

HealthWatch Prize (2005)

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
Autogenic training (AT) prophylaxis for asthma (<i>AT</i>)	[]
Leech therapy for osteoarthritis of knee (<i>Leech</i>)	[]
Sauna bathing for painful muscle cramps (<i>Sauna</i>)	[]
Ginseng to prevent flu in old people (<i>Ginseng</i>)	[]

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 2005* 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

How did you hear about this competition?
.....

Autogenic training (AT) prophylaxis for asthma

Scientific background

Autogenic training is a system developed by Luthe (1962) which combines relaxation and autosuggestion to enable an individual to cope with stressful situations. It has been shown to be effective in reducing anxiety, high blood pressure, pre-menstrual syndrome, migraine and asthma. Severe asthmatic attacks are common among young adults with learning difficulties and/or behaviour disorders who work in a secure unit. Many of these are on psychotropic medication that reacts badly with the usual bronchodilators given to treat acute asthma. There have been two deaths arising from these interactions in the last 8 months.

Aim of investigation

To see if AT enables vulnerable people to avoid asthmatic attacks in a situation in which conventional treatments for asthma are dangerous.

Methods

Greendale farm is a secure unit that provides vocational training for young adults with learning / behavioural disabilities. Two large workshops provide training in either bookbinding or wooden furniture manufacture for 47 students. They are supervised by staff who are trained both in the relevant vocational skills and also in the care of young adults with behaviour disorders. However there is a very high incidence of asthmatic attacks among the students. It was believed that these related to inhalation of synthetic resin adhesives used in the workshops, but installation of a state-of-the-art fume extraction system has not decreased the frequency of attacks. Also, it has been noted that when one student in a workshop has an attack this triggers attacks in several adjacent students in the same workshop.

AT training has been shown to reduce the frequency and severity of many stress-related disorders. It is therefore proposed that all students should attend group sessions led by a professional autogenic tutor twice a week for 5 weeks. They will learn to relax, rather than become more tense, if they experience symptoms of an impending asthmatic attack, or observe such an attack in an adjacent student.

Analysis and interpretation

We have detailed health records for each student since the training workshop opened 5 years ago. These record "primary" asthmatic attacks (those in which the student was the first to be affected) and also "secondary" attacks (those which followed within 30 minutes of an attack in another student in the same workshop). The health records following AT will be compared with those before AT to see if there is a significant decrease in the frequency and/or severity of each type of attack.

Leech therapy for osteoarthritis of knee

Scientific background

Osteoarthritis (OA) knees is a common disabling condition. There is inflammation in the surrounding soft tissues and destruction of the articular surfaces of the joint. Analgesics and anti-inflammatory drugs relieve pain and improve function, but there are significant side effects from long-term drug treatment, so it would be valuable if long-term control of symptoms could be achieved by non-drug treatment. The saliva of leeches contains hirudin (a powerful anticoagulant) and also some unidentified anti-inflammatory substances. In an uncontrolled pilot study of leech therapy applied to OA knees, pain relief was rapid, and lasted more than 4 weeks.

Aim of investigation

To compare the efficacy over 4 weeks of a single application of leeches versus topical diclofenac gel in relieving pain and improving function in OA knees.

Methods

The trial was approved by the local ethics committee. Patients attending an arthritis outpatient clinic will be eligible for the study if they have radiological evidence of OA in a knee, no evidence of rheumatoid arthritis, no recent surgery or injections in the knee, normal blood clotting and ESR, and a pain score greater than 40 (out of 100 maximum) on the WOMAC visual analogue pain and mobility scale. Those who give written informed consent to the study will be randomised to leech (L) or diclofenac (D) treatment groups by serially numbered opaque sealed envelopes which, when opened, gave the randomised treatment allocation. The (L) group will have 5 leeches applied to the affected knee as in the pilot study. The (D) group will be given tubes of diclofenac gel and shown how to apply it at least twice daily for 28 days. Use of the gel will be measured by weighing the used tubes. The WOMAC scores and any adverse effects will be recorded in the clinic one day, 7 days, 14 days and 28 days after treatment by a nurse who is blinded to which treatment a patient received.

