HealthSense

Promoting science and integrity in healthcare since 1991

2023 HealthSense student prize competition for critical evaluation of clinical research protocols

Your entry must be submitted before 23:59 BST on Sunday 30 April 2023. Entries received after that time will not be considered.

The competition is open to all full-time undergraduate students of medicine, dentistry, nursing, midwifery and professions allied to medicine, and post-graduate students taking a taught master's course in any of those subjects. 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 five runner-up prizes of £100 in each class.

How to enter

The competition consists of four hypothetical research protocols to be evaluated and critiqued.

Your first task is to rank the protocols in order of quality, from best to worst. 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 'background' summarising previous relevant research. You should assume this is work correctly cited from reliable sources.

How entries will be judged

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. The first stage of judging your entries is to compare your ranking of the protocols with this predetermined ranking.

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.

Awarding the prizes

Prize winners will be invited to the HealthSense 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 be allowed for travel expenses. Entrants who cannot attend the AGM will have their certificates and cheques sent by post. If, for any reason, large gatherings or travel are restricted the AGM may be held virtually, in which case prize-winners will be invited to attend remotely.

Submitting your entry

Submission of entries is via the HealthSense 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 HealthSense as student members, who pay no subscription, and after their graduation will be invited to continue their free membership for a further two years.

You have a few months between the launch of the competition and the deadline for submission of entries but don't 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.

By entering this competition, if you qualify for a prize or commendation, you agree to HealthSense using your name, institution and photograph in publicity on the website, on social media and at events. You also agree to receive occasional emails with further information about HealthSense; you can unsubscribe from such emails at any time. Please see our Privacy Policy and UK GDPR Compliance Statement for further details.

The judges' decision is final, and no correspondence can be entered into.

The 2023 protocols

Protocol A: Faecal transplantation for the treatment of irritable bowel syndrome

Protocol B: Cranial osteopathy for childhood colic

Protocol C: Acupuncture for the prevention of tension headache

Protocol D: 'Breathing Free' — Testing a new pharmacological intervention for managing Idiopathic Pulmonary Fibrosis (IPF)

We are grateful to the Royal College of Surgeons of England for their sponsorship of this year's competition.

Protocol A

Faecal transplantation for the treatment of irritable bowel syndrome

Background

Faecal transplantation — the introduction of specially-prepared faecal material from a healthy donor — is used for the treatment of resistant infection with Clostridium difficile. It has been suggested that it could be used for a wider group of disorders, including irritable bowel syndrome.

Aim

To investigate the usefulness of faecal transplantation in the treatment of irritable bowel syndrome.

Methods

To avoid bias, which might affect recruitment from an irritable bowel clinic (where patients may have preconceived ideas about their complaint), volunteers will be recruited from patients attending a mixture of non-medical outpatient clinics (eg orthopaedic, ENT, ophthalmology) at a group of hospitals in a city in the West Midlands. The aim of the investigators is to recruit a total of 50 subjects who have irregular or uncomfortable bowel movements. Participants will be interviewed and informed as to the nature of the treatment and will be given an information leaflet which will include a consent form; those who are willing to take part will be asked to sign the form and return it by post to the investigators.

Participants will be invited to attend a research clinic on three occasions one month apart. At each clinic visit, they will be given a faecal transplant by means of a retention enema. Participants will be asked to take particular note of changes to their bowel habit.

Analysis

After six months from the date of the first faecal transplant, subjects will be invited to attend an interview to discuss their health and the state of their bowel function.

Protocol B

Cranial osteopathy for childhood colic

Background

All body tissues are constantly going through very subtle rhythmical changes of shape, which are normal and healthy. The skull is capable of accommodating the involuntary motion of the brain but if healthy brain movement is hindered or blocked this can cause problems in the head and in organs and systems anywhere in the body. Through the involuntary motion in the tissues, cranial osteopaths are able to detect the buried traumas and stresses in the body and treat them in a gentle and effective way.

Aim

To compare cranial osteopathic manipulation with no treatment for infants suffering from infantile colic.

Methods

The study has been approved by the Local Research Ethics Committee. It is a prospective, randomized, open, controlled trial comparing cranial osteopathic manipulation with no treatment. Infants and their parent(s) will be seen weekly over a 4-week period (total of 5 visits) at a single centre with all treatments given by the same osteopath following his usual clinical practice/management. Eligible infants will be between 1 and 12 weeks of age, no previous osteopathy, have signs of infantile colic and there is no other disease. Infantile colic will be defined as at least 90 min of inconsolable crying per 24 h on 5 out of the previous 7 days (as reported by the parents), with normal behaviour outside of these periods. Inconsolable crying during a colic attack will be when the infants cannot be comforted by being held, rocked or walked, or being soothed in any way. In addition, each infant is required to have displayed typical signs of colic: loud gurgling noises from the abdomen (borborygmi), knees drawn up to the chest, fists clenched and backward bending of the head or trunk.

A written explanation of the objectives of the study will be given to each parent and written consent obtained. The infant can be withdrawn from the study at any time and, if randomized to the control group, osteopathic treatment can be made available, if required, at the end of the study. Parents will keep a daily diary to record the amount of inconsolable crying in every 24 h, the total time spent sleeping, and the time the infant was being held or rocked (taken as an indication of low-level colic). Parents are asked to continue with bringing their infant to the clinic and completing the diary card even if the symptoms of colic resolved during the 4-week period.

