

# HealthWatch Prize

## for the critical appraisal of clinical trials protocols

Each of the following four pages contains a protocol for a hypothetical clinical trial. Read these protocols carefully, and rank them in order of quality - that is, **give the rating 1 in the box opposite the trial that you consider is most likely to provide a reliable answer to the stated aim of the trial, and 4 to that least likely to do so.**

<b>Title of trial</b>	<b>Rating</b>
<b>Biomagnetic necklace for treatment of headache</b>	[     ]
<b>Dietary treatment for osteo-arthritis</b>	[     ]
<b>Ciliary muscle strengthening for long sight</b>	[     ]
<b>Lotion for spot reduction of subcutaneous fat</b>	[     ]

On a single separate sheet of A4 paper type not more than 600 words to explain your reasons for assigning these ratings. This requires you **to identify flaws in design** of the protocols, so, if the trial was carried out, the conclusion could not be firmly established.

If a protocol is fatally flawed say so: if has minor remediable flaws indicate how it could be improved.

**NB. You are assessing the quality of the protocol, not the desirability of the aim. Each protocol starts (as it should) with a "Scientific background" summarising previous relevant research.**

**Entrants should assume this is work correctly cited from good peer-reviewed journals.**

**Enter below your own particulars: do not put any identification on your typed sheet. Return this sheet and your typed sheet *before 31<sup>st</sup> July 2002* to**

**Dr Joan Gandy, PO Box 246, Pinner, Middx, HA5 3WD**

Do not return the protocols. Your typed sheet and this sheet will be assigned code numbers, and the typed sheet only will be sent to the judges who will be blind to your identity and training course.

Name and postal address: .....

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.....telephone.....email.....

College and course on which you are registered

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**Member of staff who can confirm that you are a registered undergraduate student**

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Signature of entrant ..... Date .....

# **Biomagnetic necklace for treatment of headache**

## **Scientific background**

The manufacturer of the necklace has numerous personal testimonials from satisfied customers, but there has been no formal controlled trial of its ability to reduce the frequency or severity of headaches. The rationale for the treatment is that the necklace generates a magnetic field that prevents excessive energy flow from the body to the head, which is a common cause of headache.

## **Aim of investigation**

To show that the magnetic field from the necklace reduces the frequency / severity of headaches in susceptible people.

## **Methods**

Volunteers (age 18-60 years, not on routine medication, with normal blood pressure and in good health) who have frequent headaches will be recruited by newspaper advertisement. They must keep a headache diary for 4 weeks, recording the time of day, severity and duration of headaches. Those who record fewer than 10 headaches, each lasting at least 30 minutes, in this period will be excluded. At least 10 headaches / 4 weeks from 25 participants would be needed to detect a 50% reduction in headache severity and duration ( $p < 0.025$ ).

When 30 volunteers (to allow for drop-outs) meeting these criteria have been recruited each one will be sent two necklaces, one gold and the other silver. One of the two (randomly distributed between the colours, and unknown to the participant) will be a standard biomagnetic necklace, and the other will be a necklace that has been passed through a high-frequency electric field that will have destroyed the magnetic field. However the weight, appearance, etc. of the necklace will be unchanged.

A covering letter will explain that the purpose of the study is to see which of the two types of necklace is more effective, and the participant will be allowed to keep, without charge, the preferred necklace. Also enclosed will be a pre-printed diary for 4 weeks, colour coded to show which colour of necklace should be worn on each day. Each colour will be scheduled for the same number of days, but the sequence will be random, and different for each subject. This diary form, and the less desired necklace, will be returned at the end of the test period.

## **Analysis and interpretation**

The returned necklaces will be tested to check if they are active or inactivated, and the diary forms examined to extract two end-points for each necklace-colour: the total number of headaches, and the total duration of headaches in the test period. The frequency and duration of headaches while wearing the gold, or silver, version will be compared by two-tailed t-test with the corresponding value in the baseline diary without any necklace. If the value is lower in the test than baseline periods ( $p < 0.05$ ) for the active, but not for the inactive, necklace the aim will be achieved.

## **Dietary treatment for osteo-arthritis**

### **Scientific background**

A daily oral supplement of glucosamine (a component of cartilage) stops the loss of cartilage in the knees of patients with osteoarthritis (OA), while patients on placebo lose 0.1 mm joint space annually. Calf's foot jelly (CFJ) is a traditional remedy that also contains components of cartilage. Mackerel paste (MP) contains a similar amount of protein, but not components characteristic of cartilage.

### **Aim of investigation**

To determine the effect on the progression of OA (measured by serial radiography) of dietary treatment with CFJ, with MP as a control treatment.

### **Methods**

Patients attending a hospital outpatient clinic, aged >50 years, with primary OA of knee, who consent to enter the trial (that has been approved by the hospital ethical committee), are randomly assigned to either CFJ or MP. The allocation code is in sealed opaque individual envelopes that are opened after consent has been given. Power calculations based on previous research indicate that 60 patients are required in each group, with a follow-up period of 12 months

On admission to the trial baseline radiographs are made, and the patient is issued with one month's supply of CFJ or MP in sealed containers. Subsequent supplies are collected monthly from the hospital dispensary or, if more convenient for the patient, from their GP's surgery. At the time of collecting new supplies the patient returns the old container, and also brings a urine sample for analysis. Both CFJ and MP contain a tracer dose of lithium chloride that equilibrates with total body water, so the lithium/creatinine ratio in urine reflects the compliance in taking the treatment.

