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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
Barnsley Hospital NHS Foundation Trust

Funder Name
BDGH Small Projects Fund

Results and Publications

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				

Results article	01/04/2009	Yes	No