Eligible infants will be randomized (using a random number table) into a control and test group. All infants will be brought to the osteopathic clinic once a week for 4 weeks. Equal time will be spent with all participants/parents over the study period. The initial visit and interview will last an hour. Infants in the control group will be given a brief examination with minimal touch. Those in the treated group will receive cranial osteopathic manipulative therapy as required (week 0). Treatment will be individualized, according to clinical findings, and involve standard cranial osteopathic techniques until a palpable release of tensions and dysfunction is achieved. At the four subsequent half-hourly sessions (weeks 1–4), infants in the control group will receive no physical intervention;

osteopathic manipulation in the treatment group will be dependent on findings at each visit. All parents will be able to ask questions, discuss their problems and receive counselling from the osteopath at each visit.

Analysis

The two main endpoints are the mean number of hours/24 h spent with colicky crying and the mean number of hours/24 h spent sleeping. For each infant, the difference in these parameters (daily average over the previous week) from weeks 1 to 4 will be calculated and the mean change for each group separately tested for significance using Student's t-test (paired). In addition, the difference between the means for the two groups will be compared using a two-sample t-test.

Protocol C

Acupuncture for the prevention of tension headache

Background

Traditional acupuncture is based on the belief that an energy, or 'life force', flows through the body in channels called meridians. This life force is known as Qi (pronounced 'chee'). Practitioners who adhere to traditional beliefs about acupuncture believe that when Qi doesn't flow freely through the body, this can cause illness. They also believe acupuncture can restore the flow of Qi, and so restore health. There is some preliminary evidence that acupuncture might reduce the frequency of tension headache.

A tension-type headache is the most common type of headache and the one thought of as a normal, everyday headache. It may feel like a constant ache that affects both sides of the head. One may also feel the neck muscles tighten and a feeling of pressure behind the eyes.

A tension headache normally won't be severe enough to prevent everyday activities. It usually lasts for 30 minutes to several hours, but can last for several days.

Aim

This study aims to demonstrate that a course of acupuncture will reduce the frequency and/or severity of tension headache.

Methods

25 patients presenting to one of 5 collaborating acupuncture centres with a complaint of tension headache will be invited to join the trial. They will be told that the study compares two types of acupuncture and lasts 12 weeks but they will only be charged for 6 weeks. They will be allocated to two types of treatment in random order decided by the toss of a coin, but will not be told in which order the treatments will be given. Both treatments involve a course of six 15-minute sessions spread over 6 weeks. Treatment A will use the meridian points indicated for this condition, and treatment B will use other meridian points associated with abdominal pain. (Patients will therefore be charged only for the treatment A period.) Patients will keep a weekly diary of the occurrence, duration (hours) and severity (mild, moderate or severe) of episodes of headache, and return it at each visit. Patients on anticoagulant treatment will be excluded, as will any who are acupuncture therapist (as they will recognise the treatment meridians).

Analysis

The sum of the duration multiplied by severity of the headaches will be calculated for each patient for each treatment period. As a paired t-test can be used for statistical significance the study will be able to detect even a small difference, so if this is lower for the treatment A period this will achieve the aim of the study. However, in case practice technique differs between centres and not all practitioners achieve the benefit, this calculation will also be done for each centre separately.

Protocol D

‘Breathing Free’ – Testing a new pharmacological intervention for managing Idiopathic Pulmonary Fibrosis (IPF)

Background

Idiopathic pulmonary fibrosis (IPF) is a condition associated with progressive and irreversible scarring of lung tissues. An estimated 7,000 new cases of IPF are diagnosed in the UK annually with the average life expectancy of patients diagnosed with IPF ranging from 3 to 5 years after diagnosis. IPF poses a significant challenge to the physical health of patients with knock-on effects on their socioeconomic and psychological wellbeing. Currently, there is no cure for IPF, there are few pharmacological interventions approved for use in its management.

Aim

This study, ‘Breathing Free’, is aimed at testing the efficacy of a newly developed antifibrotic pharmacological intervention in the management of IPF.

Methods

Using power calculations, a sample size of 30 was deemed adequate for this proposed randomised controlled trial, with an even split of participants between the intervention group and the control. After approval from the Local Research Ethics Committee, patients of any age within their first year of diagnosis, with a biopsy and imaging confirmed diagnosis of Idiopathic Pulmonary Fibrosis but currently not taking any pharmacological interventions, will be approached for recruitment and consideration for inclusion.

Patients beyond year one post-diagnosis or on any current pharmacological treatments will be excluded. A two-hour session will provide participants with the information needed to understand the details of the trial and to answer any questions they may have. An information document will also be provided during the session and only after this will a written consent form be offered to confirm recruitment to the study.

Using computer-generated randomisation, participants will be blindly assigned to either the intervention or the placebo branch with both sets receiving a 12-week course of unlabelled tablets to be taken once daily. (Investigators will be aware of which participants received the placebo because of the colour and shape of the tablets.) A follow-up protocol will be initiated to include a weekly recording of forced vital capacity (FVC), a fortnightly phone call to check in on participants and computed tomography (CT) imaging scheduled at the end of each month. Appropriate adaptations to data analysis will be made in case of attrition.

Analysis

At the end of the 12-week period, the rate of scarring on CT imaging determined by treatment-category blind observers, as well as variations in FVC recorded in both groups will be compared. A greater than 10% reduction in the rate of scarring of lung tissues, an improvement in or a lower proportional decline in FVC in the intervention group, will indicate that treatment aims have been achieved.