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Static magnetic field therapy: methodological challenges to conducting clinical trials

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Abstract Static magnetic field (SMF) therapy delivered by permanent magnets is being used as a self-care intervention by millions of people worldwide, despite a paucity of clinical research confirming or refuting therapeutic effectiveness. Evaluating the reported results of SMF clinical trials is difficult because researchers use heterogeneous dosing regimens, unreliable sham controls, and questionable blinding strategies. Three important methodological challenges need to be contended with when conducting and interpreting SMF studies: optimization of SMF dosimetry, use of a believable physiologically inert sham, and assurance of participant blinding in unsupervised settings. Our objectives in writing this review are to describe ten essential SMF dosing parameters that need to be reported in SMF clinical trials and to discuss sham controls and blinding procedures for SMF studies.

1 Introduction

Static magnetic field (SMF) therapy is a popular, non-invasive, self-help intervention with no apparent associated adverse effects. Datamonitor Research-2000 reported $350 million in sales of therapeutic magnets in the USA and $4 billion worldwide in 1999. The National Center for Complementary and Alternative Medicine (NCCAM) acknowledges that the kinds of "therapeutic" magnets marketed to consumers are generally considered to be safe when applied to the skin. They caution, however, that magnets should not be used by pregnant women, people who use implanted electronic medical devices, or people who use a patch medication delivery system through the skin (http://www.sld.cu/galerias/pdf/sitios/rehabilitacion-fis/magnet.pdf).

Despite its widespread use, the scientific evidence base for SMF therapeutic effectiveness is limited. In several small clinical studies, researchers report SMF therapeutic benefit for conditions such as: diabetic peripheral neuropathy (Weintraub et al. 2003), dysmenorrhea (Eccles 2005a, b), postoperative wound healing (Man et al. 1999), knee osteoarthritis (Holcomb et al. 1991; Hinman et al. 2002; Harlow et al. 2004; Wolsko et al. 2004), and chronic pain syndromes including post-polio pain syndrome (Vallbona et al. 1997), fibromyalgia (Colbert et al. 1999; Alfano et al. 2001), frozen shoulder (Kanai et al. 2004; Kanai and Taniguchi 2006), pelvic pain (Brown et al. 2002), and low back pain (Holcomb et al. 1991; Kanai et al. 1998). Four systematic literature reviews that assessed the overall effectiveness of SMF for pain relief came to contradictory conclusions (Wasiak 2001; Ratterman et al. 2002; Eccles 2005a, b; Pittler et al. 2007). Wasiak, basing his analysis on a single randomized controlled trial (RCT) of Collacott et al. (2000) in which a possibly inadequate SMF dose was used, found "no evidence for the effectiveness of therapeutic magnets in relieving pain". Ratterman's group reviewed seven RCTs and concluded that the scientific evidence to support the popular use of magnet therapy was

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lacking (Ratterman et al. 2002). Eccles, on the other hand, in a 2005 review of 21 RCTs, stated that the weight of the evidence suggests that SMFs are able to induce analgesia. In 2007, however, Pittler et al. (2007) using more stringent criteria in their assessment of 29 studies concluded that the evidence does not support the use of SMF for pain reduction, except possibly for osteoarthritis, for which "the evidence is insufficient to exclude a clinically important benefit". Of note is the fact that the latter two reviewers disagreed on their interpretations of the outcomes in 5 out of 18 commonly reviewed trials (Holcomb et al. 1991; Segal et al. 2001; Brown et al. 2002; Weintraub et al. 2003; Wolsko et al. 2004).

In 2007, while preparing to conduct a trial of SMF therapy for carpal tunnel syndrome, we carried out a critical review of ten SMF dosing parameters as reported in 56 studies (Colbert et al. 2007, 2008) (Table 1). We discovered that SMF dosing parameters were inadequately reported for the majority of studies, many of the SMF dosing regimens used may have been insufficient to elicit the desired therapeutic effect, and the majority of SMF therapeutic trials were conducted, reported, and interpreted unsatisfactorily.

