

HealthWatch Prize (2006)

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
a. Hypericum for stage fright	[]
b. Reflexology for pancreatic disease	[]
c. Omega 3 supplement for intellectual development	[]
d. Magnetic therapy for low back pain	[]

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 2006* 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:

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

College and course on which you are registered

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

Signature of entrant Date

How did you hear about this competition?

a. Hypericum for stage fright

Scientific background

Concert violinists have to remain relaxed while playing very long notes requiring smooth slow bowing, but also require extreme agility both in bowing and fingering to play fast passages. With beta blocking drugs the slow passages are made easier, but at the expense of the brilliance required in fast passages. It is suggested that a preparation of Hypericum (St John's wort) prevents tension tremor in concert violinists without decreasing the brilliance of their performance.

Aim of the investigation

To see if a single dose of Hypericum perforatum (600 mg dried extract containing 0.3% hypericin) one hour previously improves the performance of violinists.

Methods

Ethics clearance was obtained from the Executive Committee of the Royal College of Music. All candidates for the Associated Boards Violin (grade 8) examination at the Royal College of Music (RCM) will be invited to take part in the trial, of which they have a written explanation. The trial is entirely separate from the examination, but a prize of £500 will be given to the best performer. Entry to the trial will be closed when 200 volunteers have given written consent to taking part.

There are two test pieces, each of 16 bars, especially composed for this trial. One ("slow") requires prolonged slow bowing, and the other ("fast") maximum agility in both bowing and fingering. With each piece there is a recorded piano accompaniment. A copy of the violin score and the accompaniment will be given to each volunteer two weeks before the trial, so they can practice the pieces. The volunteers will play each of the test pieces once in a studio with a recording engineer. One hour before playing they will take a capsule containing the hypericum or placebo, issued by the recording engineer, and this will be documented. The sequence in which they play the fast or slow pieces, or take hypericum or placebo is determined by a randomized code.

Two experienced examiners for grade 8 at the RCM will independently give a grade to each of the recorded performances of the "slow" and of the "fast" pieces, and these scores will be compared. If there are significant differences between the two examiners these will be resolved by discussion, if necessary involving a third examiner as arbitrator. The recording engineer and the examiners are blinded to the treatments and to the sequence in which the pieces are to be played.

Analysis and interpretation

When a consensus on scores is reached the randomization code will be broken, and the scores tabulated to compare each volunteer's performance after taking hypericum or placebo. The difference in scores will be tested by two-tailed t-test. If the score after hypericum is better than that after placebo ($P < 0.05$) this shows that in these test circumstances hypericum is beneficial.

b. Reflexology for pancreatic disease

Scientific background

Reflexologists believe that the well-being of internal organs is shown by the state of reflex points on the soles of the feet: specifically that disease of the pancreas is shown by tenderness at a point at the medial part of the instep, as indicated by the map created by Eunice Ingham. The pancreas contains cells that secrete insulin, failure of which leads to diabetes mellitus (DM). This disease develops slowly, and has a strong genetic component. It would be valuable to diagnose DM at an early stage so treatment (by diet and/or appropriate drugs) could be instituted before there is advanced damage to the insulin-secreting cells.

Aim of the investigation

To see if examination of the feet by expert reflexologists can detect disease of the insulin-secreting cells of the pancreas at a stage when there is no clinical sign of DM.

Methods

By definition, it is impossible to select people who have an undetectable disorder of insulin secretion, but we know that this condition is much more likely to occur in those who have a strong family history of DM than those with no such history. We therefore intend to recruit 20 people who are clinically normal, but have a strong family history of DM ("high risk") and 20 people, matched for age, gender and body mass index, who have no such family history ("low risk").

We have already recruited two experienced reflexologists who have agreed to make independent examinations of all 40 volunteers and record their diagnosis concerning their pancreatic function.

Analysis and interpretation

The analysis will be directed towards two questions.

