



Registered Charity No 1003392

2019 HealthWatch student prize competition for critical evaluation of clinical research protocols

Your entry must be submitted before 23:59 BST on Tuesday 30 April 2019. Entries received after that time will not be considered.

The competition is open to all full-time undergraduate students and post-graduate students taking a taught master's course in medicine, dentistry, nursing, midwifery and professions allied to medicine. Post-graduate research students are not eligible to enter. Entries are welcome from eligible students in any country. Students in their final year of study are also eligible to enter.

Entries are judged in two classes: students of medicine and dentistry, and students of nursing, midwifery and professions allied to medicine. There is a first prize of £500 and up to 5 runner-up prizes of £100 in each class.

The competition consists of four hypothetical research protocols to be evaluated and critiqued. In devising the protocols, the judges have worked with a checklist of the various features that a good research protocol should include, and have ranked the protocols in order according to how many of these features are included.

Your first task is to rank the protocols, and the first stage of judging your entries is to compare your ranking of the protocols (in order of quality from best to worst) with this predetermined ranking. All entrants who have the correct ranking will receive a certificate of merit when the results are announced, and all will be assessed in the second stage of judging.

Your second task is to explain, in no more than 600 words altogether, your reasons for the ranking you have given, discussing each protocol in a separate paragraph. You should imagine that you are a member of a research funding body, and explain why you would award a grant to the protocol that you rank first, as well as explaining the strengths and weaknesses of each of the protocols. If a protocol is fatally flawed say so; if there are minor flaws, indicate how they could be improved. There is no need to comment on, or analyse, the statistical methods that are proposed. You are assessing the methodological quality of the protocol, not the desirability of the aim. Each protocol starts (as it should) with a "scientific background" summarising previous relevant research. You should assume this is work correctly cited from reliable sources.

Entries will first be assessed for the number of the key criteria of a good research protocol that you mention as being present or absent in each of the protocols. The protocols are each marked out of 10, and, in order to be eligible for a prize, you must achieve a score of 28 (70%) or more. For all entries reaching this threshold the judges will then consider your arguments and critique of the protocols to determine the prize winners. Prize winners will be invited to the HealthWatch Annual General Meeting in London in October to receive their prizes. Travelling expenses at student travel rates will be reimbursed; for entrants outside the UK up to £100 will



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be allowed for travel expenses. Entrants who cannot attend the AGM will have their certificates and cheques sent by post.

Submission of entries is via the HealthWatch website, and all entries are forwarded automatically to the student prize coordinator, who undertakes the first stage of judging — sorting those entries that have given the predetermined correct ranking. All entries that qualify are then forwarded to the judges with no indication of the name of the entrant. All entrants will be invited to join HealthWatch as student members, who pay no subscription, and in the summer of their graduation will be invited to continue their free membership for a further two years.

Your entry must be submitted before 23:59 BST on Tuesday 30 April 2019. Entries received after that time will not be considered: do not leave your entry until the last minute. Entries submitted after the deadline will not be accepted, and no extension to the deadline can be allowed for any reason.

The judges' decision is final, and no correspondence can be entered into. We cannot provide examples of winning entries, but examples of previous protocols and critiques will be made available in due course as part of Student HealthWatch learning resources.

The protocols are given below:

Protocol A: Health benefits of cupro-zinc insoles

Protocol B: Silflur for preventing tooth decay

Protocol C: Stimulating intellectual development using Omega 3 supplements

Protocol D: Treating rheumatoid arthritis with bee venom



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Protocol A

Health benefits of cupro-zinc insoles

Background

Copper is one of the most important elements in the human body and worldwide studies have shown that a deficiency may cause rheumatic aches and pains, as well as other health problems. Cupro-Zn insoles are made from high-grade, purified copper and zinc and by wearing them, copper can be absorbed through the skin and circulated throughout the body; even when a person is wearing socks or hosiery. In addition, zinc is widely known to be a crucial part of a healthy immune system and deficiency of zinc is a recognised cause of impaired immunity.

Aim

To document the health benefits of wearing cupro-zinc custom-fitted insoles.

Methods

Patients attending a large group practice in Manchester will be invited to watch a short video about cupro-zinc insoles while waiting in the surgery waiting room. They will then be approached by a representative of Cupro-Zn plc and will be offered a chance to try the insoles for four weeks. Those patients who accept the offer will have their feet measured and will be supplied with two pairs of custom-fitted cupro-zinc insoles. They will be invited to return to the surgery after four weeks, where they will be interviewed by the same Cupro-Zn representative who will use the techniques of qualitative research and will ask them to complete a questionnaire describing their experiences with the insoles.

Analysis

The results of the questionnaires will be analysed according to whether the benefits reported relate to rheumatic-type symptoms alone or to improvements in general health such as energy levels, mood, etc. Results will be expressed as a percentage of respondents.



