

Home Orthostatic Training in Chronic Fatigue Syndrome

Submission date 30/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/06/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/01/2013	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Julia Newton

Contact details
Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HOT-CFS

Study information

Scientific Title

Home Orthostatic Training in Chronic Fatigue Syndrome: a randomised controlled feasibility study

Acronym

HOT CFS

Study objectives

Home orthostatic training is safe and feasible in chronic fatigue syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sunderland Local Research Ethics Committee (LREC) approved on the 5th July 2005 (ref: 05/Q0904/37)

Study design

Randomised controlled feasibility study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Chronic fatigue syndrome

Interventions

Patients will receive routine clinical care including withdrawal of potential culprit medications, and conservative and abortive advice as is our usual practice. Following full written consent they will be enrolled in the study. Patients will be asked to return to the Tilt Room for investigation on four separate occasions over a six month period. Baseline Investigation of autonomic function and haemodynamics will be performed at visit 1 and the technique of home orthostatic training (HOT therapy) or sham will be taught. They will be encouraged to be accompanied by a relative or friend, but this will not be mandatory. There will then be three re-evaluation visits where, autonomic function and haemodynamic measures will be repeated. These will occur at

one week, four weeks and six months from the onset of training. Throughout the study period patients will receive a weekly telephone call from one of the investigators to assess progress and to provide encouragement.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Study compliance. Timepoints: 1 week, 4 weeks, 6 months.
2. Autonomic function. Timepoints: baseline, 1 week, 4 weeks, 6 months.

Secondary outcome measures

Fatigue. Timepoints: baseline, 1 week, 4 weeks, 6 months.

Overall study start date

01/01/2008

Completion date

01/01/2010

Eligibility**Key inclusion criteria**

1. Chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME) patients
2. Both males and females, aged 18 years and over
3. Patients who fulfil the Fukuda diagnostic criteria
4. Patients with an autonomic phenotype, i.e., have a composite autonomic symptom scale of greater than 32.5

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Inability to give informed consent
2. Patients on drugs which can affect the autonomic nervous system which cannot be

discontinued safely

3. Inability to stand for up to 40 minutes due to muscular or neurological disorders, cardiac transplantation, or pregnancy

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle upon Tyne

United Kingdom

NE7 7DN

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

England

United Kingdom

NE7 7DN

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Government

Funder Name

CFS/ME Northern Clinical Network, NHS Networks (UK)

Funder Name

Nuffield Foundation (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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?
Results article	results	01/01/2010		Yes	No