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A Mamum and F Willekens for their collaboration in the understanding of the life table approach.

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Randomised controlled trial of magnetic bracelets for relieving pain in osteoarthritis of the hip and knee

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Abstract

Objective To determine the effectiveness of commercially available magnetic bracelets for pain control in osteoarthritis of the hip and knee.

Design Randomised, placebo controlled trial with three parallel groups.

Setting Five rural general practices.

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

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

Main outcome measures Change in the Western Ontario and McMaster Universities osteoarthritis lower limb pain scale (WOMAC A) after 12 weeks, with the primary comparison between the standard and dummy groups. Secondary outcomes included changes in WOMAC B and C scales and a visual analogue scale for pain.

Results Mean pain scores were reduced more in the standard magnet group than in the dummy group (mean difference 1.3 points, 95% confidence interval

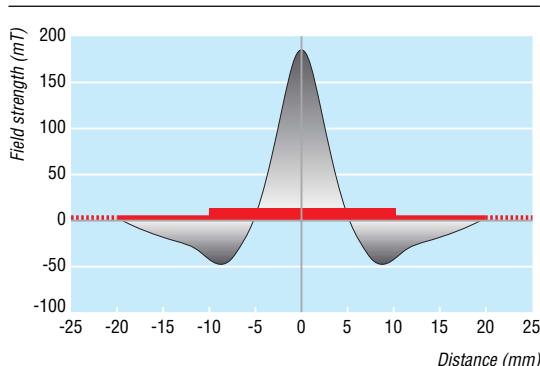
0.05 to 2.55). Self reported blinding status did not affect the results. The scores for secondary outcome measures were consistent with the WOMAC A scores.

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

Manufacturers of permanent static magnet devices claim that they reduce pain in various conditions, including osteoarthritis.¹ Worldwide sales were estimated at \$5bn (£2.6bn, €3.8bn) in 1999.² Osteoarthritis affects around 760 000 people in the United Kingdom, producing an estimated 3.02 million general practice consultations in 2000.³ If magnets were effective they would offer a cheap and probably safe treatment option.

Some studies of permanent static magnets have found significant pain reduction²⁻⁴⁻⁹ whereas others reported no effect.¹⁰⁻¹² Major differences exist in the type and strength of magnets used, the conditions

 A chart showing flow of participants is on bmj.com



Magnetic field strength (mTesla) across the surface of a standard magnetic bracelet (20 mm diameter)

treated, and treatment times. There are also methodological concerns about small sample size and difficulties in maintaining blinding.² 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

Between December 2001 and December 2003, we recruited 194 participants aged 45-80 years with osteoarthritis of the hip or knee from five rural general practices in Mid Devon (see bmj.com). Osteoarthritis was diagnosed by a consultant (orthopaedic surgeon or rheumatologist) or a general practitioner, and we sought confirmatory radiological evidence for participants who had none recorded in their general practice notes. Participants had to score 8-20 points on the Western Ontario and McMaster Universities osteoarthritis index (WOMAC A) on entry.^{13 14} We excluded people with a cardiac pacemaker, current magnetic bracelet, surgery to the index joint (excluding arthroscopy), or haemophilia and women who were pregnant or breast feeding.

Recruitment was by referral from doctors, advertising, or invitation after a search of practice records. Trial nurses arranged radiological confirmation of diagnosis if needed, and they collected data in surgery based clinics at 0, 4, and 12 weeks. Participants were given a full strength bracelet at the end of the trial.

Intervention and randomisation

The participants, trial nurse, and healthcare providers, were blinded to treatment allocation. Treatments consisted of identical looking bracelets containing three different components. The manufacturer's specifications were:

Group A—Standard neodymium magnets set in a steel backing cup, with the open side facing the ventral wrist, creating a fluctuating magnetic pattern across the bracelet (fig 1). 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 seem magnetic on testing (21-30 mTesla), but previous research suggests this is insufficient to be therapeutic.¹⁵ This was intended to provide an undetectable placebo.

