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Therapeutic effects of magnetic and copper bracelets in osteoarthritis: A randomised placebo-controlled crossover trial☆,☆

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KEYWORDS
Magnetics;
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Summary
Objectives: To test the effectiveness of a typical magnetic wrist strap for reducing pain and stiffness, and for improving physical functioning amongst patients with osteoarthritis.
Design: A randomised double-blind placebo-controlled crossover trial. Each participant wore four devices over a 16-week period.
Setting: Forty five patients with osteoarthritis were recruited from general practices in rural and urban areas of Yorkshire.
Interventions: Experimental device: a commercially available magnetic wrist strap. Control devices: a weak magnetic wrist strap, a demagnetised wrist strap, and a copper bracelet.
Main outcome measures: The WOMAC Osteoarthritis Index, the McGill Pain Questionnaire—Pain Rating Index (PRI), a pain visual analogue scale (VAS), and medication use.
Results: No difference was observed between devices in terms of their effects on pain as measured by the primary outcome measure (WOMAC A), the PRI and the VAS. Similar results were obtained for stiffness (WOMAC B), physical function (WOMAC C), and medication use. Further analyses of the PRI subscales revealed a statistically significant difference between devices ($P = 0.025$), which favoured the experimental device. Participants reported lower sensory pain after wearing the standard magnetic wrist strap, than when wearing control devices. However, no adjustment was made for multiple testing.

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Conclusions: Our results indicate that magnetic and copper bracelets are generally ineffective for managing pain, stiffness and physical function in osteoarthritis. Reported therapeutic benefits are most likely attributable to non-specific placebo effects. However such devices have no major adverse effects and may provide hope.

Introduction

Magnetic rings have been used as a 'cure' for arthritis since the beginning of the Common Era.[1] However, belief in magnetism as a force for healing dwindled following the downfall of Franz Anton Mesmer, who was discredited as a charlatan via the development of the controlled clinical trial in 1784.[2,3] Nevertheless, recent years have witnessed widespread growth in the use of permanent magnets for therapeutic purposes,[4] the claimed benefits of which require investigation.

Worldwide the number of people reaching old age is contributing to a rise in the prevalence of painful musculoskeletal conditions.[5] This may help to explain the current popularity of magnet therapy, since chronic pain is known to be an important predictor in the use of complementary and alternative medicine (CAM).[6,7] In the UK network marketing of magnet therapy products is common, with devices often sold directly at markets and community events. Widespread availability, together with ease of self-administration makes magnet therapy particularly appealing. In contrast to drug management, magnet therapy also involves a one off cost with no documented side effects. Permanent magnets are inexpensive to manufacture, although therapeutic devices typically sell for between £25 and £65. The possibility that magnet therapy may represent a safe and cost-effective means of pain control in conditions such as osteoarthritis therefore represents an intriguing prospect for treatment provision.

Evidence concerning the effectiveness of magnet therapy for specific conditions is sparse, due partly to an historical lack of funding for CAM research.[8] A recent systematic review of randomised controlled trials (RCTs) evaluating the use of permanent magnets for pain relief concluded that these cannot be recommended as a treatment. However, this was a broad review of studies involving different devices, differing treatment regimes, and pain arising from distinct clinical origins. With regard to osteoarthritis the authors also concluded that there was insufficient evidence to exclude the possibility of beneficial effects.[9]

Osteoarthritis affects more than 40% of people over the age of 70,[5,10] yet only three previous RCTs have investigated the effects of permanent magnets for this specific patient population. In each the authors reported that participants who wore commercially available magnetic devices experienced significantly improved pain outcomes compared with those who received control devices.[11–13]

Undoubtedly the greatest methodological challenge encountered by trials of magnet therapy has been that of blinding.[14,15] One approach to this problem has been to prevent participants from discriminating between devices in terms of their magnetic properties by using a low strength (attenuated) magnetic device as a placebo. Two of the three previous trials concerned with osteoarthritis adopted this approach.[12,15]

Interestingly, a recent study concerning the validity of weak magnets as placebos showed that participants were unable to discriminate between devices in terms of group allocation. However, participants allocated to the full strength magnet group reported greater expected benefit than those who received weak magnets, pointing towards the need for greater methodological rigour.[16]

Another potential solution to the placebo problem may be to compare the effects of a magnetic device against that of a copper bracelet. Copper bracelets are often worn by people with arthritis for the purpose of relieving symptoms. They may therefore be perceived as being equivalent to magnetic bracelets in terms of anticipated therapeutic effects. The only direct scientific evidence supporting the therapeutic use of copper bracelets comes from a single study which compared copper and aluminium bracelets.[17,18] However, the findings of this trial have been questioned due to analytical bias.[19] In addition, more robust research has refuted a link between transdermal copper absorption and pain relief in osteoarthritis.[20] Together this suggests that copper bracelets might serve as a valid placebo for trials of magnet therapy.

We conducted a randomised, double-blind, crossover trial to evaluate the therapeutic effects of a commercially available magnetic wrist strap for patients with osteoarthritis. We hypothesised that this device would result in a significant benefit compared to the other devices in self-reported pain. Where possible, our reporting adheres to recent recommendations for describing dosage parameters.[21]

Methods

The trial was approved by Hull & East Riding Local Research Ethics Committee. Patients with osteoarthritis were identified from records held by three general medical practices in rural and inner city areas of Yorkshire, England. Inclusion criteria for participants: 40 years old or over; a verified diagnosis of osteoarthritis; receiving active treatment for pain using prescribed non-steroidal anti-inflammatory drugs (NSAIDs) or opioid compound analgesics (e.g. paracetamol and codeine). Exclusion criteria: reported pain of less than 6 weeks in duration before recruitment; pregnancy; medical implant. Patients were contacted with information about the study from their doctor. Those who telephoned the coordinating centre were then screened for eligibility and recruited during a home-based interview (Fig. 1).

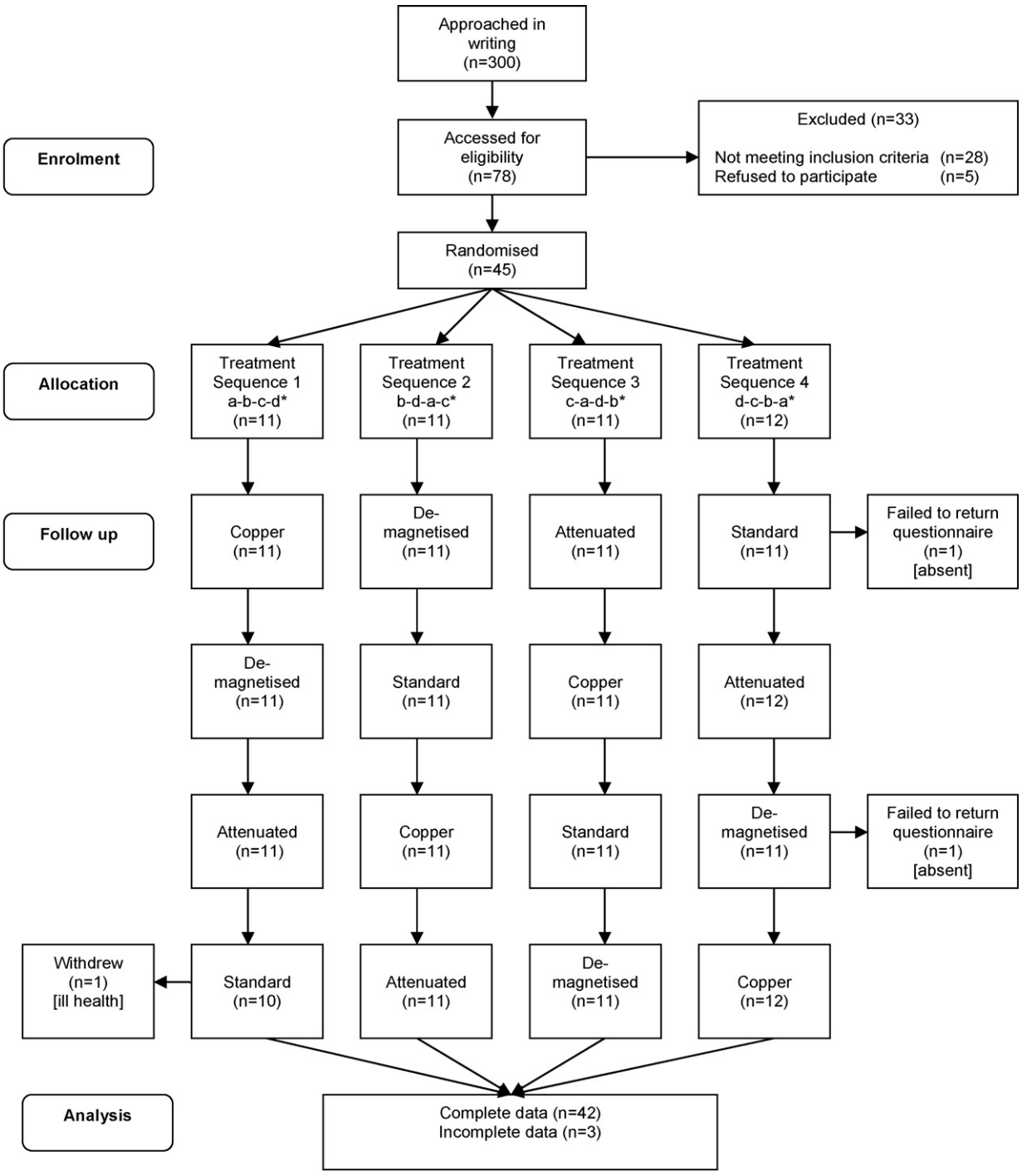

Figure 1 Participant flowchart. CONSORT flowchart illustrating the number of patients with osteoarthritis who were contacted, recruited, randomly allocated to the four treatment sequence groups, and who provided complete self-report data after each treatment phase.

Participants were allocated to one of four treatment sequences, consisting of four phases, using a Latin square crossover design.[22,23] Each participant therefore served as his or her own control, and each phase corresponded to a particular device. An independent researcher created the randomisation code using computer generated randomly permuted block sizes of 12. This determined assignment of each participant to a particular treatment sequence in advance, which was implemented using sealed boxes containing the study devices. Boxes were labelled only by study ID number and order for distribution.

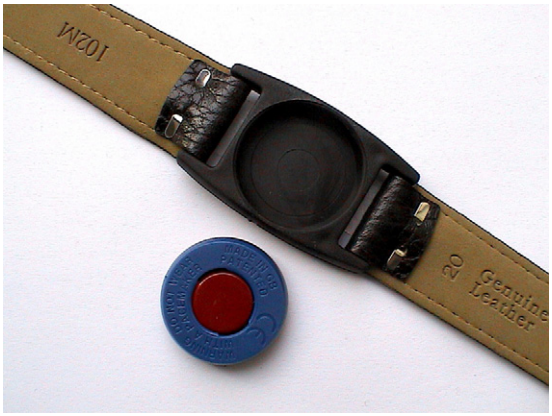

Figure 2 Standard magnetic wrist strap. Standard (experimental) MagnaMax® device, consisting of a leather wrist strap and bipolar magnetic insert.

Devices and blinding

Total participation lasted 16 weeks. Four devices were worn, each for a minimum of 8 h per day over 4 weeks.

Standard MagnaMax® wrist strap (experimental device)
These consisted of two plastic coated permanent neodymium magnets which formed a single 23 mm insert. Attached to a leather wrist strap, the insert was worn directly against the skin (Fig. 2). Testing prior to randomisation using a calibrated Hall probe showed that the average surface magnetic field reached 2009 (SD = 177) Oersteds (i.e. 201 mT). This occurred in an opposing configuration (Fig. 3).

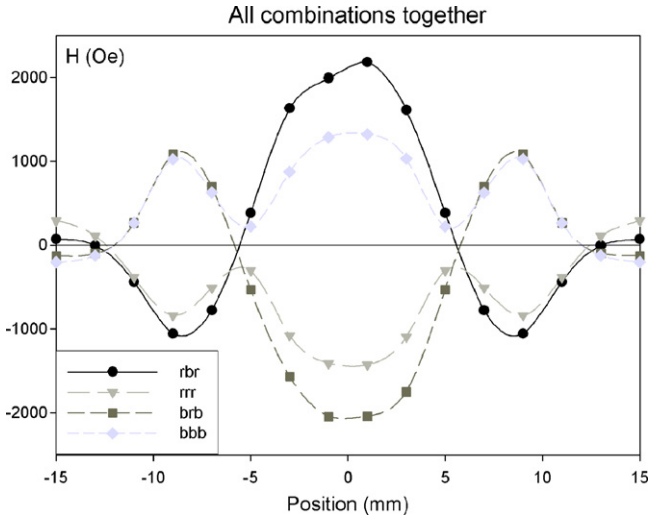

Figure 3 Magnetic fields produced by standard insert. Variation of surface magnetic field strength across all four possible configurations of inner and outer magnetic components. Both components have a red and a blue side according to the direction of magnetic polarity, where r = red or negative polarity, and b = blue or positive polarity (e.g. rbr = red blue red or − + −). The *x*-axis shows the distance across the combined magnetic insert. The *y*-axis shows the strength of the magnetic field, as measured in Oersteds.

Attenuated MagnaMax® wrist strap (placebo)
These appeared identical to the experimental device but had a much weaker surface magnetic field of 453 (SD = 120) Oersteds (i.e. 45 mT), as measured using a Hall probe. This was sufficient for adhesion to a refrigerator, thus maintaining blinding.

Demagnetised MagnaMax® wrist strap (dummy)
These looked identical to the experimental device but were non-magnetic, as demonstrated with a Hall probe, and would not even attract a paper clip. We anticipated that most participants would identify this device as a dummy.

Copper bracelet (placebo)
These were plain copper bracelets, as sold by local pharmacies, which were worn on the wrist. They weighed 13.1 g and had no magnetic properties.

Additional steps were taken to preserve the integrity of blinding. In particular, the study was presented to patients and their doctors simply as a trial of magnetic and copper bracelets for pain relief, with the intentional omission of specific details concerning the devices under investigation. Rather than specifying the number of experimental and control devices involved, participants were told only that one or more of the devices might be a placebo. The study design and procedures used also prevented participants from directly comparing devices. In addition, trial staffs were blind to device allocation. We concealed devices from the trial coordinator, who transported devices, using foam padded boxes which were securely sealed in advance using unique labels. Participants were asked in writing to prevent the trial coordinator from seeing devices and not to describe them.

Outcome measures

Questionnaires were sent to participants at recruitment and at the end of each treatment phase, which were then collected by the trial coordinator. The pain subscale of the WOMAC Osteoarthritis Index 3.1—Likert format (WOMAC A) served as the primary outcome measure. Other measures of pain intensity were the McGill Pain Questionnaire—Pain Rating Index (PRI), including sensory and affective subscales, and a standard visual analogue scale (VAS) for pain during the previous week ranging from 0 mm ''*no pain at all*'' to 100 mm ''*worst imaginable pain*''. These were included for the purposes of validation and comparison with other studies. Additional health outcomes were measured using the WOMAC B (stiffness) and WOMAC C (physical function). Medication use for each phase was measured using data from self-report diaries, prescription records and pill counts performed by the trial coordinator.

Analyses and statistics

The sample size for this trial was estimated using *GPower*.[24] This showed that complete data from 40 participants would provide 80% power to detect a clinically important improvement of 25% in pain outcomes[25,26] for the standard device using a one way analysis of variance (two-sided significance level = 0.05). This assumed a mean WOMAC A score of 9.5

points for the demagnetised device, with a difference of −2.4 for standard device and −1.2 for each of the placebo devices. An upper limit of 3.2 points was set for the common standard deviation within subjects, which was viewed as conservative, taking into account data from a previous trial that used a parallel group design.[12] We set our recruitment target to 48 participants, to allow for 15% attrition and balanced randomisation. No interim analyses were planned.

Repeated measures analyses were conducted with change in score as the dependent variable. Patient, treatment and time period were included in the model as explanatory variables with patient entered as a random effect. No interaction between treatment and period was entered due to the balanced Latin square design and nature of devices involved. Compound symmetry, Toeplitz or a general covariance structure was used for the covariance structure depending on the best model fit. The assumption that the residuals are normally distributed was examined by plotting the residuals against the predicted values, and the residuals against their ranks to assess their linearity. Responses were skewed for a number of the outcome measures, but their differences were approximately normally distributed. Analyses were by intention to treat, including all available data regardless of treatment compliance. However, we were unable to collect 3 (out of 180) questionnaires, and no attempt was made to replace these data. In particular, attrition was so low as to be unlikely to influence our results perceptibly. All statistical analyses were completed using SAS® version 9.1.3.

Results

Participant flow and follow-up

Between February and June 2005 we recruited 45 patients with osteoarthritis from 300 approached initially in writing (Fig. 1). Participants were followed up on four occasions, i.e. at the end of each treatment phase. Two participants failed to return one of the four follow-up questionnaires and one withdrew during the final phase. Complete outcome data for all devices was provided by the remaining 42 participants. Statistical comparison of the treatment sequence groups showed that these were evenly balanced in terms of participants' baseline characteristics (Table 1).

Primary outcome measure

We found no statistically significant difference amongst the four devices in terms of change in pain outcomes as measured by the WOMAC A (Table 2). Standard, attenuated and demagnetised wrist straps were each associated with improved pain outcomes. Conversely pain appeared to worsen after participants wore the copper bracelet. However, such differences were small and neither clinically nor statistically significant.

Secondary outcome measures

Analysis of change scores for the VAS, the PRI and the PRI affective subscale failed to demonstrate any statistically significant difference between devices in terms of pain relief. However there was a statistically significant difference amongst all four devices using the PRI sensory pain subscale ($P = 0.025$). This favoured the experimental hypothesis.

Further analysis of additional health outcomes showed no differences between devices in respect of either stiffness or physical function. In all the above analyses, adjustment for medication use made no important difference to the findings, and did not change the conclusions. Also there were no statistically significant differences between devices in terms of participant's use of either opioid compound analgesics or NSAIDs.

Effects of copper bracelet

Use of a copper bracelet over a period of 4 weeks had no demonstrable therapeutic benefit for patients with osteoarthritis.

Compliance and adverse events

Compliance was assessed by the trial coordinator at each visit. Participants appeared highly motivated and all of them claimed to have worn their devices as instructed, with the following exceptions. One participant complained of a rash and another complained of swelling whilst wearing the copper bracelet, resulting in discontinued use of the device. Otherwise no adverse events were reported.

Discussion

Principal findings

The results indicate that magnet therapy, involving the use of a magnetic wrist strap over a period of 4 weeks, had no statistically significant therapeutic effect amongst patients with osteoarthritis for the primary pain outcome measure. In addition, there appeared to be no difference between devices in terms of their effects on physical functioning, stiffness or medication use. Together this might be taken as evidence against the use of magnet therapy.

Of potential clinical importance, however, was an observed differential reduction in sensory pain, as measured using the McGill Pain Questionnaire, which favoured the standard magnetic wrist strap. The magnitude of this effect was equivalent to a relative difference of between 20% and 30% when compared with the three control devices, as calculated from mean estimates of change in sensory pain using a common baseline score of 11.2.

Apparent discrepancies in results obtained for the WOMAC A, VAS and PRI sensory pain subscale could relate to differences between these instruments in terms of the theoretical frameworks upon which they are based, their use of conceptually distinct pain constructs, and dissimilar measurement approaches. An alternative, and arguably more plausible, explanation for the observed difference in outcomes for the PRI sensory pain subscale is that this simply represents a spurious finding. *P*-values were not adjusted for multiple testing since most of the outcome

Table 1 Participant characteristics at recruitment according to treatment sequence. Values are means (SD) unless stated otherwise.

