adapted ACT, as described above (subject to change based on the results of the first part of the study), plus usual care
2. Usual care alone
The RCT will include an internal pilot in the first 10 months of the RCT to assess the feasibility of recruitment rates and acceptability of randomisation. After 6 and 9 months, all participants will be followed up by an independent outcome assessor to assess how clinically effective and cost effective the intervention was.

Intervention Type
Behavioural

Primary outcome measure
Phase 1:
1. Uptake rate is recorded as the number of eligible participants who consent to participate in the study
2. Initial engagement rate is recorded as the number of eligible participants who complete at least 2 sessions

Phase 2:
1. Quality of life is measured using the McGill Quality of Life Questionnaire (Cohen et al., 1995) at baseline, 6 months and 9 months post-randomisation

Secondary outcome measures

Phase 1:

1. Acceptability:
1.1. Satisfaction rate is recorded as the number of eligible participants who consent to participate in the study and give 'satisfactory' ratings of therapy using the Satisfaction with Therapy and Therapist Scale-Revised (Oei et al., 2008) at 6 months. There is no set definition of what constitutes "satisfactory" and so this will be defined as a total score of 21 or more on the Satisfaction with Therapy subscale
1.2. Failure to recruit rate due to lack of acceptability is recorded as the number of eligible participants who refuse to consent to participate in the study during the 4-month recruiting period due to lack of acceptability of the intervention
1.3. Attrition rate due to lack of acceptability is recorded as the number of eligible participants who consent to participate in the study that drop out due to lack of acceptability of the intervention by 6 months

2. Feasibility:
2.1. Referral rate is recorded as the number of eligible referrals to the study overall during the 4-month recruiting period
2.2. Failure to recruit rate for reasons other than lack of acceptability is recorded as the number of eligible participants who refuse to consent to participate in the study during the 4-month recruiting period for reasons other than dissatisfaction with therapy
2.3. Attrition rate for reasons other than lack of acceptability is recorded as the number of eligible participants who consent to participate in the study that drop out for reasons other than dissatisfaction with therapy during the 4-month recruiting period
2.4. Deliverability of the intervention within the NHS is recorded as the number of therapy sessions offered (as opposed to completed) during the 3-month therapy period

3. Patient-reported outcome measures:
3.1. Quality of life is measured using the McGill Quality of Life Questionnaire (Cohen et al., 1995) at baseline and 6 months
3.2. Anxiety and depression is measured using the Modified Hospital Anxiety and Depression Scale for MND (Gibbons et al., 2011) at baseline and 6 months
3.3. Psychological flexibility is measured using the Acceptance and Action Questionnaire-II (Bond et al., 2011) at baseline and 6 months
3.4. Health-related quality of life is measured using the EQ-5D-5L (Herdman et al., 2011) at baseline and 6 months
3.5. Non-physical adverse events is recorded as the number of non-physical adverse events other than physical self-harm at 6 months
3.6. Functioning is measured using the ALS Functional Rating Scale-Revised (Cederbaum et al., 1999) at baseline and 6 months

4. Caregiver-reported outcome measures:
4.1. Health-related quality of life is measured using the EQ-5D-5L (Herdman et al., 2011) at baseline and 6 months
4.2. Caregiver burden is measured using the Zarit Burden Interview (Zarit et al., 1980) at baseline and 6 months

5. Cost-effectiveness-related measures:
5.1. Service utilisation is measured using a short modified version of the Client Service Receipt Inventory (Beecham et al., 1992) at baseline and 6 months

Phase 2:

1. Patient-reported outcome measures:
1.1. Existential and psychological quality of life is measured using the Existential and Psychological subscales of the McGill Quality of Life Questionnaire (Cohen et al., 1995) at baseline, 6 months (primary endpoint) and 9 months
1.2. Anxiety and depression is measured using the Modified Hospital Anxiety and Depression Scale for MND (Gibbons et al., 2011) at baseline, 6 months (primary endpoint) and 9 months
1.3. Psychological flexibility is measured using the Acceptance and Action Questionnaire-II (Bond et al., 2011) at baseline, 6 months (primary endpoint) and 9 months
1.4. Health-related quality of life is measured using the EQ-5D-5L (Herdman et al., 2011) at baseline, 6 months (primary endpoint) and 9 months
1.5. Non-physical adverse events is recorded as the number of non-physical adverse events other than physical self-harm at 6 months (primary endpoint) and 9 months
1.6. Functioning is measured using the ALS Functional Rating Scale-Revised (Cederbaum et al., 1999) at baseline, 6 months (primary endpoint) and 9 months
1.7. Satisfaction rate is recorded as the number of eligible participants who consent to participate in the study and give 'satisfactory' ratings of therapy using the Satisfaction with Therapy and Therapist Scale-Revised (Oei et al., 2008) at 6 months (primary endpoint). There is no set definition of what constitutes "satisfactory" and so this will be defined as a total score of 21 or more on the Satisfaction with Therapy subscale
1.8. Survival at 9 months (primary endpoint)

