Statistical presentation in international scientific publications

Group Work

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Statistical presentation in international scientific publications

A. Paper for statistical review

Introduction

Following is a specially prepared research paper entitled “A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home”, which is about to be statistically reviewed by you in “breakout” groups. This is not a real example of a paper submitted to a journal – such papers are not in the public domain, and it would be unfair on the authors to dissect such a paper in public before it has been peer reviewed. The review paper is, in fact, based on a real research paper that was accepted for publication in a leading journal. With the permission of the authors, the paper has been edited to contain many of the common faults that occur in practice in statistical papers submitted to journals.

A statistical review will mainly concentrate on the Abstract, Methods, Results, Tables and Figures, and to a lesser extent the Discussion and References sections of a paper, as those sections contain information on the design and analysis of the study. For simplicity, the intentional statistical errors in the review paper have been inserted into the Abstract, Methods, Results and Tables and Figures sections. You can safely ignore the Introduction, Discussion and References sections as far as the statistical review is concerned, but they do put the statistical side into context. Also, the paper you are about to read and review is single spaced to save paper! Journals ask authors to submit their papers double spaced to facilitate reviewing and typesetting.

Peer reviewing in the healthcare field is usually blinded or masked in the sense that the reviewer does not know the names of the authors. The names of the authors have quite rightly been taken out of the following review paper, and their initials and the location of the study have been anonymised (so the XXXs are not mistakes!).
The review paper: A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home

Abstract

Objective: To evaluate the impact on place of death of a hospital at home service for palliative care.

Design: Pragmatic randomised controlled trial.

Setting: Former XXXXXXXX health district.

Participants: 229 patients referred to the hospital at home service.

Intervention: Hospital at home versus standard care.

Main outcome measures: Place of death.

Results: 58% of control patients died at home compared with 67% patients allocated to hospital at home. This difference was not significant; intention to treat analysis did not show that hospital at home increased the number of deaths at home. 39% of patients randomised to hospital at home were not admitted to the service. Patients admitted to hospital at home were significantly more likely to die at home (78%) than control patients. It is not possible to determine whether this was due to hospital at home itself or other characteristics of the patients admitted to the service. The study attained less statistical power than initially planned.

Conclusion: In a locality with good provision of standard community care we could not show that hospital at home allowed more patients to die at home, although neither does the study refute this. Problems relating to recruitment, attrition, and the vulnerability of the patient group make randomised controlled trials in palliative care difficult. While these difficulties have to be recognised they are not insurmountable with the appropriate resourcing and setting.
Introduction

In England and Wales in 1995, 21% of deaths from all causes and 26% of deaths from cancer occurred in people’s own homes.\(^1\) Half or more of terminally ill patients, however, express preference to remain at home until death.\(^2-4\) Dying at home is also preferred by most of the general public\(^5\) and primary care professionals. Informal carers are more likely to state that the place of death was right if the patient died at home rather than in hospital.\(^6-8\) In recognition of patients’ wishes to remain at home and the apparent discrepancy between provision of and demand for care there has been a considerable increase in the number of palliative home care teams in the United Kingdom in recent years.\(^9\) So far, however, there has been little published evaluation of their impact. A range of approaches to evaluation are possible with the randomised controlled trial posited as the gold standard.\(^10\)

A review by Smeenk et al\(^11\) found that few successful randomised controlled trials of palliative home care have been reported.\(^12-17\) Only one of these was in the United Kingdom.\(^16,17\) The limited number of such trials probably reflects the particular problems palliative care poses for trial design. Problems of recruitment and attrition, difficulty in predicting prognosis, unexpected inpatient admissions, and patients’ and carers’ frequent inability to complete measures all present obstacles to randomised controlled trials in this specialty.\(^18\) We report a further attempt to overcome these difficulties in a randomised controlled trial of the XXXXXXXX hospital at home for palliative care.

Hospital at home was set up with the aim of improving provision of care, particularly night care, for terminally ill patients and increasing their choice of place of care. We aimed to determine whether hospital at home enabled more patients to remain at home until death. Results of process measures from the randomised controlled trial and of hospital at home survey and interview studies conducted alongside it will be reported elsewhere.
Method

Study population

Hospital at home was available for terminal care for patients with any diagnosis whose prognosis was two weeks or less, as estimated by clinicians, and for respite care for patients with cancer, motor neurone disease, and AIDS. Participants were referrals to hospital at home over a 15 month period. Referrals could be made from primary or secondary care. A referral to hospital at home implied that home care was preferred by the patient.

In rare circumstances a patient could be assigned to hospital at home without randomisation and thus fail to enter the randomised controlled trial. If he or she was referred when hospital at home was “empty” the patient would be admitted to ensure hospital at home places were filled; if he or she was referred as an emergency when no standard care was available, hospital at home would be provided as a stop gap.

Intervention

Hospital at home provides practical home nursing care for up to twenty-four hours a day for up to 2 weeks. The service was used mainly for terminal care during the last 2 weeks of life. The hospital at home team consisted of 6 qualified nurses, 2 nursing auxiliaries, and 1 nurse coordinator. Agency nurses were also used as required.

Both patients allocated to hospital at home and control patients could receive the standard care services provided in the district. The intervention group, however, could also receive hospital at home. Thus the trial compared hospital at home and standard care versus standard care only. Standard care comprised care in hospital or hospice or care at home with input from general practice, district nursing, Marie Curie nursing, Macmillan nursing, evening district nursing, social services, a flexible care nursing service, or private care.

Outcome measures

Demographic data were collected on referral. Death certification, including place of death, was obtained from the ONS.
**Sample size**

Hospital at home was funded to accommodate about 100 patients a year with referrals expected at twice this rate, thus making possible a 1:1 random allocation of 180 patients to each trial arm over a 22 month period. This was felt to be adequate by a statistician. Our pilot study confirmed a referral rate of about 200 a year and an admission rate of about 100 a year. The pilot study also showed that many patients referred to hospital at home fail to obtain the service because of the particular problems associated with the patient group—for example, deterioration and death occurring shortly after referral or other unexpected changes in circumstance (such as urgent inpatient admission for control of symptoms, carer becoming unable to cope at home). Failure to obtain hospital at home was rarely due to a lack of resources. Thus to allow for attrition and ensure that hospital at home places were filled the randomisation ratio was set at 4:1 hospital at home to standard care. It was important to ensure that hospital at home operated at full capacity at all times to gain cooperation from health professionals, thus allowing the trial to be conducted. Because a large proportion of patients and informal carers were unable to complete self reported measures, redesign to retrospective data collection resulted in the trial period having to be reduced from 22 to 15 months. These changes implied a considerable reduction in statistical power as only 200 hospital at home patients and 50 control patients could now be expected to enter the trial. To achieve the planned statistical power 450 hospital at home patients and 110 controls would have had to enter the trial, which would have required the trial to run for some 34 months.

**Randomisation and blinding**

The randomisation sequence was concealed in sequentially numbered, opaque, sealed envelopes. When a patient was referred, the hospital at home coordinator opened the sealed envelope, which identified the allocation of the patient and informed the person making the referral whether the patient was to receive hospital at home or control. It was not possible to blind recipients to the fact that the hospital at home service was provided.

Of those patients referred, 21 were not randomised because of referral fluctuations and “emergency” referrals, and these patients are excluded. Of those randomised, 112 were still alive at the end of the study. Data was collected for the remaining 43 control patients and 186 patients allocated to hospital at home. Of the patients allocated to hospital at home, 61% were admitted to the service. Patients entering the trial were predominantly cancer patients, for whom the main diagnoses were gastrointestinal (31%), genitourinary (21%), breast (9%), and lung (8%) cancer. There were 14% diagnoses for conditions other than cancer.

**Statistical analysis**

We conducted an analysis using suitable parametric and nonparametric tests (Siegel and Castellan, 1988). Tests were two tailed with alpha = 0.05.
Results

No significant differences in patients’ characteristics were found between the hospital at home and control group (Tables 1-5). Patients in the hospital at home group who were admitted to the service survived significantly longer after referral than hospital at home patients who were not admitted (16 vs 8 days, \( P \leq 0.05 \)), suggesting that rapid death was associated with failure to obtain hospital at home. Patients who were admitted to hospital at home, however, did not differ from control patients in length of survival (NS). All other comparisons in the table were not significant (NS).

