estimate of the odds ratio have been available for some years. The meaning in our quoted sentence was modified during final preparation of the article by a change of "was" to "has been," whereas we had the same intention as in Armitage and Berry (p 460).¹ We gave the alternative logistic version partly for continuity with an earlier section of our paper and partly for its comparative ease of calculation. The two approaches will give similar values for the confidence interval in most cases when the sample sizes are not small—for example, as in the worked example (pp 462-5) of Armitage and Berry.¹

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Self help groups and professionals

SIR,—In her leading article Dr Mary E Black gives three reasons for doctors' uneasiness with self help groups (28 May, p 1485). I confirm her first, that doctors do not know who these groups are or what they are trying to achieve and are thus wary of referring patients to them; in most cases, however, doctors do not wish to know as I explain below. I agree with her second point that confidentiality is merely a professional excuse and is no hurdle when the patient can decide. Her third point, a fear of being called to account by a vociferous group, may be true but as this has seldom occurred in my experience it merely reflects further ignorance of the group set up.

As a doctor who has worked with a local cancer self help group since its beginning four years ago I should like to add a few points.

Few hospital consultants or general practitioners like to admit that they have not supplied all that their patient requires, and the need for a support group somehow insults their profession. They are, not surprisingly, unwilling to recommend a group to their patients, even if they are aware of how it is run. Groups tend to be treated with suspicion, particularly those concerned with cancer. In the professional mind these groups are associated with promoting weird and wonderful holistic remedies and false hope. Such is the suspicion and scepticism that it is difficult for a professional in my position even to advertise such a group. Information proffered (never pushed) is greeted by the medical profession with awkwardness and embarrassment.

As Dr Black mentioned doctors have much to give and gain from self help groups, particularly in participation. They are greatly needed to inform and correct misunderstandings. Poor communication is so often the source of much anxiety and misery and so easily remedied by a professional presence. If a patient needs to vent his or her anger, so be it. It is not a personal attack and almost always extremely therapeutic.

I have personally gained from my participation with a self help group. I have become more aware of the patient's point of view and as a result, I hope, have become a more understanding listener. In addition, it must be remembered that such groups can give what doctors cannot, the often requested companionship of others in a similar situation.

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SIR,—Dr Mary E Black's leading article on self help groups and professionals (28 May, p 1485) is timely in the light of the Griffiths report's recommendations that greater support and information must be given to "informal carers" to provide appropriate and efficient care.¹ Self help groups form part of the informal carer network, often providing the only source of education and support for relatives and friends, as well as patients.

Whatever the problems professionals may have with self help groups, or indeed such groups with professionals, the phrase "groups will let doctors know what patients want from them" does not begin to describe the wealth of information that professionals can get from a self help group. In these groups professionals can come to understand what it is like to suffer from a particular problem on a day to day basis, how it really affects ordinary life, the full impact of both the illness and regimens of treatment on patients and their families, the restrictions placed on family life, the consequences of care, and the reasons for non-compliance. The insight gained goes far beyond the research on burden on families, good though this often is.

If a professional can honestly interact with a group as an equal he or she will find out things about the illness and its impact that are never brought to a consulting room, and phrases like "this may affect everyday living" take on a whole new meaning once put into context.

As well as helping with "early detection and prevention of crises in patients," a group that has relatives participating can highlight families in crisis, making preventive intervention possible and understandable by both relatives and professionals.

Deriving this sort of benefit from a self help group requires more than a token presence at one meeting but can well repay the time spent in providing better understanding of patients and their families.

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SIR,—The leading article by Dr Mary E Black (28 May, p 1485) draws attention to the reluctance of doctors to participate in self help groups for patients. Quality, consistency, and confidentiality are perceived as problems. Patients, too, are anxious about their relationship with professionals in the context of a group.

A method of integrating professionals into self help groups has been developed by Dr M Bremer-Schulte and is known as "duo formula" group therapy.¹ A health care professional is paired with an experienced patient to lead the group in a series of weekly meetings, and a programme of topics is devised to cover the many aspects of the disease in question that are often neglected in conventional clinical consultations. This formula quantitatively improves patients' education, mutual support, and ability to care for themselves and also reduces dependent illness behaviour in patients with psoriasis² and myocardial infarction.³ More recently it has been used for patients with AIDS.

Further information on this technique is available from Dr M Bremer-Schulte, Director, Institute for Self Care Research, Boschstraat 45, 6211 AT, Maastricht, The Netherlands.

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Dietary fibre and diabetes mellitus

SIR,—Ms V A Beattie and colleagues (23 April, p 1147) have argued against the benefits of dietary fibre in the treatment of obese type II diabetics. Some of their statistical assertions are not justified by the data presented. Lack of statistical significance is taken to imply lack of clinical significance in a design with low power, and some of the clinical significance is arguable.