If we are to move forward with a rigorous program of SMF research, three major methodological challenges (choice of SMF dosimetry, sham controls, and participant blinding) need to be addressed. SMF dosimetry has not yet been optimized for specific clinical conditions. Although it is usual to determine optimal dosing parameters through successful laboratory trials before bringing a novel medical device to market, such trials have not been conducted in SMF clinical research. Reasons for the lack of preliminary trials may be that SMF therapy is in common use among the public and has been practiced for centuries. Also "therapeutic magnets" are already available to consumers, with no prescription and no regulatory control. The second methodological challenge is the lack of an appropriate sham control device that is both believable as a magnet but proven to be physiologically inert. A variety of sham controls have been used, including low strength, similar-appearing magnets, but we do not yet know how low a SMF dose elicits an effect. The third challenge, shared by researchers of other physical interventions, is the need for ethically acceptable, successful, blinding procedures that disguise the magnet and assure allocation concealment from the study participants as well as the study personnel.

Our objectives in writing this review are to describe ten essential SMF dosing parameters that should be reported in every SMF clinical trial in order to help identify optimal SMF dosing regimens, and to outline potentially suitable sham controls and blinding procedures.

Table 1 Essential SMF parameters

Target
Target tissue(s)
Site of magnet application
Distance of target tissue(s) from magnet surface
Magnet characteristics
Magnetic field strength
Material composition of magnet
Magnet dimensions: size, shape, weight, volume
Magnet polar configuration
Magnet support device
Dosing regimen
Timing of magnet application
Frequency of magnet application
Duration of magnet application

2 Static magnetic field dosimetry

The SMF that is generated by the permanent magnet and delivered to the target tissue(s) is the therapeutic agent in SMF therapy. That SMF dose is dependent on the physical properties of the permanent magnet, the site of magnet placement on the skin surface, and the magnet's distance from the target tissue(s). To quantify SMF dosimetry, detailed descriptions of the physical and biophysical properties of the magnet and the target tissue(s) are needed along with a statement about the SMF dosing regimen.

We assessed how completely each of ten SMF dosing parameters was described in 56 studies, by rating each parameter as "fully described", "partially described", or "not described" (Colbert et al. 2007). The quality of reporting was adequate for describing certain dosing parameters, such as the site, frequency, and duration of magnet application, but inadequate for describing the physical properties of the permanent magnet, the target tissue(s), and estimates of the distance of magnet from the target tissue(s) (Fig. 1). We concluded that a full description of all ten dosing parameters is needed to determine the adequacy of the SMF dosage delivered to the target tissue(s). Without confirmation that a sufficient SMF dosage was applied to the appropriate anatomical site, for a long enough period of time, outcomes reported in any trial may be erroneous or misleading.

Systemic versus local SMF effects. Although SMFs are postulated to have systemic as well as localized effects (Markov et al. 2005), our discussion will be restricted to SMF effects on localized tissue(s) that lie within the 3D field projection of the permanent magnet. It might be helpful to conceptualize the SMF as a 3D plume and the target tissue(s) as a 3D structure that is enveloped by the SMF plume. We will describe how both 3D entities should

