

Reducing emotional distress in people caring for patients receiving specialist palliative care

Randomised trial

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Background Caring for relatives with advanced cancer may cause psychological and physical ill health.

Aims To evaluate the effectiveness of increased support for distressed, informal carers of patients receiving palliative care.

Method The sample was composed of 271 informal carers who scored over 5 on the 28-item General Health Questionnaire (GHQ-28). The intervention comprised six weekly visits by a trained advisor. Primary outcome was carer distress (GHQ-28) at 4-week, 9-week and 12-week follow-up. Secondary outcomes were carer strain and quality of life, satisfaction with care, and bereavement outcome.

Results Scores on the GHQ-28 fell below the threshold of 5/6 in a third of participants in each trial arm at any follow-up point. Mean scores in the intervention group were lower at all time points but these differences were not significant. No difference was observed in secondary outcomes. Carers receiving the intervention reported qualitative benefit.

Conclusions The intervention might have been too brief, and ongoing help might have had accruing benefits. Alternatively, informal carers of patients with cancer may already receive considerable input and the advisor's help gave little additional advantage; or caring for a dying relative is extremely stressful and no amount of support is going to make it much better.

Declaration of interest None. Funding detailed in Acknowledgements.

Family members and friends who care for patients with advanced cancer living at home are at risk of psychological and physical ill health (Field *et al*, 1993; Chapman & Pepler, 1998; Payne *et al*, 1999; Rhodes & Shaw, 1999; Sothill *et al*, 2001; Thomas *et al*, 2002). Specialist palliative care services working in the community developed to respond to the complex problems experienced by these patients. Although these professionals may be in contact with patients' families and friends, their main focus is the patient (Higginson *et al*, 2003). The National Institute for Health and Clinical Excellence (NICE) in Britain recently recommended expansion of specialist palliative care services to multiprofessional support for carers, independent of patient care (National Institute for Clinical Excellence, 2004). However, there is no consensus on what sort of intervention would ease carers' burden, or its effectiveness. This trial was conceived and completed before the publication of the NICE recommendations. Specialist palliative care teams across London were actively involved in the planning, piloting and conduct of this research. In the summer of 1998 we asked 60 informal carers of patients with cancer, under the care of three local palliative care teams, to indicate their preferred mode of extra support from a number of options which included respite care, other practical help, more written information and telephone advice. Over 80% of respondents chose a weekly visit by a trained advisor.

We aimed to evaluate the effectiveness of an intervention to reduce symptoms of anxiety and depression and carer burden, improve quality of life and satisfaction with care, and reduce the intensity of grief reactions in distressed informal carers of patients with cancer. We predicted that a brief, carer-focused intervention, in addition to usual specialist palliative care, would be more effective at reducing distress than usual specialist palliative care alone.

METHOD

Study setting

Ethical approval was granted by the London Multi-Centre Regional Ethics Committee in February 2000, and subsequently by local research ethics committees. Seven specialist palliative care teams in three London cancer networks, serving a combined population of almost 2 million people, took part in the study.

Recruitment and randomisation

From January 2001 to April 2003 people providing informal care to patients in all new referrals to six of the participating teams were screened for psychological distress using the 28-item version of General Health Questionnaire (GHQ-28; Goldberg, 1970). The seventh team joined the trial in June 2001. The informal carer was identified by patients and palliative care teams as the main person who provided unpaid practical and emotional support to the patient on a regular basis and was in contact with the palliative care team. Palliative care staff introduced the study at the earliest opportunity, usually on second or third contact. The GHQ-28 was then completed immediately or if the informal carer was not present for the palliative care team visit, left for completion later. Carers returned questionnaires in pre-paid envelopes to the research team. The research team was informed if the carer declined to fill in the GHQ-28, if the patient was unlikely to survive the time it would take to introduce the intervention, or if the carer's English skills would mean they could not gain full benefit from the advisor visits. Informal carers who scored above the threshold of 5/6 (Goldberg & Williams, 1988) on the GHQ-28 were approached to obtain informed consent and complete baseline assessments, which included a measure of carer burden (Robinson, 1983) and quality of life (Weitzner *et al*, 1999). Patients' physical performance status was assessed using the criteria of the Eastern Cooperative Oncology Group (ECOG; Oken *et al*, 1982). On completion of the baseline assessments, participants were randomised using a block randomisation design, stratified according to the seven participating teams. Interviewers were masked to the block size of 12. Randomisation took place at the trial centre under the supervision of the trial statistician (R.B.).