2. Caregiver-reported outcome measures:
2.1. Health-related quality of life is measured using the EQ-5D-5L (Herdman et al., 2011) at baseline, 6 months (primary endpoint) and 9 months.
2.2. Caregiver burden is measured using the Zarit Burden Interview (Zarit et al., 1980) at baseline, 6 months (primary endpoint) and 9 months

3. Cost-effectiveness-related measures:
3.1. Cost-effectiveness is measured using health-related quality-adjusted life years and service utilisation from a short modified version of the Client Service Receipt Inventory (Beecham et al., 1992) at baseline, 6 months (primary endpoint) and 9 months

Overall study start date
01/12/2017

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Diagnosis of familial or sporadic MND (or amyotrophic lateral sclerosis, which is diagnostically synonymous with MND) - diagnosed as definite, laboratory-supported probable or probable according to the World Federation of Neurology's El Escorial criteria

Participant type(s)
Patient

Age group

Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
28 in Phase 1 and 188 in Phase 2

Total final enrolment
206

Key exclusion criteria
1. Need for gastrostomy feeding or non-invasive ventilation (i.e. those in stages 4A or 4B of the King's College London clinical staging system)
2. Comorbid diagnosis of any form of dementia using standard diagnostic guidelines
3. Already receiving ongoing formal psychological therapy (e.g. Cognitive Behavioural Therapy, psychodynamic psychotherapy, systemic therapy, counselling, etc) at the baseline assessment or unwilling to refrain from engaging in such formal psychological therapy during the receipt of ACT
4. Insufficient understanding of English to enable engagement in the intervention and completion of patient-reported outcome measures
5. Lacking capacity to provide fully informed written consent, verbal consent (for those who cannot provide written consent), or consent via the use of a communication aid
6. Requiring treatment for a severe psychiatric disorder such as schizophrenia, bipolar disorder, or suicidal ideation with active plans/suicidal behaviours and intent
7. For Phase 2 only: Already participated in Phase 1

Date of first enrolment
01/06/2018

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre

University College London Hospitals NHS Foundation Trust
London
United Kingdom
NW1 2BU

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S10 2JF

Study participating centre
King's College Hospital NHS Foundation Trust
London
United Kingdom
SE5 9RS

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
NHS Lothian
Edinburgh
United Kingdom
EH1 3EG

Study participating centre

The Walton Centre NHS Foundation Trust
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Newcastle Hospitals NHS Foundation Trust
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Preston
United Kingdom
PR2 9HT

Study participating centre
Barts Health NHS Trust
London
United Kingdom
E1 1BB

Study participating centre
Leeds Teaching Hospitals NHS Foundation Trust
Leeds
United Kingdom
LS1 3EX

Study participating centre
Plymouth Hospitals NHS Trust
Plymouth
United Kingdom
PL6 8DH

Study participating centre

Royal Free NHS Foundation Trust
London
United Kingdom
NW3 2QG

Study participating centre
Abertawe Bro Morgannwg University Health Board
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Norwich
United Kingdom
NR4 7UY

Study participating centre
Belfast Health and Social Care Trust
Belfast
United Kingdom
BT9 7AB

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

Sponsor details
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+44 (0)20 3447 5557
randd@uclh.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be disseminated to the academic and clinical community, service users and the broader public from December 2023 onwards through:
1. High impact peer-reviewed, international open-access academic journals
2. National and international academic conferences
3. Local clinical conferences and meetings
4. Talks to local MND groups, the MND Association, and other organisations
5. University media releases, Twitter feeds and the University website
6. Training and seminars delivered via ACT special interest groups and professional bodies

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
Deidentified datasets and statistical code will be available upon request, following the publication of the study results. Emails should be sent to the corresponding author Dr Rebecca Gould, r.gould@ucl.ac.uk, stating the fields required and the purpose of the request (ideally with a protocol but, at a minimum, with a research plan). The data dictionary can also be made available. The statistical analysis plan is provided in Appendix 1. Requests will be considered on a case-by-case basis and requestors will be asked to complete a data sharing agreement with the

sponsor before data transfer. Data will be retained for 10 years following the close of the study, before being destroyed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/11/2022	23/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article	Co-primary feasibility and acceptability outcomes	07/07/2023	10/07/2023	Yes	No
Results article	Effectiveness of ACT	09/05/2024	17/05/2024	Yes	No
Results article		25/04/2024	01/08/2025	Yes	No