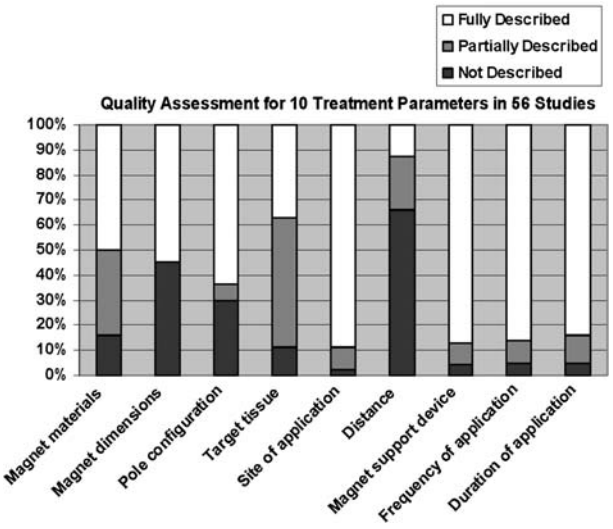

Fig. 1 Quality of reporting ten SMF treatment parameters in 56 studies. *Vertical axis* shows percentage of studies in which SMF dosing parameters were either fully described, partially described, or not described

be reported in order to appreciate the total SMF exposure of the target tissue(s).

2.1 Ten essential SMF dosing parameters

2.1.1 Target tissue(s), site of magnet application, distance of magnet from target tissue(s)

Central to determining, if the desired SMF dose reached its intended target tissue(s), is a precise identification of that target and an estimation of the distance between the target and the magnet. The target tissue(s) may be superficial anatomical structures such as a myofascial trigger points or acupuncture points located in the skin or subcutaneous tissue, or a much deeper structure such as the three-joint vertebral complex of a lumbar vertebra. Magnetic fields, unlike electric fields, penetrate all tissues equally, but the strength of the magnetic field falls off almost exponentially with distance from the magnet surface. Bench scientists can readily measure the distance between the magnet and the target, which might be a cell-free enzyme preparation (Markov 2004), an implanted tumor in mice (Williams and Markov 2001), or in vitro (Tofani et al. 2003) or in vivo tissues (Okano and Ohkubo 2001; Gmitrov et al. 2002; Morris and Skalak 2005). The target tissue(s) in human research, however, are usually deep to the skin surface and, therefore, not directly measurable, and the distance between target and magnet surface must be estimated. The majority of the 56 studies we reviewed provided inadequate descriptions of the intended target tissue(s), the distance from the magnet surface to that target or a rationale for the site of magnet application. Three studies, however, with positive outcomes serve as examples of good quality reporting in that they provide information that is essential to defining the delivered dose of SMF.

Example 1. Brown et al. (2002) when treating chronic pelvic pain, identified the target tissue as two active abdominal trigger points and appropriately applied rubberized flexible magnets (350 G field) to reach the depth of the superficial trigger points. These researchers also provided a rationale for site of magnet application. 'Three double-blind studies that used SMF on chronic pain…demonstrated a treatment effect when magnets were applied directly over pain pressure points…. Because up to 70% of women with chronic pelvic pain have abdominal pain pressure or "trigger points", 10 areas located in the upper, middle and lower abdomen were palpated for localized tender areas, or trigger points…. Devices were placed on the two areas most sensitive to palpation' (Brown et al. 2002).

Example 2. Mayrovitz et al. evaluated changes in skin blood perfusion in the hand associated with SMF application (Mayrovitz and Groseclose 2005). These investigators explicitly describe how the distance from the magnet surface to the target tissue was estimated. "The magnetic intensity at the 2nd finger dorsum skin blood perfusion (SBF) site was measured for each subject. This value depended on the finger thickness which was measured with a digital caliper. Average thickness of the 2nd finger at the site of SBF measurements was 12.0 ± 1.1 mm and the magnetic field intensity at this site was (879 ± 52)G".

Example 3. A Phase I study by Salvatore et al. (2003) was designed to establish the safety and toxicity of the combination of SMF and anti-neoplastic chemotherapy in patients with advanced-stage cancer. A permanent magnet was placed on the skin over the liver during the patient's chemotherapy administration. That site was chosen because chemotherapeutic agents are metabolized in the liver. The authors report in detail the estimated strength of SMFs that reached various levels within the liver. "The average value for the magnetic field for ten magnets at each of the distances measured was 28, 18, 14, 9, 6, 5, and 3 mT for 1, 2, 3, 6, 10, 12, and 18 cm, respectively".

