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Assessing the effectiveness of Communication Therapy in the North West

Submission date	Recruitment status	[X] Prospectively registered
26/02/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/02/2015	Circulatory System	

Plain English summary of protocol
http://www.psych-sci.manchester.ac.uk/actnow/patients/

Study website
http://www.psych-sci.manchester.ac.uk/actnow/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00831740

Secondary identifying numbers
HTA 02/11/04

Study information

Scientific Title
Assessing the effectiveness of Communication Therapy in the North West: a pragmatic, multicentre randomised controlled trial

Acronym
ACT NoW

Study objectives
This is a two-phase study.
Phase 1 - What is the feasibility of conducting a randomised controlled trial of therapy for adults with post-stroke communication impairment?
Phase 2 - What are the effectiveness, costs and service user preferences, for the provision of speech and language therapy for communication difficulties experienced by people in hospital with a stroke?

Phase 1 - Qualitative (focus groups & individual interviews) and quantitative (pilot RCT).
Phase 2 - Qualitative (focus groups & individual interviews) and quantitative (a pragmatic, multicentred, randomised controlled trial, stratified by diagnosis and therapist/centre, using an 'intention to treat' approach). Discrete choice experiments will be used to determine cost effectiveness.

Details of the study can also be found at: http://www.hta.ac.uk/1390
Protocol can be found at: http://www.ncchta.org/protocols/200200110004.pdf
The ACT NoW Pilot Study is registered with ClinicalTrials.gov: http://clinicaltrials.gov/ct2/show/NCT00158106

On 17/01/2008 the overall trial start and end dates were changed from 01/06/2004 and 30/11/2007 to 01/10/2004 and 28/02/2010, respectively.

On 23/01/2009 the following changes were made to the trial record:
1. The overall trial end date was changed from 28/02/2010 to 28/10/2010.
2. The target number of participants has been changed from 600 to 170 (85 in each arm).

On 28/01/2009 the scientific title was added.

On 10/07/2009 the overall trial end date was changed from 28/10/2010 to 31/10/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire Research Ethics Committee
Phase 1: granted 14/09/2004 (ref: 04/MRE03/30)
Phase 2: granted 14/07/2006 (ref: 06/MRE03/42)

Study design
Pragmatic multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.psych-sci.manchester.ac.uk/actnow/patients/needtoknow/

Health condition(s) or problem(s) studied
Stroke

Interventions
Speech and language therapy versus an attention control.

Added 06/02/2009: Duration of intervention depends on each patient; the maximum duration is 16 weeks. The intervention period will be followed by an 8-week 'break'/ retention period.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 28/01/2009:
The following will be assessed 6 months after randomisation:
1. Functional communicative ability. Blinded expert therapists will rate semi-structured conversation using the Therapy Outcomes Measures (TOMS) scale.
2. Economic analysis will estimate the incremental cost effectiveness and net benefit of the intervention group compared to the control group from a societal perspective. Carers will self-complete the ACT NoW 'Support for Others Questionnaire' and research assistants will gather data for participant health economics evaluation through hospital records.
3. Qualitative study will examine service users' and carers' perspectives on the process and effects of Speech and Language Therapy or the control treatment. These will be assessed using qualitative interview schedules including rating scales developed specifically for this trial.

Previous primary outcome measures:
The primary outcome will be functional communicative ability. The economic analysis will estimate the incremental cost effectiveness and net benefit of the intervention group compared to the control group from a societal perspective. The qualitative study will examine service users' and carers' perspectives on the process and effects of Speech and Language Therapy or the control treatment.

Secondary outcome measures
Added 28/01/2009:
The following will be assessed 6 months after randomisation:
1. Quality of life, assessed by Euroqol EQ-5D
2. Patients and carers self-reported ratings of functional communicative ability as measured by the Communication Outcome After Stroke (COAST) scale

Overall study start date
01/10/2004

Completion date
31/10/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/01/2009:
Adults diagnosed with aphasia and/or dysarthria following admission to hospital with a stroke.

Previous inclusion criteria:
Adults diagnosed with aphasia or dysarthria following admission to hospital with a stroke.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
170 (85 in each arm)

Key exclusion criteria
Current exclusion criteria as of 23/01/2009:
1. Subarachnoid haemorrhage
2. Progressive dementia/ learning difficulties
3. Not able to receive therapy in the English language
4. Expected recovery without therapy

Previous exclusion criteria:
Subarachnoid haemorrhage, progressive dementia, expected recovery without therapy.

Date of first enrolment
01/10/2004

Date of final enrolment
01/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Human Communication & Deafness (HCD) Group
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
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Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan

Results will be publicly available from December 2010 - the Chief Investigator, Audrey Bowen will be giving an invited presentation on the results at the UK Stroke Forum in Glasgow (30th November - 2nd Dec).
The results will be published in the NIHR HTA monograph and a short report on the results will be available from the study website. Please check the study website for updates.

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?
Results article	results of assessment of the reliability of procedure for rating a conversation sample			Yes	No
Results article	results on validation of Communication Outcome after Stroke (COAST) scale	01/12/2008		Yes	No
Other publications	evaluation	01/05/2012		Yes	No
Results article	results	13/07/2012		Yes	No