



Registered Charity No 1003392

# 2020 HealthWatch student prize competition for critical evaluation of clinical research protocols

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***Your entry must be submitted before 23:59 BST on Thursday 30 April 2020. 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.

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 them 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



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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.

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.

You have three months between the launch of the competition and the deadline for submission of entries; do not leave your entry until the last minute. Entries submitted after midnight on the day of 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.

The protocols are given below:

**Protocol A: Fertility vitamins for improving outcomes in *in vitro* fertilisation**

**Protocol B: Calf's foot jelly for osteoarthritis**

**Protocol C: Lotion for spot reduction of subcutaneous fat**

**Protocol D: Trial of a new dental implant**



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# Protocol A

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## Fertility vitamins for improving outcomes in *in vitro* fertilisation

### Scientific background

Researchers at Harvard Medical School have demonstrated that some vitamins and nutrients, particularly vitamin B12 and folic acid, may positively affect fertility. For approximately half of couples, problems with conception are due to male infertility. Healthy diets have been shown to improve semen quality but there has been little work demonstrating the impact of paternal diet on pregnancy outcomes.

### Aim of investigation

To determine the effect of paternal vitamin supplementation on pregnancy rates in couples undergoing in vitro fertilisation (IVF).

### Methods

The study proposal has been approved by the NHS Research Ethics Committee. A total of 120 couples who have demonstrable male infertility will be recruited from four NHS in vitro fertilisation providers. Men who have a very low sperm count, poor sperm morphology, or poor sperm motility are eligible for inclusion. Men who have had a previous vasectomy or who have anatomical reasons for low sperm count (eg injury, stricture, surgery, genetic condition, etc.) are not eligible for inclusion. At the first meeting, couples will receive a trial pack with detailed information. Couples will be advised that they can leave the trial at any point and that this will not affect their ongoing NHS IVF treatments. Consent will be gained at the second meeting and the patient will be randomly allocated to one of the trial arms (computer generated randomisation).

The trial will compare folic acid supplementation to vitamin B12 supplementation. Participants and researchers will be blinded to the arms of the trial; tablets appearing identical will be supplied in containers that are labelled with a code. Half of the patients will receive folic acid supplementation, half vitamin B12. All patients will continue to receive usual care along side the supplements. The patient will receive up to two years of supplements or until pregnancy is achieved, whichever comes first. The recruitment period will run from January 2020 to July 2020 or until 120 men have been recruited.

### Analysis and interpretation

The main endpoint is successful IVF pregnancy; secondary endpoints include improved sperm count, improved sperm morphology, and improved motility. A treatment arm will be deemed to improve male fertility if there is a significant difference between the two arms. The trial will be registered with AllTrials.



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# Protocol B

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## Calf 's foot jelly for osteoarthritis

### Scientific background

A daily oral supplement of glucosamine (a component of cartilage) has been shown in at least one study to reduce the loss of cartilage in the knees of patients with osteoarthritis (OA), while patients on placebo lose 0.1 mm joint space annually. Calf 's foot jelly (CFJ) is a traditional remedy that also contains components of cartilage. Unlike glucosamine, CFJ can be incorporated into many cooking recipes and is used as a condiment. If it is effective it is therefore more likely to be widely adopted by patients.

### Aim of investigation

To determine the effect on the progression of OA (measured by serial x-rays) of dietary treatment with CFJ.

### Methods

Hospital outpatients age over 50 years with painful primary OA of knee, who have no contraindications (such as potential allergy) and who have had a previous x-ray of the knees will be invited to take this food supplement for one year. Power calculations based on published research indicate that 60 patients are required with a follow-up period of 12 months. After consent baseline radiographs are taken, and the patient is issued with one month 's supply of CFJ. Subsequent supplies are collected monthly from the hospital dispensary or, if more convenient for the patient, from their GP 's surgery. At the time of collecting new supplies the patient returns the old container, and also brings a urine sample for analysis. The CFJ contains a tracer dose of lithium chloride that equilibrates with total body water, so the lithium/creatinine ratio in urine reflects the compliance in taking the treatment. Every three months patients attend the outpatient clinic for clinical examination and at 12 months for x-rays of the knees. Limitation of movement and pain are recorded on separate linear analogue scales.

