ISRCTN51553998 https://doi.org/10.1186/ISRCTN51553998

Observation with Intent to Imitate (OTI) combined with Motor Practice (MP) to enhance upper limb recovery early after stroke

Submission date
08/01/2009

Recruitment status
No longer recruiting

Registration date
30/01/2009

Overall study status
Completed

Last Edited
20/12/2012

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Observation with Intent to Imitate (OTI) combined with Motor Practice (MP) to enhance upper limb recovery early after stroke: proof-of-concept trial

Study objectives

Is there sufficient evidence of benefit from Observation to Imitate combined with Motor Practice (OTI+MP) to justify larger scale clinical trials in stroke survivors with substantial weakness early (3-31 days) after stroke?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Cambridgeshire 3 Research Ethics Committee, approved on 20/11/2008 (ref: 08/H0306/71)
2. Research Governance Approval by East Norfolk and Waveney Research Governance Committee and Research Management Team granted on 03/12/2008 (ref: 2008MFE05L [136-09-08])

Primary study design
Interventional

Study design
Phase I randomised controlled observer-blind single-centre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Upper limb paralysis after stroke

Interventions
The participants will be randomly allocated to the control and intervention groups in 1:1 ratio.

The control intervention will be routine conventional therapy as provided in the clinical centre. All conventional interventions given, to people in control and experimental groups, will be recorded on a standardised form.

The experimental group will receive Observation with Intent to Imitate with Motor Practice (OTI+MP) therapy in addition to routine conventional therapy as received by the control group. OTI+MP therapy sessions will be daily for 15 working days (15 sessions).

OTI+MP requires the participant to sit alongside the research therapist who will demonstrate the activity to be practiced in the same plane as when the participant will produce the movement. Participants will watch the activity produced by the therapist with the intention of imitating this. They will observe the therapist for 2 minutes. Then for 6 minutes they will perform the activity whilst the therapist adapts her own performance of the activity to emphasise the bits that the participant has the most difficulty with.

In every treatment session there will be 6 blocks of treatment separated by 2-4 minutes of resting. Two activities will be chosen per session. The activities will be individually chosen for each participant so that practice is of activities that participants can do partially or complete with difficulty. Activities will become harder as improvement occurs over time. Activities will be chosen form a standardised list which includes, reaching to pick up a cup, unscrewing a top off a coffee jar and placing coins in a purse.

Intervention Type

Other

Phase
Phase I

Primary outcome(s)
The following will be assessed at baseline and one/two days after the 15th intervention session:
1. Ability to produce voluntary contraction of paretic muscle, as measured by the Motricity Index arm section. The rationale for this measure is that OTI therapy is primarily directed at improving the ability to voluntarily contract paretic muscle after stroke. The Motricity Index is a clinical measure of the ability to voluntarily contract paretic muscle. It is an ordinal score with six levels of measurement within each of three categories for the upper limb (pinch grip, elbow flexion and shoulder abduction), has been used widely in clinical research, is valid, reliable and sensitive to change after stroke.
2. Ability to produce force in paretic muscle, as measured by torque about the elbow joint during isometric flexion concentric contraction using a digital myometer and maximum pinch and grip force during isometric concentric contraction using a digital pinch/grip analyser (MIE Medical Research Ltd, UK).
3. Ability to use the paretic upper limb in functional activity as measured by the Action Research Arm Test (ARAT). This is a test of upper limb function with subsections covering grasp, grip, pinch and gross movement. It has good validity and reliability and is widely used in clinical research.
4. Adverse event monitoring and recording. There is a small risk that for some people the therapy might lead to an 'overuse' syndrome which presents as pain in the arm and/or hand. We will monitor this by checking for participant report of upper limb pain, either verbal or behavioural (e.g., grimacing, postural guarding), and for decrease in Motricity Index upper limb score of at least two measurement levels.

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Adults (both males and females, 18 years +) between 3 and 31 days after stroke with an intact pre-motor area (location of mirror neurons) as confirmed by routine clinical imaging
2. A substantially paretic upper limb as measured by a grip force of between 15% and 65% of that of the non-paretic upper limb

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Unable to imitate action with their non-paretic limb (i.e. severe visual, communication or cognitive deficits precluding participation in OTI+MP). This will be assessed by the research therapist sitting along side the potential participant. The research therapist will perform 5 actions and the potential participant will be asked to observe and then perform the actions. This assessment will be videoed and saved onto a computer. The accuracy of observed activity will be assessed by 2 independent assessors from the video film using a three point scale used by Decety and colleagues: 2 = correctly reproduced action; 1 = incorrectly reproduced action; 0 = action not produced. Those scoring 8/10 or above will be considered to have the ability to imitate.

Date of first enrolment
12/01/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Queens Building
Norwich
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Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
University/education

Funder Name
University of East Anglia (UK)

Alternative Name(s)
UEA University of East Anglia, UEA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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	01/02/2013		Yes	No