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Newsletter Issue 5 Aug 2009

A Randomised Controlled Trial of healthcare by a homeopath for patients with Fibromyalgia Syndrome

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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 and accounts for 15% of outpatient rheumatology visits and 5% of GP visits.

The prognosis for recovery is poor; adequate symptom control is the treatment goal. A wide range of interventions is used in the management of FMS (antidepressants, analgesics, exercise, cognitive behavioural therapy, education, dietary interventions) but there is no clear evidence based treatment of choice.

RCTs of homeopathic medicines

Randomised controlled trials (RCTs) of the efficacy of homeopathic *medicines* have shown promising results in the treatment of FMS. A randomised double blind cross over study (Fisher et al., 1989) of patients meeting the criteria for Rhus Toxicodendron 6c, reported greater improvements in the number of painful tender points and sleep after one month on homeopathic remedy compared to placebo.

More recently, a double blind randomised parallel group placebo controlled trial (Bell et al., 2004) of homeopathy was conducted in the United States, which tested the effectiveness of a series of three consultations with a homeopath plus an individually tailored homeopathic remedy or 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.

Both of these RCTs compared homeopathic medicine to placebo medicine, providing information as to the efficacy of homeopathic medicine. However, informed clinical decision making about homeopathic treatment for FMS patients needs evidence of the comparative clinical effectiveness of healthcare by a homeopath (Relton et al., 2008).

An RCT of healthcare by a homeopath

An RCT[1] recently published in the peer reviewed online journal 'Homeopathy' has compared the clinical effectiveness of adjunctive healthcare by a homeopath for patients diagnosed with primary FMS. The abstract of the article reporting the results of this is freely available online at www.ncbi.nlm.nih.gov/pubmed/19358959 .The information below provides more detail of the results than the online abstract. The study tested the feasibility of the 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. Patients were referred to the study by consultant Rheumatologists at Barnsley Hospital NHS Foundation Trust (BHNFT). Patients had received a diagnosis of Primary FMS according to the American College of Rheumatology (ACR) criteria (Wolfe et al., 1990).

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

1. Funded by Barnsley Hospital NHS Foundation Trust & the charity Homeopathy Action Trust. Clare Relton was supported by the DH-National Co-ordinating Centre for Research Capacity Development.

group received usual care plus an initial one hour in depth interview, followed by up to four 30 minute in depth interviews (four to six weeks apart) with individually tailored homeopathic medicines prescribed at each interview.

Consultations with the two study homeopaths were conducted in the Rheumatology department at BHNFT.

The primary outcome measure was the difference between the groups at twenty two weeks in the Fibromyalgia Impact Questionnaire (FIQ) total score - a brief, validated 10-item instrument that measures physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and wellbeing.

Secondary outcome measures in this trial were the differences between the homeopath care group and the usual care group at twenty two weeks as measured by the FIQ sub-scores: pain, fatigue, tiredness on awakening score, stiffness scores; the McGill Pain Questionnaire, Measure Your Medical Outcomes Profile (MYMOP) - a patient generated outcome measure, EQ–5D Quality of Life score Hospital Anxiety and Depression scale, and Tender Point Count.

Results

Forty-seven patients were recruited and subsequently randomised. The mean baseline FIQ total scores for both groups in this RCT were significantly higher than the range of FIQ total scores reported in other RCTs of FMS treatments.

Final twenty two week outcomes were completed by a total of 36 out of 47 (76.6%) patients. 8 out of 24 patients in the usual care group did not complete twenty two week outcomes and 3 out of 23 patients in the homeopath care group completed neither the treatment nor the study outcomes. There were no reports of any serious adverse events.

Following adjustment for baseline, there was a statistically significant greater reduction in the primary outcome measure (FIQ Total Score) in the homeopath care group compared to the usual care group. There were significantly greater reductions in the homeopath care group in the FIQ Fatigue score and the FIQ Tiredness upon Waking score, as well as Pain as measured by the McGill VAS, compared to the usual care group.

Discussion

This study did not explore the question 'Do the homeopathic medicines work better than placebo?' or 'Is the effect due to the time and attention spent with the patient?'. Instead, this study tested the feasibility of a method of assessing the clinical effectiveness of adjunctive healthcare by a homeopath in addition to usual care, compared to usual care only. The usual care group did not report improvements but did report a deterioration in the McGill Pain score despite continuing with the treatment prescribed by their rheumatologist.

Future studies

Building on the positive results of the pilot RCT, thirty FMS patients are currently participating in a study at Barnsley NHS Hospital to assess the optimum duration of treatment by a homeopath, and a protocol is being developed by Dr Clare Relton (Head of Clinical Research at HRI) at the University of Leeds for a multi-centre RCT of treatment by a homeopath for this condition.

References

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