Table 1: Patients with cancer. Figures are numbers (percentages)

<table>
<thead>
<tr>
<th>Patients</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>37 (86)</td>
<td>6 (14)</td>
<td>43 (100)</td>
</tr>
<tr>
<td>Hah group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>161 (87)</td>
<td>25 (13)</td>
<td>186 (100)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>99 (88)</td>
<td>14 (12)</td>
<td>113 (100)</td>
</tr>
<tr>
<td>Not admitted to hospital</td>
<td>62 (85)</td>
<td>11 (15)</td>
<td>73 (100)</td>
</tr>
</tbody>
</table>

Table 2: Patients living alone. Figures are numbers (percentages)

<table>
<thead>
<tr>
<th>Patients</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>7 (17)</td>
<td>34 (83)</td>
<td>41 (100)</td>
</tr>
<tr>
<td>Hah group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>39 (21)</td>
<td>143 (79)</td>
<td>182 (100)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>22 (20)</td>
<td>90 (80)</td>
<td>112 (100)</td>
</tr>
<tr>
<td>Not admitted to hospital</td>
<td>17 (24)</td>
<td>53 (76)</td>
<td>70 (100)</td>
</tr>
</tbody>
</table>

Table 3: Patients’ gender. Figures are numbers (percentages)

<table>
<thead>
<tr>
<th>Patients</th>
<th>Female</th>
<th>Male</th>
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</thead>
<tbody>
<tr>
<td>Control group</td>
<td>23 (54)</td>
<td>19 (46)</td>
<td>43 (100)</td>
</tr>
<tr>
<td>Hah group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>92 (50)</td>
<td>94 (50)</td>
<td>186 (100)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>60 (53)</td>
<td>53 (47)</td>
<td>113 (100)</td>
</tr>
<tr>
<td>Not admitted to hospital</td>
<td>41 (56)</td>
<td>32 (44)</td>
<td>73 (100)</td>
</tr>
</tbody>
</table>

Table 4: Patients’ age (years). Figures are means (SDs)

<table>
<thead>
<tr>
<th>Patients</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
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<tr>
<td>Control group</td>
<td>43</td>
<td>72.126</td>
<td>11.253</td>
</tr>
<tr>
<td>Hah group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>186</td>
<td>72.561</td>
<td>13.639</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>113</td>
<td>72.768</td>
<td>13.494</td>
</tr>
<tr>
<td>Not admitted to hospital</td>
<td>73</td>
<td>72.239</td>
<td>13.949</td>
</tr>
</tbody>
</table>
Table 5: Patients’ survival time. Figures are means (SDs)

<table>
<thead>
<tr>
<th>Patients</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>43</td>
<td>30.56</td>
<td>64.138</td>
</tr>
<tr>
<td>Hah group</td>
<td>143</td>
<td>36.38</td>
<td>73.530</td>
</tr>
<tr>
<td>Total</td>
<td>186</td>
<td>36.38</td>
<td>73.530</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>113</td>
<td>45.56</td>
<td>87.019</td>
</tr>
<tr>
<td>Not admitted to hospital</td>
<td>73</td>
<td>22.16</td>
<td>42.141</td>
</tr>
</tbody>
</table>

* Difference: 2-tailed t P > 0.05. § Difference: 2-tailed t P < 0.05.

There was no significant difference between the control group and those allocated to hospital at home in the likelihood of dying at home (controls, 58.1%; hospital at home, 67.7%; P > 0.05). Of the subsample of the hospital at home group who were admitted to the service, however, 77.9% died at home. This is a significantly higher proportion than for the control group (P < 0.05). It is not clear, however, whether this difference is due to hospital at home or to differences in characteristics between patient groups.

Table 5.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Died at home</th>
<th>Died elsewhere</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>41.9 (n=18)</td>
<td>58.1* § (n=25)</td>
<td>100 (n=43)</td>
</tr>
<tr>
<td>Hah group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>33.3 (n=62)</td>
<td>66.7* (n=124)</td>
<td>100 (n=186)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>22.1 (n=25)</td>
<td>77.9§ (n=88)</td>
<td>100 (n=113)</td>
</tr>
<tr>
<td>Not admitted to hospital</td>
<td>50.7 (n=37)</td>
<td>49.3 (n=36)</td>
<td>100 (n=73)</td>
</tr>
</tbody>
</table>

* Difference: 2-tailed P > 0.05. § Difference: 2-tailed P < 0.05.
Figure 1.
Discussion

Place of death

While patients who were actually admitted to hospital at home were more likely to die at home than controls (78% v 58%), these results do not allow us to conclude that hospital at home enabled more patients to die at home. Intention to treat analysis did not show that patients allocated to hospital at home were more likely to die at home (67%) than patients allocated to standard care, and it may be that patients who were most suitable for remaining at home were also most likely to receive hospital at home care. The results are therefore inconclusive in terms of causation, but suggestive of an effect associated with receipt of hospital at home.

The community care in the study area is probably more comprehensively provided than in many other parts of the country, and patients referred to hospital at home may be more suitable for home care than the rest of the population. The home death rate for the control group was 58% compared with 21% for patients in England and Wales in general. If the preconditions for death at home are already present a new service may have little additional impact. Furthermore, when a palliative home care service is introduced so close to death (median survival from referral 11 days), the main factors determining death at home may already be present and have taken effect. The service itself may therefore do little to change the place of death at this point but may rather serve to improve the quality of death, a question we examine elsewhere.

Methodological concerns for randomised controlled trials in palliative care

The present study highlighted several issues relating to randomised controlled trials in palliative care. The first of these is the difficulty we experienced in attaining sufficient statistical power. Three factors contributed to this: the unequal randomisation ratio of 4:1; the limited time available for the study; and the base rate of death at home in the control group.

The 4:1 randomisation ratio was set because many of the patients allocated to hospital at home did not receive the service because of the particular problems of the patient group. Far more patients therefore had to be allocated to hospital at home than to the control condition to ensure that the service ran at or near capacity. In addition 8% of suitable patients had to be excluded from the study to fill hospital at home spaces during quiet periods and accommodate emergency referrals. Had we not compromised in this way, the trial would have prevented the service from helping as many patients as its resources permitted. This would have resulted in reduced cooperation from health professionals and the likely collapse of the trial as well as raising ethical concerns. Even when one can strongly argue that there is equipoise between conditions it can be difficult to justify randomisation in palliative care on grounds other than as a means of allocating limited resources. Randomisation to a waiting list is not feasible when patients have a limited life span. A patient preference design may at times be more ethical but may further limit patient numbers and reduce statistical power. Randomisation by general practice can be suitable for some interventions but entails further problems with statistical power.
the present study randomisation was justified on the basis of limited resources, and the randomisation ratio could have been improved only by increasing the rate of admissions among those allocated to hospital at home or by increasing the referral rate. Failure to admit was due to the unpredictability and complexity of terminal illness. The resolution of these problems would therefore probably be beyond the scope of most services. An increase in referrals would have allowed the trial to shift the surplus of patients over to the control condition, and to this end encouragement was given to health professionals to refer. There is probably a limit to how much referrals could increase, however, particularly if an increase in referrals meant a decreased likelihood of obtaining an admission.

The limited time available for the study reflected the time constraints common to evaluations of innovative healthcare interventions. An extended pilot period was necessary to allow the service to undergo several changes and settle down into its final form. A proper understanding of referral and admission patterns was essential to arrive at a feasible trial design. The need finally to abandon prospective data collection due to data attrition and switch to retrospective collection of process measures led to further time reduction. Once the randomised controlled trial was running, the planned statistical power could have been attained by extending the trial time frame from 15 to 34 months. The hospital at home service itself, however, was funded for only a limited period, its future funding in part dependent on the outcome of the trial. The trial therefore needed to be completed and the results analysed in time to inform this process.

In addition to loss of power, the trial may have been affected by dilution of the treatment effect, thus further reducing the likelihood of observing an impact of the service. Only 61% of patients allocated to hospital at home obtained the service. As noted this is not unusual in palliative care. The intervention itself was “contaminated” by other input. Hospital at home would be supplemented by general practitioner and district nurse input and often also by other community care when less than 24 hour hospital at home input was provided. The standard care provided for control patients was of considerable range and complexity, including both primary and secondary care, the standardisation of which was necessarily beyond the control of the trial design. Palliative care is not one simple intervention or procedure; it requires a multidisciplinary package of care, the composition of which will vary from location to location and from individual to individual. It is also possible that the hospital at home service freed up other palliative care resources, which were then available to the control group, thus “narrowing the gap” in service provision between the two patient groups.

Palliative care therefore does pose particular problems for the design of randomised controlled trials over and above those posed by evaluation of any innovative health technology where results are needed fast. These include the difficulty of attaining sufficient power due to attrition, the need to ensure that randomisation is ethically justifiable, the difficulty of data collection, dilution of treatment effect, and difficulty in standardising the intervention and control conditions. In evaluations of specific schemes with a defined life the randomised controlled trial may not be the design of first choice. Important insights may be gained from smaller scale “before and after” designs, case-control approaches that provide in depth descriptions of the service, or explorative trial methodologies, which use rolling data analysis and intervention optimisation through the pilot stages. If the effectiveness of services such as hospital at home are to be fully evaluated, however, resources will need to be found for substantial trials in appropriate
settings, as without randomisation and intention to treat analysis it is too easy to assume that an intervention is successful, as the present one superficially seemed to be in terms of home death rates.

