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A prospective double blind placebo-controlled randomized trial of ultrasound in the physiotherapy treatment of shoulder pain

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Objective. To compare the effectiveness of manual therapy and ultrasound (US) with manual therapy and placebo ultrasound (placebo US) in the treatment of new episodes of unilateral shoulder pain referred for physiotherapy.
Methods. In a multicentre, double blind, placebo-controlled randomized trial, participants were recruited with a clinical diagnosis of unilateral shoulder pain from nine primary care physiotherapy departments in Birmingham, UK. Recruitment took place from January 1999 to September 2001. Participants were 18 yrs old and above. Participants all received advice and home exercises and were randomized to additionally receive manual therapy plus US or manual therapy plus placebo US. The primary outcome measure was the Shoulder Disability Questionnaire (SDQ-UK). Outcomes were assessed at baseline, 2 weeks, 6 weeks and 6 months. Analysis was by intention to treat.
Results. A total of 221 participants (mean age 56 yrs) were recruited. 113 participants were randomized to US and 108 to placebo US. There was 76% follow up at 6 weeks and 71% at 6 months. The mean (95% CI) reduction in SDQ scores at 6 weeks was 17 points (13–26) for US and 13 points (9–17) for placebo US ($P = 0.06$). There were no statistically significant differences at the 5% level in mean changes between groups at any of the time points.
Conclusions. The addition of US was not superior to placebo US when used as part of a package of physiotherapy in the short-term management of shoulder pain. This has important implications for physiotherapy practice.

Key words: Ultrasound, Shoulder pain, Physiotherapy, Double blind, Randomized trial.

Shoulder pain is a common complaint in the general population and a debilitating one. The prevalence of shoulder pain in the UK has been estimated to be between 7% and 34% [1–4]. Most people presenting to their general practitioner (GP) with shoulder pain will be managed conservatively with treatments such as non-steroidal anti-inflammatory drugs, corticosteroid injections and physiotherapy [3]. Physiotherapists use a wide range of treatment modalities in the treatment of shoulder pain including mobilization, manipulation, acupuncture, electrotherapy and exercise [5, 6].

A systematic review of randomized clinical trials for soft tissue disorders concluded that therapeutic ultrasound (US) was not an effective treatment in the physiotherapy management of shoulder pain [5]. However, this review also highlighted the poor methodological quality of most of the physiotherapy trials evaluated. Partly due to this, the findings of the systematic review carried little weight within the UK physiotherapy community. Letters concerning the review's failure to demonstrate US as an effective treatment were published indicating a consensus of clinical opinion that lack of evidence does not confirm evidence of lack of treatment effect [7]. An audit of local practice in the West Midlands Region, carried out in 1998 evaluated how community physiotherapists treated shoulder pain and found US to be the most widely used electrotherapy modality [6]. The Development and Evaluation Committee Report UK 1998 on the therapeutic use of US concluded that, in spite of its widespread use, there was limited clinical research to support its effectiveness [8].

This article reports on a double blind, placebo-controlled randomized trial undertaken to establish whether there was a place for therapeutic US in the management of shoulder pain. The objective of the trial was to determine whether there was any clinical benefit of adding US compared with placebo US to a package of physiotherapy treatment in new episodes of unilateral shoulder pain referred from primary care.

Methods

Study participants

This was a multicentre, double blind, pragmatical randomized controlled trial in nine primary care physiotherapy treatment facilities in Birmingham, UK. Ethical approval was granted by the local research ethics committees of North, East and West Birmingham. Written informed consent was obtained from all participants prior to randomization.

Eligible participants were ≥18 yrs of age, with a clinical diagnosis of unilateral shoulder pain defined as pain in the shoulder region (including the upper arm) which was exacerbated by active or passive shoulder movement. Participants had all been referred to physiotherapy by their GP with a new episode of shoulder pain. Exclusion criteria were: a history of inflammatory arthritis or polymyalgia rheumatica; gross structural or neurological abnormality affecting the shoulder; clinical indications of ruptured rotator cuff; suspicion of serious pathology or referred pain; prior fracture or surgery to the shoulder, upper limb, neck or thorax; previous physiotherapy for this episode of shoulder pain; pregnancy or breastfeeding; anticoagulation therapy; and participants for whom US was contraindicated. Participants were also excluded if they had been referred for pain in the affected shoulder in the previous 12 months or were involved in industrial action or litigation for their shoulder pain.

