Magnetic bracelets for relieving pain in lower-limb osteoarthritis: a randomised controlled trial.

Authors: Tim Harlow,[a] Colin Greaves,[b] Adrian White,[c] Liz Brown,[d] Anna Hart[e,] Edzard Ernst[d]

[a] College Surgery, Cullompton, Devon EX15 1TG
[b] Peninsula Medical School (Primary Care), Barrack Road, Exeter EX2 5DW
[c] Peninsula Medical School, ITTC Building, Tamar Science Park, Plymouth PL6 8BX
[d] Peninsula Medical School (Complementary Medicine), 25 Victoria Pk Road, Exeter EX2 4NT
[e] Lancashire Postgraduate School of Medicine and Health, University of Central Lancashire, Preston PR1

Contributorship:

Tim Harlow: Original idea, planning, overall management of study, lead for writing, final approval of manuscript.

Colin Greaves: Planning and design, management of study (via steering group), contribution to writing, final approval of manuscript.

Adrian White: Planning and design, management of study (via steering group), contribution to and final approval of manuscript.

Liz Brown: Planning and design, implementing randomisation procedure, contribution to and final approval of manuscript.

Anna Hart: Planning and design, analysis /interpretation, contribution to and final approval of manuscript.

Edzard Ernst (guarantor): Planning and design, management of study (via steering group), contribution to and final approval of manuscript. Senior investigator and principal grantholder.

Mike Dixon: Planning and design, recruitment, comments on manuscript.

Judith Mathie: Management of study (via steering group), data collection, co-ordination of trial nurses.

Chris Rushton: Management of study (via steering group), data collection, co-ordination of trial nurses.

Address for correspondence:
Dr Tim Harlow
Hospiscare
Dryden Road
Exeter EX2 5JJ
timharlow@eclipse.co.uk

Wordcount: 1982 excluding abstract (230) excluding tables, acknowledgements references, figures.

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Abstract

Objective To conduct a trial of the effectiveness of magnetic bracelets as used in the consumer market for pain control in osteoarthritis of hip and knee.

Design Randomised, placebo-controlled trial with three parallel groups.

Setting Primary care study set in five rural general practices in Mid Devon, UK.

Subjects 194 men and women aged 45 to 80 years with osteoarthritis of the hip or knee.

Intervention Wearing a standard-strength static bipolar magnetic bracelet (group A), a weak magnetic bracelet (group B), or a non-magnetic (dummy) bracelet (group C) for 12 weeks.

Main outcome measures Change in WOMAC A osteoarthritis lower-limb pain scale between group A and group C after 12 weeks were predefined as the primary endpoint. Secondary outcomes included change in WOMAC B and C scales and a visual analogue scale for pain.

Results Mean pain scores were reduced more in group A than in the group C (mean difference 1.3 points, 95%CI: 0.05 to 2.55). There was, however, no significant difference between group A and group B. Self-reported blinding status did not affect the results. However, beliefs about bracelet type were the strongest predictor of changes in WOMAC scale. The scores for secondary outcome measures were consistent with the WOMAC A scores.

Conclusion Pain from osteoarthritis of hip and knee decreases when wearing magnetic bracelets. It is uncertain whether this response is due to specific or non-specific effects.

Introduction

Permanent static magnet devices have world-wide sales of around five billion dollars(1). Manufacturers claim that they reduce pain in various conditions, including osteoarthritis(2,3). If magnets were effective they would offer a cheap, and probably safe treatment option.

Studies of permanent static magnets yield contradictory results, with some reporting significant pain reduction(4-10) and others reporting no effect(1,11,12). Major differences exist in the type and strength of magnets used, the conditions treated, and treatment times. There are also methodological concerns about small sample size and difficulties in maintaining blinding(4).

We therefore aimed to conduct an adequately powered trial testing the hypothesis that magnetic bracelets, as used in the consumer market, reduce pain in osteoarthritis of the hip and knee.

Participants and Methods

Participants

Between December 2001 and December 2003, we recruited 194 participants aged 45 to 80 with osteoarthritis of the hip or knee, either radiologically proven or diagnosed by a consultant (orthopaedic surgeon or rheumatologist) from five rural general practices in Mid Devon (Fig.1). Participants had to score from 8 to 20 points on the WOMAC A scale on entry. Participants with a cardiac pacemaker, current magnetic bracelet, surgery to the index joint (excluding arthroscopy), haemophilia, who were pregnant or breastfeeding, were excluded.

Masking

Participants, trial nurse and healthcare providers were blinded to treatment-allocation. Treatments consisted of identical-looking bracelets containing three different components.

Group A. Standard neodymium (NdFeB) magnets set in a steel backing cup, with the open side facing the ventral wrist, creating a fluctuating magnetic pattern across the bracelet (Fig.2). The field strength at the wrist-contact surface was 170-200 mTesla.

Group B. Weak magnets with no backing plate. The field was strong enough to appear magnetic on testing (21-30 mTesla), but prior research suggests this level is sub-therapeutic(13). This was intended to provide an 'undetectable' placebo.

Group C. Non-magnetic steel washers.

Figure 1 here

Five bracelets of each type were tested by the National Physical Laboratory before the study, confirming the manufacturer's specification. After the trial all bracelets were tested using a calibrated Hall Effect Probe.

Figure 2 here

Assignment

To ensure random allocation of the three bracelet types numbers 1 to 240 were randomly ordered, using randomisation tools in Microsoft Excel, by an independent researcher. The numbers were then assigned sequentially in blocks of 80 to the three groups. A decode sheet was sealed and locked away. Numbers from each group were then allocated sequentially to batches of 15 bracelets in sealed envelopes for distribution to practices in such a way that each batch contained five bracelets from each group. A second researcher checked the procedure. On enrolment, participants were given the bracelet with the lowest available number. They were told that they would receive either an active or an inactive bracelet.

Protocol

Recruitment was via referral from doctors, advertising or invitation following searching of practice records. Trial nurses arranged X-ray confirmation of diagnosis if needed and collected data in surgery-based clinics at baseline, 4 and 12 weeks. Participants were given a full strength bracelet at the end of the trial

Measures

The pre-defined primary outcome was change in WOMAC A score measured by the Western Ontario and Macmaster Universities osteoarthritis index(14,15) after 12 weeks follow-up. Secondary outcomes were a visual analogue scale (VAS)(16) asking "How bad was the pain from your arthritis in the last week when it was at its worst?" with verbal and numerical anchors from 'none' (0) to 'worst imaginable' (100); the WOMAC B and C, measuring lower limb stiffness and functioning(14,15); the number of days participants had used analgesics in the last week; perceived monetary value of the bracelet.

Compliance with bracelet-wearing was assessed at the second and third visits by VAS. Blinding was assessed at the 3rd visit by asking whether the participant thought they had an active bracelet and the reason for such belief. The reasons given were coded as 'detection of magnetic force', 'improvement or lack of improvement in condition', or 'just guessing'. Participants were specifically asked whether they had tested their bracelet, even inadvertently.

Sample Size

The estimated effect size was based on a 20% differential reduction in WOMAC A score, which is commensurate with effect sizes in studies of analgesics and osteoarthritis(14). A sample size in each of the groups of 52 would have 80% power to detect an effect size of 0.39SD using a two-sided t-test of the contrast between means in a one-way analysis of variance with $p < 0.05$. Assuming 15% dropout we planned to recruit 64 subjects per group(17, 18). A check was made on the suitability of these numbers for an analysis of variance across the three groups by using a range of estimated small average changes for the weak magnet group.

Analysis

The analysis was specified in advance of the study. Last value carried forward was used to impute missing values for subsequent visits. With the statistician blinded, and using SPSS version 11.5, analysis of variance was conducted on all three groups with change in WOMAC A score at 12 weeks as the response. Robustness of the results was

checked with analysis of covariance on the WOMAC A score at 12 weeks with baseline WOMAC A as covariate, and checking sensitivity to baseline imbalances. Dunnett's test was then used to compare the standard and weak magnet group means separately with the standard magnet group mean. Results were confirmed by examining residuals, by bootstrapping on analysis of covariance (with 3,000 replications) in STATA 6.0, and by testing sensitivity to the missing values by imputing a range of plausible values.

Subsequent analyses were unblinded. Results were further explored by testing for an interaction between treatment groups and blinding of the subjects, and by analysing the subset of subjects who reported remaining blinded. General linear models on all subjects explored the association between outcomes and magnetic strength of bracelet and the subjects' belief about which group they were in. Similar analyses were then carried out, where appropriate, for WOMAC B and C and the global pain score.

RESULTS
Response rates and sample properties
Of the 391 participants assessed for eligibility, 144 did not satisfy the inclusion criteria, and 194(78.5%) of the remaining 247 accepted entry into the trial (Fig 1).

Group baseline characteristics were similar (Table 1). The WOMAC scores of participants with missing values were evenly spread across the three groups. Reported compliance was high with most wearing the bracelets for 100% of waking hours.

Table 1 here

Post-trial testing of magnets showed that the Standard magnets had a median strength 190mT, range 134-197, and the non-magnetic group all had zero strength. Due to manufacturing error, only 28 of the Weak magnets were within the design range (21-30mT, mean 26mT); the other 34 magnets had a strength of 69-196mT (mean 128mT).

Table 2 here

Analysis of Outcomes
The analysis of variance between the three groups on the change in WOMAC A from baseline to 12 weeks indicated a marginally significant overall difference between groups ($F_{(2, 191)} = 2.73$, (p=0.068). Results from analysis of covariance on the score at 12 weeks (covariate baseline WOMAC A score) (F(2,190)=3.07, p=0.048) were similar. The inclusion of gender in analysis of covariance showed no interaction of gender and group or main effect of gender (F(2,187)=0.42 ,p=0.66; F(1,187)=0.01,p=0.94), and gender effects were therefore not considered further.

The planned comparison (Dunnett's test) showed a significant mean difference in WOMAC A score of 1.3 between groups A and C (95% CI 0.05 to 2.55), but not between groups A and B (mean difference 0.77, 95% CI –0.48 to 2.02). Results from the bootstrapping analysis were similar, and the results were not an artefact of the imputed missing values.

A similar pattern was observed for the change in WOMAC C. The overall ANOVA was significant ($F_{(2,191)}=4.28$, p=0.015), and Dunnett's test showed a significant mean difference between groups A and C (mean difference 4.4, 95% CI 0.9 to 7.8) but not between groups A and B (mean difference 3.2, 95% CI –0.3 to 6.6). Analysis of the VAS pain score also gave similar findings with the mean difference between groups A and B of 11.2 (95% CI 2.8 to 19.6). Analysis of change in WOMAC B scores showed no statistically significant differences between groups ($F_{(2,191)}= 0.68$, (p=0.51).

This overall pattern of results was replicated in the sub-group of 97 subjects (41 (62%) of group A versus 56 (87%) of group C) who reported that they had not noticed the magnetic strength of their bracelets. There was no evidence of an interaction between blinding and treatment group. However, across all three groups, the participants' belief about which type of bracelet they were using was a better predictor of outcome than treatment group, self-reported blinding status, or the actual magnetic strength of the bracelet worn.

There was no significant difference in the participants' estimate of the monetary worth of the bracelet. Adverse reactions were rare with two patients in each group reporting dizziness, increased pain or stiffness.

DISCUSSION
We found evidence of a beneficial effect of magnetic wrist bracelets on the pain of osteoarthritis of the hip and knee. Although reduction in pain was related to beliefs about magnet type/strength, self reported blinding status did not substantially affect the results. The results for two of the secondary outcome measures (WOMAC C and global pain scores) were consistent with this pattern. The WOMAC B failed to show any change but this measure has been found to lack sensitivity[17].

The findings are consistent with the existing literature on magnetic therapies and pain. Studies that have failed to show an effect on pain[1,12,13] generally used weaker magnets (19.2 to 50mT). Studies that have shown an effect[4-9, 13] used stronger magnets (47.5 to 180mT), which were comparable with our standard-strength magnets. Together these findings suggest that field strength is important.

To what extent the effect of magnetic bracelets is due to placebo has not entirely been resolved by this study. Blinding did not affect the pattern of results, but the validity of the self-reporting of blinding status could be questioned. The fact that belief about the magnet type was the strongest predictor of reduction in pain suggests some placebo effect. On the other hand, belief of having a real magnet could be due to perceived therapeutic benefit. Therefore we cannot be certain whether our data show a specific effect of magnets, a placebo effect, or both.

Whatever the mechanism, the benefit from magnetic bracelets seems clinically useful. The mean reduction in WOMAC A scores in the intervention group of 2.9 (27% change from baseline score) was comparable to that found with NSAIDs [18,19]. Furthermore the effects seem additive to those of other treatments. The (one-off) cost of bracelets (around £30-50), compares well with analgesics (paracetamol £20pa, newer NSAIDS £250pa) [20]. Larger investigations should now test the safety of magnets relative to the well-known risks of analgesics[21, 22].

The contamination of group B with stronger magnets prevented more objective estimation of any placebo effect. This contamination may also explain the lack of a significant difference between groups A and B. However, our design seems in principle a feasible way to allow for placebo effects in future studies.

The low refusal rate favours generalisability of our findings. The sample selected was predominantly Caucasian with a minimum WOMAC A score of 8. Our results may thus not translate to other ethnic populations or milder osteoarthritis. Future studies should test whether pain reduction is sustained for longer than 12 weeks.

Further work is needed to replicate these findings. If an effect beyond placebo is confirmed, research into the underlying mechanisms of static magnet therapy would be appropriate. It would also be relevant to test for dose-response relationships and determine the optimal strength for placebo magnets.

Conclusion
Magnetic bracelets are effective in reducing the pain of osteoarthritis of the hip and knee. If this finding can be replicated magnetic bracelets might be considered as an effective, safe and cheap option for supplementing existing treatments of osteoarthritis. It is unclear whether this is due to specific or non-specific effects.
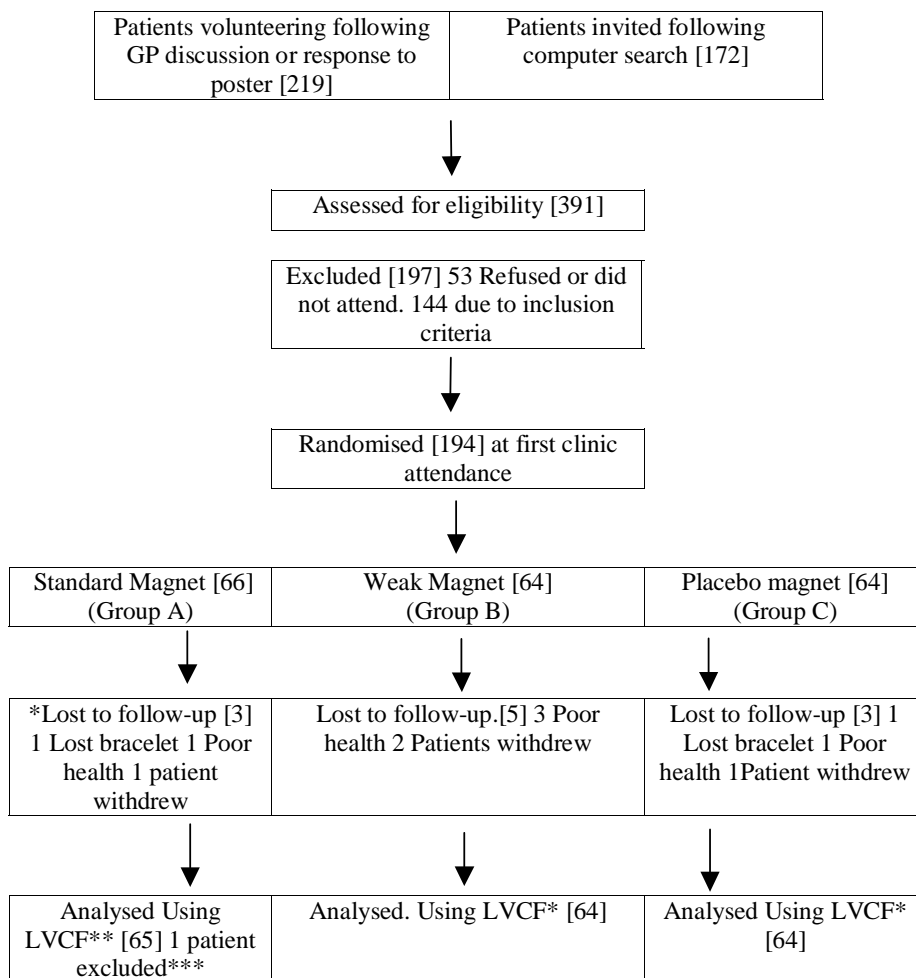
Acknowledgements

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Fig.1: Participant Flow Chart

Patients volunteering following GP discussion or response to poster [219]	Patients invited following computer search [172]

↓

Assessed for eligibility [391]

Excluded [197] 53 Refused or did not attend. 144 due to inclusion criteria

↓

Randomised [194] at first clinic attendance

↓

Standard Magnet [66] (Group A)	Weak Magnet [64] (Group B)	Placebo magnet [64] (Group C)
↓	↓	↓
*Lost to follow-up [3] 1 Lost bracelet 1 Poor health 1 patient withdrew	Lost to follow-up.[5] 3 Poor health 2 Patients withdrew	Lost to follow-up [3] 1 Lost bracelet 1 Poor health 1Patient withdrew
↓	↓	↓
Analysed Using LVCF** [65] 1 patient excluded***	Analysed. Using LVCF* [64]	Analysed Using LVCF* [64]

* Last Value Carried Forward ** X-ray showed no evidence of arthritis

Fig. 2: Magnetic field strength (mTesla) across the surface of a standard (Group A) magnetic bracelet (20mm diameter).

See file Magnetic graph b&w.jpg

NB: A colour version is available if preferred.

Table 1: Baseline characteristics of participants.

Group	group A (n=66)	group B (n=64)	group C (n=64)
Age (years)	66.4 (8.4)	66.8 (8.3)	66.3 (9.1)
Height (metres)	1.69 (0.11)	1.67 (0.11)	1.67 (0.09)
Weight (Kg)	86.5 (20.3)	*82.4 (17.1)	82.7 (16.4)
Sex -Number (%) male	35 (53)	46 (72)	39 (61)
Number of days in last week when painkillers used Median (IQR)	5.5 (1 to 7)	6.5 (2 to 7)	*7.0 (1 to 7)

*n=63
Values are mean (SD) unless otherwise stated

Table 2: Summary of Outcome Measures.

Group	group A (n=66)	group B (n=64)	group C (n=64)
WOMAC A visit 1 (baseline)	10.7 (2.1)	11.0 (2.0)	10.9 (2.1)
WOMAC A visit 2	8.9 (3.8) m=3	9.1 (2.8) m=2	9.5 (3.1) m=0
WOMAC A visit 3	7.8 (3.9) m=4	8.8 (3.2) m=5	9.3 (3.2) m=3
WOMAC B visit 1 (baseline)	4.5 (1.3)	4.5 (1.5)	4.6 (1.1)
WOMAC B visit 2	3.8 (1.5) m=3	4.2 (1.4) m=2	4.2 (1.1) m=0
WOMAC B visit 3	3.7 (1.6) m=4	3.9 (1.6) m=5	4.1 (1.3) m=3
WOMAC C visit 1 (baseline)	36.0 (9.7)	35.5 (10.2)	35.2 (9.5)
WOMAC C visit 2	32.5 (12.1) m=3	32.5 (11.6) m=2	33.5 (10.5) m=0
WOMAC C visit 3	29.1 (13.0) m=4	31.8 (12.5) m=5	32.7 (11.1) m=3
VAS pain score visit 1 (baseline)	67.1 (18.3)	64.9 (18.3)	63.5 (18.3)
VAS pain score visit 2	62.2 (20.0) m=3	60.2 (19.4) m=2	60.2 (17.6) m=0
VAS pain score visit 3	55.2 (24.5) m=4	55.7 (22.2) m=5	62.9 (22.2) m=3

Figures (using last value carried forward) are mean (SD).
m = number of imputed values.