We thank the hospital at home team and our research steering group for their input and advice on the research. The study was approved by the XXXXXXXX local research ethics committee.

**Contributors:** XX designed the trial and the research materials, liaised with hospital at home staff and other health professionals, conducted the data collection, performed the data analysis, and produced the main drafts of the paper. XX, the principal investigator of the study and guarantor, initiated the research, provided overall direction on the study, discussed core ideas, and contributed to design of the protocol, analysis, interpretation of results, and writing of the paper. XX discussed core issues, participated in protocol design, data collection, and interpretation of results, and edited the paper. XX was an applicant to the research funders, participated in the study design and management, advised on liaison with health professionals, contributed to interpretation of results, and edited the paper.

**Funding:** The hospital at home service was funded by the Elizabeth Clark Charitable Trust. Funding for the research was provided by the Elizabeth Clark Charitable Trust and the NHS research and development primary/secondary care interface programme.

**Competing interests:** None declared.

**Key messages**

- Terminally ill patients allocated to hospital at home were no more likely to die at home than patients receiving standard care
- Although the subsample of patients actually admitted to hospital at home did show a significant increase in likelihood of dying at home, whether this was due to the service itself or the characteristics of patients admitted to hospital at home could not be determined
- The need to balance ideal research design against the realities of evaluation of palliative care had the effect that the trial achieved less statistical power than originally planned
- Particular problems were that many patients failed to receive the allocated intervention because of the unpredictable nature of terminal illness, inclusion of other service input alongside hospital at home, and the wide range of standard care available
- The trial illustrated problems associated with randomised controlled trials in palliative care, none of which are insurmountable but which require careful consideration and resourcing before future trials are planned
References

20 XX, XX, XX, XX, XX. Report on an evaluation of the XXXXXXXX Hospital at Home for palliative care (H@H). XXXXXXXX: GPPCRU, Department of Community Medicine, University of XXXXXXXX, 1998.
22 Campbell MK, Grimshaw JM. Cluster randomised trials: time for improvement: the implications of adopting a cluster design are still largely being ignored (editorial)
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Statistical presentation in international scientific publications

B. Statistical review checklist

Introduction

Following is the statistical review checklist that we shall use to review the paper “A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home”. There is so much to consider when reviewing a paper statistically, and it is invaluable to have the main points listed in the form of a checklist.

The following checklist is that currently used by Health & Social Care in the Community, which itself was derived from the statistical checklist used by the BMJ (see their current version at http://bmj.bmjournals.com/advice/checklists.shtml#stats) by a previous editor of HSCC, Dr Jane Hutton. The section names indicate where the required information is likely to be found in the paper, but not a guarantee of course – you can’t rely on authors to get it right!
# Statistical Review Checklist

## Manuscript Number:

## Manuscript Title:

### Layout (All, Abstract)

<table>
<thead>
<tr>
<th>No.</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Did the paper follow the Introduction-Methods-Results-Discussion format?</td>
</tr>
<tr>
<td>2</td>
<td>Did the paper conform to CONSORT/TREND/STROBE/STARD for RCT/non-randomised design/observational study/diagnostic accuracy?</td>
</tr>
<tr>
<td>3</td>
<td>Was the Abstract correctly structured and sufficiently informative?</td>
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### Study Design (e.g., Introduction, Methods)

<table>
<thead>
<tr>
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<tbody>
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<td>1</td>
<td>Were the objectives of the study sufficiently described?</td>
</tr>
<tr>
<td>2</td>
<td>Was an appropriate study design used to achieve the objectives?</td>
</tr>
<tr>
<td>3</td>
<td>Was the design of the study sufficiently described?</td>
</tr>
<tr>
<td>4</td>
<td>Were source and inclusion/exclusion criteria clearly described for participants?</td>
</tr>
<tr>
<td>5</td>
<td>Were methods used for randomisation or sampling clearly described?</td>
</tr>
<tr>
<td>6</td>
<td>Was the sample of participants appropriate with respect to the population to which the findings will be generalised?</td>
</tr>
<tr>
<td>7</td>
<td>Were standard, validated instruments (e.g., questionnaires) used for data collection? If not, were the instruments used validated during the study?</td>
</tr>
<tr>
<td>8</td>
<td>Was the sample size based on pre-study considerations of statistical power?</td>
</tr>
<tr>
<td>9</td>
<td>Were ethical approval and participants' consent reportedly obtained?</td>
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### Statistical Methods (e.g., Methods, Results)

<table>
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<tbody>
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<td>1</td>
<td>Were the statistical methods used adequately described or referenced?</td>
</tr>
<tr>
<td>2</td>
<td>Were the statistical methods used appropriate for the data?</td>
</tr>
<tr>
<td>3</td>
<td>Were the name and version of the software used for data analysis given?</td>
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### Conduct of the Study (e.g., Methods, Results)

<table>
<thead>
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<tbody>
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<td>1</td>
<td>Were dates, clinical settings and geographical locations given for data collection?</td>
</tr>
<tr>
<td>2</td>
<td>Were satisfactory sample size/participation rate achieved and clearly reported?</td>
</tr>
<tr>
<td>3</td>
<td>Were missing data properly accounted for?</td>
</tr>
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</table>

### Statistical Analysis and Presentation (e.g., Results, Discussion, Tables)

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<thead>
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<td>Were relevant characteristics of the participants adequately summarised?</td>
</tr>
<tr>
<td>2</td>
<td>Were percentages and descriptive statistics correctly reported?</td>
</tr>
<tr>
<td>3</td>
<td>Were the statistical methods applied correctly in data analysis?</td>
</tr>
<tr>
<td>4</td>
<td>Were confidence intervals given for the main results?</td>
</tr>
<tr>
<td>5</td>
<td>Were significance test results and confidence intervals correctly reported?</td>
</tr>
<tr>
<td>6</td>
<td>Were all statistical tables and figures necessary and clearly laid out?</td>
</tr>
<tr>
<td>7</td>
<td>Were all statistical tables and figures able to stand alone from the text?</td>
</tr>
<tr>
<td>8</td>
<td>Were sufficient descriptive or inferential analyses presented?</td>
</tr>
<tr>
<td>9</td>
<td>Were conclusions drawn from the statistical analyses justified?</td>
</tr>
</tbody>
</table>
In your opinion, is the paper statistically acceptable? □ □ □ □

*Subject to the modifications indicated above
## CONSORT Checklist of items to include when reporting a randomized trial

<table>
<thead>
<tr>
<th>PAPER SECTION And topic</th>
<th>Item</th>
<th>Description</th>
<th>Reported on Page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE &amp; ABSTRACT</strong></td>
<td>1</td>
<td>How participants were allocated to interventions (e.g., &quot;random allocation&quot;, &quot;randomized&quot;, or &quot;randomly assigned&quot;).</td>
<td></td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td>2</td>
<td>Scientific background and explanation of rationale.</td>
<td></td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td>3</td>
<td>Eligibility criteria for participants and the settings and locations where the data were collected.</td>
<td></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>4</td>
<td>Precise details of the interventions intended for each group and how and when they were actually administered.</td>
<td></td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>5</td>
<td>Specific objectives and hypotheses.</td>
<td></td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>6</td>
<td>Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).</td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>7</td>
<td>How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.</td>
<td></td>
</tr>
<tr>
<td><strong>Randomization</strong></td>
<td>8</td>
<td>Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification).</td>
<td></td>
</tr>
<tr>
<td><strong>Sequence generation</strong></td>
<td>9</td>
<td>Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.</td>
<td></td>
</tr>
<tr>
<td><strong>Randomization</strong></td>
<td>10</td>
<td>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</td>
<td></td>
</tr>
<tr>
<td><strong>Allocation concealment</strong></td>
<td>11</td>
<td>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.</td>
<td></td>
</tr>
<tr>
<td><strong>Blinding (masking)</strong></td>
<td>12</td>
<td>Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.</td>
<td></td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td>13</td>
<td>Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.</td>
<td></td>
</tr>
<tr>
<td><strong>Participant flow</strong></td>
<td>14</td>
<td>Dates defining the periods of recruitment and follow-up.</td>
<td></td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
<td>15</td>
<td>Baseline demographic and clinical characteristics of each group.</td>
<td></td>
</tr>
<tr>
<td><strong>Baseline data</strong></td>
<td>16</td>
<td>Number of participants (denominator) in each group included in each analysis and whether the analysis was by &quot;intention-to-treat&quot;. State the results in absolute numbers when feasible (e.g., 10/20, not 50%).</td>
<td></td>
</tr>
<tr>
<td><strong>Numbers analyzed</strong></td>
<td>17</td>
<td>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).</td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes and estimation</strong></td>
<td>18</td>
<td>Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.</td>
<td></td>
</tr>
<tr>
<td><strong>Ancillary analyses</strong></td>
<td>19</td>
<td>All important adverse events or side effects in each intervention group.</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse events</strong></td>
<td>20</td>
<td>Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.</td>
<td></td>
</tr>
<tr>
<td><strong>DISCUSSION</strong></td>
<td>21</td>
<td>Generalizability (external validity) of the trial findings.</td>
<td></td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>22</td>
<td>General interpretation of the results in the context of current evidence.</td>
<td></td>
</tr>
<tr>
<td><strong>Overall evidence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Statistical presentation in international scientific publications