Recruitment

Physiotherapists in each participating department notified the study co-ordinator of any new shoulder referrals from a GP. Participants were assessed for eligibility for the trial by the study co-ordinator. An assessment appointment with the study co-ordinator was made where written consent was obtained, baseline demographic information was collected and participants were allocated a unique study number.

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The study co-ordinator undertook the baseline assessment prior to registering the participant into the trial. Participants were then randomized using a computer generated randomization sequence generated by the Birmingham Clinical Trials Unit (BCTU). Each participant was then given a sealed envelope by the study co-ordinator. The envelope was opened by the treating physiotherapist and the allocated intervention, as identified within the envelope as either treatment 1 or 2, was undertaken by setting the US machine to setting 1 or 2. The study co-ordinator was blind as to whether patients received treatment 1 or 2. The treating physiotherapists and participants were all blinded regarding whether the machine setting administered active or placebo US. The success of such strict blinding was evaluated in a convenience sample of 35 participants.

Randomization

The random allocation sequence was generated by computer at the BCTU, University of Birmingham, in random-sized blocks. Stratification was by age (<60 yrs old, ≥60 yrs old), gender and capsular pattern (present or not) as these factors, alone or in combination, were deemed by the physiotherapists to possibly influence the effect of the treatment interventions. Individual envelopes for each group of strata were prepared and sealed by the BCTU.

Interventions

All participants were randomized to receive either:

(i) US with advice, exercise and manual therapy.
(ii) Placebo US with advice, exercise and manual therapy.

The study interventions were delivered by 28 musculoskeletal physiotherapists who, prior to the start of the trial, attended a study training day to agree the content of the intervention protocol and standardize treatment approaches.

All participants were assessed and managed within the study protocol as the treating physiotherapist deemed appropriate. Participants had a maximum of eight 20-min sessions. All trial US machines were fitted with electronic chips to maintain blinding that enabled them to deliver either active or placebo US when the machine was in trial mode, or routine US when the machine was not being used for the trial. Treatment included manual therapy and exercises but treating-physiotherapists were asked not to administer acupuncture or other electrotherapy modalities. All participants were given an advice sheet about shoulder pain and a home exercise programme. The number of treatment sessions and dose of US administered were recorded for each participant by the treating physiotherapist.

Outcomes

Outcome assessments, previously used in a study of local steroid injections administered by GPs and practice base physiotherapy for unilateral shoulder pain [4], were performed by the study co-ordinator who was unaware of the treatment allocation. The primary outcome measure was disability at 6 weeks measured using the Shoulder Disability Questionnaire (SDQ-UK) (Appendix 1) [4, 9–11]. This instrument was first published by Croft *et al*. [9] and was then modified for use in clinical trials [4, 10, 11]. It is commonly used in the evaluation of shoulder disability in clinical trials, has proven levels of validity, and consists of 23 symptoms that participants respond to with either 'yes', 'no', or 'not applicable' [4, 9–11]. The SDQ has demonstrated strong associations with quality of life measures and compares favourably with other published shoulder disability questionnaires in terms of overall validity and patient acceptability [10]. The questionnaire score is the number of positive responses divided by the number of answered questions multiplied by 100. This results in a score ranging from 0 to 100.

Secondary outcome measures included participant's global assessment of change in level of shoulder problem from baseline measured on a 5-point rating scale of 'complete recovery' to 'much worse'; participant's perception of the severity of the average pain experience during the previous 24 h during the day and then during the night [two 10 cm visual analogue scales (VAS)]; participant's perception of how affected they have been by this shoulder problem (10 cm VAS); global health related Quality of Life measures (the utility measure the 'EuroQol EQ-5D' and the 'EuroQol health thermometer' measuring health state from 0 to 100) [12]; range of movement (active and passive abduction and rotation of the shoulder; active flexion/extension and rotation of the neck); number and type of co-interventions. All measures were recorded at baseline, 2 weeks later, 6 weeks and 6 months later. In order to assess how representative the sample was to the local population Townsend scores, a measure of deprivation [13] were also calculated for all participants.

Objectives

The purpose of the study was to determine whether manual therapy with the addition of US provides better clinical outcome at 6 weeks than manual therapy with the addition of placebo US in the physiotherapy treatment of new episodes of unilateral shoulder pain referred from primary care.

