Author's response to reviews

Title: The MRC Trial of Assessment and Management of Older People in the community: objectives, design and interventions

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Version: 2 Date: 22 Aug 2002

PDF covering letter
Compulsory Revisions

1. **Rationale of randomisation to three methods of administering the brief assessment.**
   
   The trial design requires all participants to be offered a brief assessment and hence provided the opportunity for an additional randomisation to different methods of administering the brief assessment. The three methods chosen (nurse, lay or postal) were all examples of screening methods that had been advocated as part of an assessment process (with obvious differences in cost implications) but no formal evaluation of their performance in a single trial has been carried out. We were interested in establishing whether response rates, levels of missing information and, for certain health conditions, sensitivity and varied for the three methods. We have now added a section describing the objectives of the comparison of the three methods (page 4 lines 8-14). It would not have been possible to use the three methods in the same patients as this would have led to increased extra burden on patients and might have affected the response rates. Randomising large groups of patients also provides useful and unbiased information on the extent to which different methods vary with in term of response and missing data.

2. **PCT versus GEM**
   
   We agree that the presentation of the main comparator groups is rather confusing and have amended accordingly (page 4, lines 17-21). The trial is essentially a 2x2 randomisation of the main interventions of interest (Universal versus Targeted and GEM versus PCT) and the analysis is of the “package” and therefore includes the other main randomisation. For this reason the PCT v GEM comparator group includes all patients randomised irrespective of whether they were actually referred to GEM. It will be possible in secondary analysis to make a direct comparison of the outcomes in those who were actually referred to the teams.

3. **Difference between PCT and GEM**
   
   The primary care team i.e. the general practitioner (plus such primary care staff that may be seen by the patient) is the usual method of care of elderly patients who receive the over 75s health check. The alternative intervention is the hospital multidisciplinary geriatric team, which would not usually deal directly with the management of patients identified from the over 75s checks. The comparison therefore is of usual management by a general practitioner versus management by a “specialist” service. Whether or not patients are “better” managed by their own GP or a specialist is not known- multidisciplinary geriatric teams are thought to have in-depth and wider subject expertise but the general practitioner may have
the advantage of better understanding of the patient and their environment. There are no specific treatment protocols for the GEM or PCT nor would this have been appropriate as we are testing different skills mixes rather than testing the ability to follow a specified protocol. Process data is collected for both groups for each patient referred which includes number of visits, health professionals seen, investigations, services and treatments and diagnoses. It is possible that the PCT may refer to the geriatrician but this is part of usual care and this information will be collected. In the UK, the GEM team cannot “refer” to the GP but they do discharge patients back to the GP when they deem that the patient no longer requires specialist management. The geriatricians taking part in the study are the local geriatric services for the general practice and were not selected for any particular interest in the research topic. We have added text in page 7, lines 14-15, page 16, lines 8-10 to clarify these points.

4. (i) Rationale for primary outcomes
   As we described on page 3 (end of first paragraph) and page 14 (first paragraph of the Discussion) a number of trials of multidimensional assessment have suggested benefits on mortality, institutional (or nursing home) and hospital admissions. The three meta-analyses have presented the results for mortality (Stuck 1993, 2002, Elkan 2001), hospital admission (Stuck 1993, Elkan 2001), and nursing home admissions (Stuck 2002, Elkan 2001). Individual studies and meta analyses have also looked at outcomes such as functional decline or physical morbidity – we used quality of life to capture these aspects of the trial. We have added a sentence in the discussion (page 14, lines 17-22) to justify our choice of outcomes

   (ii) Size of benefit to be detected
   The size of benefit that the study was powered to detect was in line with results from earlier studies (e.g. Hendriksen) at the time we were planning the trial and also were thought to be both worthwhile in terms of public health impact. We have added a sentence in the discussion explaining this (Page 11, lines 11-12). The large size of the trial is a consequence of cluster randomisation and the cluster effect will be included in the analysis. The effect of taking account of clustering will be to increase the standard errors and make spurious “significant” results unlikely. We have included a discussion on the choice of cluster randomisation (page 14, lines 14-15 and under Analysis page 13, lines 2-5 we have discussed the implications of adjustment for clustering.