	Sequence				Total sample
	1a—b—c—d[a] ($n = 11$)	2b—d—a—c[a] ($n = 11$)	3c—a—d—b[a] ($n = 11$)	4d—c—b—a[a] ($n = 12$)	($N = 45$)
Age in years (range)	68.1(51—81)	68.9(50—83)	67.6(61—76)	67.8(57—84)	68.1(50—84)
No. (%) males	6 (55)	5 (45)	7 (64)	6 (50)	24 (53)
No. (%) post-school education	6 (55)	3 (27)	6 (55)	5 (42)	20 (44)
Previous CAM use: 0—15[b]	2.5 (1.5)	1.4 (1.6)	1.7 (1.2)	2.2 (2.3)	2.0 (1.7)
WOMAC A—pain: 0—20	8.5 (2.9)	11.4 (4.6)	9.2 (2.4)	9.9 (2.7)	9.8 (3.3)
VAS—pain: 0—100	69.6 (15.8)	74.6 (25.0)	66.7 (12.1)	64.3 (18.5)	68.7 (18.2)
PRI total—pain: 0—78	14.2 (8.7)	16.5 (8.9)	18.4 (11.0)	19.8 (12.0)	17.2 (10.2)
PRI—sensory pain: 0—42	9.5 (6.6)	9.7 (4.6)	12.2 (7.9)	13.0 (8.5)	11.2 (7.0)
PRI—affective pain: 0—14	1.4 (2.1)	1.8 (2.1)	1.7 (2.0)	1.6 (1.7)	1.6 (1.9)
WOMAC B—stiffness: 0—8	4.4 (1.2)	4.5 (1.3)	4.3 (1.8)	4.4 (1.4)	4.4 (1.4)
WOMAC C—physical function: 0—68	23.6 (13.0)	35.0 (15.6)	28.9 (14.4)	32.3 (10.6)	30.3 (13.7)
Location of pain					
No. (%) knees	9 (81.8)	9 (81.8)	5 (45.5)	8 (66.7)	31 (69)
No. (%) wrists or hands	7 (63.6)	7 (63.6)	6 (54.5)	8 (66.7)	28 (62)
No. (%) hips	7 (63.6)	7 (63.6)	5 (45.5)	6 (50)	25 (56)

[a] a = copper bracelet; b = demagnetised device; c = attenuated device; d = standard device.
[b] Total number of therapies tried previously from a list of 15 common forms of complementary or alternative medicine.

measures would have correlated with one another. One primary analysis and a further eight secondary analyses were completed. The influence of medication use on the findings was also tested. Therefore, if the standard device had no effect, we may have expected one result to have a *P*-value of less than 0.05 due to chance alone.

Strengths and limitations

The principal strength of the present study was the use of multiple control devices, to overcome problems associated with blinding participants and control for differences in anticipated benefit. This counters possible objections which might otherwise be levelled against reliance on one particular control device as a valid placebo. The present research is also unique in being the first published randomised controlled trial to compare magnetic and copper bracelets in terms of their effects.

Within this study we did not allow for wash out periods between treatment phases. However, we did not consider them necessary. The study was designed in order to incorporate multiple control devices, with the expectation that they would lack any meaningful active properties. The trial also used a balanced Latin square design, in which each device was followed in sequence by every other device an equal number of times. The possibility of a residual effect from a previous treatment systematically favouring a change in outcomes associated with a specific device therefore appeared remote. Moreover, unlike drug trials, we had

Table 2 Treatment outcomes by device type. Values are least square (LS) means for change after 4 weeks (95% CI) unless otherwise stated.

	Standard ($n = 43$)	Attenuated ($n = 45$)	Demagnetised ($n = 44$)	Copper ($n = 45$)	*P*
Pain					
WOMAC A	−0.21(−0.88 to 0.47)	−0.46(−1.13 to 0.21)	−0.45(−1.12 to 0.22)	0.46(−0.20 to 1.13)	0.26
VAS	1.48(−4.19 to 7.15)	−2.70(−8.33 to 2.92)	−1.82(−7.43 to 3.80)	3.25(−2.37 to 8.87)	0.51
PRI total	−2.81(−4.86 to −0.76)	1.12(−0.92 to 3.16)	−0.63(−2.66 to 1.40)	0.67(−1.36 to 2.70)	0.057
PRI affective	−0.12(−0.59 to 0.36)	0.31(−0.16 to 0.78)	−0.13(−0.60 to 0.34)	−0.03(−0.50 to 0.44)	0.60
PRI sensory	−2.52(−4.05 to −0.99)	0.80(−0.72 to 2.32)	−0.34(−1.86 to 1.17)	0.48(−1.03 to 2.00)	0.025
Stiffness					
WOMAC B	0.06(−0.24 to 0.37)	−0.12(−.042 to 0.18)	−0.18(−0.48 to 0.12)	0.05(−0.25 to 0.35)	0.69
Physical function					
WOMAC C	0.78(−0.94 to 2.50)	−1.19(−2.90 to 0.51)	−1.90(−3.61 to−0.20)	1.19(−0.52 to 2.89)	0.063
Medication use: number of tablets or capsules taken during treatment phase					
Analgesic	58.9(41.6 to 76.2)	57.2(39.9 to 74.5)	58.6(41.4 to 75.8)	54.5(39.2 to 73.7)	0.97
Anti-inflammatory	29.6(19.2 to 40.0)	26.6(16.2 to 37.0)	25.7(15.4 to 36.1)	26.1(15.6 to 36.6)	0.80

no serious concerns regarding possible adverse treatment interactions.