Sample size

The sample size calculation was based on the primary outcome measure of the baseline to 6 week change in the SDQ score based on the minimum clinically significant differences. To detect between group differences in disability change scores of nine scale points with 80% power and a 5% significance level (two-tailed), a minimum of 200 participants were needed in the study. A total of 220 participants were required to allow for 10% loss to follow-up at 6 weeks.

Statistical methods

Collection of data and statistical analyses were performed blind to treatment allocation. All patients were included in all analyses on an intention-to-treat basis. Statistical significance was based on a 5% level. The trial was monitored by an independent Data Monitoring and Ethics Committee who considered the progress of the trial, recruitment, adherence to the eligibility criteria, trial form completion and return rates, adherence to the protocol and descriptive data with group membership concealed. No interim analyses were undertaken during the study period.

Differences between treatments in terms of timing of follow-up visits and the baseline to 6 week change in the SDQ score, VAS pain, the EuroQol EQ-5D, the EuroQol health thermometer and objective measurements, were assessed by use of Wilcoxon rank sum tests. Drop out rates over time and patient completed improvement scales were compared across treatments using chi-squared tests with continuity corrections.

Additionally, for comparison with other studies [4], patients were categorized into whether their SDQ scores had halved since baseline or not and chi-squared tests with continuity corrections tested for differences between treatments.

It was hypothesized that gender, age and also whether there was a capsular pattern or not to the shoulder complaint would affect US effectiveness. Multiple regression was thus used to assess the influence these factors had, in addition to treatment, on outcome.

Results

Recruitment and follow-up

From 9 centres 28 physiotherapists recruited 221 participants into the trial between January 1999 and September 2001;

113 participants were randomized to US and 108 to placebo US. Eight physiotherapists recruited two thirds of the participants leading to two centres randomizing 70% of all trial participants. The majority of treating-physiotherapists were senior experienced musculoskeletal therapists. The drop-out rate was similar for patients in both treatment arms, with 76% of all patients with follow-up at 6 weeks and 71% at 6 months. Figure 1 illustrates the progress of participants through the trial.

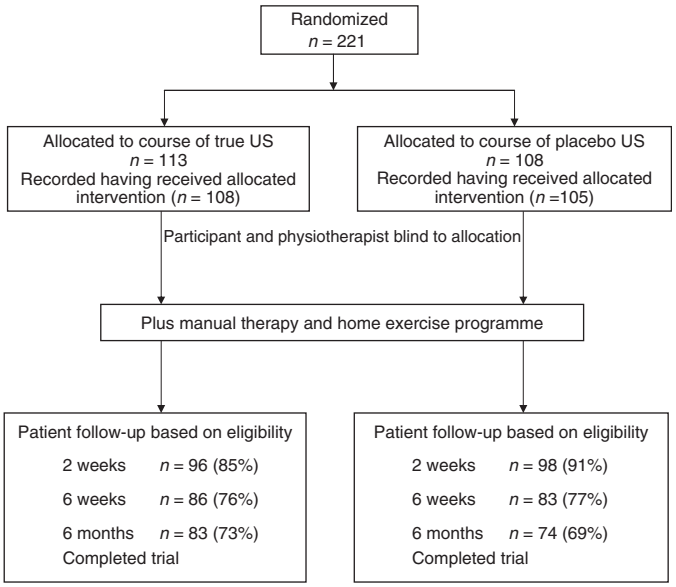

FIG. 1. Trial profile.

Baseline characteristics

The mean age of participants was 55 yrs and 51% were female. Townsend scores of participants (mean = 0.3 (S.D. = 3.7)) were slightly higher (more affluent) than the West Midlands population at large [14] (mean = 1.2 (S.D. = 3.6)), with the previously mentioned two main recruiting centres covering differing areas: mean = −1.8 in one centre compared with mean = 2.1 in the other. All baseline characteristics of the randomized participants were balanced between the two treatment arms (Table 1).

Interventions

Completed treatment visit records were available for 213 (96%) participants; 108 (96%) true US and 105 (97%) placebo US participants (Table 2). The median treatment length was 38 days for US and 35 days for placebo US ($P = 0.14$). In total, 1141 treatment visits were made and the average number of treatment sessions per participant in each arm of the study was 6 (range: 1–8, $P = 0.28$). US was administered in 1004 (88%) of the treatment visits. US dose information was available for 869 of these visits (76%) by 180 participants representative of the total sample. The average US dose (SD; range) was 0.5 W/cm^2 (0.2; 0.2–1.0). The average duration of ultrasound was 4.5 min (range 3–7 min). In over 95% of treatments ultrasound was given in pulsed mode at a mark:space ratio of 1 : 4. Physiotherapists selected from frequencies of 1 or 3 MHz where 1 MHz was given to 46% of participants and 3 MHz given to 39% of participants. Frequency data were missing in 15% of cases.

Primary outcome

At each of the three follow-up time points the median SDQ score showed both groups improving from baseline. The median (interquartile range [IQR], 95% CI) fall in SDQ score at 6 weeks was 17 points (IQR 4–35, 95% CI 13–26) for US and 13 points (IQR 0–26, 95% CI 9–17) for placebo US. No statistically significant

TABLE 1. Baseline characteristics of individuals randomized according to treatment group

	True US ($n = 113$)	Placebo US ($n = 108$)	Total ($n = 221$)
Demography			
Mean age in yrs (range)	55 (23, 82)	55 (20, 88)	55 (20, 88)
<60 yrs	68 (60%)	67 (62%)	135 (61%)
≥60 yrs	45 (40%)	41 (38%)	86 (39%)
Females	57 (50%)	56 (52%)	113 (51%)
Ethnic origin			
White	101 (90%)	102 (94%)	203 (92%)
Non-white	6 (5%)	3 (3%)	9 (4%)
Not given	6 (5%)	3 (3%)	9 (4%)
Townsend Score[a]			
Median (range)[b]	−0.65 (−6.7, 6.3)	0.35 (−6.7, 6.9)	−0.40 (−6.7, 6.9)
Clinical measures			
Capsular pattern positive	32 (28%)	31 (29%)	63 (29%)
Median SDQ score (range)	48 (0, 91)	42 (0, 87)	43 (0, 91)
Median pain severity during day (range)	4.8 (0, 10)	4.9 (0, 10)	4.8 (0, 10)
Median pain severity during night (range)	5.0 (0, 10)	4.5 (0, 10)	4.9 (0, 10)
Median score of how affected by shoulder problem (range)	3.4 (0, 10)	3.7 (0, 10)	3.5 (0, 10)
Median duration of shoulder problem months (range)	3 (0.25, 72)	5 (0.25, 180)	4 (0.25, 180)
Median EuroQol score (range)	66 (−24,100)	69 (−24,80)	69 (−24, 100)
Median EuroQol Thermometer score (range)	7.5 (0, 10)	7.0 (0, 10)	7.4 (0, 10)

[a]Categories 5–7 according to the National Statistics Socio-economic Classification (NS-SEC) based on the Standard Occupational Classification [11]; Low negative Townsend score = affluent, high positive Townsend score = poor.
[b]Data from 210 patients; 106 true US, 104 placebo US.

TABLE 2. Summary of US interventions by treatment group from case notes audited

	True US	Placebo US	Total
Number of patients who received their allocated treatment	108 (96%)	105 (97%)	213 (96%)
Mean (S.D.) of Power settings (W/cm^2)	0.5 (0.2)	0.5 (0.2)	0.5 (0.2)
Mean (S.D.) of duration of ultrasound treatment (min)	4.7 (0.7)	4.3 (0.7)	4.5 (0.7)

TABLE 3. Participants' change from baseline in SDQ scores at 2 weeks, 6 weeks (primary outcome) and 6 months follow-up by treatment group

		True US	Placebo US	*P* value
SDQ scores				
2 weeks	*n*=	96	98	
	Median (IQR) change score	4 (−3, 17)	4 (−4,13)	0.43
	Participants halving their baseline score	17%	17%	0.99
6 weeks	*n*=	86	83	
	Median (IQR) change score	17 (4, 35)	13 (0, 26)	0.07
	Participants halving their baseline score	49%	37%	0.18
6 months	*n*=	83	74	
	Median (IQR) change score	26 (13, 43)	28 (13, 39)	0.59
	Participants halving their baseline score	67%	68%	0.99

IQR, interquartile range.

