

## **Preventing Obesity in Children**

### **Background**

The prevalence of obesity and overweight in children and adults is increasing worldwide. Government responses in various countries have included the funding of after-school activities; removal of vending machines in schools; modification of school meals; and labelling of food products. Numerous intervention studies in different geographical and cultural settings have been reported in the literature, but most did not show any significant improvement in fatness, as expressed by Body Mass Index (BMI), which is partly due to the short duration (only 3 – 12 months) of many studies. Considering obesity-linked morbidity and extra cost to the NHS, a Primary Care Trust in the North of England plans to undertake a 2-year obesity prevention study in children, so as to reduce future health problems.

### **Aim**

To determine if extra physical activity and dietary intervention leads to sustained avoidance of obesity in children.

### **Method**

With the agreement of head-teachers, all 8 – 10 year old pupils at three primary schools will be invited to take part, their parents having previously been informed of the study. Ethics Committee clearance from the Primary Care Trust was obtained.

School A will provide focused nutritional education for pupils on an ongoing basis, and their parents will be invited to attend dietary advice sessions from a dietician at 6-monthly intervals.

School B which has extra sports facilities, will provide 2 hours per week of additional physical activity, including soccer, basket ball, indoor exercises, depending on time of year.

School C will act as control.

At study entry, all pupils will have their weight and height recorded, BMI calculated, and measurements of waist circumference and triceps skinfold thickness documented by the same researcher. These measurements will be repeated every 6 months.

### **Statistics**

The above anthropometric measurements obtained during the study will be compared with their pre-study values to determine changes in BMI scores and prevalence of overweight at the 6-monthly pre-determined time points, and to see if possible benefits at one year of intervention are sustained at year two.

## Cherry Extract for the Treatment of Gout

### **Introduction**

Gout is a common inflammatory arthritis caused by the deposition of monosodium urate crystals within the joints after a period of chronic hyperuricaemia. It is caused by an interaction of genetic, constitutional and environmental risk factors; the main one being inefficient renal urate excretion. Diagnosis is clinical. The joints are affected suddenly; most commonly at night. Pain is very severe. The joints swell and are a dusky pink in colour. Attacks subside spontaneously within 2 weeks.

Established preventative treatments have side effects. Cherries and cherry extract tablets have been claimed to be helpful in the prevention of acute attacks.

### **Aim**

To determine if cherry extract tablets reduce the frequency of acute gout attacks.

### **Methods**

The study will be conducted by the Gout Society of the UK a charity which receives some funding from the lottery. An Ethics Committee within the Gout Society has approved the study and each hospital and GP surgery recruiting subjects has local Ethics Committee approval. 400 hundred subjects will be recruited; a previous pilot study has shown that 400 volunteers will be sufficient to demonstrate a significant difference between cherry extract and placebo. Volunteers will be recruited from hospital outpatients, GP surgeries and by advertisement in national newspapers.

Volunteers will be eligible for inclusion if they have a clinical diagnosis of gout and have had at least three attacks in the past 18 months. Exclusion criteria are those taking established preventative treatments; pre menopausal women, those allergic to cherries and those taking drugs known to increase plasma urate.

At the initial interview a full medical history will be taken. Those who fulfil the inclusion criteria will be asked to avoid changes in their diet for the duration of the study.

If they agree they will sign a consent form and will then be randomly allocated to either cherry extract or placebo by a computer generated code. The investigator at each centre will ring a specified telephone number to obtain the code. This investigator will be blind to the treatment given. Each volunteer will take cherry extract tablet or placebo once daily for 12 months. They will record any episodes of gout on a diary card which will also record their compliance with medication. Each volunteer will be seen by the investigator at 3 monthly intervals. At each visit the volunteer will be asked about compliance and the number of episodes of gout. Their diet will be enquired about and note will be taken of any other medication taken. They will be weighed to see if their BMI has changed.

### **Statistics**

The analysis will be performed by statisticians employed by the Gout Society who were not involved with the study. The number of acute gout attacks suffered by those taking placebo will be compared with those taking cherry extract.

## Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Relief in Labour

### **Background**

TENS is a non-pharmacological method for relieving pain, which has been used in a variety of settings and for a range of conditions, including back-pain and dysmenorrhoea. Since the 1970s, TENS have also been used in childbirth. TENS is a device that emits low voltage electrical pulses, that are believed to stimulate nerve pathways in the spinal cord, which block the transmission of pain. To date, there is only limited evidence that TENS reduces pains in labour. If further studies could show a clear beneficial effect, more women might chose this medication-free means of pain control.

### **Aim**

To see if TENS is effective in relieving pain in labour.

### **Method**

All primigravid women with a singleton pregnancy, booked for delivery at two London hospitals, are screened at 36-weeks gestation for possible inclusion. Those with specific medical conditions (eg pre-eclampsia, epilepsy, heart-rhythm problems, use of heart pace-makers), breech presentation, and elective caesarean section are ineligible to join.

Eligible women then receive verbal and written information about the range of pain-control modalities, including the use of TENS, available to them during labour, and they are shown a sample of the device. They are told that the unit consists of a hand-held unit, connected to electrodes, which are attached to the lower back on both sides of the spine, and that it emits low-voltage impulses, the intensity and frequency of which can be adjusted by the woman herself.

On admission in labour, those who elect to try TENS, will be taught by the midwife how to use the device, including how to vary the impulses, thus giving them a sense of control during painful contractions. A full medical/obstetric history will be recorded and the women will complete visual analogue scales (VASs), documenting the intensity of pain on admission, and the anticipated maximum level of pain as labour progresses. Further VAS scores will be obtained at regular intervals during labour, and patients will complete a 'Satisfaction Questionnaire' shortly after delivery, documenting their overall satisfaction with the pain relief obtained. The need for additional pharmacological pain relief and the type/dosage administered, will also be recorded.

### **Statistics**

At the end of the trial, the midwife will compare the mean of the VAS scores obtained during labour with those recorded on admission for 'anticipated maximum pain'. If the former are markedly lower, the device is judged to have given effective pain relief.

## Does sleeve length affect bacterial contamination of doctor's wrists?

### **Background**

In 2007 the Department of Health introduced a guideline banning healthcare workers from wearing white coats or other long sleeved garments. The aim was to reduce nosocomial bacterial transmission and help in reduction of hospital acquired infection.

There is no conclusive evidence to support this policy. The clinical staff at St Jude's hospital, a major teaching Hospital in London, expressed their concern at this "bare below elbows policy" and have planned a trial to see if there was a difference in bacterial contamination of the wrists in those wearing short or long sleeves.

### **Aim**

A study to determine if sleeve length affects bacterial contamination of doctor's wrists.

### **Method**

The study will be conducted in St Jude's Hospital. All doctors will be invited to participate. The ethics committee have given approval.

200 doctors will be randomly allocated to wear either a freshly laundered short sleeve shirt or their own white coat. White coats are supplied by the hospital and are infrequently laundered. Randomisation will have been conducted previously and will be computer generated. The principal investigator will not be involved in the randomisation but will allocate a white coat or short sleeved shirt to each doctor.

At the end of an eight hour period swabs will be taken from doctors' wrists, cuffs and pockets. The swabs will be labelled and cultured in the laboratory. The laboratory staff will be unaware of whether the doctor was wearing long or short sleeves.

### **Statistics**

Contamination with bacterial or metacillin staphylococcus aureus will be compared between doctors in short sleeves and those in long sleeved coats. Contamination of the wrists, cuffs and pockets will be compared separately. Colonies of bacteria will be counted. A simple T test will be used in the analysis.