   (iii) Follow-up periods for outcomes
   The reason for the different durations of endpoints is to do with the expected impact of the interventions. We would expect any effect on hospital admissions to be seen at an earlier rather than later stage whereas mortality effect might show some lag. Quality of life is measured both at 18 months and at 3 years, which covers the same period as both the hospital admissions and the mortality. Additionally funding did not permit collection on hospital admissions over a longer period. We have added a sentence in the discussion on the differing follow-up periods (page 8, lines 10-13)
Discretionary Revisions

1. *Procedures in 3 methods of administering the brief questionnaire*  
   We have added a few sentences on page 6, lines 2-5 to provide some more details on the administration of the brief questionnaire.

2. *Reliability of data from hospital discharge letters.* We have added a sentence on page 8, lines 1-2 to explain that this is the standard method in the UK of providing feedback to the general practitioner on the results of the hospital attendance.

3. *(i) page 8 typo on though use of services* this has been corrected  
   *(ii) additional information on the two methods of collection of use of services* we have added a few sentences on page 8, lines 20-23 to explain the reason for the two methods.

4. *Background section and mention of other trials.*  
The introduction refers to the trial published before the 1990 contract of service and highlights the lack of evidence at the time the policy was introduced. In the Discussion we describe the systematic overviews and meta analyses, which have been conducted since then, and these include the trials mentioned by the reviewer. We have added a sentence to make it clearer that there have been a number of trials published after the 1990 contract (page 14, lines 3-6)
Response to reviewers comments

Reviewer : Dr Leslie Huson

Discretionary revisions

1. Check exponent in sample size formula
   We thank the reviewer for pointing this out and have put it in superscript to ensure the exponent is clearer.

2. Assumptions about levels of matching
   We used different assumptions about the level of matching when the original sample sizes were calculated but the final calculations were based on assuming no matching as a conservative assumption. We have added a sentence on this in the text (page 9, lines 19-21).
Response to reviewers comments

Reviewer Dr Steve Illiffe

Compulsory revision (reviewers’s point numbering)

2. Protocol for referral and how this might differ from usual care
   Because of the size of the study and the implications for costs we are not able to collect detailed information on which health professionals and agencies are already involved in the care of a particular patient. We agree that this is a limitation of the study and have added a sentence in the discussion on this (page 15, lines 10-14).

3. Focus on disease versus disablement
   We agree with the reviewer that the GEM versus PCT referrals are mainly related to clinical disease and we consider this is appropriate. However the trial interventions also address functional disability through the detailed nurse assessment (such as hearing and vision problems, difficulties with ADLs, incontinence etc) and the referral protocol allows the practice nurse to refer to a wide range of agencies and services for these disablements. We have added a sentence in the discussion to cover these points (page 15, lines 4-7)

   We are indeed testing the hypothesis that usual care by the general practitioner is no different from specialist geriatric services. We are collecting process information on the teams which, for each individual patient referred, includes any additional referrals made – hence we will be able to describe whether GPs manage the clinical problems themselves, or refer on to hospital specialists and if so which ones. We have added a sentence on page 7, lines 14-15 giving this information. We agree that the nomenclature PCT for the primary care team could be confused with Primary Care Trust and have made a global change to GEM and PCT to GM and PC respectively.

5. Expand discussion of policy context and limitations of evidence from RCTs
   We have added to the Discussion the question of the applicability of our results concerning the clinical management teams outside the UK. We regard the intervention of assessment plus management by a specialist geriatric team to be analogous to the use of “multidimensional geriatric assessment and follow-up” described by Stuck et al in their 2002 published meta analysis, (page 15 lines 1-4 added). We have added a section in the discussion on the generalisability of evidence from this trial (page 15, lines 22-23 and page 16, lines 1-13).

Discretionary Revision (reviewers’s point numbering)

1. We have included a few sentences discussing the problems of obtaining evidence after the introduction of a policy (page 15, lines 17-21).