# Sleep intervention in patients with fibromyalgia

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> Stopped	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
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

Protocol serial number 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

#### Study type(s)

Quality of life

### 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(s)

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

## Key secondary outcome(s))

Increased understanding of the association between sleep, pain and fatigue

## 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** 

## Healthy volunteers allowed

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

## 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

**United Kingdom** 

England

# 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

# Funder(s)

## Funder type

Government

## Funder Name

Hillingdon Hospital NHS Trust (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration