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Home Orthostatic Training in Chronic Fatigue Syndrome

Submission date	Recruitment status	[ ] Prospectively registered
30/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/06/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2013	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Fatigue. Timepoints: baseline, 1 week, 4 weeks, 6 months.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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)

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)
NuffieldFound

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes