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Participant Information Sheet

A feasibility study of Acceptance and Commitment Therapy for people with motor neuron disease (COMMEND)

Invitation to participate in a research study

We would like to invite you to join our research study that is being funded by the National Institute for Health Research. Before you make a decision, it is important for you to understand why the study is being carried out, and what it will involve. Please take your time to read the following information carefully, and discuss it with your partner, relatives or friends if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of this study is to develop a new form of talking therapy called Acceptance and Commitment Therapy for people with motor neuron disease. We would like to see how acceptable this newly developed therapy is to people with motor neuron disease, and whether it is possible to provide it in the NHS.

What is motor neuron disease?

Motor neuron disease is a neurological disease that affects parts of the brain and spinal cord, and results in loss of the ability to move, speak, swallow and breathe. Many people with motor neuron disease experience distress due to the nature of the disease and its impact. However, we do not know whether talking therapy is helpful for improving wellbeing in people with this condition.

What is Acceptance and Commitment Therapy?

Acceptance and Commitment Therapy is a new form of talking therapy that helps people to learn how to live with difficult or distressing thoughts, feelings or bodily sensations, while still doing things that really matter to them. It has been found to be helpful for improving wellbeing in other conditions including other life-limiting illnesses (such as cancer) and disabling long-term conditions. It may be particularly suited to people with motor neuron disease due to its focus on helping people learn how to best live their lives, alongside any difficulties they may be experiencing that are out of their control.

Why have I been invited?

You have been invited because you have been diagnosed with motor neuron disease. We are inviting up to 56 people with motor neuron disease to take part in this study, of whom we hope that 28 will agree. You have been given this information sheet because you expressed an interest in the study.

Do I have to take part?

No. It is up to you to decide whether you would like to take part in this study. We will go through this

information sheet with you, and you will be able to ask any questions you have about it. If you do decide to take part you will be given this information sheet to keep and you will be asked by the researcher to sign a consent form. If you decide to take part you will be free to withdraw from the study at any time without having to give a reason as to why you want to withdraw. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive or your future medical care or legal rights.

What will the study involve if I take part?

If you take part in the study, you will meet with a researcher who will discuss the study with you and ask you some questions to find out whether you are suitable to participate in the study. If you are, then you will be offered up to 8, 1-hour sessions of Acceptance and Commitment Therapy over 3 months. Some of these sessions will be face-to-face and you will be asked to meet with a therapist on your own. This will either be in your own home, in the clinic, or via online video calls, depending on your physical needs and preference and the availability of therapists. Some of these sessions will involve watching videos, which you will be able to do in your own time. You will be able to discuss these videos with your therapist via online video calls, instant messaging, telephone or email, depending on your physical needs and preference.

You will work with your therapist to develop an understanding of the difficulties you have been experiencing. You will learn about new ways of living with difficult thoughts, feelings and bodily sensations, so that you can take part in more activities that are meaningful to you. You will be encouraged to try out these strategies in real-life as putting them into practice will be an important part of treatment.

All of your sessions will be recorded using an encrypted digital voice recorder so that we will be able to see whether the therapists are working with people in similar ways. These recordings will be reviewed by an independent therapist with training in Acceptance and Commitment Therapy. If Acceptance and Commitment Therapy does not suit you, or you find it difficult participating in the sessions then you will be free to finish them at any point. This will not affect the standard of care you receive or your future medical care or legal rights.

While receiving Acceptance and Commitment Therapy, you will be asked to avoid receiving other forms of talking therapy (such as Cognitive Behavioural Therapy) as taking part in different types of therapy at the same time may be confusing for you. Although it is preferable that you do not receive other forms of talking therapy at the same time as Acceptance and Commitment Therapy, we cannot insist on this. Therefore, we will ask you about other treatments you may have received while receiving Acceptance and Commitment Therapy at the end of therapy.

You will be asked to complete some questionnaires on two separate occasions in order for us to see how you find Acceptance and Commitment Therapy: before therapy starts (at 0 months) and at the end of therapy (at 6 months). You will be able to complete these questionnaires over the phone, online or face-to-face with a member of the research team. Each of these assessments will take around 1.5 hours to complete. You will be given the opportunity to take rest breaks while completing these assessments or to complete them in two sessions.

After you have completed the therapy, you may also be invited to take part in a 1-hour interview to talk about your experience of taking part in the therapy, and how we can improve it. The interview will be audio recorded on an encrypted digital voice recorder, and then transferred and stored onto University College London's password-protected secure electronic network. All data on encrypted digital voice recorders will be deleted after the data have been transferred. Transcriptions of your interview will be completed as soon as possible after we have met with you either by a member of the research team or by a transcription service that has been approved by UCL (Way with Words). All data will be anonymised (that is, your name will not be included on the transcript), will only be used for analysis, and will only be viewed by members of the research team. Any travel expenses incurred by yourself during the course of the study will be reimbursed.

Who else will the study involve?

Your caregiver will also be invited to take part in the study, with your consent. If they take part in the study, they will meet with a researcher who will discuss the study with them and ask them some questions to find out whether they are suitable to participate in the study. If they are, then they will be asked to complete some questionnaires on two separate occasions in order for us to see whether your participation in Acceptance and Commitment Therapy impacts on their quality of life or level of caregiver burden. They will be able to complete these questionnaires over the phone, online or face-to-face with a member of the research team. Each of these assessments will take around 10 minutes to complete. Any travel expenses incurred by them during the course of the study will be reimbursed.

