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ORIGINAL PAPER

Healthcare provided by a homeopath as an adjunct to usual care for Fibromyalgia (FMS): results of a pilot Randomised Controlled Trial

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Objectives: **To assess the feasibility of a Randomised Controlled Trial (RCT) design of usual care compared with usual care plus adjunctive care by a homeopath for patients with Fibromyalgia syndrome (FMS).**
Methods: **In a pragmatic parallel group RCT design, adults with a diagnosis of FMS (ACR criteria) were randomly allocated to usual care or usual care plus adjunctive care by a homeopath. Adjunctive care consisted of five in depth interviews and individualised homeopathic medicines. The primary outcome measure was the difference in Fibromyalgia Impact Questionnaire (FIQ) total score at 22 weeks.**
Results: **47 patients were recruited. Drop out rate in the usual care group was higher than the homeopath care group (8/24 *vs* 3/23). Adjusted for baseline, there was a significantly greater mean reduction in the FIQ total score (function) in the homeopath care group than the usual care group (−7.62 *vs* 3.63). There were significantly greater reductions in the homeopath care group in the McGill pain score, FIQ fatigue and tiredness upon waking scores. We found a small effect on pain score (0.21, 95% CI −1.42 to 1.84); but a large effect on function (0.81, 95% CI −8.17 to 9.79). There were no reported adverse events.**
Conclusions: **Given the acceptability of the treatment and the clinically relevant effect on function, there is a need for a definitive study to assess the clinical and cost effectiveness of adjunctive healthcare by a homeopath for patients with FMS.** *Homeopathy* (2009) **98**, 77–82.

Keywords: Fibromyalgia syndrome; Homeopathy; Randomised Controlled Trials

Introduction

Fibromyalgia syndrome (FMS) is a chronic musculoskeletal pain disorder of unknown aetiology characterised by widespread pain and muscle tenderness, often accompanied by fatigue, sleep disturbance and depressed mood.[1] FMS accounts for 15% of outpatient rheumatology visits and 5% of general medicine visits.[2] The prognosis for symptomatic recovery is poor and adequate symptom control is the treatment goal.[3] A wide range of interventions is used in the management of FMS (antidepressants, analgesics, exercise, cognitive behavioural therapy, education, dietary interventions[3]) but there is no clear evidence based treatment of choice; the recent European League Against Rheumatism (EULAR) guidelines[4] are based more on expert opinion than evidence from Randomised Controlled Trials (RCTs).

Patients suffering from FMS have high rates of Complementary and Alternative Medicine (CAM) use,[5,6] and report use of a wide range of CAM therapies for symptom relief and support. Research using homeopathic medicines has shown promising results in the treatment of FMS.[7,8]

Prior to this study there have been two RCTs[7,8] of the efficacy of homeopathic medicines in the treatment of FMS. A randomised double blind cross over study[7] of patients meeting the criteria for a single homeopathic remedy, *Rhus toxicodendron* 6c, reported greater improvements in

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the number of painful tender points and sleep after one month on active homeopathic remedy compared to placebo. More recently, a double blind randomised parallel group placebo controlled trial[8] of homeopathy was conducted in the USA. The homeopathy intervention involved a series of three consultations with a homeopath plus an individually tailored homeopathic remedy or an indistinguishable placebo. This study demonstrated that six months of verum individualised homeopathic remedy was significantly better than placebo in lessening tender point pain and improving the quality of life and global health of FMS sufferers.[8]

Both RCTs[7,8] compared homeopathic medicine to placebo medicine providing information as to the efficacy of homeopathic medicine. But informed clinical decision making about homeopathic treatment for FMS patients needs evidence of the comparative clinical effectiveness of healthcare by a homeopath as well as the efficacy of homeopathic medicines alone.[9] Healthcare by a homeopath is best understood as a complex intervention[10] consisting of a series of in depth interviews with a focus on the patient's subjective experience, plus individually tailored homeopathic medicines.

We report the conduct and results of a RCT comparing the clinical effectiveness of adjunctive healthcare by a homeopath for patients diagnosed with primary FMS.

Aims

This study was designed to:

(A) Assess the feasibility of the design, including referral, randomisation, outcome measures, follow up at 22 weeks.
(B) Obtain data on recruitment rates, drop out rates and changes in outcome measure scores to facilitate a power calculation for a full study.

Methods

Design

This study tested the feasibility of an open pragmatic parallel group RCT design. The objective of the RCT was to assess the clinical effectiveness of usual care, compared to usual care plus adjunctive care by a homeopath, for NHS patients with a diagnosis of primary FMS who were under the care of consultant rheumatologists.

Participants

Patients were referred to the study by consultant rheumatologists at Barnsley Hospital NHS Foundation Trust (BHNFT). Patients who gave informed consent were enrolled to the study by the research nurse.

Inclusion criteria

Adults who had received a diagnosis of primary FMS according to the American College of Rheumatology (ACR) criteria.[11]

Exclusion criteria

Pain from traumatic injury or structural disease, rheumatoid arthritis, inflammatory arthritis, autoimmune diseases, immunosuppressant treatment, oral steroid treatment, acupuncture treatment, homeopathic treatment, substance abuse, primary psychiatric diagnosis or illness, chronic sedative use, pregnancy or lactation.

Based on the literature[12–15] we calculated that a sample size of 20 participants in each group would be sufficient to detect a difference in the Fibromyalgia Impact Questionnaire (FIQ) total scores between the two groups with a significance level of 5% and 80% power. Allowing for a drop out rate of 20% a sample size of 48 (24 in each group) was needed.

Randomisation

The randomisation protocol was created by an independent statistician (Young, University of Sheffield) using an SPSS random number generator and block randomisation. Patients who met the inclusion criteria were given a consecutively numbered opaque sealed envelope containing their group assignment.

Intervention

The usual care group received one or more of the following: physiotherapy, aerobic exercise, analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), anti depressants. The homeopath care group received usual care plus an initial one hour in depth interview followed by up to four 30 min in depth interviews (4–6 weeks apart) with individually tailored homeopathic medicines prescribed at each interview.

Consultations with the two study homeopaths (CW & JR) were conducted in the rheumatology department at Barnsley Hospital (BHNFT). Both study homeopaths jointly agreed on every remedy selection, similar to a previous RCT.[8]

Masking

As this was an open pragmatic study, there was no requirement, (nor was it feasible) for either the patients or the clinicians to be masked to treatment allocation. Assessment of the non-patient reported outcome Tender Point Count (TPC) was conducted by an independent assessor (research nurse) who was masked to group allocation.

Outcome measures

The primary outcome measure was the difference between the groups at 22 weeks in the Fibromyalgia Impact Questionnaire (FIQ) total score. Reviews have identified the FIQ as the main outcome measure for RCTs of FMS.[4,16,17] It is a brief, validated 10-item instrument that measures physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and wellbeing.[18] The FIQ score is a composite score for functional status, pain, sleep, fatigue, stiffness, anxiety and depression.

The secondary outcome measures in this trial were the differences between the homeopath care group and the usual care group at 22 weeks as measured by the FIQ subscores: pain, fatigue, tiredness on awakening score, stiffness scores; the McGill Pain Questionnaire,[19] Measure Your Medical Outcomes Profile (MYMOP) – a patient generated outcome measure where patients choose the two symptoms