Trial arms

Usual care

Specialist palliative care was provided by a team of clinical nurse specialists, with specialist medical support and sometimes specialist social work support, giving advice to patients at home, to their families and to their primary healthcare teams. Patients were assisted with control of pain and other physical symptoms as well as with social, psychological, emotional and spiritual issues. Some people are referred for palliative care close to death in the context of a rapidly changing clinical picture, whereas others remain in contact with palliative care services for many months.

The carer advisor intervention

The intervention was developed by the research team. Two part-time carer advisors with experience in community nursing and social work delivered the intervention, which consisted of six visits over a 6-week period. The advisors aimed to meet the carer alone, if necessary arranging meetings outside the home or at the carer's workplace, sometimes during evenings or weekends. A comprehensive assessment of domains of need was made; past, present and future issues were discussed and advice, information and emotional support provided. The intervention was kept to giving advice and support rather than taking action on behalf of carers; however, advice might go as far as (for example) helping carers to calculate their benefit entitlements. In the event of a patient's death during the intervention period, the advisors continued to offer visits, up to a total of six. Sometimes a telephone call took the place of a visit. Telephone calls enabled flexibility in the intervention and helped some carers to broach issues that were difficult to discuss face-to-face. Such calls were discussed with the research team to decide whether they were equivalent to a full intervention visit. The mean number of advisor contacts was 5.0 (s.d.=2.0), and the mean number of contacts up to the death of the patient was 3.6 (s.d.=2.6).

Both advisors undertook 1 month's training, involving fieldwork in palliative care in the community, a hospice and a hospital setting. The advisors met weekly with the research team for debriefing, for advice on any issues that arose and to ensure that all domains of carer need were covered in the intervention. These domains were:

(a) patient care;

- (b) physical health needs;
- (c) need for time away from the patient in the short term and longer term;
- (d) need to plan for the future;
- (e) psychological health, relationships and social networks;
- (f) relationships with health and social service providers;
- (g) finances.

After 1 year, a further half-day in-service training session took place in which the delivery of the intervention was reviewed.

Study outcomes

Informal carers completed postal questionnaires at 4 weeks, 9 weeks and 12 weeks after randomisation (see Fig. 1). The first follow-up, part-way through the 6-week intervention, was chosen to achieve at least one research assessment in most cases before the patient died. When a patient died, the study participant was sent a sympathy

card and contacted again 4 months later for the final follow-up. A patient's death therefore necessarily ended the carer's participation in the subsequent follow-up assessments. Our primary outcome was the proportion scoring above threshold (5/6) on the GHQ-28 at follow-up. Secondary outcomes were GHQ-28 score, Carer Strain Index (Robinson, 1983) and Care-Giver Quality of Life Index (Cancer) (Weitzner *et al.*, 1999) scores 4 weeks, 9 weeks and 12 weeks after randomisation, and scores on Core Bereavement Items (CBI; Burnett *et al.*, 1997) and satisfaction with care 4 months after the death of the patient. Brief, semi-structured interviews at the final follow-up provided a qualitative assessment of acceptability and helpfulness of the support provided by the intervention.

Power and statistical analysis

Power and sample size

All carers scored above the threshold 5/6 on the GHQ-28 at entry to the trial. Prospective

