

Mental techniques and stretching in spasticity - A randomised controlled trial

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/07/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0176189947

Study information

Scientific Title

Study objectives

1. Stiffness of limbs, with marked weakness is common in people with neurological disease. This can cause pain, discomfort, and significant difficulty in carrying out personal activities such as dressing (or having them done by a carer). Treatment using therapy and drugs is not very effective. The first treatment used is to stretch the affected muscle or joint. We wish to discover whether this can be made more effective, easier and less uncomfortable by asking the person to practice the movement in their mind (imagination) even though they cannot do it. We will compare 'mental practice' with simply relaxing.
2. If the technique does work with a therapist, to discover whether the person can continue to use it effectively with carers after the treatment phase. Also: to gain an estimate as to the size of any benefit so that a full trial can be undertaken if necessary and appropriate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Nervous System Diseases: Spasticity

Interventions

1. One group will be taught to relax using relaxation techniques such as breathing
2. The other group will be taught to practice mentally stretching the affected muscles

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. The primary patient outcome measure will be the change in the numerical scale rating of pain /discomfort experienced during the passive stretch of the selected limb/muscle group, this rating being 0-11, this change being calculated from the baseline to the assessment at 9 weeks.
2. The primary external outcome measure will be the change in the numerical scale rating of the difficulty of undertaking the stretch of the selected limb/muscle group, this rating being 0-11, this change being calculated from the baseline to the assessment at 9 weeks.

Secondary outcome measures

Change from baseline to 9 and 12 weeks in:

1. Modified Ashworth Scale measure of spasticity applied to the selected joint
2. Degrees of stretch achieved measured using a goniometer
3. Time taken to achieve 30 degrees of change in joint angle measured in seconds

Overall study start date

01/08/2006

Completion date

01/08/2007

Eligibility**Key inclusion criteria**

Participants will be recruited from consultant neurologists if they have a neurological condition, are aged 18 years and over and have a stiff muscle group that needs regular stretching to prevent deterioration and /or to reduce existing problems (such as difficulty in being dressed).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

No specific exclusion criteria.

Date of first enrolment

01/08/2006

Date of final enrolment

01/08/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Oxford Centre for Enablement

Oxford

United Kingdom

OX3 7LD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Oxford Radcliffe Hospitals NHS Trust (UK)

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?
Results article	pilot study results	01/02/2009		Yes	No