C. Completed statistical review checklist

Introduction

Here is a completed statistical review checklist for the specially prepared research paper “A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home”. Remember that the statistical shortcomings of the paper were inserted intentionally, but they are typical of the kinds of errors that occur in papers submitted to healthcare journals. There may be others errors in the review paper that have been missed – reviewers, even statistical reviewers, are not infallible, and some points may be down to matters of interpretation.
Statistical Review Checklist

Manuscript Number:

Manuscript Title: A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home

<table>
<thead>
<tr>
<th>Layout (All, Abstract)</th>
<th>Yes</th>
<th>Unclear</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Did the paper follow the Introduction-Methods-Results-Discussion format?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2 Did the paper conform to CONSORT/TREND/STROBE/STARD for RCT/non-randomised design/observational study/diagnostic accuracy?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>3 Was the Abstract correctly structured and sufficiently informative?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Comments:
Findings are introduced towards the end of the Methods section. The paper does not conform to CONSORT: the paper does not explicitly say that the main analyses were by intention to treat (critical for this study), there is no flowchart of subjects, and confidence intervals are not given for the main analysis. The Abstract does not give dates of data collection, the sizes of the intervention and control group are not clear, and percentages are given without numbers.

<table>
<thead>
<tr>
<th>Study Design (e.g., Introduction, Methods)</th>
<th>Yes</th>
<th>Unclear</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Were the objectives of the study sufficiently described?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Was an appropriate study design used to achieve the objectives?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Was the design of the study sufficiently described?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Were source and inclusion/exclusion criteria clearly described for participants?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>5 Were methods used for randomisation or sampling clearly described?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>6 Was the sample of participants appropriate with respect to the population to which the findings will be generalised?</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Were standard, validated instruments (e.g., questionnaires) used for data collection? If not, were the instruments used validated during the study?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>8 Was the sample size based on pre-study considerations of statistical power?</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Were ethical approval and participants’ consent reportedly obtained?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:
Although it may not be obvious from the Methods, the study design is appropriate given the aim of evaluating the impact of a hospital at home palliative care scheme on place of death. The report of this pragmatic RCT could make an important contribution to a debate on the feasibility of RCTs in palliative care research. The authors were very honest about the need to change their protocol and re-calculate their sample size given the practical problems they encountered. No inclusion/exclusion criteria are given and it is not clear whether the findings can be generalised to all palliative care patients or just those referred to the hospital at home scheme. Although they clearly stated how random allocation was performed, with the hospital at home coordinator being blind to allocation, the authors did not say how the randomisation sequence was generated. The sample size calculations themselves need to be clarified. Ethical approval was obtained from a local research ethics committee, but the authors do not report requesting or receiving patient consent. The paper does not report any participants refusing to participate.

<table>
<thead>
<tr>
<th>Statistical Methods (e.g., Methods, Results)</th>
<th>Yes</th>
<th>Unclear</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Were the statistical methods used adequately described or referenced?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2 Were the statistical methods used appropriate for the data?</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Were the name and version of the software used for data analysis given?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Comments:
The statistical methods are not clearly described and it is not clear what tests are being applied. A t-test appears to have been used for analysing a highly skewed variable (survival time). Software used for data analysis is not identified.

<table>
<thead>
<tr>
<th>Conduct of the Study (e.g., Methods, Results)</th>
<th>Yes</th>
<th>Unclear</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Were dates, clinical settings and geographical locations given for data collection?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2 Were satisfactory sample size/participation rate achieved and clearly reported?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>3 Were missing data properly accounted for?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Dates of data collection are not given [the geographical location has been anonymised]. There appears to be an inconsistency in the number of consecutive referrals to the hospital at home service during the 15-month data collection period: a total of 362 were apparently referred when about 250 were expected. Of these 362 referrals, only 21 (6%) were not randomised and excluded from the study (there is no mention of refusal to participate). Of the 241 who were apparently randomised, only 229 (67%) died and were included in the analysis. No information is given on the other 112 (33%), who were not followed up as they were still alive at the end of data collection. If these numbers are correct, insufficient time seems to have been allowed for the study.

<table>
<thead>
<tr>
<th>Statistical Analysis and Presentation (e.g., Results, Discussion, Tables)</th>
<th>Yes</th>
<th>Unclear</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Were relevant characteristics of the participants adequately summarised?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>2 Were percentages and descriptive statistics correctly reported?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>3 Were the statistical methods applied correctly in data analysis?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>4 Were confidence intervals given for the main results?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>5 Were significance test results and confidence intervals correctly reported?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>6 Were all statistical tables and figures necessary and clearly laid out?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>7 Were all statistical tables and figures able to stand alone from the text?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>8 Were sufficient descriptive or inferential analyses presented?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>9 Were conclusions drawn from the statistical analyses justified?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

Comments:
Percentages are quoted without numbers and with varying numbers of decimal places, and descriptive statistics for age have too many decimal places. Some of the randomised patients were not included in the analyses as they were alive at the end of the study, and more details of these should be given, if possible. Because of a potential imbalance in the remainder of the randomised groups included in the analysis, the results of the baseline comparison tests should be given in full. The authors should make it clearer in their Results section which analyses are intention to treat and which are per protocol, as the two approaches lead to different conclusions in this study. The authors discuss the implications of this well in their Discussion. Confidence intervals for the difference in the percentages dying at home (the main outcome variable) in the two groups are not given. No test statistics are given, and p-values are reported in ranges only. Tables and a figure are mixed in with the text; there are two Table 5s, and the last table and figure do not have titles. There are many small tables that could be compressed and combined, and the three-dimensional bar chart should be deleted as it repeats information in a table. All of the tables use an acronym that would not be clear to a reader looking at the tables only.

<table>
<thead>
<tr>
<th>Overall Assessment</th>
<th>Yes</th>
<th>Minor Revision*</th>
<th>Major Revision*</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your opinion, is the paper statistically acceptable?</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

Comments:
This paper can make an important contribution to the methodology of quantitative research in palliative care. Before it can be considered for publication, the authors need to state whether patient consent was obtained, and if not, why not. The reasons behind the sample size calculation need to be given explicitly. The authors also need to clarify the numbers of patients involved and comment on the number of patients not followed up by the end of the study (this appears to be 112/341) and any impact this may have on the findings. Confidence intervals are needed for the comparison of the main outcome variable (place of death) by allocation group. Considerable if relatively minor work is required on the statistical presentation of results before the paper can be considered statistically acceptable.

*Subject to the modifications indicated above
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Statistical presentation in international scientific publications

D. Detailed statistical review

Introduction

Here is a more detailed statistical review of the specially prepared research paper “A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home”. There are detailed comments structured according to the headings used in the paper for ease of reference. The content of tables and figures are discussed at the end of the review (they should have been submitted separately after the text of the paper).

The statistical shortcomings of the paper were inserted intentionally, but they are typical of the kinds of errors that occur in papers submitted to healthcare journals. Comments in square brackets refer to the content of the original research paper on which the review paper was based. There may be others errors in the review paper that have been missed – reviewers, even statistical reviewers, are not infallible, and some points may be down to matters of interpretation.
A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home

Detailed statistical review

Title

The Title does not indicate the study design.
- It is not essential, but it will increase its readership if it does, especially if it is a randomised controlled trial (RCT).
- [The title of the original paper was more succinct and included the study design: “Does hospital at home for palliative care facilitate death at home? Randomised controlled trial.”]

Abstract

The Abstract does not give dates of data collection.
- This is a very common error, and it is important to tell a reader how up-to-date the data are, in case circumstances change.
- Note that the Abstract is structured. Not all journals use structured Abstracts, so you should check before submission. Even if the journal to which you plan to submit does not, it can be helpful when planning your paper to structure the Abstract as this helps make sure that all of the relevant points are included. Be sure to remove the structure before submission if the journal does not use structured Abstracts.
- [The original paper did not give dates of data collection here or in the main body of the paper.]

Participants

This paragraph gives the total number of participants in the study (229) but it does not say how many were randomised to each group. One would naturally think of roughly equal numbers, but this study was unusual in using an allocation ratio of 4:1 for intervention:control.
- [In the original paper, this paragraph went on to say “43 randomised to control group (standard care), 186 randomised to hospital at home.”]
Results

This paragraph contains percentages but not numbers, another common fault. Authors should give both numbers and percentages unless this affects the readability of the text. It should also be clear to a reader what the base total from which the percentages have been calculated, ie the denominator; this need not always be given explicitly, but it should be straightforward to work out what it is.

