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Constraint Induced Movement Therapy (CIMT) for acquired brain injury: a clinical feasibility RCT.

Submission date
19/01/2015

Recruitment status
No longer recruiting

Registration date
02/02/2015

Overall study status
Completed

Last Edited
19/02/2020

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary

Background and study aims
Having an acquired brain injury (stroke or traumatic) often results in difficulty with completing everyday tasks due to people having a decreased ability to use their arm effectively. This may often lead to a decreased quality of life and decreased independence in everyday activities. The aim of this study is to investigate how easy/difficult a therapy called Constraint Induced Movement Therapy (CIMT) is to deliver to patients and also to indicate if any improvements in their upper limb use occurs after using this therapy. It is hoped that this information will provide a better understanding of the therapy and show what further research is needed to be completed on the therapy.

Who can participate?
Both male and female patients, currently attending the Regional Acquired Brain Injury Unit (RABIU) in Musgrave Park Hospital are eligible to attend, providing they meet baseline arm movement requirements and upper limb treatment is a main therapy goal for the patient.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (experimental) are given CIMT for one and a half hours a day, 5 days per week for 3 weeks. Those in group 2 (control) are given standard (Bobath based) therapy over the same time period. Arm function, psychological effects (for example, improvements in depression or anxiety) and adherence to the treatment are assessed for all participants before their treatment starts, on the last day of treatment and then 12 weeks later.

What are the possible benefits and risks of participating?
There are both potential benefits and risks of taking part in the study including improvement in the amount and quality of movement in the patients' arm. One potential risk is an increase in the amount of pain due to overuse of the arm; this will however be closely monitored by the therapy team and the therapy will be stopped or adapted if this occurs.

Where is the study run from?
Regional Acquired Brain Injury Unit -Belfast Health and Social Care Trust (UK)

When is the study starting and how long is it expected to run for?
September 2008 to September 2011

Who is funding the study?
Department of Employment and Learning, Northern Ireland (UK)

Who is the main contact?
Dr Katie Pedlow

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V2.09.07.09

Study information

Scientific Title
Constraint Induced Movement Therapy (CIMT) for acquired brain injury: a clinical feasibility RCT investigating CIMT versus a Bobath based upper limb intervention.

Study hypothesis
Despite its robust evidence, gaps remain within CIMT research. The majority of studies have been completed in controlled laboratory settings in the United States of America and clinical

settings in Asian countries such as China, Thailand and Taiwan; both of which are not directly comparable to the United Kingdom (UK) National Health Service (NHS). Although similarities could be drawn between the clinical settings of the UK and Asia, many differences exist such as the higher level of private healthcare in Asia (WHO 2009). To our knowledge there has only been one registered CIMT trial within the UK which is currently exploring web based CIMT (LifeCIT: NCT01350453); none have been completed in the UK clinical setting. In addition there have been no trials reporting the use of a multi disciplinary therapy team (both physiotherapists and occupational therapists) to deliver CIMT as well as very few trials investigating CIMT with the traumatic brain injury (TBI) population; the majority of research to date has focused on the stroke population. The aim of this current study was to address these research gaps and apply CIMT in the UK NHS clinical setting with both the stroke and traumatic brain injury population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern Ireland Office for Research Ethics Committees, 11/11/2009, ref: 09/NIR01/53

Study design
Feasibility single-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
Not available in web format, please use the contact details to request a patient information sheet

Condition
Acquired brain injury, specifically traumatic brain injury and stroke.

Interventions
1. Constraint induced movement therapy for the upper limb (experimental)
2. Conventional interdisciplinary upper extremity programme (control)

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Motor activity log
2. Graded wolf motor function test

The time points are baseline, immediately post intervention and three months post intervention completion

Secondary outcome measures
1. EuroQOL
2. Stroke self efficacy questionnaire
3. Hospital anxiety and depression scale

The timepoints are baseline, immediately post intervention and three months post intervention completion

Overall study start date
28/09/2008

Overall study end date
01/09/2011

Eligibility

Participant inclusion criteria
1. Participants with upper limb treatment as a main therapy requirement
2. Male and female (aged ≥ 18 years old)
3. Six months to five years post first episode of ABI (stroke or TBI)
4. Movement criteria: Have a minimum of the following criteria and be able to complete three times:
4.1. 100 wrist extension
4.2. 100 extension/abduction of the thumb
4.3. Extension of 2 fingers > 00
4.4 450 shoulder flexion and abduction
4.5. 200 elbow extension from 900 flexed position
5. Follow two part spoken or written commands
6. Perform their baseline level of mobility with the mitt on their less effected upper extremity including walking/transfer/wheelchair use (independently/with supervision/with assistance)

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Participant exclusion criteria

1. Progressive neurological condition
2. Gross cognitive impairment or disorientation.

Recruitment start date
18/12/2009

Recruitment end date
18/04/2011

Locations

Countries of recruitment
United Kingdom

Study participating centre
Regional Acquired Brain Injury Unit - Belfast Health and Social Care Trust
United Kingdom
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Sponsor information

Organisation
University of Ulster

Sponsor details
Centre for Health and Rehabilitation Technologies
Newtownabbey
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United Kingdom
BT37 OQB

Sponsor type
University/education

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
Department of Employment and Learning, Northern Ireland (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

2013 results in thesis: https://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.593635 (added 19/02/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request