The data presented in table II do not justify the assertion that body mass index fell significantly between weeks 4 and 12 in groups A and C. The overlap of the confidence intervals given seems to negate any statistical significance. Possibly the asserted significance arises from an equivalent of a paired analysis (within the within-group analysis), but in that case the confidence intervals given are misleading and unhelpful.

Detecting changes in body weight or body mass index is difficult because of the large spontaneous variability between individuals and with time, especially in the obese. Change, or lack of it, in an eight week period may not be meaningful in the context of a lifelong condition. The patients achieved a 4 kg weight loss in 20 weeks—about average for routine clinic practice. This is equivalent to underating by 117 MJ (assuming all loss to be of adipose tissue) or 0.8 MJ/day. Body weights are, unfortunately, not given, but if an average energy requirement for weight maintenance is 8.4 MJ/day¹ the diet consumed by these subjects was about 7.5 MJ/day. The obvious discrepancy from the prescribed diet of 5 MJ would allow many confounding factors to obscure the effects of a 15 g dietary fibre supplement.

The interesting result that there was a statistically significant fall in fasting plasma glucose concentration in groups B and C when taking a high fibre diet between weeks 4 and 12 is dismissed by the assertion that "there was no overall significant difference . . . at the end of the trial." There was a fall in plasma glucose concentration in groups B and C when receiving fibre supplements, but it remained static in group A on the low fibre diet. The subsequent assertion that "plasma glucose concentration fell significantly more in dietary period 1 than period 2 irrespective of diet" has ignored the results from group A, in whom period 1 produced a rise in mean plasma glucose concentration.

The data presented suggest a clinically significant fall in glycated haemoglobin concentration in all groups. The falls in group A (low fibre) from 58% (52 to 64%) to 50 (40 to 60) and to 50 (38 to 61) are said to be non-significant and significant respectively, indicating that the significant fall in this group must be marginal. Thus the statistical significance of the falls in all groups at the end of the study should not obscure the more rapid and convincing falls in treatment groups B and C (high fibre).

In at least five places in the paper the lack of statistical significance is used to suggest a lack of clinical significance. This is a common error of statistical analysis. A failure to reject the null hypothesis can be taken as evidence to support that hypothesis only if the experiment had sufficient power to have a good chance of revealing a statistically significant result when a real clinical difference exists.² This power depends on the experimental design and the sample sizes. In the present case it is likely that the small sample sizes

gave a very low power, so the lack of statistical significance may have arisen by chance rather than because no differences exist (a so called type II error, or beta error). This paper does not present convincing evidence against the benefits of dietary fibre in the diabetic diet.

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- 2 Armitage P, Berry G. *Statistical methods in medical research*. 2nd ed. Oxford: Blackwell, 1987:181.

SIR,—Ms V A Beattie and others asked whether adding fibre to a low energy, high carbohydrate, low fat diet confers any benefit to the management of newly diagnosed overweight type II diabetics (23 April, p 1147). In their abstract and discussion they conclude that neither cereal fibre nor viscous fibre produced benefits beyond those achieved by reduced energy intake and weight reduction. These conclusions are not justified for two reasons.

Firstly, it is always difficult to be confident about a negative result. The three diet groups each consisted of seven to nine patients, and the 95% confidence intervals for both the glycated haemoglobin and fasting plasma glucose concentrations (table II) include values that could have resulted in different conclusions.

Secondly, Ms Beattie and others made no attempt to assess compliance with their dietary advice, perhaps because they felt that many of the methods for doing so are not reliable. Despite the few patients studied, however, their data provide some evidence that their patients may not have altered their diets beyond a reduction of total energy: total cholesterol concentrations were unchanged throughout the study. Reduction of saturated fat to the extent that must have been advised to produce a 60% carbohydrate diet (180 g carbohydrate, 5.0 MJ) should have achieved, if the advice was followed, appreciable reduction in cholesterol concentrations. In view of the fact that the patients seem not to have reduced their intake of fat as directed it seems conceivable that they might also not have followed the advice about fibre, and no conclusions can be drawn beyond the already well established effect of energy restriction and weight reduction on glycaemic control. We urgently need information on the long term effects of dietary fibre in diabetes. Unfortunately this study provides no helpful data.

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AUTHORS' REPLY.—We concluded that there was little evidence that supplementing a low energy, high carbohydrate diet with fibre confers any therapeutic benefit to type II diabetics on the basis of comparisons of the reductions in body mass index (3 kg/m² on the low fibre diet compared with 2 and 4 kg/m² on the high fibre diets), glycated haemoglobin concentrations, and fasting plasma glucose concentrations. Admittedly, these results were weighted by the reductions occurring during the low fibre run in period. The results from week 4 onwards showed trends in favour of the high fibre diets. The inclusion of greater numbers of patients would certainly have clarified the

situation from a statistical aspect, but even if we had been able to demonstrate a statistical difference in favour of fibre we doubt that it would have been sufficiently large to be relevant therapeutically. We ended the study after two years because we thought that further input would be unlikely to change our conclusions. Perhaps this was not justified.