- Numbers put percentages into context and suggest how reliable the percentages might be; percentages allow numbers to be compared and assessed.
- [The original paper gave numbers and percentages, eg “… compared with 124 (67%) patients allocated to hospital at home.”]

Some sentences start with numerals; conventionally, those numerals should be written in words, eg “Thirty-nine per cent of patients randomised to hospital at home…”.

- [In the original paper, the authors correctly started sentences with numerals written in words, eg “Twenty five (58%) control patients died at home…”]

Introduction

No alterations were made here!

- This section of a paper rarely contains any statistical material, as it concentrates on the clinical background of a study and the reasons for performing a study.
- [What you see in the paper for review is exactly what appeared in the original.]

Method

Although it may not be obvious from the “doctored” version of the paper, the aim of the real study was to evaluate the impact of a hospital at home palliative care scheme on place of death, and the study design, a pragmatic randomised controlled trial, was most appropriate. The paper describes a number of practical problems encountered by the researchers prior to and during the trial, and the authors were very honest about the need to change their protocol and re-calculate their sample size in the circumstances.

- [This is to the credit of the authors of the original paper.]
The paper notes in an **Acknowledgements** paragraph that ethical approval was obtained from a local research ethics committee. It would be better to include this in the **Methods** section.

- Reviewers usually have to ask authors whether their study was granted ethical approval.
- [The original paper indicated ethical approval in an acknowledgements paragraph towards the end of the text.]

The paper does not report requesting or receiving patient consent, which one would have expected in a study such as this. The paper does not report any participants refusing to participate.

- Authors usually remember to report informed consent.
- [There was no mention of patient consent in the original paper. It was a conscious omission, as the issue was too complicated to cover in the original paper, given the word limit of the journal in which it was published. (This is an argument for journals not to stick rigidly to word limits for papers.) For a number of reasons, patients were not asked for consent for admission to the randomised controlled trial, and given the circumstances of the trial, the local ethics committee agreed with the researchers’ reasoning and granted ethical approval.]

**Study population**

The text states “Participants were referrals to hospital at home over a 15 month period.” There is no mention whether these were *consecutive* referrals, as this helps minimise the possibility of recruitment bias since all potential subjects are considered.

- Many authors forget to point out whether their study attempted to recruit consecutive subjects.
- [The original paper did, in fact, state “Participants were consecutive referrals to hospital at home over a 15 month period.”]

Full inclusion criteria are not stated. RCTs generally have quite strict inclusion criteria to keep the recruited sample homogenous and the trial manageable. It is not clear whether the findings can be generalised to all palliative care patients or just those referred to this particular hospital at home scheme.

- Problems with generalisability of findings from RCTs are inevitable.
- [The original study was as pragmatic as possible, but because participants were accessed on referral to the hospital at home coordinator, it is difficult generalising to all palliative care patients, even in the locality. The original paper did give inclusion criteria: “Patients were aged 16 years or above and residents of the former Cambridge health district.”].
**Intervention**

Numbers less than 10 are given as numerals (“last 2 weeks of life”, “6 qualified nurses, 2 nursing auxiliaries, and 1 nurse coordinator”), whereas one greater than 10 is given in words (“twenty-four hours”). Conventionally, numbers less than 10 should be given in words (“last two weeks of life”, “six qualified nurses, two nursing auxiliaries, and one nurse coordinator”) and numbers greater than 9 should be given as numerals (“24 hours”). An exception can be made for quantities with units, when numbers should be used (e.g., 5 kg).

- These are very simple rules, but many authors seem to be unaware of them.
- [The original paper correctly followed the convention.]

**Outcome measures**

An acronym is used unnecessarily (“ONS”). Authors should avoid acronyms and abbreviations wherever possible, as they may not be familiar to readers from other disciplines or countries. The latter is particularly important for international journals.

- Most authors ignore this and use acronyms and abbreviations widely, sometimes without explaining their meaning.
- [The original paper did not use the acronym but said “Office for National Statistics” in full.]

**Sample size**

The rationale for the sample size calculation, “This was felt to be adequate by a statistician”, is, of course, completely inadequate. It does not give the rationale underlying the calculation, or, indeed, guarantee that it was appropriate. Most authors do not include sample size calculations in their submitted papers, even though they may have been required at the planning stage of their study. Such calculations are a CONSORT statement requirement, and they should be included for all quantitative study designs except for pilot studies and purely exploratory studies.

- [The sentence in the original paper was actually “This would have yielded 80% power to detect a 15% difference (50-65%) in numbers of patients dying at home at alpha = 0.05”, which is acceptable.]

**Randomisation and blinding**

The authors say very clearly how the random allocation of patients to groups was performed, but they do not say how the random numbers were generated in the first place.

- According to the CONSORT guidelines for reporting RCTs, authors should say how the randomisation process was implemented, although most authors do not.
- [The original paper did say how the randomisation sequence was generated: “The randomisation sequence was generated from a statistical table of random numbers and concealed in sequentially numbered, opaque, sealed envelopes.” This minimal information is sufficient; there are software packages for generating randomisation sequences more efficiently.]
A paragraph of findings (information not known until after data were collected) appears in the Methods section; these findings should have been given at the start of the Results section.

- This is a very common fault in quantitative papers submitted to journals.
- [In the original paper, this paragraph was, in fact, correctly positioned at the start of the Results.]

According to the paragraph of findings, a total of 362 patients were referred to the hospital at home coordinator. The data were collected during a 15 month period of data collection, and a pilot study had confirmed referrals at the rate of around 200 a year. One would expect around 250 referrals, and 362 appears to be too large. The authors would have to check the numbers before a subsequent submission. If the numbers were correct, a question would have to be raised about the design of the study, as a large number of randomised patients (112/341) were not followed up until death, suggesting that insufficient time was allowed for the study.

- Papers submitted to journals sometimes contain apparently inconsistent numbers of patients. It is very easy to mistype numbers and it helps when a paper gives totals and subtotals.
- [The original paper was very explicit about the numbers of patients (which were also shown in a flow chart). The original text was as shown below. A total of 262 patients were referred, and only 12 were alive at the end of the study (the “112” in the review paper is an intentional typographical error). Nothing is said in the original paper, however, about the characteristics or allocation groups of the 12 survivors.
  - “Of 262 patients referred, 21 (8%) were not randomised because of referral fluctuations and “emergency” referrals (fig), and these patients are excluded. Of the 241 patients randomised, 12 were still alive at the end of the study. Data were collected for the remaining 43 control patients and 186 patients allocated to hospital at home.”]

That findings paragraph includes the phrase “Data was collected…”; the word “data” is a noun plural and the phrase should have been “Data were collected…”.

- This is quite a common fault among British authors; authors whose first language is not English seem to get it right.
- [The original paper used “Data were collected…”].

Two sentences in the paragraph begin with numbers (“362 patients were referred. 21 (6%) were not randomised…”). Conventionally, those numbers should be written in words, long-winded though it may seem (“Three hundred and sixty-two patients were referred. Twenty-one (6%) were not randomised…”).

- [The original paper used a form of wording that avoided starting a sentence with a number: Of 262 patients referred, 21 (8%) were not randomised…”].
Percentages are given without numbers for main diagnoses: “… gastrointestinal (31%), genitourinary (21%), breast (9%), and lung (8%) cancer. There were 14% diagnoses for conditions other than cancer.” Where possible, numbers and percentages should be given together.

- This is quite a common fault too, and occasionally occurs even when the base for the percentages is changed within a paragraph.
- [The original paper only gave percentages for the cancer patients, but at least gave number and percentage for the group without cancer: “… gastrointestinal (31%), genitourinary (21%), breast (9%), and lung (8%) cancer. There were 31 (14%) diagnoses for conditions other than cancer.”]

**Statistical analysis**

The paragraph does not say whether the analysis was (mainly) by intention to treat, and intention to treat and per protocol approaches are not clearly identified in the Results section. This is a CONSORT statement requirement.

- *Intention to treat* is the recommended method of analysis for RCTs, in which subjects are analysed according to the group to which they were randomised, regardless of whether they received that intervention or not. Statistically, this approach maintains the balanced nature of the groups following randomisation, so that the effects of known and unknown confounders are in theory balanced out between the groups.
- [The original paper clearly stated intention to treat analysis, and the analyses reported in the Results section are primarily intention to treat.]

The description of the statistical methods used for data analysis (“suitable parametric and nonparametric tests”) is too vague

- This or a variation on it occurs quite often in research proposals in particular. Authors should be more specific about the statistical methods used, unless the analyses are purely descriptive. This is especially true when unusual methods are used.
- [The original study used standard methods, and the original wording was as follows:
  
  “We conducted an intention to treat analysis using Pearson $\chi^2$ tests for nominal data, while interval data were analysed by Student’s $t$ test when normally distributed and Mann-Whitney U tests when skewed.”]

The referencing system used for the paper is Vancouver (references are identified by subscripted numbers). This paragraph contains a Harvard reference (“Siegel and Castellan, 1988”).