### Analysis and interpretation

Cartilage thickness is assessed by the width of the joint space on knee x-rays (the inter-bone distance). Therefore, in those patients who complete the protocol (that is, take the CFJ for one year and are therefore in a position to gain the benefits of treatment) joint space narrowing (change in inter-bone distance) will be measured with a ruler and will be compared to the annual rate of joint space narrowing calculated from the x-rays taken before the study and the study baseline x-rays. Change in movement and pain will also be calculated. Although a reduction in the rate of joint space narrowing is the main purpose of the treatment, improvements in movement or pain will also be considered a successful outcome.



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# Protocol C

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## Lotion for spot reduction of subcutaneous fat

### Scientific background

The deposition and remobilisation of triglyceride (fat) in adipose tissue is under hormonal control. Release of fat is achieved mainly by the action of tissue lipases in fat cells, which split the triglyceride and release fatty acids into the bloodstream. The hormones adrenaline and noradrenaline activate these tissue lipases. This does not affect the total body fat, but makes it possible to remove fat deposited locally, which will be re-synthesized elsewhere.

### Aim of investigation

To test the ability of a lotion containing a synthetic noradrenaline analogue to remove fat from a subcutaneous depot.

### Methods

Following ethics committee approval, 120 women age 20 to 60 years, who are keen to lose fat and/or 'cellulite' from their thighs, will be recruited from local slimming clubs. Women who are currently using other forms of 'anti-cellulite' treatments are ineligible to join. Detailed trial information will be issued and written informed consent obtained. Participants will receive two containers, marked with code numbers only, one containing the active lotion, the other an identical-looking placebo. Women are advised to apply one lotion to the anterior surface of one thigh, and the other lotion in the same manner to the other thigh, daily for six weeks. The type of lotion applied to each thigh (active or placebo) is chosen at random by means of computer-generated randomisation numbers, and both the women and investigators are blind as to which treatment was used on which thigh. To demonstrate compliance, women are required to complete a brief daily treatment chart. Photographs of both thighs in a standard position (seated with thighs horizontal, camera 1 m above anterior surface of the thighs, lighting from the side to display skin texture) will be taken at the start and finish of the trial period.

### Analysis and interpretation

The pairs of photographs (baseline and post-trial) will be examined independently by two judges, who do not know which thigh was treated with the hormone or the control lotion. The picture-pairs will be rated R, L or O, if the judge considers that the right, left, or neither thigh show a reduction in fat or cellulite. These judgements for each judge will be converted into a score of +1 if the thigh treated with hormone was judged to be more reduced, 0 if neither was reduced, or -1 if the control thigh was more reduced. The scores will be added together. If the total score of the judges is >1 this will indicate that the lotion containing the hormone analogue was more effective control lotion.



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# Protocol D

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## Trial of a new dental implant

### Scientific Background

Dental implants are often used by dentists to replace teeth lost to decay. A new implant has been designed that is said to be easier to place and have a greater longevity compared to existing implants.

### Aim

To see if this new dental implant is easier for dentists to place and lasts longer than existing dental implants available on the market.

### Method

Dentists will be asked to participate in the trial by advertising in the Journal of British Dentistry. To be included in the trial, they must regularly place dental implants.

Three dentists will be chosen and asked to select ten candidates each from their patient list. These patients must be missing a tooth and will be offered the chance to have an implant to replace it at a reduced cost.

They will be blinded to the study by not being informed that they may receive a normal implant or the new implant. The dentists will be asked to place some of the normal implants they use and some of the new implants. They may choose who gets which based on which one they feel will have the best aesthetic outcome.

After they have placed an implant, they must record how easy/hard they thought the placement was to place using a score out of 10. Following placement of the implant, each time the patients attend for a check-up, the dentist must record whether the implant is still present. Recording can stop if the patient moves to a different practice or if the dentist retires.

### Analysis

After all implants have failed, the patients have left the practice, or the dentists have retired, the data will be gathered together and analysed by one statistician. The data for the new implant will be compared against the data for the normal implants to determine which implant is the easiest to place, and which lasts the longest.