Once the target tissues/s is identified and its depth from the skin surface estimated, the appropriate permanent magnet that is capable of delivering the desired SMF dose is chosen. In addition to consideration of distance from the target, the choice of a permanent magnet is based on the

magnet's field strength, material composition, dimensions, and polar configuration.

2.1.2 Permanent magnet characteristics

Magnetic field strength. Basic science studies suggest that different magnetic field strengths and projections result in different outcomes but clinical researchers have only recently begun to investigate this relationship. It should be noted that there are two systems of units for magnetic field strength, Gauss and Tesla. They are closely related: 1T = 10,000 G. For example, 10 mT = 100 G. Effective SMF dosages identified by bench scientists have sometimes shown a nonlinear response. For instance, Markov (2004) found changes in a cell-free calcium calmodulin phosphorylation preparation when he applied 150 and 450 G but not with a 300 G application. Morris and Skalak (2008) demonstrated that a 10 or 70 mT, but not a 400 mT SMF, led to significant edema reduction in a rat's hindpaw. While, McLean et al. (2003) observed that a decrease in seizure activity in mice depended on both the magnetic flux density and duration of exposure to the magnetic field.

The SMF dose reported in many studies is difficult to interpret because authors interchangeably use terms such as "manufacturers' gauss rating" and "magnetic strength" for the surface field strength (Colbert et al. 2007). The surface field strength of an individual magnet or an array of magnets should be reported as the field strength measured with a high quality gauss meter at the geometric center of the individual magnet or the magnet array. The actual measured surface field strength is then used to estimate the strength of SMF that is delivered to the target tissue(s). The following is an example of how a permanent magnet might be chosen based on the depth at which the target tissue lies.

> *Example*. Khoromi et al. (2007) describe their choice of magnet strength for treating patients with lumbar radiculopathy: "The 200 G surface field strength was chosen so that the static field at the level of the nerve roots was ~20 times the ambient magnetic field of the earth, that is 5-10 G, in accord with field strengths that have reportedly relieved pain in published studies."

Magnet material composition. A wide variety of permanent magnets of different material composition are commercially available. The magnets most commonly used for clinical application are three types: rubberized flexible, ceramic ferrite, or neodymium.

Rubberized flexible magnets impregnated with magnetic powder have the weakest strength per unit volume and least depth of penetration. Advantages of flexible magnets, however, are that they are easily formed into complex shapes and less prone to the corrosion that occurs with ferrite and neodymium magnets. Flexible magnets can also be readily magnetized with multiple magnetic poles on one surface. Rubberized magnets can be magnetized to a maximum energy product of only 0.5–1.5 MGOe with penetration of only a few millimeters. Because of the shallow depth of penetration, the main utility of flexible magnets is in treating superficial tissues. Weintraub et al. successfully used flexible magnets to treat the nociceptors in the dermis and epidermis of the foot in patients with diabetic neuropathy (Weintraub et al. 2003). Flexible magnets have also been effective in treating superficial trigger points (Brown et al. 2002; Vallbona et al. 1997). Flexible magnets should not, however, be used when the target tissue lies deep to the skin surface. In one SMF study with reported negative results, the SMF generated by the chosen bipolar flexible magnet (surface field strength 300 G) was insufficient to reach the intended target, the three-joint complex of the vertebral spine, which is located at a depth of 6–7 cm from the skin surface (Collacott et al. 2000).

Ceramic magnets, made of strontium ferrite or barium ferrite, are typically two times stronger per unit volume than flexible magnets, having an energy product between 1.5 and 3.5 MGOes. Moderately priced ceramic magnets have a greater depth of penetration than flexible magnets which permit treatment of deeper internal tissues. Salvatore et al. (2003) used rectangular ceramic magnets (10 × 15 cm and 1.2 cm thick) to penetrate 18 cm into the liver. Disadvantages of ceramic magnets are their weight and bulkiness, which make wearing them difficult. Ceramic magnets are often incorporated in foam-type materials for use as seat cushions or mattress pads.

