

Pilot study of Homeopathic Treatment of Fibromyalgia Syndrome

Submission date 28/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 28/09/2007	Overall study status Completed	☐ Protocol
Last Edited 07/07/2009	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ 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

Primary study design

Interventional

Study design

Prospective pragmatic parallel group single blind randomised controlled pilot study

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