1. Is there good concordance between the independent diagnoses of the two reflexologists? If there is not, this suggests that at least one of them is not a reliable detector of pancreatic dysfunction.
2. Is there a significant difference in the diagnoses made in the high risk, compared with the low-risk groups, by either, or both of the reflexologists? If not, it suggests that reflexology is not a reliable method for detecting pre-clinical pancreatic disorder.

c. Omega 3 supplement for intellectual development

Scientific background

Normally the main dietary source of omega 3 fatty acids is oily fish, but they can be added to milk to make a more palatable food supplement. It is claimed that this supplement improves concentration, learning and reading ages in children.

Aim of the investigation

To see if increasing the intake of Omega 3 improves reading skills in children.

Methods

Since reading skills are affected by genetic and environmental factors, as well as nutrition, the children selected as eligible for the trial will be those between the ages of 4 and 8 years, who also have a sibling in the same age range at the school. The register of the primary schools in the Norwich area have been scanned to determine the names and addresses of siblings who meet these criteria, and lists of these names will be submitted to the head teachers of the affected schools to seek permission for a trained nurse to interview the siblings, in the presence of a parent or other responsible adult. If the parent is agreeable, and if neither child in the pair has a major learning disability, or is on any medication, the siblings will be recruited. They will then be randomly allocated to one of two groups and each given a code number.

The manufacturers have offered, without payment, to supply each day for one year a bottle containing 400 ml of enriched milk and a bottle of identical looking standard milk to the doorstep of the children's home. The bottles will be labeled with the children's names and corresponding code numbers.

In collaboration with the class teacher, the nurse will be responsible for maintaining a register of the reading progress of all the children involved in the trial, and ensuring that if an event affects any child in the trial (such as prolonged absence from school), that pair of children will be withdrawn from the trial.

Analysis and interpretation

At the end of the academic year the trial will be terminated, and the reading progress of each pair of children completing the trial will be compared. If the progress of the children receiving the supplement is better than that of the control sibling this will show that increasing the intake of Omega 3 in children improves their reading skills.

d. Magnetic therapy for low back pain

Scientific background

Magnetic devices have been found to be effective in the relief of pain, and especially low back pain. Annual sales of these devices in the US are estimated to be worth \$300m, so they are certainly popular, but reports about their efficacy are conflicting. The mode of action is probably that the magnetic field permits the back muscles to relax, but this relieves pain only if the device is worn virtually 24 hours per day. A new device is now available that is a comfortable and inconspicuous magnetic belt that has been shown to relieve back pain, and which incorporates a chip that records the hours for which the belt is worn.

Aim of the investigation

To see if failure of a magnetic device to relieve back pain is explained by failure to wear the device for a sufficiently high proportion of the day.

Methods

The device is a soft flesh-coloured nylon belt 15 mm wide and 3 mm thick. It contains a layer of very flexible fine magnetized steel wires. It is fitted individually to the purchaser, and fastened with a clasp the size of a ladies' wrist-watch. This contains a chip powered by a small battery that records the temperature of the belt, and the time of day at which the clasp is fastened or unfastened. A memory chip stores the periods during which the clasp is closed and the temperature is in the range 30 to 36°C, indicating that the belt is being worn by the purchaser. The data on the chip can be read by placing a sensor onto the clasp, using technology developed for monitoring implanted electronic heart pacemakers.

At the time of purchase and fitting of the belt the customers will be provided with a daily chart on which to record the time and severity of pain experienced, and they will be asked to return in two weeks to have any needed adjustments made to the belt. At this second visit the memory chip will be read, and the time of wearing the belt will be related to the periods at which pain was experienced.

Analysis and interpretation

It is expected that the higher the proportion of time the customers wore the belt the greater would be the relief of pain. It is not necessarily expected that the timing of the pain would correspond exactly to the time of not wearing of the belt, because if they were not wearing the belt, and noticed that pain was coming on, they would be likely to put on the belt. Therefore they might be wearing the belt at a time when greatest pain was recorded.