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.**

Title of trial	**Rating**
Acupuncture for chronic low back pain *(Acupuncture*)	**[ ]**
Tai Chi Chuan and balance in elderly people *(Tai Chi)*	**[ ]**
Antenatal hypnosis training for pregnant teenagers *(Hypnosis)*	**[ ]**
Chelation therapy for stable ischaemic heart disease *(Chelation)*	**[ ]**

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 31st July 2003* 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
……..
Signature of entrant …….. Date ……

Acupuncture for chronic low back pain

Scientific background

Acupuncture to traditional body and ear points has been shown to be very effective in the treatment of non-radiating chronic low back pain (NRCLBP) with normal neurological examination. However, it is not clear if this benefit arises from a placebo effect of needling, or if puncture at the traditional sites (which are on energy meridians) is superior to sham acupuncture at other sites.

Aim of investigation.

To see if acupuncture gives better pain relief in NRCLBP than sham acupuncture, or routine physiotherapy.

Method

We will recruit from the hospital outpatient orthopaedic clinic patients with NRCLBP for at least 6 months. Those who give informed consent to enter the trial will have a full neurological examination and radiology of the spine to ensure that there is no malignant or degenerative disease in the spine. Patients who are diabetic, on a non-steroidal anti-inflammatory drug, or over the age of 70 years will be excluded. We expect to recruit 60 patients who meet these entry criteria. These will all receive routine physiotherapy over 12 weeks. They will also be randomised to three treatment groups: controls (no further treatment); acupuncture (20 sessions at traditional points); and sham acupuncture (equal amount of needling at points off the energy meridian). The last two groups will not know whether they have received traditional or sham acupuncture. Adverse events and use of analgesic drugs will be monitored during the trial.

Efficacy of treatment will be assessed by the assessment at baseline, and after 3, 6 and 9 months, of pain (by visual analogue scale), disability due to pain, and spine flexion by standard validated tests. These tests will be performed by staff blinded to the treatment group of individual patients.

Analysis and interpretation

The null hypothesis is that there will be no significant ($p<0.05$) difference between the three intervention groups. If the true acupuncture group shows better pain relief than the control group it will show that needling, added to standard physiotherapy, improves the outcome. If the true acupuncture group shows better relief than the sham acupuncture this will show that needling at the traditional points is better than needling at points away from the traditional energy meridians.

Tai Chi Chuan and balance in elderly people

Scientific background

About 30% of people over 65 years old sustain a fall, and this often leads to hip fracture and severe disability. Tai Chi (shadow boxing) is widely practised in China and has been shown to cause both physical and spiritual benefits, especially in old people. It has been noted that regular practitioners of Tai Chi seldom suffer falls and hip fractures in old age, probably because they have good muscular coordination and a calm personality.

Aim of investigation

To see if the mental and physical stability and co-ordination of people regularly practising Tai Chi is better than that of age- and fitness-matched controls who do not practice Tai Chi.

Method

Volunteers aged 65-80 years will be recruited who have attended sessions lasting 30 minutes at least twice weekly for 2 years at a well-established Tai Chi school on the outskirts of Birmingham. This is led by a master who has a thorough understanding of the philosophy of Tai Chi. Control subjects, matched for age, gender, fitness (assessed by pulse rate during a standard step test) and duration of regular attendance will be recruited from a neighbouring keep-fit class led by a qualified physiotherapist with no knowledge of Tai Chi. Measurements of static postural stability, dynamic balance and muscular co-ordination will be made in the Birmingham hospital rehabilitation unit by staff who are blind to the treatment group of the subjects being tested. Mental state of participants (especially confidence and anxiety) will be assessed by the Minnesota questionnaire: the completed forms will be sent for scoring to the hospital Department of Clinical Psychology. All the forms (identified only by a code number) will be scored independently by two clinical psychologists who are blind to the treatment group.

Analysis and interpretation

The 5 major endpoints (postural stability, dynamic balance, muscular co-ordination, confidence and anxiety) will be compared within each pair of Tai Chi and control, and the results analysed by a sequential design. For each end-point, in each test-control pair, the result will be scored positive if the test individual scores better, negative if the control scores better, and the result is discarded if the two are exactly equal. With this design to reach a significant result ($P<0.05$) will require a minimum of 7 and a maximum of 48 pairs to reach the top boundary (Tai Chi better) the middle boundary (no significant difference) or the lower boundary (control better). The hypothesis will be supported if at least 3 of the 5 end-points reach the upper boundary.