Neodymium magnets are the strongest and most expensive of the permanent magnets. Magnets made from neodymium, cobalt/samarium, or other rare earth elements are stronger than ceramic magnets by an order of magnitude and can display a potential energy product of 30–50 MGOe. Because of their high strength per unit volume, neodymium magnets have been successfully applied where depth of penetration with a minimum volumetric profile is required, as in treatment of the knee joint in patients with osteoarthritis (Hinman et al. 2002; Wolsko et al. 2004).

Magnet dimensions: *size, shape, and volume*. The magnet's size, shape, and volume need to be described as these characteristics also influence the SMF dose delivered to the target tissue(s). The following exemplifies good reporting of the permanent magnet's dimensions and supplies information needed for replication of a study.

> *Example*. Segal et al. (2001) evaluated the therapeutic effects of SMF on the knees of patients with rheumatoid arthritis. "The MagnaBloc is a quadrapolar

static magnetic device with four permanent center-charged, rare earth magnets arrayed with alternating polarity in a hypoallergenic plastic case. It is ~3.5 cm in diameter, weighs approximately 30 g, and generates magnetic fields of about 190 mT over each pole… the magnetic field produced by the square array of magnets (neodymium–iron–boron) penetrates 5 cm into cadaver tissue, as determined with a hand-held meter."

Magnet polar configuration. Magnets are manufactured with different polar configurations, described as "unipolar", "bipolar", or "multipolar" meaning, respectively, that the magnetic device has a single north or south pole on a single surface (unipolar) or both poles on the same surface (bipolar/multipolar). It has not yet been demonstrated whether unipolar or multipolar magnets are therapeutically more effective, or even if different results occur when the north or south pole of a unipolar magnet is applied to the skin. In general, the depth of penetration of a unipolar magnet is approximately four to eight times greater than that of a similar multipolar magnet. Figure 2 illustrates field strength measurements of two same-size magnets, one ceramic with a unipolar configuration and the other "Bioflex" with a bipolar configuration, as measured by one of us (MM). The bipolar configured magnet has approximately the same surface field strength at 1 cm from the magnet surface as the unipolar magnet has at 4 cm, indicating an almost fourfold greater depth of penetration by the unipolar magnet.

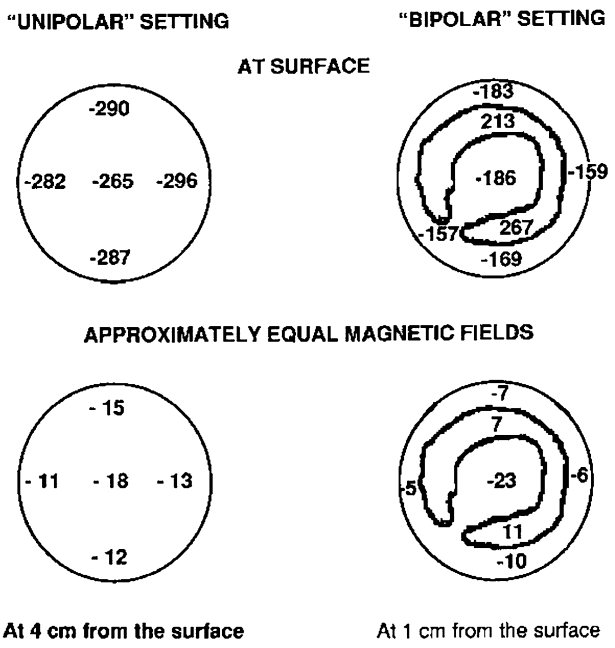

Fig. 2 Magnetic strengths (in Gauss) of similar size magnets. A ceramic unipopular magnet generates approximately the same field strength at 4 cm from the magnet surface as a bioflex bipolar magnet generates at 1 cm from the magnet surface

