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EncoreAnywhere use in motor neurone disease

Submission date
10/02/2016

Recruitment status
No longer recruiting

Registration date
10/02/2016

Overall study status
Completed

Last Edited
12/02/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Motor neurone disease (MND) is an incurable condition which affects the nervous system. It is often called amyotrophic lateral sclerosis (ALS) in some countries. When a person is suffering from MND, the nerve cells in the brain and spinal cord which control the movement of muscles (motor neurons) are gradually lost (neurodegeneration). MND is ultimately fatal, as it affects the muscles involved with breathing. The diaphragm is a large dome-shaped muscle which separates the lungs from the digestive organs in the abdomen. It is one of the most important muscles involved in ventilation (breathing in and out), helping to inflate and deflate the lungs by moving down and up. When the diaphragm is weakened, a person is not able to breath out the waste gas carbon dioxide from their lungs (respiratory failure) and coughing becomes difficult. This eventually leads to death. Non-invasive ventilation therapy (NIV) is the standard treatment given to respiratory failure patients with MND. In this type of treatment, patients wear a mask over their nose and/or mouth which provides extra assistance with breathing at night, and for some people, in the day. Although it has been shown to help improve the symptoms caused by breathing problems and, in some cases, help people live longer, it can be challenging to use and some patients struggle to follow the required regime meaning they fail to receive the benefits. Timely support is important to help patients to overcome the early hurdles and barriers in order to become regular NIV users. The Philips EncoreAnywhere is a system that allows continuous monitoring of the use and effectiveness of ventilation, allowing the treating clinician to instantly adjust the ventilator settings from a distance (telemonitoring). The aim of this study is to find out whether “real time” feedback and support, as well as being able to remotely change NIV settings using the EncoreAnywhere system could increase the number of MND patients successfully using NIV.

Who can participate?
Adults with MND and respiratory failure who are starting to use NIV which is provided by the MND clinic in Sheffield MND care and research centre at the Royal Hallamshire Hospital.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in both groups are given instructions to use NIV, which involves wearing a face mask connected to a ventilator (breathing machine) every night and in the daytime if needed. All patients have access to telephone advice from the respiratory therapist as well as online instructions using www.niv.mymnd.org.uk. All patients will have the EncoreAnywhere system installed on their breathing machine which will

automatically collect information about their use of the machine. The staff caring for patients in the intervention group will be able to use the EncoreAnywhere system to see the data it collects every day. They will be able to see how it is used and can contact patients if they detect a problem with the machine or if the patient is not using it effectively. It also allows them to adjust the settings on the NIV device remotely. Those in the second group receive NIV but do not receive any additional monitoring than usual. After three months, participants in both groups are followed up to see how they are using NIV and what symptoms of breathing problems they are experiencing. Patients in the control group will have their data collected automatically by the EncoreAnywhere system but it will only be available to the staff looking after the patients after the study has finished.

What are the possible benefits and risks of participating?
Patients receiving extra monitoring may benefit from receive extra calls from the MND team, which may improve their use of NIV. There are no notable risks of taking part in the study.

Where is the study run from?
Motor Neurone Disorders Clinic, Royal Hallamshire Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to February 2017

Who is funding the study?
1. National Institute for Health Research (UK)
2. Philips Healthcare (UK)

Who is the main contact?
Dr Esther Hobson

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20428

Study information

Scientific Title
Monitoring and promoting adherence to non-invasive ventilation in motor neurone disease using EncoreAnywhere telemonitoring

Study objectives
The aim of this study is to:
1. Explore if “real time” feedback and support, as well as remote changes to NIV settings using the EncoreAnywhere system could increase the number of individuals successfully using NIV
2. Explore the impact of using EncoreAnywhere on the process of initiation of NIV, on both patients and staff

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 15/12/2014, ref: 194801

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Dementias and neurodegeneration; Subtopic: All Diagnoses, Motor neurone disease; Disease: Motor neurone disease

Interventions
Participants are randomly allocated to one of two groups using computerised 1:1 block randomisation.

Participants in both groups are given instructions to use NIV, which involves wearing a face mask connected to a ventilator (breathing machine) every night and in the daytime if needed. All patients have access to telephone advice from the respiratory therapist as well as online instructions using www.niv.mymnd.org.uk. All patients will have the EncoreAnywhere system installed on their breathing machine which will automatically collect information about their use of the machine.

Group 1: Patients will receive usual care plus monitoring using the EncoreAnywhere system for 3 months. The staff caring for patients in the intervention group will be able to use the EncoreAnywhere system to see the data it collects every day, and will be able to contact patients if they detect a problem with the machine or if the patient is not using it effectively immediately.
Group 2: Patients will have their data collected automatically by the EncoreAnywhere system but it will only be available to the staff looking after the patients after the study has finished.

Participants in both groups are followed up at three months.

Intervention Type
Other

Primary outcome measure
Adherence to NIV is measured using data collected from automatically from the EncoreAnywhere system at 3 months.

Secondary outcome measures
1. Adherence to NIV is measured using data collected from automatically from the EncoreAnywhere system at 1, 2, 4, 8 and 12 weeks
2. Efficacy of NIV:
2.1. Number of episodes of leak or obstruction collected from automatically from the EncoreAnywhere system at 1, 2, 4, 8 and 12 weeks
2.2. Patient satisfaction/perception of service delivery is measured using a patient questionnaire designed for the study at 3 months
2.3. NIV tolerance is measured using a patient questionnaire designed for the study at 1 and 3 months
2.4. Presence of symptoms are measured using a patient questionnaire designed for the study at 1 and 3 months
2.5. Quality of life using patient questionnaire RAND-36 at 3 months
2.6. Daytime arterial PaCO2 and PaO2 using information collected from clinical notes at 3 months
2.7. Home nocturnal PaCO2 and PaO2 average, mean and episodes of desaturation is measured using TOSCA at 1 and 3
3. Recruitment and retention rates:
3.1. Adherence to data collection points collected from study records at 3 months
3.2. Standard deviation of primary outcome measure (to predict sample size for future evaluation) at 3 months

Overall study start date
27/11/2015

Completion date
06/02/2017

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Patients with motor neurone disease diagnosed by a consultant neurologist
3. Patients receiving care from the Sheffield Teaching Hospitals NHS Trust MND clinic
4. Patients with respiratory failure diagnosed by the clinical team
5. Determined to be suitable for and willing to commence non-invasive ventilation including the EncoreAnywhere features as part of their usual care at the Royal Hallamshire Hospital MND clinic

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Patients already established on non-invasive ventilation e.g. in obstructive sleep apnoea
2. Those with no mobile internet reception in their homes (required to use EncoreAnywhere)
3. Patients unable to give informed consent

Date of first enrolment
22/01/2016

Date of final enrolment
27/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Hallamshire Hospital
Motor Neurone Disorders Clinic
Neurology Outpatients Clinic
Sheffield Teaching Hospitals NHS Trust

Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust

Sponsor details
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Philips Healthcare

Results and Publications

Publication and dissemination plan
The results of this study will be published on the Sheffield Institute for Translational Neurosciences website http://sitran.org and in academic journals.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request