What is the purpose of the study?
Motor neurone disease (ALS) affects approximately 2 people in every 100,000 in the UK. One of the main symptoms of ALS is breathlessness. The muscles that people use to help them breathe (the main muscle being the diaphragm) become weak and so patients cannot breathe as well as they once could. This study will determine if adding a new treatment to the usual treatments for ALS breathing problems are of benefit to patients.

What are we studying?
One of the treatments that is available to patients is a face mask attached to a machine that helps them to breathe more effectively. This is called non-invasive ventilation or NIV. This is a common treatment for breathing problems in ALS. The mask fits over the nose or mouth or both. As you breathe in, the machine gives an extra push of air to support the breathing muscles enabling a bigger deeper breath.
Another possible treatment is Diaphragm Pacing (DP). DP is a new technique to help increase the strength of the diaphragm muscle contraction and consequently improve breathing.
The purpose of this study is to find out if having the DP Device fitted as well as receiving NIV offers added benefits, such as prolonging life and improving quality of life, to treatment just with NIV. We do not know if adding DP treatment to standard NIV will be beneficial and this is why we are asking for your help.

Why have I been chosen?
Your relative will have been advised that NIV is a potential treatment option for them to help with their breathing and we have invited them to take part in this study. We would now like to invite you, as their main carer, to participate in this study. You do not need to make a decision immediately as to whether or not you want to take part.

Your involvement will be limited to questionnaires and interviews. We are contacting people in a number of NHS hospitals to take part including Sheffield, Manchester, Oxford, Birmingham and Newcastle.

Do I have to take part?
No. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you and your relative to sign a consent form. You are free to withdraw at any time, without giving a reason. We will ask you if you are happy for us to use the information that you have already contributed. Withdrawal from the study will not affect your relative's ongoing care.

What will happen to me if I take part?
You will be asked to complete the following questionnaires:
1. The EQ5D – this is a 5 point questionnaire which will be collected at each of the follow up time points. The information will be based on your understanding of your relative's health.

2. The caregiver burden inventory – this is a questionnaire which gives a measure of impact that your care giving has on aspects of your life such as physical and emotional well being and your life in general.
Questionnaires will be administered at the first visit then at 2, 3, 6, 9 and 12 months visits into the trial.
You and your relative may be invited to participate in interviews. 12 patients and their carers will be chosen to take part in the interviews at 1 and 6 months after implantation. The purpose of the interviews is to explore in detail the effects that DP is having. If chosen, you will have the option to opt out of the interviews at the time.

What are the benefits?
Potential benefits associated with the trial have been explained to your relative. We do not anticipate any directs benefits for carers involved in the study.

Are there any risks or discomforts?
Potential risks and discomforts associated with the trial have been fully explained to your relative. We do not anticipate that participating in this study poses any physical risk for you. We appreciate that you may find it upsetting completing any questionnaires about your relative's experiences. If you become upset we will stop and let you decide what you want to do. If you wish to postpone the assessments, this can be arranged. If you feel you want to withdraw from the study altogether you can do so without your relative's care being affected in any way.

What happens if I don't want to continue with the study?
You are free to withdraw from the study at any time. If you withdraw we will ask whether we can keep the data we have already collected from you. Alternatively if it is your preference all data can be destroyed. This will not affect your relative's participation in the study or the treatment that your relative receives.

Will it cost me any money?
No. Any expenses incurred as a result of extra visits over and above usual clinic attendances for your relative will be reimbursed.

What happens if something goes wrong?
Any complaints should be addressed to your local doctor in the first instance (contact details are given at the end of this information sheet). If you have any concerns about the study you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure. Details can be obtained from [insert site specific details].

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised. Data collected for the study will be looked at by authorised persons from the University of Sheffield organising the research. They may also be looked

at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

What will happen to the results of the study?
We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You will not be personally identified in any report or publication we produce. Please contact us using the details below if you would like to see a summary of the results when the trial is completed.

Who is organising and funding the research?
The research is organised by the University of Sheffield and funded by the Department of Health and the Motor Neurone Disease Association.

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Cambridge Central Research Ethics Committee.

Further information can be obtained from:
<insert local PI name>
<insert local PI address>
<insert local PI telephone number>

Or contact the Chief Investigator:
Dr Christopher McDermott, Chief Investigator

Sheffield Institute for Translational Neuroscience
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