The inconsistent use of the terms "north/south" or "±" polarity, and the lack of standard nomenclature for north or south poles among magneto-therapists, leads to confusion. In the absence of consistent naming of north and south poles, it is difficult to assess claims of practitioners that north and south poles elicit opposing therapeutic effects. As we begin to systematically investigate all aspects of magnetotherapy, it is important that an accurate description of the magnetic polar configuration be provided in order to evaluate every component of SMF dosimetry in clinical studies. We recommend the following naming convention. When a magnet is freely suspended in air, the side of the magnet that points (approximately) toward the earth's geographic north pole should be labeled the north pole of that magnet and correspondingly, the side of the magnet that points towards the geographic south pole should be labeled the south pole of that magnet. A pole may also be described in terms of its relationship to a compass.

An example of a complete description of the magnetic polar configuration used in a study of magnetic mattress pads in patients with fibromyalgia follows:

> *Example*. "Each pad contained 270 domino-shaped ceramic pieces, measuring 2.0 × 4.5 × 1 cm. The ceramic pieces were placed 4 cm apart and arranged in a pattern of 15 rows across and 18 rows down….The ceramic pieces were magnetized with a surface field strength of 1,100 ± 50 G. With this surface field strength and the positioning of magnets in the pad, it is estimated that between 200–600 G is delivered to the skin surface at various anatomical sites. Unidirectional magnets were placed such that the field direction facing the body attracted a north-seeking compass needle" (Colbert et al. 1999).

2.1.3 Magnet support device

The supporting device that contains the permanent magnet influences the SMF dosage delivered to the target tissue(s) in two ways; by how securely it adheres the magnet to the skin and how much it increases the distance between the magnet surface and the target tissue(s). The following examples provide clear descriptions of ways that magnet support devices may be applied and how the material thickness of the support may or may not increase the distance between magnet and target tissue.

> *Example 1* is taken from a study assessing SMFs for controlling the pain of dysmenorrhea (Eccles 2005a, b). "The LadyCare (LC; Bristol, UK) magnetic device is designed for attachment to the underwear by

magnetic force. LC is plastic-coated and is comprised of two parts. The pear-shaped piece is worn inside of the ladies' underwear, directly against the pelvis. The LC contains a magnet within the pear-shaped piece. The second part is a circular plastic case that contains another magnet, with a stainless steel directional plate adherent to its outside. The second part is positioned on the outside of the underwear".

Example 2 is taken from a study of wound healing in post suction lipectomy patients (Man et al. 1999). "All magnetic patches were placed on the skin overlying the areas that had been suctioned, with various sizes and shapes of magnets used so as to best fit the area being treated. All patches were fixed with compressive dressings".

2.1.4 *Timing, frequency, and duration of permanent magnet application*

Our critical review of SMF dosing parameters revealed that the frequency and duration of magnet application vary enormously (Colbert et al. 2007). Magnets have been applied both intermittently and continuously. Protocols involving one time magnet applications were conducted (Vallbona et al. 1997; Chaloupka et al. 2002; Carter et al. 2002), as well as applications at a frequency of 3 days per week (Collacott et al. 2000), continuous application for 4 months (Weintraub et al. 2003), and night time use only for 6 months (Alfano et al. 2001). Duration of magnet application also varied from 3 min (Chaloupka et al. 2002) to 45 min (Vallbona et al. 1997; Carter et al. 2002; Reeser et al. 2005), 4 h (Wolsko et al. 2004), 1 week (Segal et al. 2001), 4 weeks (Brown et al. 2002), 4 months (Colbert et al. 1999; Weintraub et al. 2003), and 6 months (Alfano et al. 2001).

