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ReaDySpeech: clinical testing

Submission date
04/02/2015

Recruitment status
No longer recruiting

Registration date
05/02/2015

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Dysarthria, or slurred speech, is caused by muscle weakness and is common after stroke. It leads to people feeling isolated, unconfident and uncomfortable in social situations. Speech therapy can offer support and reduce symptoms but is not always provided in the NHS. So we want to develop technologies, to enable more patients to access speech rehabilitation. This study will try the technology out with clinicians and patients to see what they think of it. If clinicians and patients think using technology is acceptable we will try it out with more people so we can fully test the technology.

Who can participate?
Clinicians that have agreed to be involved in both the preliminary testing phase of the study and the future feasibility study. Patients that have dysarthria as a result of stroke that had occurred at least 12 weeks ago.

What does the study involve?
This stage of the study involves clinicians testing out the computer based intervention with a small number of patients. The clinicians will continue their usual care but will also offer some patients the opportunity to try this new technology. Patients will be set up with a programme that they can access through any Wi-Fi enabled device such as a PC, laptop, mobile phone, tablet computer.
Patients will be asked to use it and to tell their clinician what they think of it. The clinician will be interviewed by the researcher following this clinical testing. The information from these questions along with the history of patient use will enable changes to be made to the next part of the study. It will help guide support and information needs for patients and therapists. It will also help the team to look at any improvements to ReaDySpeech.

What are the possible benefits and risks of participating?
There are no known benefits to take part as this intervention is still at an initial testing phase. There are no known risks to participating. It could be anticipated that patients will feel pressure to use the intervention and find this stressful. Patients will be reassured that they should only use the intervention as much or as little as they wish.

Where is the study run from?
The study is run from the University of Manchester and using four NHS sites; Central Manchester

University Hospital Foundation Trust, South Manchester University Hospital Trust, East Lancashire Hospital Trust, Salford Royal Hospital Trust.

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Claire Mitchell

Contact information

Type(s)
Scientific

Contact name
Mrs Claire Mitchell

ORCID ID
http://orcid.org/0000-0002-2445-8468

Contact details
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18337

Study information

Scientific Title
ReaDySpeech for people with dysarthria after stroke: initial clinical testing prior to feasibility study

Study objectives
This study is an initial clinical testing for the technology ReaDySpeech. ReaDySpeech has been developed to use with people with dysarthria following stroke and needs to be tested out in

clinical practice before the next part of the study which is a feasibility randomised controlled trial. The ethics application for this initial clinical testing will involve asking a minimum of four speech and language therapists to test out the ReaDySpeech technology with two selected patients who have dysarthria following stroke. This initial test phase will help the researchers to find out what training and support is needed to use the ReaDySpeech technology, what clinicians and patients think of it and if any technical amendments need to be made to it. This initial part of the project will enable this information to be taken forward into the next part of the study, the feasibility study for which separate ethics approval will be sought.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 20/11/2014, ref: 14/SC/1320

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Rehabilitation; Disease: Therapy type

Interventions
This is an initial clinical testing of ReaDySpeech, a computer based programme to deliver speech therapy exercises to patients. Patients will be set up with a programme in ReaDySpeech to test it out for a maximum of ten weeks or a minimum of one week.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
Structured and open questions following testing phase of the intervention. The questions intend to find out training needs for patients and clinicians as well as support needs for patients and clinician.

Secondary outcome measures
Adherence to the online programme. Measured by online history of interaction.

Overall study start date
01/02/2015

Completion date
31/07/2015

Eligibility

Key inclusion criteria
Inclusion criteria for clinicians: Clinicians will be recruited from 4 North West NHS sites that have already agreed to be involved in both the preliminary testing phase of the study and the future feasibility study. These clinicians will have a stroke caseload.

Inclusion criteria for patient participants:
1. Patients with dysarthria as a result of stroke as diagnosed by a speech and language therapist
2. Patients more than 12 weeks post stroke with no upper limit post stroke
3. Patients who are willing to trial the computer based programme ReaDySpeech.
4. Participants will present with dysarthria, willing and able to undertake communication therapy (in clinicians' opinion)
5. Sufficient ability in English to participate in therapy without a translator
6. Medically stable
7. Able to give informed consent to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
There is no clinician exclusion criteria.

Patient participant exclusion criteria:
1. Patients with cognitive or language difficulties that will prevent them giving informed consent or using a computer
2. Patients with insufficient grasp of English

Date of first enrolment
01/03/2015

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

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

Results and Publications

Publication and dissemination plan
Dissemination will be comprehensive and include academics, clinicians and service users. To ensure patient groups are reached appropriately the best approaches will be decided with the PPI partners involved in this study. This may include presenting at local stroke groups, local network PCPI groups, information in an accessible report format for those wanting written information for example.
To target relevant professional clinicians, presentations will be carried out at various speech and language therapy (National Royal College of Speech and Language Therapy conference) and stroke specific National (UK Stroke Forum). The findings from this initial testing phase will feed into the next stage of the research a clinical feasibility trial. It is intended that training needs, instruction information and any programme amendments will be provided as a result of this.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/12/2016	24/01/2019	Yes	No
HRA research summary			28/06/2023	No	No