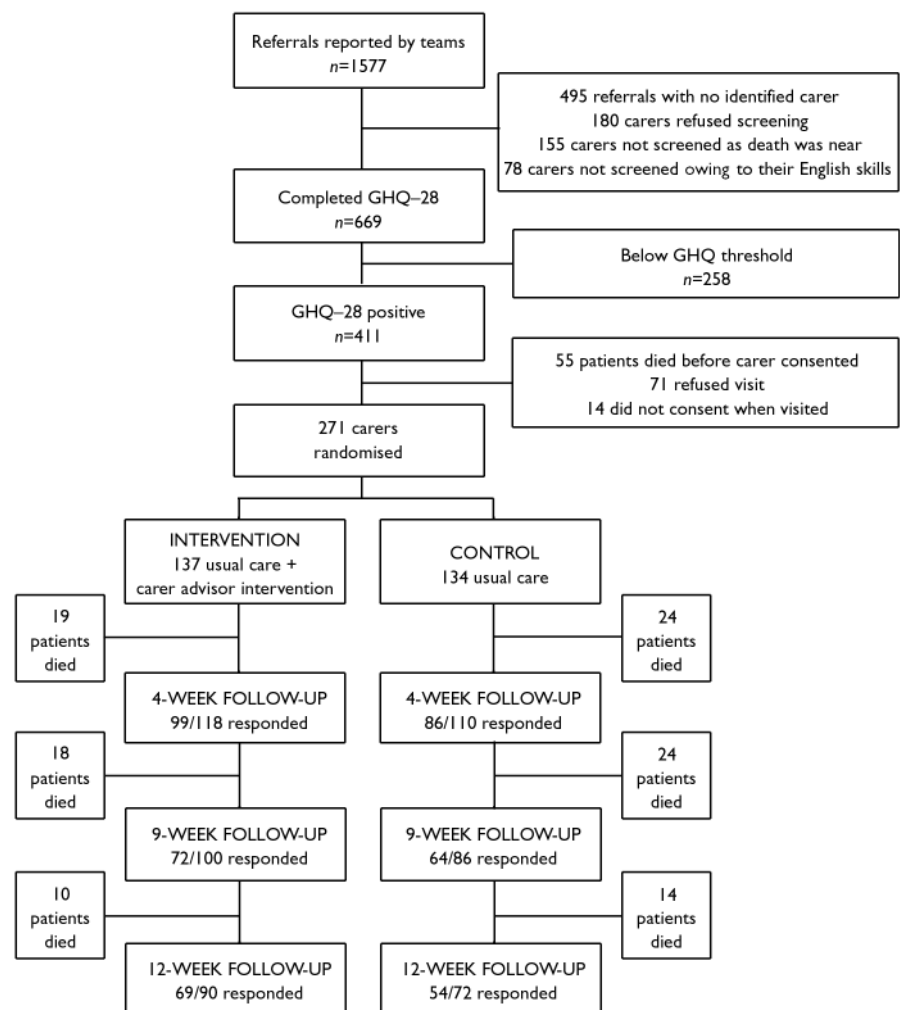


Fig. 1 Study profile (GHQ-28, 28-item General Health Questionnaire).

Table 1 Baseline characteristics of the sample

| Characteristic | Usual care group (n=134) | Care advisor group (n=137) | Total (n=271) |
|-----------------------------------------------------------|-----------------------------|-------------------------------|------------------|
| Gender: male, n (%) | 27 (20) | 29 (21) | 56 (21) |
| Age, years: mean (s.d.) | 56.1 (13.2) | 56.4 (14.6) | 56.3 (13.9) |
| Tertiary education | 45 (34) | 38 (28) | 83 (31) |
| Married or cohabiting, n (%) | 107 (80) | 114 (83) | 221 (82) |
| White ethnic group, n (%) | 118 (88) | 114 (83) | 232 (86) |
| Socio-economic groups 1, 2 ¹ | 93 (72) | 92 (69) | 185 (70) |
| Relationship to patient, n (%) | | | |
| Spouse or partner | 80 (60) | 92 (68) | 172 (64) |
| Child | 38 (28) | 29 (21) | 67 (25) |
| Other | 16 (12) | 16 (12) | 32 (12) |
| Patient's diagnosis, n (%) | | | |
| Lung cancer | 47 (35) | 32 (23) | 79 (29) |
| Gastrointestinal cancer | 32 (24) | 23 (17) | 55 (20) |
| Genito-urinary cancer | 13 (10) | 27 (20) | 40 (15) |
| Head and neck cancer | 9 (7) | 15 (11) | 24 (9) |
| Breast cancer | 12 (9) | 6 (4) | 18 (7) |
| Other cancers | 21 (16) | 34 (25) | 55 (20) |
| Time since diagnosis, months: median (range) ² | 4 (1–89.5) | 8 (2–75.6) | 6 (1–82.8) |
| Time to death, weeks: median (range) ³ | 11 (1–39.6) | 13 (2–41.1) | 12 (1.2–39.8) |
| GHQ–28 score at screening: mean (s.d.) | 13.0 (5.2) | 12.8 (5.1) | 12.9 (5.1) |
| Carer Strain score: mean (s.d.) | 30.2 (11.5) | 27.1 (10.6) | 28.6 (11.1) |
| Caregiver Quality of Life score: mean (s.d.) | 66.4 (21.1) | 72.8 (21.1) | 69.6 (21.3) |
| ECOG score: mean (s.d.) | 2.8 (0.94) | 2.7 (0.91) | 2.7 (0.93) |
| Completed follow-up assessment, n (%) | | | |
| None | 43 (32.1) | 37 (27.0) | 80 (29.5) |
| At least one | 45 (33.6) | 42 (30.7) | 87 (32.1) |
| All three | 46 (34.3) | 58 (42.3) | 104 (38.4) |