- This can happen when authors submit to one journal, are rejected, and submit to a second that uses a different style of referencing.
- [The original paper used Vancouver referencing throughout.]
The book by Siegel and Castellan is named as “Non-parametric statistics for the behavioural sciences. 2nd ed.” in the references. Pedantically, the first word should be “Nonparametric” without the hyphen.

- The reference is probably unnecessary, as the methods used are standard (non-standard or advanced methods should always be referenced).
- [Indeed, the nonparametric text book would cover Pearson’s $\chi^2$ test and the Mann-Whitney U test but not Student’s t-test, and in the original paper, it is given as a reference for the whole sentence, implying a reference for all three approaches.]

The software used for data analysis is not mentioned.

- Strangely enough, this is not a requirement of the CONSORT guidelines, and most authors fail to say what software was used. It is good scientific practice to give the name and version of the software used for data analysis, as this allows a reader to replicate a study. It is possible that different software packages may use different computational algorithms and come up with slightly different results, and not all packages support all advanced statistical methods. Lang and Secic (1997) recommend reporting the software used throughout their definitive textbook on how to report statistical findings.
- [The original paper named the software as SPSS 6.0 for Windows, even though that was and still is not a requirement for the journal in which the paper was published.]

A large number (112/341, 33%) of patients were reported to be still alive and therefore not followed up by the end of the study. Depending on what information is available for these patients, an alternative approach may be to consider some form of survival analysis.

- [As explained later, the 112 turns out to be a misprint for 12 in the original paper, so that relatively few patients survived and were not followed up.]
Results

If possible, more details should be given of the patients who were randomised but not included in the analyses as they were alive at the end of the study. As a minimum, their allocation group should be given. Because this causes a potential imbalance in the remainder of the randomised groups included in the analysis, the results of the baseline comparison tests should be given in full.

- [In the original paper, there were 12 patients who were still alive and were not followed up. No further details were given, and the baseline test results were reported as “No significant differences in patients’ characteristics were found between the hospital at home and control group.” Test results were given for analyses involving survival time.]

The authors should make it clearer in their Results section which analyses are intention to treat and which are per protocol, as the two approaches lead to different conclusions in this study in the main analyses comparing place of death by allocation group.

- This is a requirement of the CONSORT statement for reporting RCTs.
- [The two approaches were not clearly identified in the original paper but the authors discussed the implications well in their Discussion.]

In both paragraphs, no test statistics are quoted, and it is not clear what tests are being applied. *P*-values are given as ranges (eg “*P* <= 0.05”) or “NS”, whereas actual *p*-values should always be given to maximise the information to the reader.

- This is a very common fault in statistical papers submitted to journals. Many years ago, before *p*-values were calculated by computer, statistical tests were calculated by hand and values of test statistics were compared against tables of critical values at significance levels of 0.05, 0.01 and 0.001. At that time, it was only possible, after comparing the observed value against the critical values to conclude that *p* < 0.05, or *p* < 0.01 or *p* < 0.001. Nowadays, statistical software uses algorithms to accurately give actual *p*-values, and these should usually be reported either to at most three decimal places (eg “*p* = 0.123” or “*p* = 0.012”) or at most two significant digits (eg “*p* = 0.12” or “*p* = 0.012”) depending on the journal, or if the actual *p*-value is less than 0.0005, conventionally as “*p* < 0.001”. (Theoretically *p*-values can never be zero, despite what packages like SPSS might say, and it is wrong to report a *p*-value such as 0.000; this should be reported as “*p* < 0.001. Actual *p*-values should be given even when the result turns out to be non-significant.)

- [The original paper correctly gave test statistics, degrees of freedom where applicable, and actual *p*-values, eg “(Z = 1.666, *P* = 0.096)” and “(controls 25/43, 58%; hospital at home 124/186, 67%; \( \chi^2 \) 1.12, df = 1, *P* = 0.29)”. It might not have been clear to a reader that the Z in the first set of results was a test statistic for the Mann-Whitney U test – they could have made that clearer with “(M-W Z = 1.666, *P* = 0.096)”.]
In the second paragraph, percentages are quoted without actual numbers (eg “controls, 58.1%; hospital at home, 67.7%”). Numbers and percentages should be given wherever possible and it should be clear what the denominators are.

- This was covered earlier: numbers indicate how reliable percentages are, and percentages allow numbers to be compared.
- [The original paper gave numerators, denominators and percentages, eg “controls 25/43, 58%; hospital at home 124/186, 67%”.]

Also, percentages are given in this paragraph to one decimal place; elsewhere, the paper rounds all percentages to the nearest whole number.

- Quite often, authors of papers submitted to journals vary the number of decimal places for percentages throughout a paper. Authors should be consistent within the text and consistent within tables. There are no absolute rules on decimal places for percentages, but Lang and Secic (1997, p 41) suggest
  - when the sample size is greater than 100, use no more than one decimal place
  - when the sample size is less than 100, use whole numbers
  - when the sample size is less than, say, 20, consider reporting actual numbers rather than percentages
- [The original paper rounded all percentages to whole numbers for readability, eg “controls 25/43, 58%; hospital at home 124/186, 67%”.]

In the second paragraph, confidence intervals for the difference in the percentages dying at home (the main outcome variable) in the two groups should be given (this is a requirement of the CONSORT statement for reporting RCTs).

- Authors of RCTs usually but not always provide confidence intervals, but they are recommended in other situations too (eg for important percentages in surveys; important correlations in correlation studies; accuracy, sensitivity, specificity and agreement in diagnostic or agreement studies; coefficients in regression models; odds ratios in logistic regression models; risk ratios in Cox regression), where authors usually forget about them.
- [In the original paper, the authors did not give confidence intervals for the main analysis.]

Discussion

No alterations were made here either!

- The only parts of this section that are relevant to the statistical reviewer are a discussion of any limitations of the study and a discussion of the conclusions. Many authors forget to include a limitations paragraph, but it is important to warn a reader of the inevitable potential shortcomings in a real-life study. Many of these may be statistical in nature, concerning the populations underlying the study, restrictions in the way subjects were accessed and recruited, and strict inclusion criteria, all of which may limit the generalisability of the findings; assumptions about the behaviour of the main variables in the data and the suitability or flexibility of the statistical methods used, which may limit the interpretability of the findings. The statistical reviewer also needs to check whether the authors’ conclusions are justified in terms of their data and methods of analysis.
- [What you see in the paper for review is what appeared in the original.]
Tables and figures

Tables and figures should be submitted one per page separately from the text.

- This is standard practice and some authors, perhaps those who have not submitted to journals before, are unaware of this, even though it is usually stated in the instructions to authors.
- [The authors of the original paper would not have made that mistake.]

There is a large number of tables, which could be combined into a smaller number to save space.

- In papers submitted to journals, sometimes tables are too compact with insufficient results reported, and sometimes they are too verbose with too many results reported. Space is at a premium in academic journals, and it is important to strike a balance between providing all important results and not overwhelming the reader.
- [In the original paper, only one table was given, covering the first five tables in the review paper. For dichotomous variables such as whether a patient had cancer, lived alone or was female, only the numbers and percentages of “yes” responses were reported.]

There are two Table 5s.

- Such a simple error does occur in the scramble to submit papers to journals.
- [In the original paper, there was only one table.]

In all tables, the acronym “Hah” is used for “Hospital at home”; this may not be clear to a reader. A table should be able to stand alone from the text so that a reader can interpret its contents without having to cross-reference the text, if at all possible.

- This is a very common fault indeed: most authors save space within a table by using acronyms of abbreviations introduced in the text wherever possible in the table without explaining their meaning in the table, eg in footnotes.
- [In the original paper, the authors used “Hospital at home” in full.]

In all tables, the row labels “admitted to hospital” and “not admitted to hospital” are misleading. They could be interpreted by a reader as “died in hospital” and “died at home”.

- A statistical reviewer often has to suggest changes to the layout or labelling within a table to improve its readability.
- [The row labels “admitted to hospital” and “not admitted to hospital” actually appeared in the original paper, despite the efforts of the lead researcher.]

The second Table 5 and Figure 1 are not referenced in the text and do not have titles.

- Again, such simple errors do occur in the scramble to submit papers to journals.
In Table 3, the numbers of males and females admitted and not admitted to hospital at home do not add up to the respective totals for the hospital at home group. (The cells in the bottom row were swapped over.)

- A statistical reviewer should check tables for such errors wherever possible, as they do occasionally occur. A reader will often add up rows or columns to agree with a total when attempting to understand a table.
- [The original paper reported a total of 92 females in the hospital at home group, of which 60 were admitted to the service and 41 were not.]

In Table 4, ages are given to too many decimal places. The usual rule is to use one more decimal place than the number to which the variable is usually measured. Age is usually quoted to a whole number of years, so one decimal place is sufficient.