Group C—Non-magnetic steel washers.

The National Physical Laboratory tested five bracelets of each type before the study, confirming the manufacturer's specification.

An independent researcher randomised participants in blocks of 15 (five of each bracelet type per block), using random numbers generated in Microsoft Excel. A decode sheet was sealed and locked away. A second researcher checked the procedure. On enrolment, participants were told that they would receive either an active or an inactive bracelet.

Outcome measures

The predefined primary outcome measure was change in WOMAC A score after 12 weeks' follow up.^{13 14} Secondary outcomes were a visual analogue scale 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)¹⁶; WOMAC B and C scores, measuring leg stiffness and functioning^{13 14}; the number of days participants had used analgesics in the past week; and perceived monetary value of the bracelet.

We assessed compliance with wearing the bracelet at 4 and 12 weeks using a visual analogue scale. Blinding was assessed at 12 weeks by asking whether participants thought they had an active bracelet and the reason for such belief.

The estimated effect size was based on a 20% differential reduction in WOMAC A score, which was considered commensurate with effect sizes in studies of analgesics and osteoarthritis.^{13 17} A sample size of 52 in each of the groups would have 80% power to detect a difference in one way analysis of variance of change scores, assuming mean changes of 3, 1.5, and 1 and a common standard deviation of 3.4. Assuming 15% dropout, we planned to recruit 64 subjects to each group.¹⁸ We checked 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 as follows. Last value carried forward was used to impute missing values for subsequent visits. The blinded statistician conducted analysis of variance on all three groups using SPSS version 11.5, with change in WOMAC A score at 12 weeks as the response. The 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 means for the dummy and weak magnet group separately with the mean for the standard magnet group. The protocol specified that

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Table 1 Baseline characteristics of participants randomised to standard, weak, and dummy magnetic bracelets.

Group	Standard (n=65)	Weak (n=64)	Dummy (n=64)
Mean (SD) age (years)	66.6 (8.4)	66.8 (8.3)	66.3 (9.1)
Mean (SD) height (m)	1.69 (0.11)	1.67 (0.11)	1.67 (0.09)
Mean (SD) weight (kg)	86.7 (20.3)	82.4 (17.1)*	82.7 (16.4)
No (%) of men	34 (52)	46 (72)	39 (61)
Median (interquartile range) No of days in past week when painkillers used	5.5 (1 to 7)	6.5 (2 to 7)	7.0 (1 to 7)*

*n=63.

the primary comparison was dummy versus standard magnets, the other comparison being secondary, unless a high degree of unblinding was observed. Models were checked by examination of residuals and sensitivity to imputed values.

Subsequent analyses were unblinded. We used general linear models on all subjects to explore the association between outcomes and magnetic strength of individual bracelets. 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 people assessed for eligibility, 144 did not satisfy the inclusion criteria and 194 (78.5%) of the remaining 247 accepted entry into the trial (see bmj.com). Group baseline characteristics were similar (table 1). Very few participants were lost to follow up. These were evenly spread across the three groups, and their baseline WOMAC A scores were not markedly different from those of participants with complete data. Reported compliance was high, with most wearing the bracelets for 100% of waking hours.

After the trial, we tested all the returned bracelets using a calibrated Hall effect probe. This showed that the standard magnets had a mean strength of 186 (range 134-197) mTesla (only one was outside the specified range) and the non-magnetic group all had zero strength. Because of a manufacturing error, only 28 of the weak magnets were within the specified range (21-30 mTesla). The mean for these 28 magnets was 26 mTesla; 34 magnets had a strength of 69-196 (mean 128) mTesla, and two were not returned (these were assumed to be in the specified range as they were part of a good batch).

Analysis of outcomes

Table 2 shows the scores for the three groups at baseline and after 4 and 12 weeks. Analysis of variance between the three groups on the change in WOMAC A from baseline to 12 weeks showed a difference that was just non-significant ($F=2.90$, $df=2$, 190; $P=0.057$). Results from analysis of covariance on the score at 12 weeks (with baseline WOMAC A score entered as a covariate) were significant ($F=3.24$, $df=2$, 189; $P=0.041$).

