ReaDySpeech for people with dysarthria after stroke

Recruitment status	[X] Prospectively registered		
No longer recruiting	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Circulatory System	[] Individual participant data		
	No longer recruiting Overall study status Completed Condition category		

Plain English summary of protocol

Background and study aims

Dysarthria, or slurred speech, is caused by muscle weakness and is common after a stroke. It happens when areas of the brain or nervous system that control the muscles used for speech are damaged. Dysarthria can lead to people feeling isolated, unconfident and uncomfortable in social situations. Speech therapy can offer support to people with dysarthria and help to reduce its symptoms, but this treatment is not always provided within the NHS. The aim of this study is to test a new technology called ReaDySpeech, a specially designed computer programme which aims to provide patients with greater access to personalised speech rehabilitation. ReaDySpeech technology will be trialled in this study with both clinicians and patients to see what they think of it. If clinicians and patients find the technology acceptable, a larger study will be designed from its results so that it can be tested with more people.

Who can participate?

Adults with dysarthria following a stroke.

What does the study involve?

All participants are given access to the ReaDySpeech computer programme. Users are asked to provide feedback on ReaDySpeech.

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

Where is the study run from? University of Manchester (UK)

When is the study starting and how long is it expected to run for? September 2015 to November 2016

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

Contact information

Type(s)

Scientific

Contact name

Mrs Claire Mitchell

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

18964

Study information

Scientific Title

ReaDySpeech for people with dysarthria after stroke: a feasibility study

Study objectives

This study will test the feasibility of a new speech rehabilitation technology, ReaDySpeech, developed for patients with dysarthria. This study will assess its acceptability with clinicians and patients, and the results will be used in the design of a larger study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ref: 15/NW/0371.

Study design

Randomised interventional treatment study

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

Stroke rehabilitation for dysarthria

Interventions

Participants will be given access to ReaDySpeech, a computer based programme designed to deliver speech therapy exercises to patients.

Intervention Type

Other

Primary outcome measure

Activity measure.

Secondary outcome measures

Not available at time of registration.

Overall study start date

01/09/2015

Completion date

01/11/2016

Eligibility

Key inclusion criteria

- 1. Participants will be selected by the clinician, within the inclusion criteria of more than 1 week post stroke
- 2. No upper limit to time post stroke
- 3. Participants will present with dysarthria, willing and able to undertake communication therapy (in clinicians' opinion)
- 4. Sufficient ability in English to participate in therapy without a translator
- 5. Medically stable
- 6. Able to give informed consent to participate

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

UK Sample Size: 36

Key exclusion criteria

- 1. Dysarthria for reason other than stroke
- 2. Not fluent in the English language (this may make using ReaDySpeech difficult)
- 3. Coexisting communication, cognitive, hearing or visual problems, significant enough to make using ReaDySpeech difficult
- 4. Coexisting progressive neurological condition

Date of first enrolment

01/09/2015

Date of final enrolment

01/11/2016

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

Wythenshawe Hospital Southmoor Road Manchester England United Kingdom M23 9LT

Sponsor type

Hospital/treatment centre

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

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	20/07/2017		Yes	No
Results article	results	01/08/2018	24/01/2019	Yes	No
HRA research summary			28/06/2023	No	No