- This is quite a common fault, even though it is a simple rule to adopt. It has its roots in the number of decimal places shown in computer output.
- [In the original paper, the authors correctly used one decimal place for mean and standard deviation, e.g., "72.1 (11.3)"]

In the first Table 5, the standard deviations for patients’ survival time are considerably larger than the means, suggesting a high positive skewness. The footnote to the table suggests that t-tests were used, but these may produce unreliable results if the data are highly skewed. The authors should repeat the analyses using a nonparametric equivalent of the t-test (the Mann-Whitney U test) or by transforming survival time to reduce the skewness (e.g., by taking logarithms) before using t-tests.

- This happens quite often in papers submitted to journals. The t-test is robust to skewness if the sample size is large, but means many not be useful measures of the centre of the distribution when the skewness is very high or very low. Sometimes, authors submit tables of means without standard deviations or other measures of spread about the centre, and it may not be obvious that the data are skewed.
- [In the original paper, the authors applied the Mann-Whitney U test.]

The second Table 5 has a different format (percentage (n=number)) to the other tables (number (percentage)) for presenting numbers and percentages. Both formats are acceptable, the latter being more usual, but authors should be consistent in their presentation. The percentages in this table are to one decimal place, whereas others are rounded to the nearest whole number. Finally, the table shows row percentages, whereas column percentages (shown in the other tables) would be more appropriate.

- It is surprising how often tables in papers submitted to journals show inconsistencies in the way results are presented in tables, whether headings, row or column labels, or numbers.
- [The original paper did not include this table; the findings were given in the text, as follows: “There was no significant difference between the control group and those allocated to hospital at home in the likelihood of dying at home (controls 25/43, 58%; hospital at home 124/186, 67%; χ² 1.12, df = 1, P = 0.29).”]
Figure 1 is unnecessary and repeats information given in the Results section and the second Table 5.

- Authors often repeat information contained in the text in a table/figure or *vice versa*. A more common fault is for authors to summarise findings in a chart instead of using a more descriptive table.

Furthermore, Figure 1 is a three-dimensional bar chart that might look visually impressive, but it distorts the comparison of the two groups due to the introduction of the unnecessary dimension. The bar to the right may appear relatively larger because it is in the foreground. Figures with three-dimensional graphics should not be submitted to journals unless the third dimension represents an additional variable.

- A surprising number of figures in papers submitted to journals have an unnecessary third dimension added for emphasis or to make the graphic, in their eyes, look more “professional”. In the eyes of a Statistician, it looks more amateur.

According to the CONSORT statement, there should be a flow chart included in the paper to show the number of patients involved at different stages of the RCT.

- Despite this being a recognised requirement for RCTs, a number of authors forget to include a patient flow chart. These can be useful for other kinds of study design too where numbers of patients change, such as longitudinal cohort studies.

- [The original paper quite rightly included one, shown below. This very clearly the numbers of patients at different stages in the study.]

![Patient Flow Chart]

**References**

No alterations were made here either!

- The only parts of this section that are relevant to the statistical reviewer are any statistical or methodological references.

- [What you see in the paper for review is what appeared in the original.]
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Statistical presentation in international scientific publications

E. Original version of paper

Introduction

Following is the original version of “A comparison study of the effect of a hospital at home service for palliative care on whether or not a patient dies at home”, the paper that was specially prepared for statistical review. The style and content of the original version are reflected by the journal (BMJ) in which it was published and to some extent the year of publication (1999).

The full reference for the original paper is as follows:

Does hospital at home for palliative care facilitate death at home? Randomised controlled trial

Gunn E Grande, Chris J Todd, Stephen I G Barclay, Morag C Farquhar

Abstract

Objective To evaluate the impact on place of death of a hospital at home service for palliative care.

Design Pragmatic randomised controlled trial.

Setting Former Cambridge health district.

Participants 299 patients referred to the hospital at home service; 43 randomised to control group (standard care), 186 randomised to hospital at home.

Intervention Hospital at home versus standard care.

Main outcome measures Place of death.

Results Twenty-five (58%) control patients died at home compared with 124 (67%) patients allocated to hospital at home. This difference was not significant; intention to treat analysis did not show that hospital at home increased the number of deaths at home. Seventy-three patients randomised to hospital at home were not admitted to the service. Patients admitted to hospital at home were significantly more likely to die at home (88/113; 78%) than control patients. It is not possible to determine whether this was due to hospital at home itself or other characteristics of the patients admitted to the service. The study attained less statistical power than initially planned.

Conclusion In a locality with good provision of standard community care we could not show that hospital at home allowed more patients to die at home, although neither does the study refute this. Problems relating to recruitment, attrition, and the vulnerability of the patient group make randomised controlled trials in palliative care difficult. While these difficulties have to be recognised they are not insurmountable with the appropriate resourcing and setting.

Introduction

In England and Wales in 1995, 21% of deaths from all causes and 26% of deaths from cancer occurred in people's own homes.1 Half or more of terminally ill patients, however, express preference to remain at home until death.2 3 Dying at home is also preferred by most of the general public4 and primary care professionals.5 Informal carers are more likely to state that the place of death was right if the patient died at home rather than in hospital.5 6 In recognition of patients' wishes to remain at home and the apparent discrepancy between provision of and demand for care there has been a considerable increase in the number of palliative home care teams in the United Kingdom in recent years.7 8 So far, however, there has been little published evaluation of their impact. A range of approaches to evaluation are possible with the randomised controlled trial posited as the gold standard.9

A review by Smeenk et al10 found that few successful randomised controlled trials of palliative home care have been reported.11 12 Only one of these was in the United Kingdom.13 14 The limited number of such trials probably reflects the particular problems palliative care poses for trial design. Problems of recruitment and attrition, difficulty in predicting prognosis, unexpected inpatient admissions, and patients' and carers' frequent inability to complete measures all present obstacles to randomised controlled trials in this specialty.15 We report a further attempt to overcome these difficulties in a randomised controlled trial of the Cambridge hospital at home for palliative care.

Hospital at home was set up with the aim of improving provision of care, particularly night care, for terminally ill patients and increasing their choice of place of care. We aimed to determine whether hospital at home enabled more patients to remain at home until death. Results of process measures from the randomised controlled trial and of hospital at home survey and interview studies conducted alongside it will be reported elsewhere.

Method

Study population

Hospital at home was available for terminal care for patients with any diagnosis whose prognosis was two weeks or less, as estimated by clinicians, and for respite care for patients with cancer, motor neurone disease, and AIDS. Patients were aged 16 years or above and residents of the former Cambridge health district. Participants were consecutive referrals to hospital at home over a 15 month period. Referrals could be made from primary or secondary care. A referral to hospital at home implied that home care was preferred by the patient.

In rare circumstances a patient could be assigned to hospital at home without randomisation and thus fail to enter the randomised controlled trial. If he or she was referred when hospital at home was "empty" the patient would be admitted to ensure hospital at home places were filled; if he or she was referred as an emergency when no standard care was available, hospital at home would be provided as a stop gap.
journal: BMJ
volume: 319
issue: 7211
year: 1999
pages: 1472-1474

Intervention
Hospital at home provides practical home nursing care for up to 24 hours a day for up to two weeks. The service was used mainly for terminal care during the last two weeks of life. The hospital at home team consisted of six qualified nurses, two nursing auxiliaries, and a nurse coordinator. Agency nurses were also used as required.

Both patients allocated to hospital at home and control patients could receive the standard care services provided in the district. The intervention group, however, could also receive hospital at home. Thus the trial compared hospital at home and standard care versus standard care only. Standard care comprised care in hospital or hospice or care at home with input from general practice, district nursing, Marie Curie nursing, Macmillan nursing, evening district nursing, social services, a flexible care nursing service, or private care.

Outcome measures
Demographic data were collected on referral. Death certification, including place of death, was obtained from the Office for National Statistics.

Sample size
Hospital at home was funded to accommodate about 100 patients a year with referrals expected at twice this rate, thus making possible a 1:1 random allocation of 180 patients to each trial arm over a 22 month period. This would have yielded 80% power to detect a 15% difference (50-65%) in numbers of patients dying at home at α=0.05. Our pilot study confirmed a referral rate of about 200 a year and an admission rate of about 100 a year. The pilot study also showed that many patients referred to hospital at home fail to obtain the service because of the particular problems associated with the patient group—for example, deterioration and death occurring shortly after referral or other unexpected changes in circumstance (such as urgent inpatient admission for control of symptoms, carer becoming unable to cope at home). Failure to obtain hospital at home was rarely due to a lack of resources. Thus to allow for attrition and ensure that hospital at home places were filled the randomisation ratio was set at 4:1 hospital at home to standard care. It was important to ensure that hospital at home operated at full capacity at all times to gain cooperation from health professionals, thus allowing the trial to be conducted. Because a large proportion of patients and informal carers were unable to complete self reported measures, redesign to retrospective data collection resulted in the trial period having to be reduced from 22 to 15 months. These changes implied a considerable reduction in statistical power as only 200 hospital at home patients and 50 control patients could now be expected to enter the trial. To achieve the planned statistical power 450 hospital at home patients and 110 controls would have had to enter the trial, which would have required the trial to run for some 34 months.

