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Telehealth in Motor Neurone Disease: a single-centre, randomised controlled feasibility and pilot study of the use of the TiM telehealth system to deliver highly specialised care in Motor Neurone Disease, at a distance

Submission date
05/09/2014

Recruitment status
No longer recruiting

Registration date
05/09/2014

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Care of patients with motor neurone disease (MND)/amyotrophic lateral sclerosis (ALS) is best provided by a specialist multidisciplinary team, but access to this care is not universal. Technology-enabled care has the potential to improve access to specialist care in MND. The aim of this study is to test a telehealth system (TiM: Telehealth in Motor neurone disease) which was developed to allow patients and carers to share information about their condition using the internet with a specialist MND nurse. The patients and carers use an app which asks a series of questions about their condition and wellbeing which are automatically sent to the MND nurse.

Who can participate?
Patients aged 18 or over MND and their primary informal carers

What does the study involve?
Patients and their carers are randomly allocated to receive either usual MND care or usual care plus the use of the TiM system for a minimum of 6 months and maximum of 18 months. The first aim is to test the study methods and determine whether a larger study of the TiM is possible. The second aim of the study is to better understand the processes occurring when the TiM is in use in clinical care, whether it is acceptable to patients, carers and healthcare professionals, what works, for whom and how it could be used in the wider NHS. The study collects clinical outcomes (such as quality of life) using postal questionnaires and interviews with participants and clinicians are conducted to assess the feasibility of the study and the TiM system.

What are the possible benefits and risks of participating?
The potential benefits of taking part include better access to specialist MND care. There are few foreseeable risks, and the TiM system has been designed in collaboration with patients to ensure it can be used by those with disabilities.

Where is the study run from?
Sheffield Institute for Translational Neuroscience (UK)

When is the study starting and how long is it expected to run for?
September 2014 to March 2016

Who is funding the study?
1. Motor Neurone Disease Association (MNDA) (UK)
2. National Institute for Health Research (UK)

Who is the main contact?
Dr Esther Hobson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02464748

Secondary identifying numbers
17022

Study information

Scientific Title

Telehealth in Motor Neurone Disease: a single-centre, randomised controlled feasibility and pilot study of the use of the TiM telehealth system to deliver highly specialised care in Motor Neurone Disease, at a distance

Acronym
Telehealth in Motor Neurone Disease

Study objectives
Motor neurone disease is a rare but debilitating neurological condition that causes paralysis of the bodys muscles leading to severe disability and eventually death. Patients often struggle to travel the long distances to specialist clinics to receive the care they require whilst this expert care is often unavailable in the community. Telehealth has the potential to enable a specialist team to monitor the health and wellbeing of patients and their carers whilst they are at home. This could improve the patient's health, improve the quality of life of both patients and their carers, and lead to more effective use of health resources. This is a pilot study. It aims to determine the feasibility and acceptability of the telehealth system to patients, carers and their health care providers. It also aims to determine how a larger trial could successfully evaluate the clinical and cost-effectiveness of the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 15/07/2014, REC ref: 14 /YH/1068

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

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

Interventions

This is a randomised controlled pilot study that will involve 40 patients who are cared for by the Sheffield Motor Neurone Disease care centre and their main informal carer. Half of the participants will use the telehealth system for a minimum of 6 months and maximum of 18 months and information will be collected from patients, carers and their care team. This will include collecting clinical outcome measures, health resource use and the opinions and experience of using the system. All participants will continue to receive their usual care.

The TiM telehealth system is a system through which patients and their carers can enter data about their condition on a weekly basis. Their answers are automatically analysed and are available to their MND team. The team are automatically alerted to a change in their condition. The system involves using an Android app on a tablet computer. This relays data via 3G mobile signal to the internet and stored on a server after analysis. The tablet computer also provides education and feedback. Follow Up Length: 18 month(s)

Intervention Type
Supplement

Primary outcome measure
Feasibility and acceptability; Timepoint(s): End of the trial

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2014

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Patients aged 18 years or over with ElEscorial clinically definite or clinically probable categories of MND who have attended the MND clinic at the Royal Hallamshire Hospital, Sheffield
2. Live within 120 minute drive from Sheffield

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
77

Key exclusion criteria
The main circumstances where patients or carers will be excluded are those in which individuals would be unable to use the telehealth system or give informed consent.
1. Patients attend another MND care centre in the UK.
2. Significant impairment in decision making capacity preventing informed consent by the subject due to a major mental disorder including frontotemporal dementia.
3. Patient unable to use the system due to physical, intellectual or language difficulties and unwilling to permit carer to operate it on their behalf
4. The patient has no eligible informal carer willing to participate in the trial
5. No available mobile or landline telephone or 3G mobile phone reception at the patients home (this is required to use the TiM system)
6. Any other major impairment that may affect their ability to participate in the study

Date of first enrolment
01/09/2014

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Institute for Translational Neuroscience
Sheffield
United Kingdom
S10 2HQ

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details
Research Department
11 Broomfield Road

Sheffield
England
United Kingdom
S10 2SE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Charity

Funder Name
Motor Neurone Disease Association (MNDA) (UK)

Alternative Name(s)
MND Association, MNDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
National Institute for Health Research (UK); Grant Codes: Research contract

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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Esther Hobson (e.hobson@sheffield.ac.uk). Data will be available after publication in 2018/2019 (depending on data). Access criteria: to those with an analysis protocol agreed by University of Sheffield and host institution. Analysis type: quantitative and secondary qualitative analysis. Type of data: anonymised patient and carer reported outcomes, TiM usage data, anonymised semi-structured interview transcripts. Ethical restrictions: interview transcripts will require anonymisation at source.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/10/2019	22/10/2020	Yes	No
HRA research summary			26/07/2023	No	No