The planned comparison (Dunnett's test) showed a significant mean difference in change in WOMAC A score of 1.3 between the standard and dummy magnet groups (95% confidence interval 0.09 to 2.60; $P=0.03$), but not between the standard and weak groups (mean difference 0.81, -0.44 to 2.07; $P=0.26$). A similar pattern was observed for the change in WOMAC C score. The overall analysis of variance gave significant results ($F=4.45$, $df=2$, 190; $P=0.013$), and Dunnett's test showed a significant mean difference between the standard and dummy groups (4.4, 95% confidence interval 1.0 to 7.9; $P=0.01$) but not between the standard and weak groups (3.3, -0.2 to 6.7; $P=0.07$). Analysis of the visual analogue pain score showed a significant mean difference between the standard and dummy groups of 11.4 (95% confidence interval 3.0 to 19.8). Change in WOMAC B scores did not differ

Table 2 Mean (SD) scores at baseline and 4 and 12 weeks by randomisation to standard, weak, and dummy magnetic bracelet

Outcome measure	Standard (n=65)	Weak (n=64)	Dummy (n=64)
WOMAC A:			
Baseline	10.7 (2.1)	11.0 (2.0)	10.9 (2.1)
4 weeks	8.9 (3.8) m=2	9.1 (2.8) m=2	9.5 (3.1) m=0
12 weeks	7.8 (3.9) m=3	8.8 (3.2) m=5	9.3 (3.2) m=3
WOMAC B:			
Baseline	4.5 (1.3)	4.5 (1.5)	4.6 (1.1)
4 weeks	3.8 (1.5) m=2	4.2 (1.4) m=2	4.2 (1.1) m=0
12 weeks	3.7 (1.7) m=3	3.9 (1.6) m=5	4.1 (1.3) m=3
WOMAC C:			
Baseline	36.0 (9.8)	35.5 (10.2)	35.2 (9.5)
4 weeks	32.5 (12.2) m=2	32.5 (11.6) m=2	33.5 (10.5) m=0
12 weeks	29.0 (13.1) m=3	31.8 (12.5) m=5	32.7 (11.1) m=3
Pain on visual analogue scale:			
Baseline	66.8 (16.2)	64.9 (18.3)	63.5 (18.3)
4 weeks	61.8 (20.0) m=2	60.2 (19.4) m=2	60.2 (17.6) m=0
12 weeks	54.8 (24.5) m=3	55.7 (22.2) m=5	62.9 (22.2) m=3

WOMAC=Western Ontario and MacMaster University osteoarthritis index.

m=number of values imputed from last recorded figure.

between groups ($F=0.73$, $df=2$, 190; $P=0.48$). No important differences in these results emerged when either sex or analgesic use (at 12 weeks) was included as a covariate.

Table 3 provides data on participants' beliefs about group allocation and the reasons given for their beliefs. Around a third of participants in the standard and dummy groups were correct in their beliefs about their bracelet, although the reasons differed between groups. In the standard group beliefs were mainly based on noticing the magnetic force—for example, bracelets were often reported to stick to keys in pockets—or on improved symptoms. In the dummy group, few noticed the magnetic force and beliefs were most commonly based on a lack of symptom improvement.

Comparing the outcomes for the different belief groups is not appropriate because belief may follow benefit or lack of it, and any differences would therefore be hard to interpret.¹⁹ However, we have a more direct way of estimating the effect of unblinding, as participants reported whether they had noticed the magnetic strength of their bracelets (table 3). The overall pattern of results was replicated in the subgroup of 97 participants (41 (63%) in standard group v 56 (88%)

Table 3 Participants' beliefs about magnet type and reasons given for beliefs. Values are numbers (percentages)