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Protocol B

Silflur for preventing tooth decay

Scientific Background

Children presenting with early enamel lesions are often treated with the topical fluoride supplement Fluorstop (silver-diamine fluoride) to prevent progression of tooth decay. Silflur is a new preparation applied in the same way that does not have the staining properties of the original. It has been licensed for the same use, but it is possible that it is more effective at stopping dental decay than Fluorstop.

Aim

To see if treatment with Silflur is more effective at stopping early enamel lesions in children than Fluorstop.

Method

Patients and parents attending the community general dental clinic for routine assessment will be clinically assessed and those meeting the selection criteria offered the opportunity to participate in the trial. Those patients/parents not interested in participating will receive conventional treatment. Any treatment received will be free of charge.

The selection criteria are children between 8 and 10 years old, male or female, with an active early enamel lesion on one surface of one posterior tooth that could be treated with Fluorstop. If more than one lesion is present all will be treated, but only the most posterior lesion will be included in the study. Those who are currently experiencing tooth pain or who have any medical, learning or behavioural issues will be excluded.

Parents will be given a verbal and written explanation of the trial, detailing that they may receive either the Fluorstop or Silflur. They may choose to stop participating at any time and conventional treatment will be provided if requested. A parental signature on a clinical trial consent form will be obtained before starting. A practice session applying the treatment from the tubes supplied will be undertaken at the clinic.

Fluorstop inactivates 50% of lesions over 3 months. If Silflur inactivates 80% then 102 lesions are required to have a 90% probability of identifying this difference ($p=0.05$) so 102 patients will be recruited and randomly assigned (1:1) to either the control group (treatment with Fluorstop) or to the trial group (treatment with Silflur) using a computer algorithm. Neither patients/parents nor investigators will know to which group they have been assigned.

All dentists providing treatment will be trained in the Fluorstop/Silflur application technique and enamel lesion assessment technique. The Fluorstop and Silflur will be provided to the dentists in plain white tubes, and will have the same appearance and consistency.

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After 3 months the patients will be reviewed in clinic, and the active or inactive status of the enamel lesion recorded. Unused treatment tubes will be returned and counted as an estimate of compliance.

Analysis and Interpretation

After all patients in the trial have been reviewed and the enamel lesion status recorded, the trial will end. The number of early enamel lesions rendered inactive by the Fluorstop and Silflour will then be compared.

Funding for this trial will come from the National Institute for Health Research (NIHR) Health Technology Assessment programme and a methodology will be submitted to the Research Ethics Committee for approval prior to commencement.



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Protocol C

Stimulating intellectual development using Omega 3 supplements

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

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 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 to supply, free of charge, 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 labelled with the children's names and corresponding code numbers. The milk will also contain minute traces of an element that is incorporated into growing hair.

In collaboration with the class teacher, who will be blind to which treatment group a child is in, 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 participating child (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. A small sample of hair will be taken and analysed for the trace element, and this will be used as a measure of compliance with the treatment. 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.

Protocol D

Treating rheumatoid arthritis with bee venom

Scientific Background

Bee venom (BV) (api-toxin) contains many active compounds and bee stings have been used in the treatment of rheumatoid arthritis, where they have been claimed to reduce the pain in the inflamed joints following an initial painful response to stinging.

Aim

To test the hypothesis that injecting bee venom into inflamed knees reduces the symptom of pain in patients with rheumatoid arthritis.

Methods

Patients choosing to attend our traditional medicine clinic for the symptoms of pain and inflammation in the knee caused by rheumatoid arthritis will be offered the opportunity to take part in this investigation. To encourage participation, for those agreeing to have bee sting treatment it will be provided at no cost. The bees will be calmed by prior exposure to smoke, then introduced to the knee using tweezers (see illustration) and gently agitated to induce stinging. Bees will be removed once two or more stings have been noted.



The patient's recollection of the amount of pain in the knee over the previous 2 weeks will be recorded using a standard pain scale before the bees are introduced. At a follow up appointment 2 weeks later patients will be reminded of their previous pain score and asked if pain in the knee over the previous 2 weeks was better than this as a result of the bee stings.

Patients who prefer other types of treatment (principally acupuncture or moxibustion) will also record their recollection of pain in the knee over the previous 2 weeks, then will be invited to return 2 weeks later when they will be reminded of their previous pain score and asked if pain in the knee has been better or worse while they were waiting for their treatment. Their alternative treatment will then be administered. These patients will be used for comparison to the bee stings.

Analysis

Recruitment of patient will continue until at least 10 have undergone bee sting treatment and returned for assessment and at least 10 who have postponed their treatment by 2 weeks have acted as comparison patients. The proportion of patients improving after the bee stings will be compared to the proportion improving while awaiting alternative treatment.