Sleep intervention in patients with fibromyalgia

Submission date	Recruitment status	Prospectively registered
28/09/2007	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Stopped	Results
Last Edited	Condition category	Individual participant data
31/08/2012	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Alice Theadom

Contact details

The Hillingdon Hospital NHS Trust Pield Health Road Uxbridge United Kingdom UB8 3NN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0388179219

Study information

Scientific Title

Study objectives

To explore whether a sleep intervention tailored to people's individual needs can improve sleep quality and quality of life in patients with fibromyalgia.

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)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Fibromyalgia

Interventions

Current practice vs current practice and psychological intervention.

2 groups: a treatment group and an intervention group.

31/08/2012: Please note that this trial was abandoned before starting due to a lack of funding.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

To improve sleep quality and quality of life of patients with fibromyalgia syndrome.

Secondary outcome measures

Increased understanding of the association between sleep, pain and fatigue

Overall study start date

01/07/2006

Completion date

01/01/2009

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

Patients with fibromyalgia.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

- 1. Sleep disorder
- 2. Change in medical treatment in the last 3 months
- 3. No experience of sleep difficulties

Date of first enrolment

01/07/2006

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre The Hillingdon Hospital NHS Trust

Uxbridge United Kingdom UB8 3NN

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 +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

Hillingdon Hospital 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