The CRASH trial — the first large-scale randomised controlled trial in head injury

To the Editor: The CRASH Trial (Corticosteroid Randomisation After Significant Head Injury) is a large-scale randomised controlled trial, among adults with head injury and impaired consciousness, of the effects of a short-term infusion of corticosteroids on death and on neurological disability. Following a successful pilot phase (1 000 randomised participants), the main phase of the trial is now underway. For the next 5 years the trial aims to recruit 20 000 patients. Such large numbers will only be possible if hundreds of doctors and nurses can collaborate all over the world.

There are many reasons for conducting the CRASH Trial now: (i) results from animal studies show that high-dose methylprednisolone (MP) can reduce post-traumatic neuronal degeneration; (ii) patients with spinal cord injury who are treated with corticosteroids rather than placebo within 8 hours of injury may have improvement in motor function, and in sensation to pinprick and touch; (iii) there are wide variations within and between countries in the use of corticosteroids in head injury; and (iv) a meta-analysis of randomised trials of corticosteroids in head injury shows that existing trials are too small to demonstrate or to refute the possibility of a moderate but clinically important benefit.

The CRASH Trial aims to determine reliably the effects of high-dose MP infusion on death and on disability following significant head injury. Head-injured adults with impaired consciousness are eligible for inclusion in the trial if the responsible doctor is for any reason substantially uncertain whether or not to use corticosteroids. Patients with head injury and impaired consciousness may be unable to give properly informed consent, and in this emergency situation it may not be appropriate to delay the start of treatment until relatives’ consent can be obtained. Hence, the doctor in charge should take responsibility for entering such patients, just as they would take responsibility for choosing other treatments.

However, the requirements of the relevant research ethics committee must be adhered to. Numbered drug or placebo packs will be available in each participating emergency department. Randomisation involves calling a 24-hour free phone service or by use of fax. Once the call is made, the service will specify to the caller which numbered treatment pack to use. The outcome measures are death from any cause within 2 weeks of injury, and death or dependence at 6 months. In-hospital deaths, complications and short-term recovery are recorded on a single-sided outcome form that can be completed entirely from the hospital notes and no extra tests are needed.

Long-term recovery is assessed at 6 months, either by a simple postal questionnaire, sent directly to each trial participant from the national co-ordinating centre, or by telephone interview, and will not involve any additional work for collaborating hospitals.

The global epidemic of head injuries is just beginning. Currently over a million people die annually and a similar number are disabled from brain injuries, with profound effects on the quality of life of the affected individuals and their careers. Road traffic accidents account for most of the deaths and car use is rapidly increasing in many countries. It is estimated that by 2020 road traffic crashes will have moved from 9th to 3rd in the world disease burden ranking, as measured in disability-adjusted life-years, and 2nd in developing countries.

The identification of effective treatments for head injury is of global health importance. The CRASH trial is already the largest randomised controlled trial in head injury ever conducted but it will only be possible to reach our recruitment target of 20 000 patients if doctors and nurses worldwide join the trial and help to make it a success.

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Effects of the changing political dispensation in South Africa on growth of urban secondary schoolchildren

To the Editor: Changing environmental conditions impact on all aspects of growth and development in humans. Improvements in socio-economic conditions lead to faster and greater growth and better development in children. A multitude of studies have compared anthropometric characteristics in humans over time in order to show the trends occurring. In certain population groups there seems to be a trend towards increasing height and weight, directly related to changing health and nutrition, and possibility resulting in
ATTITUDES TO DISCLOSURE OF HIV STATUS TO SEXUAL PARTNERS

To the Editor: There have been no South African studies describing or evaluating disclosure of HIV status to partners, and there is therefore little understanding of the extent of partner disclosure, and of its potential harms and benefits. Studies conducted elsewhere in the world have shown how difficult it is for health workers to successfully encourage HIV partner notification. In a study done in neighboring Zambia the impact of social stigma towards HIV/AIDS was apparent even with regard to talking about HIV/AIDS. Women indicated that talking to partners about HIV-related issues was difficult because of the stigma that still surrounds HIV/AIDS in Zambia. Men said that they would rather remain ignorant than talk about sensitive issues. This reluctance to communicate openly between couples suggests an expectation of harms from doing so.