Analysis and interpretation

The primary outcome measure is change in WOMAC score from baseline to 7 and 28 days after treatment. A difference of 10 points between the two treatments groups is considered clinically important. On the basis of the pilot study, a sequential study has been designed with 80% power to detect this difference with a 2-sided error of 5%, or a conclusion that there is no difference of this magnitude, in a maximum of 60 patients. Since there are about 4 eligible patients per week seen at the clinic it should be possible to complete the study in 15 weeks.

Sauna bathing for painful muscle cramps

Scientific background

The cause of painful nocturnal muscle cramps is not well understood. It is likely that the pain arises from ischaemia of the muscle when it goes into spasm. When the muscle contracts the blood supply is reduced, so metabolites which maintain the contraction accumulate in the muscle. Sauna bathing causes extensive relaxation of blood vessels and flushing out of these metabolites. Quinine is often recommended as a cure for cramps, but the mechanism of action is unclear: it acts on the nervous system rather than the blood vessels, and is often ineffective.

Aim of investigation

To assess the prevention of night cramps achieved by sauna bathing for 15 min at 60°C three times per week, compared with one oral dose of 300 mg quinine dihydrochloride at bedtime. Since the two treatments are aimed at different systems (either vascular or nervous) it is hoped that the outcome of the trial will throw light on the aetiology of the cramps.

Methods

The trial was approved by the local ethics committee. Volunteers will be recruited from a health centre that has four full-time general practitioners. Each patient complaining of night cramps will be referred to a physiotherapist who will record the frequency and severity of cramps. If the cramps occur at least once a fortnight the GP will tell the patient what is involved in either sauna or quinine therapy, and obtain his/her informed consent to participate. The next patient will be offered the other therapy, so the numbers in each group will be balanced. The physiotherapist will see all patients every fortnight at the surgery so the incidence of cramps, and their severity (on a scale of 1-5) will be reviewed. Patients in the sauna group will be issued with a passbook that entitles them to three free sessions per week for 8 weeks at a local spa. A trainer at the spa will record that they have had the prescribed therapy. The quinine group will receive a two-week supply of quinine tablets at each visit, and their compliance will be checked by counting unused tablets.

Analysis and interpretation

Data on patients who have completed the full 8 weeks will be analysed. The cramp score at 2, 4, 6 and 8 weeks will be compared with baseline, and the change in the sauna group will be compared with the change in the quinine group.

Ginseng to prevent flu in old people

Scientific background

Panax ginseng is extracted from the root of a Chinese perennial herb that has for centuries used as a cure-all: the name *Panax* means cure-all, as in "panacea". There are no reported adverse effects to a dose of 750 mg dry extract twice daily which reduces inflammation and strengthens immune responses. There has been no controlled trial of its efficacy against acute respiratory viral infections such as influenza or respiratory syncytial virus (RSV). In residential homes for the elderly winter epidemics of flu or RSV infections are common and serious. It would be very valuable to increase the resistance of these residents to acute viral infections.

Aim of investigation

To observe the incidence and severity of acute viral infections in residents who are given capsules of *Panax ginseng* 750 mg twice daily from October to March, compared with a control group who are given similar appearing placebo capsules.

Methods

Only care homes that cater for mentally competent residents will be approached. Pre-coded active and identical looking placebo capsules are supplied by the manufacturer. Thirty residents will be recruited and assigned to either the active or the control group. However, neither residents nor carers will know who receives ginseng and who placebo capsules. If asked, the carers will say it may contain a herbal mixture to help them keep well during the winter. A General Practitioner who provides medical cover for the home, and who also is "blind" to the contents of the capsules, visits weekly, and will assess the incidence and severity of viral infection in the residents involved in the trial and record this in a log book, together with the code number of the capsules given to that resident. If any resident dies, or ceases to take the capsules for any reason, or changes other medication in a way (such as systemic steroids) that is likely to affect immune status, this also will be recorded. At the end of March the GP will prepare a summary sheet ranking the severity of viral infections among the residents who completed the trial but, to preserve confidentiality, individuals will be identified only by the code number of the capsules taken.

Analysis and interpretation

At the end of the trial a representative of the manufacturers will visit the home and exchange a copy of the code indicating the contents of the capsules for a copy of the summary sheet of viral infections. These two documents will then be sent to an independent statistician for analysis.