	Standard (n=65)	Weak (n=64)	Dummy (n=64)
Belief about magnet:			
Real	35 (54)	24 (38)	10 (16)
Dummy	5 (8)	12 (19)	30 (47)
Don't know	22 (34)	23 (36)	22 (34)
Lost to follow up	3 (5)	5 (8)	2 (3)
Reasons given*:			
Condition improved	14 (22)	10 (16)	8 (13)
Noticed magnetic force	21 (32)	13 (20)	4 (6)
No change	0	5 (8)	20 (31)
Condition worsened	1 (2)	2 (3)	2 (3)
No reason/guessing	4 (6)	5 (8)	4 (6)
Missing	0	1 (2)	2 (3)

*Participants who responded don't know were not asked for reasons, but percentages are of total in group.

Table 4 Individual responses between baseline and 12 weeks

	Standard magnet group (n=65)		Weak magnet group (n=64)		Dummy magnet group (n=64)	
	No with high pain at baseline [†]	No (%) meeting response criterion [†]	No with high pain at baseline	No (%) meeting response criterion [†]	No with high pain at baseline	No (%) meeting response criterion [†]
WOMAC A pain[*]:						
Walking on flat surface	51	22 (34)	55	16 (25)	54	18 (28)
Going up or down stairs	63	19 (29)	63	12 (19)	62	11 (17)
At night in bed	46	24 (37)	51	18 (28)	47	17 (27)
Sitting or lying	44	24 (37)	43	22 (34)	42	16 (25)
Standing upright	52	17 (26)	50	16 (25)	50	9 (14)
Visual analogue scale for pain[†]:						
High level of improvement		13 (20)		9 (14)		6 (9)
Moderate improvement		24 (37)		27 (42)		14 (22)

^{*}Criterion for meaningful change was shifting from categories of moderate, severe, or extreme pain to no or mild pain at week 12 compared with baseline.¹⁷

[†]OMERACT criteria for high and moderate levels of improvement in osteoarthritis trials (minimum 50% and 20% change from baseline respectively).²⁰

in dummy group) who did not report noticing or testing the magnetic strength of their bracelets at week 12. Results from analysis of covariance estimated the mean difference in WOMAC A between the standard and dummy groups as 1.3 (95% confidence interval 0.003 to 2.62).

To examine the impact of the contamination of the weak magnets on the trial, we analysed data from only the bracelets that met the defined specification (30 weak magnets, 64 dummy magnets, and 64 standard magnets). Analysis of variance showed a significant difference for change in WOMAC A score ($F=3.73$, $df=2, 155$; $P=0.026$). The post-hoc Dunnett's test showed a significant difference between real and dummy magnets (mean difference 1.39, 95% confidence interval 0.11 to 2.68), and a non-significant difference between real and weak magnets, although there was a strong numerical trend (mean difference 1.52, -0.09 to 3.13, $P=0.067$).

Table 4 gives data on individual responses to treatments categorised according to predefined criteria for improvement.¹⁷⁻²⁰ Participants' estimate of the monetary worth of the bracelet did not differ significantly. Adverse reactions were rare, with two participants 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. Self reported unblinding to treatment group did not substantially affect the results. Although there were problems with the weak magnets, a per-specification analysis suggested (but could not confirm) a specific effect of magnetic bracelets over and above placebo. Other reasons for suspecting a specific effect are that the data on belief show a low level of unblinding in the dummy group and the data on individual responses (table 4) show that more people achieve high levels of improvement in the standard magnet group. The results for two of the secondary outcome measures (WOMAC C and visual analogue pain scores) were consistent with this pattern. No change was seen in WOMAC B score, but this measure has been found to lack sensitivity.¹⁸

The findings are consistent with previous studies on magnetic therapies and pain. Studies that have failed to show an effect on pain¹⁰⁻¹² generally used

weaker magnets (19 to 50 mTesla). Studies that have shown an effect used stronger magnets (47 to 180 mTesla), which were comparable with our standard strength magnets.²⁻⁴⁻⁸ Together these findings suggest that field strength is important.

Is the effect real?