Randomisation and blinding
The randomisation sequence was generated from a statistical table of random numbers and concealed in sequentially numbered, opaque, sealed envelopes. When a patient was referred the hospital at home coordinator opened the sealed envelope, which identified the allocation of the patient and informed the person making the referral whether the patient was to receive hospital at home or control. It was not possible to blind recipients to the fact that the hospital at home service was provided.

Statistical analysis
We conducted an intention to treat analysis using Pearson χ² tests for nominal data, while interval data were analysed by Student’s t test when normally distributed and Mann-Whitney U tests when skewed. Tests were two tailed with α=0.05. Analysis was conducted with spss 6.0 for Windows.

Results
Of 262 patients referred, 21 (8%) were not randomised because of referral fluctuations and “emergency” referrals (fig), and these patients are excluded. Of the 241 patients randomised, 12 were still alive at the end of the study. Data were collected for the remaining 43 control patients and 186 patients allocated to hospital at home. Of the patients allocated to hospital at home, 113 (61%) were admitted to the service. Patients entering the trial were predominantly cancer patients (n=198), for whom the main diagnoses were gastrointestinal (31%), genitourinary (21%), breast (9%), and lung (8%) cancer. There were 31 (14%) diagnoses for conditions other than cancer.

No significant differences in patients’ characteristics were found between the hospital at home and control group (table). Patients in the hospital at home group who were admitted to the service survived significantly longer after referral than hospital at home patients who were not admitted (16 v 8 days, Z=3.005, P=0.003), suggesting that rapid death was associated with failure to obtain hospital at home. Patients who were admitted to hospital at home, however, did not differ from control patients in length of survival (Z=1.666, P=0.096). All other comparisons in the table were not significant (P>0.2).

There was no significant difference between the control group and those allocated to hospital at home in the likelihood of dying at home (controls 25/43, 58%; hospital at home 124/186, 67%; χ² 1.12, df=1, P=0.29). Of the subsample of the hospital at home
group who were admitted to the service, however, 88/113 (78%) died at home. This is a significantly higher proportion than for the control group (χ² 6.07, df = 1, P = 0.014). It is not clear, however, whether this difference is due to hospital at home or to differences in characteristics between patient groups.

Discussion

Place of death

While patients who were actually admitted to hospital at home were more likely to die at home than controls (78% vs 58%), these results do not allow us to conclude that hospital at home enabled more patients to die at home. Intention to treat analysis did not show that patients allocated to hospital at home were more likely to die at home (67%) than patients allocated to standard care, and it may be that patients who were most suitable for remaining at home were also most likely to receive hospital at home care. The results are therefore inconclusive in terms of causation, but suggestive of an effect associated with receipt of hospital at home.

The community care in the study area is probably more comprehensively provided than in many other parts of the country, and patients referred to hospital at home may be more suitable for home care than the rest of the population. The home death rate for the control group was 58% compared with 21% for patients in England and Wales in general. If the preconditions for death at home are already present a new service may have little additional impact. Furthermore, when a palliative home care service is introduced so close to death (median survival from referral 11 days), the main factors determining death at home may already be present and have taken effect. The service itself may therefore do little to change the place of death at this point but may rather serve to improve the quality of death, a question we examine elsewhere.

Methodological concerns for randomised controlled trials in palliative care

The present study highlighted several issues relating to randomised controlled trials in palliative care. The first of these is the difficulty we experienced in attaining sufficient statistical power. Three factors contributed to this: the unequal randomisation ratio of 4:1; the limited time available for the study; and the base rate of death at home in the control group.

The 4:1 randomisation ratio was set because many of the patients allocated to hospital at home did not receive the service because of the particular problems of the patient group. Far more patients therefore had to be allocated to hospital at home than to the control condition to ensure that the service ran at or near capacity. In addition 8% of suitable patients had to be excluded from the study to fill hospital at home spaces during quiet periods and accommodate emergency referrals. Had we not compromised in this way, the trial would have prevented the service from helping as many patients as its resources permitted. This would have resulted in reduced cooperation from health professionals and the likely collapse of the trial as well as raising ethical concerns. Even when one can strongly argue that there is equipoise between conditions it can be difficult to justify randomisation in palliative care on grounds other than as a means of allocating limited resources. Randomisation to a waiting list is not feasible when patients have a limited life span. A patient preference design may at times be more ethical but may further limit patient numbers and reduce statistical power. Randomisation by general practice can be suitable for some interventions but entails further problems with statistical power. In the present study randomisation was justified on the basis of limited resources, and the randomisation ratio could have been improved only by increasing the rate of admissions among those allocated to hospital at home or by increasing the referral rate. Failure to admit was due to the unpredictability and complexity of terminal illness. The resolution of these problems would therefore probably be beyond the scope of most services. An increase in referrals would have allowed the trial to shift the surplus of patients over to the control condition, and to this end encouragement was given to health professionals to refer. There is probably a limit to how much referrals could increase, however, particularly if an increase in referrals meant a decreased likelihood of obtaining an admission.

The limited time available for the study reflected the time constraints common to evaluations of innovative healthcare interventions. An extended pilot period was necessary to allow the service to undergo several changes and settle down into its final form. A proper understanding of referral and admission patterns was essential to arrive at a feasible trial design. The need finally to abandon prospective data collection due to data attrition and switch to retrospective collection of process measures led to further time reduction. Once the randomised controlled trial was running, the planned statistical power could have been attained by extending the trial time frame from 15 to 34 months. The hospital at home service itself, however, was funded for only a limited period, its future funding in part dependent on the outcome of the trial. The trial therefore needed to be completed and the results analysed in time to inform this process.

In addition to loss of power, the trial may have been affected by dilution of the treatment effect, thus further reducing the likelihood of observing an impact of the
service. Only 61% of patients allocated to hospital at home obtained the service. As noted this is not unusual in palliative care.29 The intervention itself was “contaminated” by other input. Hospital at home would be supplemented by general practitioner and district nurse input and often also by other community care when less than 24 hour hospital at home input was provided. The standard care provided for control patients was of considerable range and complexity, including both primary and secondary care, the standardisation of which was necessarily beyond the control of the trial design. Palliative care is not one simple intervention or procedure; it requires a multidisciplinary package of care, the composition of which will vary from location to location and from individual to individual. It is also possible that the hospital at home service freed up other palliative care resources, which were then available to the control group, thus “narrowing the gap” in service provision between the two patient groups.

Palliative care therefore does pose particular problems for the design of randomised controlled trials over and above those posed by evaluation of any innovative health technology where results are needed fast. These include the difficulty of attaining sufficient power due to attrition, the need to ensure that randomisation is ethically justifiable, the difficulty of data collection, dilution of treatment effect, and difficulty in standardising the intervention and control conditions. In evaluations of specific schemes with a defined life the randomised controlled trial may not be the design of first choice. Important insights may be gained from smaller scale “before and after” designs, case-control approaches that provide in depth descriptions of the service, or explorative trial methodologies, which use rolling data analysis and intervention optimisation through the pilot stages. If the effectiveness of services such as hospital at home are to be fully evaluated, however, resources will need to be found for substantial trials in appropriate settings, as without randomisation and intention to treat analysis it is too easy to assume that an intervention is successful, as the present one superficially seemed to be in terms of home death rates.

We thank the hospital at home team and our research steering group (Woody Caan, David Gilligan, Suam Goh, Janet McCabe, Richard Osborne, Allan Price, Rosemary Rooks, and Sheila Walton) for their input and advice on the research. We also thank Ann Louise Kinmonth and Paul Murrell for their helpful comments on this paper. The study was approved by the Cambridge local research ethics committee.

Contributors: GG designed the trial and the research materials, liaised with hospital at home staff and other health professionals, conducted the data collection, performed the data analysis, and produced the main drafts of the paper. CT, the principal investigator of the study and guarantor, initiated the research, provided overall direction on the study, discussed core ideas, and contributed to design of the protocol, analysis, interpretation of results, and writing of the paper. MF discussed core issues, participated in protocol design, data collection, and interpretation of results, and edited the paper. SB was an applicant to the research funders, participated in the study design and management, advised on liaison with health professionals, contributed to interpretation of results, and edited the paper. Funding: The hospital at home service was funded by the Elizabeth Clark Charitable Trust. Funding for the research was provided by the Elizabeth Clark Charitable Trust and the NHS research and development primary/secondary care interface programme.

Competing interests: None declared.

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Statistical presentation in international scientific publications

F. References

Here is a selection of references to help with writing and/or reviewing papers for peer-reviewed healthcare journals.

Writing for publication


Peer review


Reporting guidelines


**Statistical guidelines**


