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Pilot study of Homeopathic Treatment of Fibromyalgia Syndrome

Submission date 28/09/2007	**Recruitment status** No longer recruiting
Registration date 28/09/2007	**Overall study status** Completed
Last Edited 07/07/2009	**Condition category** Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
United Kingdom
SW1A 2NL
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Sponsor type
Government

Website

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

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?
Results article	results	01/04/2009		Yes	No