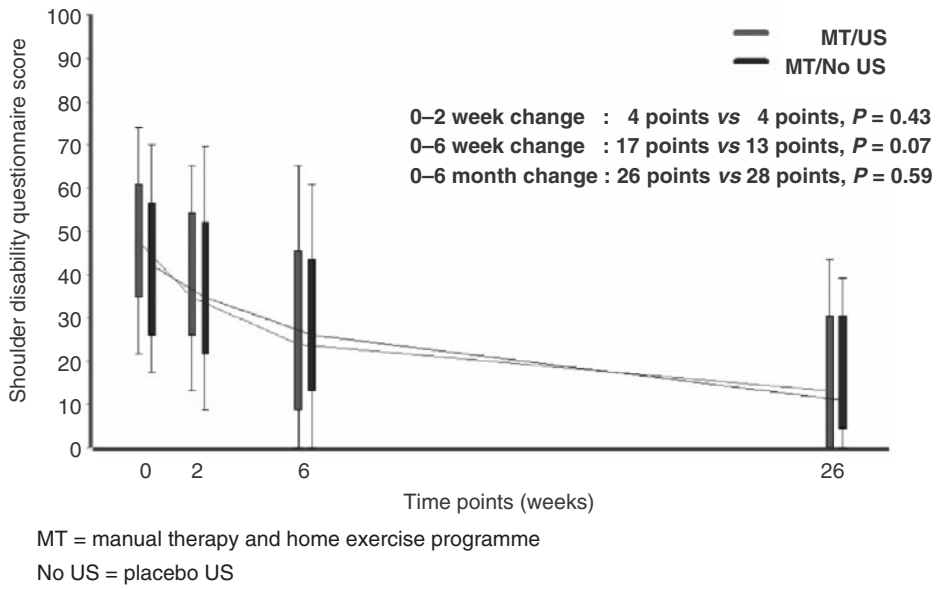

FIG. 2. Median, IQRs and 80% CI of SDQ scores.

differences in changes from baseline (crude or adjusted) were detected between groups at any of the three time points (Table 3, Fig. 2).

The percentage of participants halving their baseline SDQ scores was similar across treatment groups for all three analysed time points, with a non-significant trend towards more US participants halving their baseline scores at 6 weeks compared with placebo US (49% *vs* 37%, $P = 0.18$).

Secondary outcomes

Table 4 shows participants' changes in secondary outcome measurements at 6 weeks. Baseline to 6 week changes in the VAS scores measuring pain during the night showed a trend towards greater reduction in pain in the US group compared with the placebo US group ($P = 0.19$). However, there were no statistically significant differences between the mean changes, in this measure or any other of the secondary outcome measures.

Co-interventions

Self reported co-interventions collected at the follow-up time points showed the number of participants receiving additional treatments was low, with injections being the most commonly reported co-intervention (11% of participants) and non-steroidal anti-inflammatory drugs the second most commonly used (8% of participants). Over the trial period there were no statistically significant differences in frequencies of additional treatments administered between the treatment arms.

Blinding

In a sub sample of 35 participants, opinion as to which treatment the participant had received showed 54% of correct guesses; 53% of US participants and 55% of placebo US participants ($P = 0.88$).

Discussion

We report the results of a multicentre, double blinded, placebo-controlled randomized trial in physiotherapy departments in the UK, investigating the effectiveness of US and manual therapy with placebo US and manual therapy in the treatment of shoulder pain. The study demonstrates no additional benefit from the addition of US over placebo US to a package of physiotherapy treatment in the management of unilateral shoulder complaints.

The results of this trial confirm conclusions of previous systematic reviews which were based on other physiotherapy studies with limited methodology [5]. The results of a recent randomized controlled trial with 40 participants confirmed the findings of the systematic review and this study [15].

Strengths of this trial are the relatively large sample size, the good completion of questionnaires at each of the time points and a low non-response to questions in the SDQ. A weakness

TABLE 4. Change in secondary outcome measures at 6 weeks follow-up, by treatment group

Clinical outcomes	True US ($n=86$)	Placebo US ($n=83$)	P value
Median reduction in pain severity during day (IQR)	2.1 (0, 3.6)	1.7 (−0.1, 3.7)	0.61
Median reduction in pain severity during night (IQR)	2.2 (0, 5.4)	1.2 (0, 4)	0.19
Median reduction in score of how affected by shoulder problem (IQR)	1.6 (0.2, 3.7)	1.5 (0.1, 3.1)	0.76
Median improvement in EuroQol score (IQR)	4 (−5, 31)	4 (0, 22)	0.85
Median improvement in EuroQol Thermometer score (IQR)	0.5 (−3.1, 2)	0.8 (−0.6, 2)	0.75

IQR, Interquartile range.

of this study is the drop-out observed during follow-up period, which may lead to bias and thus reduces the generalizability of the findings. Drop-out tended to be greater among the younger patients and those who did not have a capsular pattern for their shoulder complaint.