ECOG, Eastern Cooperative Oncology Group; GHQ–28, 28-item General Health Questionnaire.

1. National Statistics Socio-Economic Classification three-class classification (http://www.statistics.gov.uk/methods_quality/ns_sec/class_collapse.asp); data missing for 5 people in usual care group and for 3 people in intervention group.

2. Interdecile range.

3. Interdecile range; n=113 (usual care group) and n=108 (intervention group).

research in other settings (Weich *et al*, 1997) indicated that, given the stresses involved, 70% of the usual care group would be likely to score above this threshold at follow-up. Thus our per protocol power calculation indicated that in order to detect a drop to 50% caseness in the experimental group at 90% power and the 5% level of significance, 124 carers would be required in each arm. To cover an expected 10% attrition from the trial we needed to recruit 280 carers, a sample that would also provide sufficient power for examination of GHQ–28 score as a continuous measure.

Analysis

Treatment success was defined as any drop in GHQ–28 score to below threshold, measured 4 weeks, 9 weeks or 12 weeks

after randomisation. More detailed analyses were performed on GHQ–28, Carer Strain Index and quality of life scores from baseline, 4 weeks, 9 weeks and 12 weeks by a mixed model approach using the random intercept random slope facility provided by the generalised linear latent and mixed models (GLLAMM) procedure in Stata release 8 (Rabe-Hesketh & Everitt, 2004). The model was built in the following order:

- effect of treatment to detect overall difference between the groups;
- effect of time to detect linear change over time as a result of taking part in the trial;
- linear interaction to detect whether treatment groups changed over time in a different linear fashion;

(d) quadratic term for time to detect whether the change was curvilinear;

(e) quadratic interaction to detect whether the groups differed in their curvilinear change over time.

The most parsimonious model was selected, conditional on the inclusion of the main effect of the intervention. Group means on the CBI and satisfaction with care were compared in a one-way analysis of variance (ANOVA).

RESULTS

Results of screening and recruitment

During the 28 months of recruitment 1577 new referrals were reported by the participating teams (Fig. 1). Referral details were sometimes lost if the informal carer did not meet the palliative care team and the GHQ–28 form had to be passed on by the patient, or when informal carers agreed to complete the GHQ–28 at a later time but failed to do so. In total 669 carers completed the GHQ–28 of whom 411 (61%) scored above the threshold. Fifty-five patients died before carer consent could be obtained. We invited 356 carers to take part in the trial and 271 (76%) of them agreed.

Follow-up rates at 4, 9 and 12 weeks

As expected, a number of participants were lost through the death of the patient. At 4 weeks 43 (16%) patients had died, by 9 weeks 85 (31%) had died and by 12 weeks 109 (40%) had died. Refusal rates at each follow-up point where the patient remained alive were 19% (43/228), 27% (50/186) and 24% (39/162) respectively (Fig. 1).

Follow-up rates at 4 months after death

Two hundred and twenty-one patients had died by end of data collection at the end of July 2003. Ninety-seven of 113 carers (86%) in the usual care arm and 84 of 108 in the intervention arm (78%) participated in the 4-month follow-up (82% overall).