The fact that no meaningful analgesic effect was detected for the primary outcome measure might be attributed to a number of factors. The sample size was modest. However, the trial did not suffer from a lack of statistical power, due mainly to the use of a crossover design. Participant attrition was lower than expected and the required sample size was exceeded. Another possibility is that participants did not wear the devices for a sufficient length of time. Whilst this may be the case with the copper bracelet, we believed that a 4-week treatment period was sufficient for the magnetic wrist strap. Promotional material for the device described a 30-day satisfaction or refund guarantee. In addition, a previous trial of magnet therapy for osteoarthritis, which used the WOMAC A, claimed to have demonstrated statistically significant analgesic effects from a magnetic knee sleeve after just 4 hours exposure.[11]

Comparison with previous findings

Findings from the present study diverge from those reported elsewhere.[11–13] Of most relevance are the findings of another UK-based trial which allocated patients with osteoarthritis to wear either standard, attenuated or demagnetised wrist straps.[12] This appeared to show that participants who wore a standard bipolar magnetic wrist strap demonstrated lower (i.e. better) WOMAC A (pain) and WOMAC C (physical function) scores after 4 and 12 weeks than those who wore either weak or demagnetised devices. However results from the present trial for both of these outcome measures showed no advantage of wearing standard as opposed to weak or demagnetised wrist straps. Interestingly, although produced by different manufacturers, the standard magnetic wrist straps tested in both trials were almost identical in terms of their magnetic properties. It is unlikely therefore that any disparity in findings between studies could be attributed to differences in the experimental devices used. Rather it should be noted that differences in group outcomes reported by the previous study were only statistically significant when directly comparing the standard device with the demagnetised dummy, and not with the attenuated placebo. The summary statement from this earlier study, i.e. that magnets help to alleviate pain in osteoarthritis over and above that of a placebo, might therefore be attributed to reliance on data from a demagnetised control device, due to manufacturing problems, together with associated difficulties in blinding.[14,15]

Conclusions

The results of this trial suggest that both magnetic wrist straps and copper bracelets represent ineffective treatment options for managing pain, stiffness and physical function in osteoarthritis. Reported analgesic benefits associated with wearing these devices may therefore be attributed to the psychological effects of a placebo. Although we did find some evidence of a specific treatment effect in terms of pain perception, this could simply be explained as a statistical artefact arising from multiple testing.

People who experience persistent and disabling pain may be especially vulnerable to misleading claims relating to unproven treatments. Patients with osteoarthritis should therefore be informed that wearing a magnetic or copper bracelet may not help. Aside from personal expense, however, such devices have no major adverse effects and may offer hope.

Further research

Additional RCTs involving rigorous methodology are required to determine the effectiveness of magnet therapy for other conditions involving chronic pain. To this end, researchers may wish to build upon the present study by using multiple control devices within their design, or by incorporating copper bracelets as a placebo. This approach has recently been adopted in another trial concerning rheumatoid arthritis, the results of which are now being analysed.[19]

Authors' contributions

SR conceived the trial and was the principal investigator. He took primary responsibility for designing the trial, writing the protocol, calculating the sample size, coordinating the research team, interpreting the findings and drafting this manuscript. SB was trial coordinator. She developed trial materials, recruited patients, collected data and helped to prepare the manuscript for publication. PC proposed the use of a crossover design, assisted in securing funding and ethical approval, recruited practices and helped to manage data. AP was responsible for statistical analyses, and helped to draft the statistical content of this paper. JKM, DJ and VF amended the study protocol. They also helped to champion, plan and manage the study as members of the trial steering group. DJ conducted the randomisation. AT contributed to data collection and analysis. All authors revised and approved the final manuscript.

Conflict of interest

The authors declare that they have no competing interests.

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study; data collection, analysis, interpretation of results; or preparation of this manuscript.

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