

# Pilot study of Homeopathic Treatment of Fibromyalgia Syndrome

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/07/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N0034178702

# Study information

## Scientific Title

## Study objectives

Does the addition of a homeopathy referral to usual care improve short term outcomes for patients with a diagnosis of Primary Fibromyalgia?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Prospective pragmatic parallel group single blind randomised controlled pilot study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Fibromyalgia

## Interventions

Homeopathy referral + usual care vs usual care.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Homeopathy

## Primary outcome measure

Difference between the Fibromyalgia Impact Questionnaire (FIQ) total score (0-80 with 0 indicating no impact), at week 22, between the experimental and control groups.

## **Secondary outcome measures**

1. Short form McGill Pain Questionnaire
2. Measure Your Medical Outcomes Profile (MYMOP)
3. FIQ Pain score
4. FIQ fatigue score
5. FIQ tiredness on awakening score
6. FIQ stiffness score
7. EQ-5D Quality of life score
8. Hospital anxiety and depression scale (HAD)
9. Tender point count (Performed by blinded assessor)
10. Medication Change Questionnaire

## **Overall study start date**

01/01/2006

## **Completion date**

07/07/2007

# **Eligibility**

## **Key inclusion criteria**

1. Primary Fibromyalgia diagnoses (According to American College of Rheumatologists criteria for FMS)
2. Aged 18 years old and over
3. Score of 4 or more on FIQ pain scale (score 0-10 with 10 indicating very severe pain) at initial recruitment/assessment interview

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Not Specified

## **Target number of participants**

30 test participants, 30 controls

## **Key exclusion criteria**

1. Pain from traumatic injury or structural disease
2. Secondary Fibromyalgia
3. Rheumatoid Arthritis
4. Inflammatory Arthritis
5. Autoimmune Disease
6. Immunosuppressant Drugs
7. Current oral steroid treatment

8. Substance abuse in last year
9. Primary psychiatric diagnosis or medication prior to onset of Fibromyalgia
10. Unstable medical or psychiatric illness
11. Chronic use of sedatives
12. Pregnant or breast feeding
13. Current acupuncture treatment
14. Homeopathic treatment in the previous three months
15. Patients not fluent in English

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

07/07/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Dept of Rheumatology**

Barnsley

United Kingdom

S75 2EP

## **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

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**Sponsor type**

Government

**Website**

## Funder(s)

### Funder type

Government

### Funder Name

Barnsley Hospital NHS Foundation Trust

### Funder Name

BDGH Small Projects Fund

## 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?
<a href="#">Results article</a>	results	01/04/2009		Yes	No