While both studies are to be congratulated on their pragmatic approach, the ill-defined patient entry data criteria and heterogeneity of study groups limits their interpretation and generalizability. I would suggest that the results should inform a future research agenda rather than purchasing policy.[1]

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References

1. Harvey I, Nelson S, Lyons R, *et al.* A randomized controlled trial and economic evaluation of generic counselling in primary care. *Br J Gen Pract* 1998; **48:** 1043-1048.
2. Baker R, Allen H, Gibson S, *et al.* Evaluation of a primary care counselling service in Dorset. *Br J Gen Pract* 1998; **48:** 1049-1053.

Sir,

Harvey *et al* (March *Journal*) undertook a randomized controlled trial and health economic evaluation of counselling in primary care. They found no difference in functional or mental health outcome at four months between subjects referred to counselling or those given usual care by their GP. They also found no clear difference in the cost effectiveness of the two interventions.[1] However, the emphasis given by the authors on functional and mental health outcomes may hide some of the other benefits of counselling identified within the study.

Table 6 of the paper identifies that patients in the counselling group made substantially lower demands on GP time, were prescribed fewer drugs, and were less likely to be referred to specialist mental health services.

These are benefits in themselves, but are not highlighted in the conclusions of the report. They are also outcomes that are directly sought from counselling.[2,3] This trial shows that it is possible to achieve these benefits, which are improvements in the quality of care, through counselling, while maintaining the same outcome as traditional care and within a broadly similar cost envelope.

In conclusion, it appears that this trial should be seen as being broadly supportive to counselling, given that it offers quality improvements with no effect on outcomes and no significant evidence of increase in costs.

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References

1. Harvey I, Nelson S, Lyons R, *et al.* A randomized controlled trial and economic evaluation of generic counselling in primary care. *Br J Gen Pract* 1998; **48:** 1043-1048.
2. Fletcher J, Fahey T, McWilliam J. The relationship between the provision of counselling and the prescribing if antidepressants, hypnotics, and anxiolytics in general practice. *Br J Gen Pract* 1995; **45:** 467-469.
3. Scott A, Vale L. Increased general practice workload due to a primary care led National Health Service: the need for evidence to support rhetoric. *Br J Gen Pract* 1998; **48:** 1085-1088.

Cluster randomization

Sir,

We agree with Underwood *et al* (March *Journal*)[1] that researchers are often unaware of the effect of cluster randomization on the power of the study. This is understandable as it is largely ignored in texts on medical statistics, even including specialists books on sample size calculations. The standard work on sample size for clinical trials[2] only included cluster randomization in the second edition.[3] We have written a series of articles for clinicians demonstrating the dangers of an incorrect analysis[4,5] and describing appropriate sample size calculations.[6,7] We have used examples from a range of general practice situations but we have not encountered a design effect as large as 24.5, as Underwood *et al* have quoted. The reported calculations contain an error either in the design effect or in the intracluster correlation coefficient (ICC).

Applying the formula $1+(\bar{n}-1)r$, where r is the ICC, gives an inflation factor of 4.58 where $\bar{n}$ is 200 and r is 0.018, not 24.5 as the authors state. This would result in a total sample size of 6074 patients, which could be obtained from 36 practices. Although greater than the original 24 the authors had planned to use, it would be far more realistic and practicable to recruit another 12 practices than the 162 required to satisfy the design effect of 24.5.

A design effect of 24.5 could result from an ICC of 0.118. In our experience, values of ICC in general practice trials are likely to be between 0.001 and 0.05. This is in agreement with the authors' own report. A value of 0.118 would seem unusually high, particularly as HbIAC is an outcome measured on the patient directly, and is affected by many patient factors as well as GP care. High values of ICC, greater than 0.01, are more likely to be found for outcomes such as prescribing, which measure doctor behaviour directly.[6]

Cluster randomization may indeed be a trap for the unwary, but not as deep as the authors suggest.

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References

1. Underwood M, Barnett A, Hajioff S. Cluster randomization: a trap for the unwary. *Br J Gen Pract* 1998; **48:** 1089-1090.
2. Machin D, Campbell MJ. *Statistical tables for the design of clinical trials.* London: Blackwell Scientific Publications, 1987.
3. Machin D, Campbell MJ. *Statistical tables for the design of clinical trials.* 2nd edition. London: Blackwell Scientific Publications, 1997.
4. Kerry SM, Bland JM. Statistics notes. Analysis of a trial randomised in clusters. *BMJ* 1998; **316:** 54.
5. Kerry SM, Bland JM. Trials which randomise practices I: how should they be analysed. *Fam Pract* 1998; **15:** 80-83.
6. Kerry SM, Bland JM. Statistics notes. Sample size in cluster randomisation. *BMJ* 1998; **316:** 549.
7. Kerry SM, Bland JM. Trials which randomise practices II: sample size. *Fam Pract* 1998; **15:** 84-87.

Urine sample collection

Sir,

The article by Giddens and Morrison (February *Journal*)[1] highlighted the importance of accurate diagnosis of urinary tract infection in small children and the difficulties of accurate urine collection.

In our study (May *Journal*),[2] we discussed GPs' problems with urine collection. We found that GPs collected more satisfactory urine samples from infants than from older children. This may be the result of the widespread introduction of urine collection pads in the geographical area studied.

The high cost and inpractibility of adhesive urine collection bags (frequently commented on by GPs) has been resolved by the introduction of urine collection pads (UCPs),[2-9] which are cheap, easy to use, and available from National Health Service (NHS) supplies (order no. CFQ 152), with savings of about £114 000 since their introduction. Cost estimates in