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

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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 229 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.[2–4] Dying at home is also preferred by most of the general public[5] and primary care professionals.[6] Informal carers are more likely to state that the place of death was right if the patient died at home rather than in hospital.[7 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 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.

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

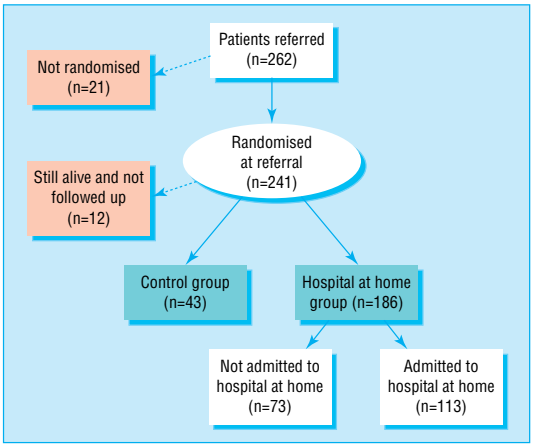
Demographic data were collected on referral. Death certification, including place of death, was obtained from the Office for National Statistics.

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 $\alpha = 0.05$. 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.



Distribution of patients entering randomised controlled trial of hospital at home versus standard care for terminally ill patients

Statistical analysis

We conducted an intention to treat analysis using Pearson χ^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.[19] Tests were two tailed with $\alpha = 0.05$. 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%; χ^2 1.12, df = 1, $P = 0.29$). Of the subsample of the hospital at home

Characteristics of patients in trial of hospital at home scheme. Figures are numbers (percentage) of patients unless stated otherwise

Patients	Cancer	Living alone	Female	Mean (SD) age (years)	Median (quartiles) survival from referral (days)
Control group (n=43)	37 (86)	7/41 (17)	23 (54)	72.1 (11.3)	11 (3-26)*
Hospital at home group:					
Total (n=186)	161 (87)	39/182 (21)	92 (50)	72.6 (13.6)	11 (4-34)†
Admitted to hospital (n=113)	99 (88)	22/112 (20)	60 (53)	72.8 (13.5)	16 (5-42.5)*‡§
Not admitted to hospital (n=73)	62 (85)	17/70 (24)	41 (56)	72.2 (13.9)	8 (3-18)§

*Difference: Z=1.666; P=0.096. †For 185 patients. ‡For 112 patients. §Difference: Z=3.005; P=0.003.

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 (χ^2 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% *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.[1] 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.[20]

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.[18] 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.[18] A patient preference design[21] 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[16] but entails further problems with statistical power.[22] 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[20] 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.[18] 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.

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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.

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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

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