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Care augmentation by location-linked messaging

Submission date
08/01/2015

Recruitment status
No longer recruiting

Registration date
12/01/2015

Overall study status
Completed

Last Edited
14/12/2022

Condition category
Nervous System Diseases

[X] 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 a rare condition that progressively damages parts of the nervous system, causing muscle weakness. People with MND may attend an A&E department if they become unexpectedly unwell. The most common reason for this is a chest infection, and the A&E staff may provide standard treatment, consisting of oxygen and antibiotics. This is not always the correct thing to do for someone with MND because oxygen can make breathing more difficult in some situations. The A&E staff will usually try to admit the person to a hospital ward, again because this is standard treatment, but for someone with MND it may be better to be treated at home or in the local hospice. If the specialist MND team, a neurologist or the patient's GP could be involved, treatment could be better tailored to the patient, with a safer and better outcome. In this study we are testing a smartphone app running on the Android system to alert medical staff from the MND specialist team, the local neurologist or palliative care specialist, or GP that someone with MND has arrived in the A&E department, so that they can contact the A&E team and provide advice if necessary. All studies of MND done so far rely on a snapshot of someone seen on a particular day in a hospital. They do not tell us much about what is happening outside the hospital, which is what really matters. We do not know how our measures of how much MND affects someone when we see them in clinic compare with how MND really affects them at home. In this study we also hope to gather this extra information in order to learn more about this.

Who can participate?
Patients aged 18 or over with MND

What does the study involve?
Participants are randomly allocated to one of two groups. One group receive standard care including regular three monthly visits to the King's Motor Nerve Clinic. The other group use a smart phone with the built in app. The app detects when participants are in an A&E department and sends an automated message to the study team. Participants also use the app to perform some tests to provide information on speech, mobility, strength and sleep in between clinic appointments.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2014 to December 2020

Who is funding the study?
Motor Neurone Disease Association (UK)

Who is the main contact?
Prof. Ammar Al-Chalabi

Contact information

Type(s)
Scientific

Contact name
Prof Ammar Al-Chalabi

Contact details
King's College London
Institute of Psychiatry
P043, 16 De Crespigny Park
London
United Kingdom
SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17557

Study information

Scientific Title
Assessment of Care Augmentation by Location-Linked MEssaging in amyotrophic lateral sclerosis with respiratory impairment compared with current standard care

Acronym
CALL-Me

Study objectives
To use a custom-designed location detecting smartphone app to send predefined text messages to pre-specified individuals on arrival of a patient with ALS in an A&E department to allow advice, education and intervention to be targeted, and avoidance of the morbidity and mortality associated with high dose oxygen, and monitor patient disability between clinic visits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/1544

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Amyotrophic lateral sclerosis

Interventions
A smartphone running the Android operating system will be loaded with a custom designed app specifically designed to send text messages to predefined members of the patient's care team when the phone is detected in an A&E department for more than 15 minutes. The app will be loaded and programmed by HW Communications Ltd (www.hwcomms.com, Lancaster, UK) with A&E departments specified in conjunction with the patient, and text messages specified in conjunction with the ALS team at King's, the patient's GP and the patient's local specialist ALS care team. The recipients of the text messages and a person-specific message will be derived by examination of an online calendar, allowing for different team members to be contacted at different times of day, or during absences. The text content will also include the patient name, the name of the A&E department they are in and an automated call facility, allowing contact by the text message recipient with the A&E department through a simple on-screen button.

Intervention Type
Other

Primary outcome measure
Number of inappropriate hospital admissions from A&E, in ALS patients, at 12 months

Secondary outcome measures
1. Reduction in morbidity or mortality associated with high dose oxygen use in ALS will be measured by determining the difference between arms of the number clinical incidents associated with high dose oxygen use
2. Tolerability of the smartphone app system in participants of the intervention arm will be compared at 3, 6, 9 and 12 months, for user and app generated data
3. Feasibility will be measured by the differences between user and App generated logs of A&E visits at 3, 6, 9 and 12 months and examination of the quality and usability of disease-progression data collected

Overall study start date
15/01/2014

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Diagnosis of ALS
2. Subjects of either sex aged 18 years or over
3. Stage 3 or 4 ALS
4. Capable of understanding the information given and giving fully informed consent prior to any study specific procedures
5. Willing for the study team to contact patient's GP about the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Total final enrolment
20

Key exclusion criteria
1. Patients at high risk of A&E admission for respiratory care unrelated to ALS because of underlying respiratory disease

2. Any patient involved in another study in which an intervention is designed to improve diaphragmatic function
3. Refusal of palliative care
4. Impaired cognition as judged by clinician

Date of first enrolment
01/06/2017

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Institute of Psychiatry
Department of Psychology
Henry Wellcome Building
Box PO77
16 De Crespigny Park
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England
United Kingdom
SE5 8AF

Sponsor type
University/education

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Motor Neurone Disease Association

Alternative Name(s)
MND Association, MNDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No