Characteristics of the study group by trial arm

Four-fifths of trial participants were women, 86% were White and 64% were spouses or partners of patients. Their mean age was 56.3 years (range 16–92) (Table 1). No major difference occurred between the

Table 2 Outcome in terms of threshold scoring on the 28-item General Health Questionnaire

| | Usual care group n/N (%) | Care advisor group n/N (%) | Significance |
|---------------------------------------------------------------|-----------------------------|-------------------------------|--------------------------|
| Below GHQ-28 threshold at any follow-up point with no relapse | 21/91 (23) | 21/100 (21) | $\chi^2(1)=0.73, P=0.73$ |
| Below GHQ-28 threshold at any follow-up point | 29/91 (32) | 35/100 (35) | $\chi^2(1)=0.65, P=0.76$ |

GHQ-28, 28-item General Health Questionnaire.

randomised groups at baseline on demographic variables, GHQ-28 score or the patient's physical performance status assessed using the criteria of the ECOG (Oken *et al*, 1982). However, there was some imbalance in carer strain and quality of life. There was no difference between trial arms in willingness of participants to complete follow-up assessments or in the patients' life expectancies; median survival time from trial entry was 12 weeks (Table 1).

Primary outcome

Approximately a third of carers in each trial arm reduced their distress enough to record a GHQ-28 score below the threshold of 5/6 at any follow-up point (Table 2).

Secondary outcomes

We examined GHQ-28 scores in more detail. The GLLAMM models assume that data are missing at random. There was no difference in the follow-up GHQ-28 scores of those attending and those not attending their next follow-up assessment and the assumption is justified. Mean scores dropped by the 4-week and 9-week follow-up assessments but increased again by 12 weeks (Fig. 2, Table 3). Although the intervention group appears to experience greater improvement, the results of GLLAMM did not reach significance for the interaction effects. The most parsimonious model included significant values for time ($z=-4.70, P<0.001$), which was curvilinear ($z=3.00, P<0.004$); the treatment effect was not significant ($z=-1.10, P=0.272$). Carer quality of life deteriorated over time (Table 3) but there was no significant interaction between time and trial arm on this outcome or carer strain; nor were differences found in bereavement phenomenology or satisfaction with care 4 months after the patients' death (Table 4).

Carers' views

The most valued aspect of the service was the additional emotional support, with fewer carers reporting value from the added information, advice or practical or financial

help. One-fifth of respondents felt the allocation of an advisor came too late in the patient's illness and almost a third thought more sessions with the advisor would have been helpful (Table 5).

DISCUSSION

We failed to support our main hypothesis that a brief intervention by a carer advisor would reduce psychological symptoms in distressed informal carers of cancer patients. Although a small treatment effect (Cohen, 1988) for the carer advisor intervention in reduction of psychological distress was observed in our secondary analysis, it was short-lived and did not reach statistical significance. To demonstrate

that the treatment effects detected at 4 weeks and 9 weeks (s.d.=0.22 and s.d.=0.20 respectively) were statistically significant would have required 323 and 382 participants respectively in each trial arm.

Strengths and limitations

Recruitment to this trial demonstrates that large-scale randomised controlled trials are possible in palliative care. Follow-up rates were acceptable, with face-to-face contact after the death of the patient exceeding 80%. Sixty-one per cent of carers scored above threshold on the GHQ-28 and were eligible for the trial, which means that there is considerable psychological morbidity in