Precisely, when during the course of an injury or illness the magnet is applied, appears to critically affect outcomes. When Man et al. (1999) applied a magnetic pad over the site of suction lipectomy, immediately after the surgical procedure, they observed a significant reduction in post-operative pain. Quite the opposite occurred, when the magnet application was delayed until postoperative patients had already awakened from their anesthesia, no pain reduction was observed (Cepeda et al. 2007). Borsa and Ligget (1998) also observed no response when magnet application was delayed for 24 h after inducing a biceps microinjury. The reported negative outcomes in these latter two clinical trials might be explained by findings from a recently published animal experiment. To test whether an SMF could reduce edema formation, histamine was injected into rats' hind paws (Morris and Skalak 2008). A permanent magnet was applied at one of three time points: just prior to histamine injection, just after histamine injection, or when edema formation was at its maximum. The researchers found a 20–50% reduction in edema formation only when the magnet was applied just after histamine injection. Edema formation was not significantly reduced if the magnet was applied either before the histamine injection or when edema formation was at its maximum.

2.2 Sham control magnetic devices

Use of sham or placebo controls is necessary in experimental studies to avoid systematic biases that might result from differences in the perceived or desired effectiveness of treatments. In pharmacologic trials, a placebo pill is generally used as the control. In trials of non-pharmacological interventions, the control treatment may be a sham device that is similar in appearance to the active device, or another active comparator treatment, or usual care or a wait list (Boutron et al. 2008). If usual care is to serve as the control, the precise components of "usual care" must be defined and must include provision of the same amount of personal attention given to trial participants in the active magnet group. A waitlist control simply means comparing outcomes in participants who are wearing an active magnet with people who are enrolled in the study but waiting to receive a magnet. The expectations of people in the waitlist control group are likely to impact outcomes.

Using a sham control device is more scientifically rigorous than comparisons with a usual care or a waitlist control group. Finding a device that looks and feels like a magnet but does not exert a physiological effect, however, is problematic. Magnet studies have typically employed either non-magnetized metal disks similar in appearance to the active magnets or low strength magnets. The trouble with a non-magnetized disk is that the lack of magnetic properties is easily detectible if a curious participant chooses to test his/her magnet with a paperclip.

Lower strength magnets, with enough magnetism to pick up a paperclip, serve as believable sham controls. Yet, results using these devices may be questionable because we do not yet know the minimum SMF strength that exerts a physiological effect. Segal et al. (2001) compared the effects of a ~1,900 G active magnet to a ~720 G "control" magnet in patients with rheumatoid arthritis of the knee. Participants wore the magnets, at home, continuously for 1 week. The researchers' intent in choosing the ~720 G magnet as a sham control was to enhance participant blinding by convincing participants of its magnetic properties, in case they intentionally or unintentionally, tested their device. Both the active and sham groups experienced statistically significant improvement on the WOMAC pain scale. In retrospect, the authors questioned whether the

sham control, rather than being physiologically inert as they had assumed, was actually an active intervention and that they had in fact conducted a dose ranging rather than an efficacy study.

A believable sham control device was developed by Wolsko et al. (2004). A low strength array of magnets was sewn into a knee sleeve for treating patients with knee osteoarthritis. The magnet array was shielded in such a way that the magnetic field was directed away from the knee, but if participants tested the exterior of the knee sleeve, the device would attract a paperclip. If the paperclip was exposed to the inside of the knee sleeve, there would be no attraction. Two potential problems are identified in this situation. Although most of the magnetic field was directed away from the knee and there was no measurable magnetic field directly under the magnet, some magnetism would be expected to overflow the edges of the magnet and possibly affect important trigger points and/or acupuncture points on the skin around the knee. The second problem is that participants were required to wear a knee sleeve for a period of 6 weeks. Donning and doffing a knee sleeve daily might be inconvenient for some people. Also the knee sleeve itself may have some therapeutic effect that could not be easily separated from the effect of the magnet.