We do not altogether accept Dr Mann's comments about compliance. The reductions in weight and glycated haemoglobin and fasting plasma glucose concentrations indicate dietary compliance. The average plasma concentrations of cholesterol were also reduced but these results were not statistically significant. The cholesterol concentrations were not abnormally high in most patients at the beginning of the study. It is true that the methods for assessing compliance are unreliable, but we paid particular attention to this aspect of the protocol. The patients were interviewed by the same person at two weekly intervals throughout the study. During these interviews they were asked to recall what they had eaten on the previous day and during the previous week. In addition they were asked to return any guar gum that they had not used. We found no reason from this information to suspect that the patients were not complying with diet requirements.

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Nonoxinol 9 and HIV infection

SIR,—Nonoxinol 9, a non-ionic surfactant, is the active ingredient of several spermicides. Laboratory studies have shown that it inhibits the growth of *Treponema pallidum*,¹ *Neisseria gonorrhoeae*,¹ *Chlamydia trachomatis*,^{2,4} herpes simplex virus,^{4,5} and human immunodeficiency virus (HIV) type I.^{6,8} Its use has been recommended, in addition to condoms, as a measure to inactivate human immunodeficiency virus in genital secretions. Preparations contain between 2 and 8% nonoxinol 9 (w/w), and it is incorporated in the lubricant in some condoms. One manufacturer has recently attempted to promote the use of nonoxinol 9 as a lubricant for vaginal and rectal examinations.

If nonoxinol 9 is totally non-toxic to genital tract epithelia and, when appropriate, the rectal mucosa all well and good. If this is not the case can we be certain that it is not increasing the permeability of cells to HIV and thus enhancing the likelihood of infection? Reitmeyer *et al* state that "Nonoxinol 9 containing spermicides are generally considered to have no toxic side effects in penile-vaginal intercourse, but the safety of nonoxinol 9 in rectal use has not been established."⁷ Allergies are known to occur, and stopping the use of nonoxinol 9 is recommended by all manufacturers if penile or vaginal itching develops. Preliminary studies of cytotoxicity reported by Hicks *et al* indicated that 35% of peripheral blood lymphocytes were killed after treatment with 1% nonoxinol 9 and that a 5% solution significantly reduced viability.⁶ Although spermicidal preparations may seem to be acceptably tolerated by those who use them, low grade epithelial damage may remain undetected. If a clinically inapparent inflammatory process is induced the genital tract epithelium or rectal mucosa may be rendered more permeable to HIV. Nonoxinol 9 might also impair local immune defences by damaging cells of the immune system or enhance the risk of infection with HIV by activating Y lymphocytes.

Any putative antiretroviral agent must be assessed for potential benefit and toxicity. Nobody would support introducing a systemic antiretroviral drug without evidence from clinical trials that its benefits outweigh any danger. The same principles should surely be applied to topical preparations such as nonoxinol 9, and recommendations for its use in preventing infection with HIV should be based only on carefully controlled clinical trials.

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Hospital visiting hours

SIR,—Arrowe Park Hospital is one of those referred to by Dr D N W Griffith (7 May, p 1303) which has returned to restricted visiting hours after a trial of open visiting.

This is a new district general hospital which opened in 1982. From the time of commissioning it was decided to have open visiting from 8 am to 8 pm. This proved to be a disaster, primarily because of abuse of the system by visitors. Many would arrive promptly at 8 am and stay all day. They would bring sandwiches and flasks of coffee and camp out by their relative's bed for the day. Others would eat patients' food, ask for extra cups of tea, etc.

The hospital is fortunate in that the wards are modern and divided into four or six bedded bays. During ward rounds it was only necessary to ask visitors to leave one bay at a time. Nevertheless, visitors often refused or left the bay only with ill grace. On at least one occasion there was even a threat of violence from a visitor asked to leave temporarily.

We tried leaving the visitors in during ward rounds but this was even more problematic. Privacy and confidentiality is inevitably limited in a ward. Patients in adjacent beds are bound to hear conversations between doctor and patient. To erode this privacy further by allowing other patients' visitors in at the same time seemed undesirable. Nursing staff became tired of having to ask visitors in the whole bay to leave while an individual patient was on a bed pan or receiving treatment.

Eventually the pressure to change came from the patients themselves, who were exhausted by the constant presence of visitors. We restricted the visiting to six hours (2 pm to 8 pm) which is still fairly liberal by many standards. Even this did not