Our study has not entirely resolved the extent to which the effect of magnetic bracelets is specific or due to placebo. Blinding did not affect the pattern of results, but the validity of the self reporting of blinding status could be questioned. Although the analysis of per-specification bracelets also suggests a specific effect, the result is only a trend and needs confirmation. 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) and the difference above placebo (1.3 points) is similar to that found in trials of frontline osteoarthritis treatments, including non-steroidal topical creams,²¹ oral non-steroidal drugs (including cyclo-oxygenase 2 inhibitors),¹⁷ and exercise therapy.²² In a pivotal trial of cyclo-oxygenase 2 inhibitors¹⁷ in osteoarthritic patients with similar baseline pain (mean WOMAC A score 10.7) and the same follow up period (12 weeks), the treatment effects (change above placebo) were 0.8, 1.5, and 1.9 points for the three doses studied. The difference we found in physical function scores (WOMAC C) also compares well with the above trials. Furthermore, the effects seem additive to those of the participants' usual treatment. The (one off) cost of bracelets (around £30-£50 (\$58-\$96, €43-€92)), compares well with that of analgesics (paracetamol £20 a year, newer non-steroidal anti-inflammatories £250 a year).²³ Larger investigations should now test the safety of magnets relative to the well known risks of analgesics.¹⁷⁻²³⁻²⁴

The low refusal rate favours generalisability of our findings. However, the sample selected was predominantly white with a minimum WOMAC A score of 8. Our results may thus not translate to other ethnic populations or people with milder osteoarthritis. Further work is needed to replicate our findings and determine whether the effect extends beyond 12

What is already known on this topic

Static magnets are widely used for the relief of pain

Evidence about their efficacy in osteoarthritis is contradictory

Placebo effects are particularly difficult to control because of the easy detection of magnetism

What this study adds

Bracelets with static magnets decrease the pain from osteoarthritis of the hip and knee, over and above the effects of placebo

These benefits are supplementary to those from usual treatments

weeks. The contamination of group B with stronger magnets prevented a more objective estimation of any placebo effect. However, our design seems in principle a feasible way to allow for placebo effects in future studies.

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Contributors: TH had the original idea, led the writing, participated in planning, and was responsible for the overall management of study. CG and AW participated in planning and design, management of study (via steering group), and writing the manuscript. LB implemented the randomisation procedure and contributed to planning and design and writing the manuscript. AH took part in planning and design, analysis and interpretation, and writing the manuscript. EE participated in planning and design, management of study (via steering group), and writing. Mike Dixon took part in planning, design, and recruitment, and commented on the manuscript. Judith Mathie and Chris Rushton participated in management of study (via steering group), data collection, and coordination of trial nurses. Mark Taylor suggested the use of weak bracelets. All authors approved the final manuscript. EE is guarantor.

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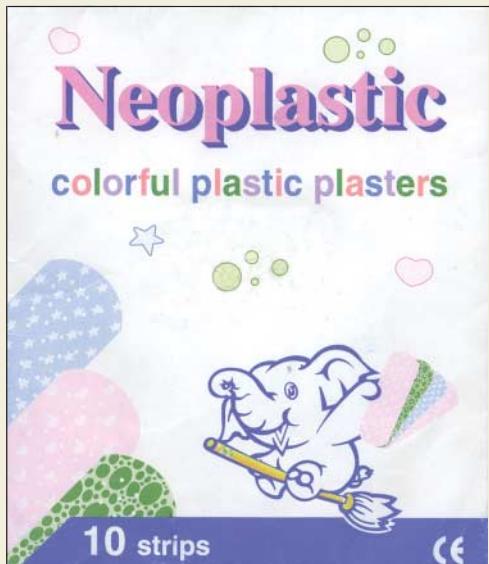
Competing interests: None declared.

Ethical approval: North and East Devon local research ethics committee and West Somerset local ethics research committee.

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Colourful new use for a word



I bought these plasters in Malaysia; they are manufactured in Thailand.

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