A descriptive study was undertaken during 1999 where 28 women were recruited into the study after informed consent. The interviews were conducted in Xhosa using a semi-structured questionnaire, while women were collecting baby milk from the clinic. All had received their HIV diagnosis at least 3 months before they were interviewed. Ethical approval for the study was obtained from the Ethics Committee, University of Cape Town.

The women ranged in age from 17 to 35 years, 79% had reached high school, and 46% were married. Of the women 46% had disclosed their status. Women who disclosed to their partners, reported trusting and loving relationships and a sense of responsibility about disclosure. For example, one said: ‘He is the person I am in love with, there is no other person. He must know that I have this problem.’

Of the non-disclosers, 12 were afraid to disclose to their partners because they feared rejection. ‘If I were to tell my partner, he will chase me away and that will end the relationship.’ Five of the non-disclosers feared gossip, discrimination and stigma: ‘People despise you when you are HIV-positive, or they treat you badly, and you suffer spiritually.’ Two of the non-disclosers planned to disclose their status when their disease had progressed. ‘I’m open, I share my ideas, but I will only be able to talk about this illness when my condition gets worse.’

Table I illustrates reported condom use at last intercourse among those who did and did not disclose their status to their partners.

Of the women who reported not using a condom, 12 said that they were influenced by their partners not to use one. One of the women who had disclosed her HIV status to her partner said that he didn’t want to use it, and ‘if I ask him to use it we end up fighting about it.’

Two of the women said that their partners were adamant about sticking to past beliefs, which did not sanction condom
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led by my grandfathers". The other, who had also disclosed to her partner, said: 'My husband doesn't want to use it. He says he is testing his seed when he uses that thing.'
Of the women 12 said that they were influenced by their partners not to use a condom. This is what one had to say: 'When he sees the condoms here at home, he throws them away.'
With the evidence that voluntary counselling and testing (VCT) reduces risk behaviour and overall unprotected intercourse, counselling and partner notification programmes need to respect women's fears about disclosure, and support them in their decisions about disclosure.
We thank all the women who participated in the study, the counsellors, members of the Khayelitsha AIDS Task team, Dr Debbie Bradshaw, Dr Nicol Coetzee, Dr Kariem Saadiq, and the supporting staff at Empelisweni Clinic.

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 HYPERBARIC OXYGEN THERAPY FOR
CHILDREN WITH CEREBRAL PALSY

To the Editor: We are concerned about reactions to the publication of the Canadian 'Collet' study in the Lancet of February 2001, both in print and on the Internet (www.oceanhbo.com). Well-meaning parents and a few professionals in hyperbaric medicine are trying to discredit this study or to use the scientific results to infer a positive benefit through hyperbaric oxygen treatment (HOT).

The Cerebral Palsy Hyperbaric Research Committee (CPHRC) was established in 1998 to research the efficacy of hyperbaric oxygen treatment (HOT) in children with cerebral palsy following the growing informal use of the therapy in South Africa and the widely reported anecdotal evidence relating to this new treatment.1 We developed a methodologically sound research protocol (approved by the Medical Ethics Committee of 1 Military Hospital), but prior to securing funds the Canadian study was conducted and completed. This well-designed, adequately funded and placebo-controlled double-blind study, accepted by and published in the Lancet, included all the recognised disciplines involved in the management of children with cerebral palsy.

Our results demonstrated a 3% improvement in gross motor function in both the study group and the control group, with changes being more pronounced in children with a lower gross motor function level. This improvement equates to that achieved with intensive physiotherapy.2 Although the results were statistically significant, albeit in both groups, the explanation for these improvements was less clear. The researchers suggest that the improvement seen in these children may have resulted from one of two things, either the additional attention and stimulation associated with participation in such a trial, or the effects of the additional pressure received by both groups during the HOT. They favour the former explanation. Until such time as there is sufficient evidence to support the benefits of the pressure effect, we strongly advocate that parents and therapists rather focus on regular daily attention and interaction with the child. If the 'attention factor' is the explanation for the improvement found in the study, perhaps the most exciting aspect of this research is that provision of greater levels of attention and stimulation is an intervention that is available to all. It involves no costs or equipment, requires minimal skills and holds no inherent risks (such as barotrauma to the ear).

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