Every 3 months patients attend the outpatient clinic for clinical examination and radiology of knees. Limitation of movement and pain are recorded on separate linear analogue scales.

### **Analysis and interpretation**

The primary outcome measures are joint-space narrowing, limitation of movement, and pain. These measures are scored by a radiologist and rheumatologist who are blind to the treatment allocation. The scores are analysed for patients who complete the protocol in each group, and also on an intention-to-treat basis for those who do not complete, or whose lithium / creatinine excretion indicates that they did not comply with the protocol.

If the scores are significantly better in the CFJ group than the MP group the conclusion is that the chosen dosage of CFJ improves the outcome of OA over a 12 month period.

## **Ciliary muscle strengthening for long sight**

### **Scientific background**

In a normal person the relaxed eye focuses on distant objects. To focus on near objects (eg. in reading print) the ciliary muscle contracts and makes the crystalline lens more convex. Children who have difficulty with reading are sometimes given reading spectacles which help, but the ciliary muscles are not exercised, and hence do not develop their proper strength. An instrument is proposed to avoid this problem.

### **Aim of investigation**

To determine if exercising ciliary muscles improves accommodation.

### **Methods**

Children who are referred to an ophthalmic department for reading glasses will have their accommodation measured by determining the nearest point (NP) at which they can read a given line of Snellen type. They will be offered a trial of an alternative management by exercises, rather than by glasses.

The exercise is provided by an optical box in which there is a screen that is 35 cm from the eyepieces through which the child views a videotape of his/her choice. However, by a system of mirrors the optical path from the child's eye to the screen can be varied from 35 cm to 4 m, but the screen image remains the same size. Initially the viewing distance is set at 4 m, by positioning the mirrors so the tape can be viewed with the eye relaxed. However, in later sessions the NP viewing distance is altered by moving the mirrors. The mirrors are automatically switched in and out of the optical path, so the videotape (which runs for 30 minutes) is then viewed alternately at 4 m and at the newly-set NP. Thus, to see the image, the child must focus on a closer plane every 2 minutes, and then relax again, during the projection of the videotape. In successive sessions the NP setting is reduced at a rate dependent on the progress of the child.

Pilot studies with this instrument indicate that after 20 weekly sessions almost all children have reduced the NP at which they can read the baseline Snellen type line, and some children achieve normal accommodation (ie. can read the line at 35 cm without glasses).

For the purposes of this research the NP for reading among the children who have completed a course of exercises will be compared with that of a control series of children, matched for age and refractive error, who have been given reading glasses.

### **Analysis and interpretation**

If the NP of children treated with exercise is significantly less than that of matched controls who were prescribed glasses, this will show that exercising ciliary muscles improves accommodation.

## **Lotion for spot reduction of subcutaneous fat**

### **Scientific background**

The deposition and remobilisation of triglyceride (fat) in adipose tissue is under hormonal control. Release of fat is achieved mainly by the action of tissue lipases in fat cells which split the triglyceride and release fatty acids into the bloodstream. The hormones adrenaline and noradrenaline activate these tissue lipases. This does not affect the total body fat, but makes it possible to remove fat deposited locally, which will be resynthesised elsewhere.

### **Aim of investigation**

To test the ability of a lotion containing a synthetic noradrenaline analogue to remove fat from a subcutaneous depot.

### **Methods**

Women will be recruited from local slimming clubs who are particularly concerned to lose fat and/or "cellulite" from their thighs. (Cellulite is a name given to a dimpled "orange peel" appearance, due to subcutaneous fat in a matrix of fibrous connective tissue). They will sign a form to consent to a trial in which they will apply the test lotion containing the hormone to the anterior surface of one thigh, and a control (the same lotion, but without the added hormone) to the other thigh, daily for six weeks. Photographs of both thighs in a standard position (seated with thighs horizontal, camera 1 m above anterior surface of the thighs, lighting from the side to display skin texture) will be taken at the start and finish of the trial period. At the completion of the trial the participants will be eligible to receive a 6 month supply of the lotion without charge.

### **Analysis and interpretation**

The pairs of photographs (baseline and post-trial) will be examined independently by two judges, who do not know, for each participant, which thigh was treated with the hormone or the control lotion. The picture-pairs will be rated R, L or O, if the judge considers that the right, left, or neither thigh show a reduction in fat or cellulite.

These judgements for each judge will be converted into a score of +1 if the thigh treated with hormone was judged to be more reduced, O if neither was reduced, or -1 if the control thigh was more reduced. The scores will be added together.

If the total score of the judges is  $>1$  this will indicate that the lotion containing the hormone analogue was more effective in removing fat and/or cellulite than the control lotion.