HealthWatch Prize (2007)
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.**

Title of trial	**Rating**
New boot design to prevent foot injury in army recruits	**[ ]**
Sage to alleviate menopausal flushes	**[ ]**
Acupunture in labour	**[ ]**
Chinese herbal cream for weight loss	**[ ]**

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 reliable sources.

Enter below your own particulars: do not put any identification on your typed sheet.
Return this sheet and your typed sheet *before 31st July 2007* 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: ……
……
……Post code……
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
……

Signature of entrant …….. Date …….

How did you find out about the prize?.....

HEALTHWATCH PROTOCOLS 2007

NEW BOOT DESIGN TO PREVENT FOOT INJURY IN ARMY RECRUITS

Scientific Background

The army marches on its feet, literally. Regular army boots cause considerable foot problems in their first month of usage. Recruits suffer from damaged toe nails and skin blistering often severe enough to stop training. A new boot has been designed with a soft leather toe insert and cushioning of the heel. It is thought the new boot will result in fewer lost training days due to foot injury.

Aim

To determine if the new boots result in fewer foot problems and less loss of training than the boots currently in use.

Methods

All the recruits joining the Welsh Guards, the paratroopers and the Calvary over a twelve month period will be enrolled in the study. Approval by the respective regiment's commanding officers has been obtained.

In the first six months of the study all new recruits will be issued with the existing boots, in the second six months all will be issued with the new boots.

At the end of the study period the number of days lost in training due to foot problems will be calculated by collecting data for missed training sessions from the sergeant majors in charge of training. The recruits will be not told which boots have been issued or why the design has changed.

Interpretation

The number of days of training which were lost in each study period will be calculated. If there are fewer days lost in the period that the new boots are issued it will be evidence that these new boots are better than the existing design.

HEALTHWATCH PROTOCOLS 2007

SAGE TO ALLEVIATE MENOPAUSAL FLUSHES

Scientific Background

Sage extract is widely thought to help alleviate the symptoms of hot flushes and night sweats in menopausal women. Since the publication of the WHI study and the Million women study which demonstrated little benefit from conventional hormone replacement therapy in terms of protection from cardiovascular disease and showed and increase in breast cancer and stroke women have sought alternative treatments.

Aim

To determine if tablets containing sage extract are beneficial in the management of menopausal hot flushes and night sweats.

Methods

This will be a multi-centred study; women will be recruited from menopause clinics in hospitals and by advertising for volunteers in GP surgeries and Women's magazines. Each centre will have a designated principal investigator and ethics committee approval will be obtained from each centre.

Potential volunteers will be interviewed over the telephone and if they fulfil the entry criteria will be invited to attend for a more formal interview and medical examination. After the woman has given informed consent (and signed a consent form) she will be randomly allocated to receive either one tablet of sage extract (400mg tablet which is equivalent to 2000mg whole leaf) or placebo daily for six months. Neither the volunteer nor the investigator will be aware which preparation is being taken. In the first month no medication is taken but a diary card is kept in which is recorded a daily record of hot flushes and night sweats. The tablets are taken for the next six months; the volunteer is reviewed at 1, 3 and 6 months after the start of tablet taking when the diary card will be reviewed and a blood sample taken for serum sage levels. The women will be asked not to take any other preparations for menopausal symptom relief during the study period.

Interpretation

The analysis will be performed centrally by an independent scientific group. The randomisation code will be broken and by analysis of the blood samples compliance with the medication can be checked. Women who did not take the sage tablets when they were allocated to do so will be excluded from the analysis as will women who test positive for sage if they were in the control group. The diary cards will be studied and by comparing the number of hot flushes/night sweats a week during treatments as compared to baseline it will be determined if the sage extract was effective in reducing these menopausal symptoms.

HEALTHWATCH PROTOCOLS 2007

ACUPUNTURE IN LABOUR

Scientific Background

If the membranes rupture before the onset of labour both mother and baby are at risk of infection. It is usual practice for labour to be induced with either prostaglandins or oxytocin if labour does not start within 48 hours of membrane rupture at term. There is some evidence that acupuncture can augment labour in women delivering at term; if so it would reduce the amount of prostaglandin or oxytocin needed in the induction of labour in these women.

Aim

To investigate if Acupuncture would reduce the amount of prostaglandin and oxytocin required to induce labour in women with ruptured membranes at term.

Methods

Women who have a singleton pregnancy at term, whose membranes have ruptured, but who have not started contracting will be invited to enter the study. 200 women are required in order to demonstrate a statistically significant difference between those who do and do not receive acupuncture. After giving consent the woman will be invited to choose whether or not she will receive acupuncture. The study will be completed when 100 women have chosen to receive acupuncture and 100 women have not received acupuncture. If labour does not start within 48hour it will be induced with either prostaglandin or oxytocin (this depends on the cervical examination which will be performed immediately prior to induction). Ethics committee approval has been sought.

Analysis

The two groups will be compared; the time from membrane rupture to spontaneous onset of contractions and the amount of oxytocin/prostaglandin required to induce labour will be compared between those women who had acupuncture and those who did not.

HEATHWATCH PROTOCOLS 2007

CHINESE HERBAL CREAM FOR WEIGHT LOSS

Scientific Background

Chinese medicine is increasing in popularity in the UK. In the Hospital in Guelin scientists have developed a cream which results in weight loss if rubbed into the abdomen once a day.

Aim

To determine if the daily administration of the Chinese cream will result in weight loss of grater than 5kg if rubbed into the abdomen daily for 8 weeks.

Methods

All women who book with Thomas Cook for the China holiday with the Guelin extension will be asked to participate. Those who accept the invitation will be invited to send their weight and the date it was recorded in a letter with their final booking confirmation. When they attend the Guelin hospital (which is included in the tour) those who have agreed to be part of the study will be given two bottles of cream. They will be asked to apply it to their abdomen and rub it in well daily for two months. The study will start when they return home (to remove bias from holiday food). After two months they will be asked to fill in the card supplied with their weight.

Analysis

It is expected that most women will return their cards. The weight they are after two months of cream use will be compared with that they were prior to cream usage. The loss in weight will demonstrate that the Chinese Herbal cream causes their weight loss.