The external validity of the study would have been enhanced by a third trial arm, one of manual therapy and exercise but with no US. We acknowledge the powerful effect a placebo treatment has on treatment outcomes and this warrants further study.

The physiotherapy intervention was pragmatic rather than prescriptive, to ensure that findings could be transferred into a variety of clinical settings. There was a clear albeit non-statistically significant effect for US compared with placebo US in most outcomes in the short term. External validity would have been enhanced if defined US dosages could have been selected based on efficacy studies. The paucity of such studies at the time made this difficult. The pragmatic design of this clinical effectiveness trial does not allow for clear-cut conclusions on dosage and reduces external validity.

Whilst the pragmatic approach could be considered a weakness, in stratifying the patients into capsular and non-capsular patterns this followed an approach commonly adopted in practice. A specific diagnosis often involves costly, intrusive and untimely tests and the findings may not reflect accurately the cause of a patient's pain [16]. Whilst we recognize that there is a wide variation in both the skill of clinicians and their chosen management, additional to the US, attempts were made to ensure that any interventions used were based on sound clinical reasoning. This was undertaken by inclusion of all treating physiotherapists in a training day prior to the study launch covering the trial protocol, a refresher course on shoulder treatment techniques and the clinical application of therapeutic US. The physiotherapy training session included the concept of attenuation with depth, and consideration of effective dose at the depth of target structure taking account of overlying tissues (e.g. thin person/bulky muscular person etc). As this was a pragmatical study it was left to the practitioner to make the correct judgement about depth of structure needing treatment. In 39% of the participants 3 MHz was used. It is recognized that 3 MHz has a reduced penetration effect and is unlikely to have a therapeutic effect on pain or mobility in shoulder lesions. Frequency was not recorded in 15% of the participants, which may reflect the relative importance physiotherapists place on the frequency. This has important implications for practice. In the absence of a clear theoretical framework for the use of specific doses of US on target populations, a pragmatical approach reflecting usual physiotherapy practice was adopted. Trial physiotherapists tailored their US treatments according to the individual patient, but within the constraints of a pre-defined protocol used in a previous study [4], and in line with current UK practice.

Our trial is further enhanced by its broad eligibility criteria. Precise clinical diagnosis and classification of shoulder problems is hampered by two main limitations. Firstly, there has been little agreement as to the use and reliability of such diagnostic and classification systems and secondly, a more useful approach of managing patients in primary care (a red flag approach) has been adopted for patients referred from general practice [4, 16]. This approach, focusing on inclusion rather than exclusion, has been shown to be successful elsewhere [4]. Our study was therefore not powered to perform subgroup analysis.

US is widely considered an important therapeutic intervention in clinical practice and has recently been recommended as an approach to the treatment of hand osteoarthritis by the European League Against Rheumatism (EULAR) Standing Committee for International clinical Studies Including Therapeutics (ESCISIT) [17]. However, in the absence of evidence from robust studies such recommendations are based upon expert opinion alone. Further research into the effects of parameter-controlled therapeutic US is needed in order to inform the development of treatment guidelines.

This trial demonstrates that most participants presenting with unilateral shoulder pain referred to physiotherapy from primary care improve during a 6-month period, however, US contributes no additional value to the physiotherapy management.

Conclusions

US is commonly used by physiotherapists in the treatment of shoulder pain. This double blind, placebo-controlled, randomized clinical trial suggests that US provides no clinical benefit beyond that of placebo US in the physiotherapy treatment of shoulder pain referred from primary care. Further research into the effects of parameter-controlled therapeutic US is warranted.

Rheumatology key messages

- Ultrasound is a commonly used treatment in the physiotherapy management of musculoskeletal pain in peripheral joints.
- We have demonstrated that ultrasound provides no clinical benefit beyond that of placebo ultrasound in the physiotherapy treatment of shoulder pain referred from primary care.

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