Your caregiver does not have to take part in the study if they do not want to. If they decide to take part they will be free to withdraw from the study at any time without having to give a reason as to why they want to withdraw. A decision to withdraw at any time or a decision not to take part will not affect the standard of care they receive or their future medical care or legal rights. In addition, a decision to not take part or to withdraw from the study will not affect your standard of care, future medical care or legal rights. If your caregiver decides not to take part or to withdraw from the study then this will not affect your participation in the study.

What are the possible disadvantages or risks of taking part?

The risk of taking part could be that you experience distress when discussing your current difficulties in assessments, interviews and therapy sessions, or your mood may worsen by the end of therapy. As is the case with all talking therapies, we cannot guarantee that Acceptance and Commitment Therapy will benefit everyone who receives it. However, we will monitor how you are feeling throughout the study. If your mood does get worse and you express an intention to harm yourself or another person, we will notify your MND Care Team and GP so that you can receive more support, if necessary. Similarly, if you continue to experience significant symptoms of anxiety or depression at the end of therapy then we will notify your MND Care Team and GP so that you can be referred for further support. If you decide to take part, it will require some of your time. You may feel fatigued or anxious when completing screening and outcome assessments, interviews or therapy sessions. You can take a break, ask to complete any or all of these activities at another time or decline to complete any or all of these activities at any time. If you do decide to take part, we will discuss your preferences for where these activities take place, such as face-to-face in an MND clinic, in your own home or via telephone. You will be asked not to take part in other types of talking therapy (e.g. cognitive behavioural therapy) whilst participating in this study.

What are the possible benefits of taking part?

You may benefit from taking part in this study because you will receive a new type of talking therapy that has been shown to benefit people with other conditions including life-limiting illnesses (such as cancer) and disabling long-term conditions, as well as mood disorders (such as depression and anxiety) and chronic pain. This is not yet widely available to people with motor neuron disease in the UK. Although we are hopeful that you would see the same benefits as other people, this may not be the case. You will receive reimbursement of travel expenses if you travel to the clinic for your appointments.

Will my taking part in this study be kept confidential?

Yes. All of the information we collect about you will be anonymised using a unique identification number so that it will not be possible to identify you from any of your information. Your data will be stored using this unique identification number and not your contact details (i.e. names or addresses) so that you cannot be identified from it. All data will be kept strictly confidential, and will only be seen by members of the research team.

All of the information about yourself (such as your contact details and your responses to screening questions, interview questions and paper questionnaires) will be stored in one of two ways so that we can verify the information at a later date, if necessary. All electronic data will be held on a secure database on a password-protected computer and on University College London's password-protected secure electronic network. All electronic data will be stored at University College London for 10 years, and will be destroyed after this. Personally identifiable data in paper format (e.g. consent forms, completed questionnaires) will be stored securely in locked cabinets at University College London for 10 years. Data will be securely destroyed after this.

If you take part in an interview after receiving Acceptance and Commitment Therapy, your interview will be recorded on an encrypted digital voice recorder, and then transferred and stored on University College London's password-protected secure electronic network. All data on encrypted digital voice recorders will be deleted after the data have been transferred. A transcription of your interview will be completed as soon as possible after we have met with you and anonymised.

Will my doctor be informed?

If you decide to take part in the study, with your permission, we will write to your GP and MND Care Team to inform them of this, and again at the end of your treatment to update them regarding the outcome. As outlined above, we will also contact your GP and MND Care Team during the study if we become concerned for your safety or another person's safety (e.g. if you express an intention to harm yourself or another person). This is so that you can be referred for more support.

What will happen if I don't want to carry on with the study?

If you don't want to carry on with the study, you will be free to withdraw from it at any time, without having to give a reason. Withdrawing from the study will not affect the standard of care you receive or your future medical care or legal rights. If you were to withdraw from the study then we would use any identifiable information collected in the study up to the point that you withdrew from the study.

What will happen once the study has ended?

Once the study has ended your clinical care will continue to be managed by your GP and MND Care Team. If you continue to experience significant symptoms of depression or anxiety (or other symptoms that need addressing) at the end of therapy then your GP and MND Care Team will be notified so that you can be referred for further treatment, if necessary.

What will happen to the results of the study?

At the end of the study, we will analyse all of your information with other participants' information. We will then publish our findings in an academic journal and at relevant conferences. We will also send you a summary of these if you request this. Your information will not be identified in any publication arising from this study.

Who is organising and funding the research?

This study is funded by the NIHR Health Technology Assessment (HTA) Programme (ref: 16/81/01). The research is being led by Dr Rebecca Gould who is a clinical psychologist and a Senior Research Associate at University College London. The research is sponsored by University College London.

Who has reviewed the study?

All NHS research is looked at by an independent group of people, called a Research Ethics Committee in order to protect participants' safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by London - Dulwich Research Ethics Committee (REC reference number: 18/LO/0227).

Who can I contact for further information?

You can contact Dr Rebecca Gould, who is the Chief Investigator in the study, if you have any questions or require any further information about this study. Her details are: Dr Rebecca Gould, Division of Psychiatry, University College London, Wing A, 6th floor Maple House, 149 Tottenham Court Rd, London W1T 7NF. Tel: 020 7679 9925. Email: r.gould@ucl.ac.uk.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or [University College London](#) complaints mechanisms are available to you. Please ask your doctor if you would like more information on this. You can make a formal complaint by following the standard NHS Complaints Procedure. You can find more details about this by contacting your local hospital Patient Advice and Liaison Service: [local contact details for each site to be added].

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's ([University College London](#)) or the hospital's negligence then you may be able to claim compensation. After discussing with your doctor, please make the claim in writing to [Dr Rebecca Gould](#), who is the Chief Investigator for the [research](#) and is based at [University College London](#). The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Thank you for considering taking part in this research study.

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