An active comparator, such as a copper bracelet that is marketed commercially as having therapeutic benefits, has been suggested for use as a control device (Richmond 2008). However, the same concerns as with the low strength magnet apply. Until that so-called ineffective comparator is proven conclusively to have no effect, it should not be used as a control. We are currently planning a study in which we will compare the effects of a 2,000 G magnet, a 75 G magnet and a non-magnetized metallic disk for treating knee osteoarthritis pain. We have determined a priori that the 75 G magnet will only be used as a control device if its effectiveness is no more than 15% better than the non-magnetized disk.

2.3 Blinding procedures

Lack of blinding may be associated with biased estimates of treatment effect. It is therefore imperative that even though it may be impossible to assure complete participant blinding, the investigative team in an SMF study must be strictly blinded, including the principal investigator, personnel who are dispensing and retrieving the magnets, those collecting data and those analyzing results.

It must be acknowledged that concealing allocation assignment from both participants and study personnel in SMF trials is complicated because magnetic properties are easily detected if the device happens to come in contact with any ferromagnetic materials. Also patients who are most likely to try SMF therapy or be enrolled in SMF clinical trials generally have chronic painful conditions. These conditions require lengthy treatments (up to 6 months) in unsupervised settings, making it extremely difficult to maintain the blind because of many opportunities to intentionally or inadvertently discover a device's magnetic properties. To get around this problem, we devised a blinding strategy which, thus far, appears to be reasonably successful (For detail, see Colbert 2006–2009). There are two components of our strategy. First, we partially blinded participants to the study hypothesis. Although our trial is an effectiveness study, comparing two different strength magnets to a non-magnetized disk, we told participants that we are conducting a dose ranging study to determine which of three strength magnets offers maximum benefit. We told participants they would receive one of three different strength magnets. We did not tell them that they had a one in three chance of receiving a non-magnetized metallic disk. This type of "participant deception" may be frowned upon by some, but has been exemplified by the CONSORT committee as a "creative solution" to blinding in non-pharmacological trials (Boutron et al. 2008).

The second strategy we used was to minimize opportunities for the participant or the study personnel to handle the magnet. The research assistant who dispensed the magnet and instructed participants in its application was not permitted to handle the magnet. The participant's magnet was stored in a Styrofoam mold in a $3'' \times 6''$ plastic container. When in its container, magnetic properties of the device could not be discovered. The study coordinator used a demonstration device to show the participant how to apply his/her device. This was done on a metal-free examination table. The participants were instructed to only wear their device during sleep and to keep the magnet in its Styrofoam mold and box at all other times. These strategies have achieved successful blinding in 74% of our study participants to date.

In non-pharmacological trials such as SMF therapy, success of blinding should be evaluated with a post-treatment questionnaire administered to the participants and the study personnel. Researchers are still working on how best to deal with some of these sham control and blinding challenges. In the meantime, authors should report how they have handled them in order to allow progress in understanding these potential biases.

3 Summary and conclusions

Static magnetic field therapy delivered via permanent magnets is commonly practiced among the general population who seek advice regarding its safety and effectiveness. Before medical personnel and/or the research

community can recommend or discourage the use of permanent magnets, rigorous controlled trials to assess SMF efficacy need to be carried out. The methodology used in many previous individual studies and systematic reviews of SMF therapy for humans has been seriously flawed. When conducting and reporting SMF therapy trials, careful reporting of SMF dosing parameters, including a delineation of the precise target tissue(s) with full characterization of the permanent magnet that is applied, is essential. Complete details of the dosing regimen must also be reported to document when, how often, and how long the magnet was worn. Preliminary, Phase I and Phase II dose ranging trials are recommended to optimize SMF dosimetry. Preliminary studies are also recommended to confirm the presumed non-physiological effect of the sham control device to be used. Participant adherence to the treatment protocol should be recorded so as to document as closely as possible the total SMF exposure in each individual participant. It is only with this type of scrupulous reporting that we will be able to critically appraise the validity and applicability of trial results and be able to replicate promising studies.

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