Table 3 Mean scores on primary and secondary outcomes over the study period

| Outcome measure | Pre-randomisation | Follow-up assessment | | |
|------------------------------------------|-------------------|----------------------|-------------|-------------|
| | | 4 weeks | 9 weeks | 12 weeks |
| GHQ-28¹ | | | | |
| Usual care group | | | | |
| Score: mean (s.d.) | 13.0 (5.2) | 11.9 (6.4) | 10.7 (7.3) | 11.7 (7.8) |
| n | 133 | 85 | 64 | 54 |
| Intervention group | | | | |
| Score: mean (s.d.) | 12.8 (5.1) | 10.5 (6.3) | 9.3 (6.5) | 11.3 (7.3) |
| n | 137 | 97 | 70 | 69 |
| Carer strain¹ | | | | |
| Usual care group | | | | |
| Score: mean (s.d.) | 30.2 (11.5) | 27.8 (11.5) | 25.1 (10.1) | 27.3 (10.2) |
| n | 134 | 86 | 63 | 54 |
| Intervention group | | | | |
| Score: mean (s.d.) | 27.1 (10.6) | 27.7 (11.6) | 26.7 (11.4) | 27.2 (11.7) |
| n | 137 | 99 | 73 | 69 |
| Carer quality of life¹ | | | | |
| Usual care group | | | | |
| Score: mean (s.d.) | 66.4 (21.1) | 63.9 (19.3) | 65.2 (17.0) | 62.2 (19.8) |
| n | 132 | 82 | 59 | 52 |
| Intervention group | | | | |
| Score: mean (s.d.) | 72.8 (21.1) | 69.6 (22.4) | 69.3 (22.7) | 65.2 (21.3) |
| n | 130 | 93 | 71 | 64 |

GHQ-28, 28-item General Health Questionnaire.

1. Higher scores indicate more psychological distress, greater carer strain and lower quality of life.

Table 4 Grief scores and satisfaction with care by trial arm

| | Usual care group (n=97) | Intervention group (n=84) | Total (n=181) | Significance |
|-----------------------------|--------------------------|---------------------------|---------------|--------------------------|
| CBI score: mean (s.d.) | 45.6 (11.6) ¹ | 47.1 (11.2) ² | 46.3 (11.4) | $t(176)=-0.91, P=0.37$ |
| Considered care poor, n (%) | 21 (22) ³ | 16 (19) ⁴ | 37 (21) | $\chi^2(3)=0.96, P=0.81$ |

CBI, Core Bereavement Items.

1. One CBI questionnaire incomplete.

2. Two CBI questionnaires incomplete.

3. Data missing for two people.

4. Data missing for one person.

this population and that we were not simply dealing with a distressed minority of carers in particularly difficult circumstances. The carer advisor intervention arose from pilot work to identify carer preference for support as well as from the research literature; it was operationally defined, and was available in manual form to the advisors (copies of the manual are available from the authors upon request); and the intervention can be replicated. However, we cannot be certain that all distressed carers were invited to participate. Service providers may influence recruitment by 'gate-keeping', fearing that trials are intrusive or inappropriate. Conversely, carers who are more engaged with services may be more prepared to participate. Carers working away from the home or not living with the patient were less accessible to the trial. These limitations will affect its external validity. Finally, a major difficulty was management of missing data (not completely at random; Streiner, 2002) owing to death of the patient. For ethical reasons our protocol excluded research contact with participants in cases where the person cared for died before the 4-week, 9-week or 12-week follow-up. However, the death

Table 5 Carers' views of the content and timing of the carer advisor intervention (n=81)

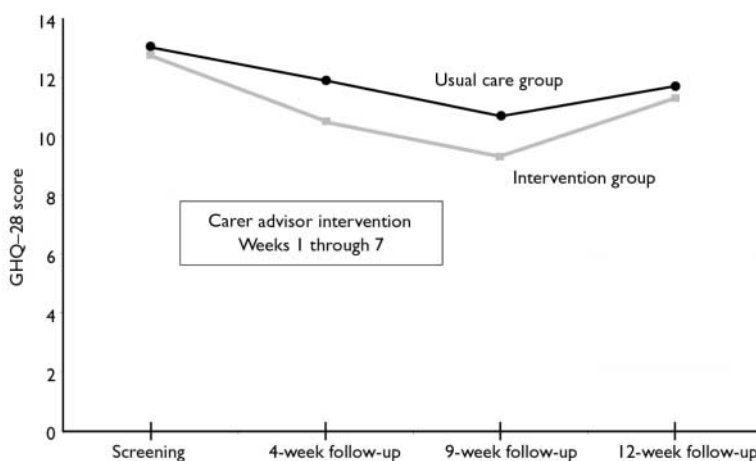
| | n (%) |
|----------------------------------------------------------------------------------|---------|
| Content of the intervention | |
| Carer received additional practical or financial help | 20 (25) |
| Carer found the additional advice useful | 45 (56) |
| Carer found the additional information useful | 47 (58) |
| Carer felt added emotional support | 68 (84) |
| Overall the help was very/fairly useful | 69 (85) |
| Timing of the intervention | |
| Carer thought more sessions would have been useful | 26 (32) |
| Carer felt the sessions with the advisor came at the right time | 46 (57) |
| Carer felt the sessions with the advisor came too early in the patient's illness | 6 (7) |
| Carer felt the sessions with the advisor came too late in the patient's illness | 17 (21) |

