Title: Self-applied soft tissue therapy for fibromyalgia syndrome: A randomised controlled feasibility study.

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Purpose: Previous evidence has indicated that deactivating peripheral areas of musculoskeletal sensitivity (myofascial trigger points (TrPs)) may reduce nociceptive input, central sensitisation and associated pain and symptoms in fibromyalgia syndrome (FMS). This study aimed to evaluate the acceptability of self-applied soft tissue therapy (SSTT) when used as an adjunct to a six-week FMS self-management programme (FSMP) and the feasibility of conducting a future trial in this area.

Methods: Participants who were attending the Royal National Hospital for Rheumatic Diseases' six-week FSMP, who were formally diagnosed with FMS, and had either lower leg/foot or forearm/hand pain and active TrPs were included. Participants were randomised to control (attending the FSMP) or intervention (attending the FSMP plus SSTT). Outcome measures included pain (Pressure Pain Threshold (PPT) and verbal Numerical Rating Scale (NRS)); range of movement (ROM) (ankle or wrist ROM Kapanji Thumb opposition score) and function (Lower Extremity Functional Scale (LEFS) or the Disabilities of the Arm, Shoulder and Hand (DASH) score). All participants answered two qualitative questions on acceptability of the procedure and intervention. The intervention group participants attended two additional sessions, where they received TrP therapy and were taught a SSTT home programme and issued with an advice booklet. Follow up assessments were conducted at 6 weeks and 3 months by an independent researcher blinded to group allocation.

Results: Sixteen people with FMS were initially screened - five did not meet the inclusion/exclusion criteria and one was excluded from data analysis as they missed the follow up assessments. 10 participants were included in analysis (9 women; mean age 45 years). By chance, seven were randomly allocated to the intervention group. To facilitate comparison between groups and across outcomes, all data was

converted to % change from baseline. Effect size estimates (and 95% confidence intervals) were calculated. The majority of outcomes favoured the intervention, with a 'large' effect size (>0.8) for PPT at 3 months. 'Medium' effect sizes (>0.5) were observed for trigger point prevalence at 6 weeks, and ROM and disability at 3 months. As expected with such a small study, effect size estimates were associated with large confidence intervals, all of which crossed zero. All participants answered positively regarding the acceptability of the study procedure and intervention protocol. All participants in the intervention group attended each session with no attrition and no adverse reactions reported.

Conclusion: Overall the results support the possibility of a favourable outcome in the intervention group. Limitations include the small sample size, variability of baseline measures and unequal group sizes.

Implications: The procedure and SSTT intervention appeared acceptable, although a more extensive pilot study and further RCT is recommended to ascertain the effectiveness of SST in the physiotherapy management of FMS.

Three key words: Fibromyalgia syndrome; self-soft tissue therapy; self-management.

Funding: Research time granted via formal application, Faculty of Health & Applied Sciences, University of the West of England, Bristol.

Ethics:

Granted by Fulham Research Ethics Committee, 6th May 2016

REC reference:16/LO/0598

IRAS project ID:196976