Antenatal hypnosis training for pregnant teenagers

Scientific background

Hypnosis has been shown to be effective in reducing anxiety and permitting muscular relaxation in conditions such as phobias. Excessive muscular tension and anxiety are among several explanations for the difficulties in labour experienced by teenagers, since psychosocial factors cause them to approach delivery with greater apprehension than that of more mature women. It is therefore reasonable to hypothesise that antenatal training in self-hypnosis and visualisation techniques would reduce the complications of delivery among teenage mothers.

Aim of investigation

To determine if antenatal training in self-hypnotic techniques improves outcomes during labour and delivery.

Method

Pregnant women are eligible for the trial if they are aged 18 years or less at conception, nulliparous, come for prenatal care before week 24 of a normal pregnancy, and give informed consent to be randomised to one of two antenatal training programmes. Baseline data for each entrant to the trial will be transmitted by e-mail to a trial control centre in a different hospital, which then replies with the group allocation from a randomised sequence. Each programme involves four meetings, starting between week 20 and 24, and completed by week 34. The test group receives instruction on self-hypnosis and its use in labour and delivery, and how to respond to complications and stress. The control group receives standard prenatal counselling from the midwife, and may discuss concerns related to their pregnancy. The groups have an equal amount of contact with the counsellors, who are the same staff who will be present during their delivery, so they will regarded the labour-room staff as friends rather than strangers.

The main outcome measures are medication prescribed during labour and delivery, complications and surgery during delivery, and length of stay in hospital for the mother, or in the intensive care unit for infants, and the overall cost to the hospital for the delivery.

Analysis and interpretation

If the group who were given training in hypnosis use less medication, have fewer complications, a shorter hospital stay and less cost to the hospital, this will show both direct medical and economic benefits from self-hypnosis training before delivery.

Chelation therapy for stable ischaemic heart disease

Scientific background

Ethylene diamine tetraacetic acid (EDTA) binds strongly to toxic heavy metals (such as lead), and the resulting compound is excreted rapidly by glomerular filtration. Intravenous infusion of EDTA is a standard treatment for heavy metal poisoning. It has also been advocated for the treatment of coronary heart disease or peripheral vascular diseases, in which the vessels are partially blocked by calcified fibrinous deposits, but no well-designed trials have been reported to assess the value of this treatment.

Aim of investigation

To determine if chelation therapy improves ischaemia and the quality of life of patients with stable ischaemic heart disease.

Method

Patients will be recruited from the cardiology outpatient clinics at four teaching hospitals in London. Men over 45 years with stable angina will be assessed by ECG, exercise testing on a treadmill, and coronary angiography. Requirement for entry to the trial will be coronary artery disease and calcification proven by angiography, ischaemia on treadmill testing giving at least 1 mm ST-segment depression on the ECG, and consent to randomisation to either EDTA or placebo infusion. Allocation to EDTA or placebo infusion will be by a random sequence held at a central trial control office. The infusions will be given twice weekly for 15 weeks, and then once per month for a further 3 months. To cover possible nutrient deficiencies caused by the infusions all participants will take daily multivitamin capsules. Previous anti-anginal medication will be continued.

Coronary artery perfusion will be assessed at baseline, after 15 weeks of twice weekly infusion, and at the end of the trial at 27 weeks. The main outcome measure is change in time on the treadmill to cause ischaemia (1 mm ST depression). Other outcome measures are reported angina and disability on a standard five-point disability questionnaire.

Analysis and interpretation

Efficacy of the chelation treatment will be shown if there is a significantly ($p<0.05$) greater increase within the EDTA than in the placebo group, between baseline and 15 weeks, or baseline and 27 weeks, in time to ischaemia on the treadmill, and decrease in reported angina and disability. Since the study lasts 27 weeks, in patients who have established heart disease, it is anticipated that some of those enrolled will not complete the trial. Therefore two sets of analysis will be made: a comparison between completers in the two groups, and an intention-to-treat analysis assigning zero change among those who dropped out.