rate exceeded pre-trial estimates, was the major source of attrition and inevitably reduced power. Although palliative care referrals are increasingly made earlier in advanced illness (Department of Health, 2000), in practice, community palliative care teams managed their workloads in times of pressure by responding only to the most acute referrals, sometimes when death was imminent. This meant that many

carers were not considered for this trial and 16% of those recruited experienced the death during the first 4 weeks of the trial.

Interpretation

There are several possible reasons for our negative result. First, the intervention might have been too brief. Qualitative data collected after the death of the patient suggested that carers experienced some subjective benefit from the advisor visits, but also a sense that the intervention was too brief. Second, informal carers of patients with cancer might already have been receiving considerable input from specialist palliative care services and the care advisor's extra help might have had little additional advantage; for example, our intervention might have had greater impact in cases of chronic cardiac failure where routine support for patients and carers is less well developed. Third, caring for a dying relative is extremely stressful and no amount of support is going to make it much better. Fourth, our intervention might simply have been wrongly planned and thus unhelpful; however, our qualitative results

**Fig. 2** Mean scores on the 28-item General Health Questionnaire (GHQ-28) over the follow-up period.

do not support this possibility. Fifth, our outcome measures might have been insensitive to change or there was simply too much variance in the trial to allow detection of important change. Finally, given that nurses in the 'treatment as usual' group were aware of the nature of the trial and the intervention under evaluation, they might have tried harder to provide carer support. Given what we know about the workloads for nurses in these teams, we believe the last possibility is unlikely.

Implications and challenges for health service research

National guidance published since the start of this trial acknowledges the central role of families and carers in the informal care of cancer patients, particularly in the palliative phase (National Institute for Clinical Excellence, 2004). Each domain of care addressed by our intervention is referred to in the guidance, which contains a chapter specifically devoted to carer issues. Transitory benefits are not unusual in studies of brief service interventions and highlight a paradox in our concept of the effectiveness of such interventions (Bower *et al*, 2003): when a medication is seen to be effective in treating a medical or psychological condition, it is not regarded as ineffective if the condition relapses on withdrawal of that drug; in psychological or supportive interventions, however, loss of benefit when the intervention is withdrawn is often interpreted as indicating that the intervention is ineffective. Measuring change once the agent of change has been removed may be inappropriate in supportive care, especially near the end of life in rapidly progressive clinical and emotional circumstances. Our quantitative and qualitative results suggest that the carer advisor intervention was too brief and that ongoing help might have had accruing benefits. This would mirror the policy direction of earlier referral for palliative care services and contribute to more effective supportive care (National Institute for Clinical Excellence, 2004). Nevertheless, rigorous analysis of the effectiveness of care for patients and carers in trials such as this provides valuable evidence for service development in

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(First received 8 March 2006, final revision 28 June 2006, accepted 1 September 2006)

palliative and supportive care and responds directly to the recommendations and requirements set out in the NICE guidance (National Institute for Clinical Excellence, 2004).

ACKNOWLEDGEMENTS

We thank the carers who participated, staff of the specialist teams and carer advisors Andrea Beetson and Margaret Perkins. Participating specialist palliative care teams were: Royal Free; Camden and Islington; Whittington Hospital (Islington); North London Hospice; Harrow; Haringey Macmillan Team, and St Joseph's Hospice, Hackney. We also thank Ula Nur and Gerhart Knerer for their statistical advice and the Camden and Islington Mental Health and Social Care Trust and the Royal Free Hampstead NHS Trust for their support. The trial was funded by the former Cancer Research Campaign, now Cancer Research UK (grant number CI432/AI79).

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