

# Sleep intervention in patients with fibromyalgia

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## 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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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**

No

**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