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Brief report

A pilot randomised controlled trial to reduce suffering and emotional distress in patients with advanced cancer

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ABSTRACT

Introduction: A pilot trial was carried out to determine if a focussed narrative interview could alleviate the components of suffering and anxiety and depression in advanced cancer patients.
Intervention: Patients recruited were invited to participate in a focussed narrative interview and reflect on their perspectives on their sense of "meaning", regarding suffering and their psychological, physical, social and spiritual well being – the emphasis was on allowing the patient to tell their story. Patients were encouraged to share what resources they themselves had utilised in addition to what professional care they may have received, to maintain a sense of well being.
Method: Patients with advanced metastatic disease were recruited from hospices in the North West of England – the only exclusion criteria were not being able to understand written and spoken English and a non cancer diagnosis. At recruitment patients were asked to complete a numerical scale for suffering; the Brief Edinburgh Depression Scale, Edmonton Symptom Assessment Scale (ESAS), FACIT Spiritual well being questionnaire, Demographic information was collected and patients were randomised to either the intervention arm of the trial or the usual care arm of the study. Patients in both groups were invited to complete each measure at 2, 4 and 8 weeks.
Results: One hundred people were recruited into the study – 49 were randomised to intervention group and 51 to control group. The median age of patients was 66 years age range (31–89 years) and 68% of patients were female. At baseline the ECOG performance of 75% of patients recruited was 1 or 2. The median survival of all patients in the study was 169.5 days (range 10 days to still alive at end of study). There was no significant difference at any timepoint in scores on suffering measure between intervention group and control group. At each time point the intervention demonstrated mean improvement in scores for depression and anxiety on ESAS – the greatest changes for both depression and anxiety were seen at 4 weeks.
Conclusion: This pilot randomised controlled trial of a focussed narrative intervention demonstrated an improvement in mean changes in scores for depression and anxiety at 2, 4, and 8 weeks. We suggest this intervention may have beneficial effects on depression and anxiety, but a larger powered trial is required to determine the full effects.

1. Introduction

Suffering in advanced cancer is complex (Kuuppelomaki and Lauri, 1998; Daneault et al., 2004; George, 2009; Baines and Norlander, 2000) however not universal. Wilson et al., (2007) reported that nearly half of advanced cancer patients did not consider themselves to be suffering and in moderate to extreme levels of suffering, depression or anxiety disorder was a significant factor.

There has been much interest recently in delivering interventions to alleviate suffering and emotional distress in patients with advanced cancer. Dignity therapy has shown benefit in terms of an improvement in dignity and quality of life (Chochinov et al., 2005, 2006) In the original study, Dignity therapy was found to positively impact on depressive symptoms however a later study, reported no differences for depression or spiritual well being (Chochinov et al., 2011). A similar therapy – Supportive expressive group therapy reduced new symptoms of depression (Kissane et al., 2007) in advanced cancer.

An intervention which allows patients to focus on issues that are concerning them and allowing time to reflect on resources and support from professionals may be helpful. It has been found that "narrative therapy" makes an important contribution to the

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holistic support of the dying patient (Noble and Jones 2005; Carlick and Biley 2004).

We report the findings of a pilot randomised controlled trial of a focussed narrative intervention to alleviate suffering in patients with advanced cancer.

2. Patients and methods

The study was carried out in hospice day units in North West of England. Recruitment into the study commenced on 1st November 2009 and ended December 20th 2010. All patients older than 18 years with a diagnosis of advanced progressive cancer and attending Hospice day care services were invited to participate in the study. The only specific exclusion criteria were severe cognitive impairment or insufficient understanding of the English language.

3. Procedure

Eligible patients were informed of the study by letter. Patients who agreed to be contacted by the researcher received detailed information. One hundred and forty six patients were given information and 100 patients participated – reasons for non participation are included in the attached flow chart. Patients recruited completed the Numerical Visual analogue scale of suffering, the six item Brief Edinburgh Depression Scale (BEDS), FACIT Spirituality questionnaire and Edmonton Symptom Assessment Scale (ESAS). Patients were allocated to intervention arm or usual care by means of randomly allocated opaque envelopes opened in presence of the patient after collection of baseline measures. All patients randomised to the usual care were offered the intervention, out of trial after completing 8 week follow-up. Follow-up questionnaires were completed at 2 weeks, 4 and 8 weeks following the delivery of intervention and following baseline data for usual care arm. Any patient found to have high scores on any measures at any time points were referred onto the hospice team and managed according to hospice practice. Full ethical approval for the study was obtained (Reference 09/H1017/95).

4. Questionnaires

The Edmonton Symptom Assessment Scale (ESAS) was developed for symptom assessment of palliative care patients – in addition to presence and severity of nine symptoms common in cancer patients, there is also an opportunity to add an item and "will to live" was included (Bruera et al., 1991) – a cut off of 2 can be used for screening anxiety and depression (Vignaroli et al., 2006). The Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp) comprises two subscales – measuring a sense of meaning and peace and the role of spiritual belief in illness. A total score for spiritual well-being is also produced (Peterman et al., 2002). The Brief Edinburgh Scale (Lloyd-Williams et al., 2007) for depression has been developed and validated for use in palliative care patients. The 10 point numerical suffering scale was devised and piloted within clinical settings and found to have good face validity and reliability. Performance status was assessed using ECOG performance status (Oken et al., 1982) which is scored from 0 to 4 – a score of 0 indicating no dependence and 4 maximum dependence.

5. Statistical analysis

Date was entered onto SPSS version 14. Descriptive statistics were carried out at each time point. Inferential statistical tests were applied to determine any between group or within group differences at each time point. The usual care and the intervention and usual care group were compared for both primary and secondary outcomes at 2, 4 and 8 weeks for both groups. The two groups were compared as regards baseline demographic information. Information regarding attrition and date of death was collected

6. The intervention

Patients were invited to participate in a focussed narrative interview. The researcher prompted the patient to discuss perspectives on their sense of "meaning", their psychological, physical, social and spiritual well being and sense of suffering – the emphasis was on allowing the patient to tell their story. Patients were encouraged to share what they felt had been the main causative factor for any suffering but also to share what resources they had utilised to maintain a sense of well being. A random selection of digital recordings were assessed to ensure consistency and rigour of intervention during the trial. The intervention was conducted at randomisation or if patients requested, a few days later.

7. Results

One hundred people were recruited into the study – 49 randomised to intervention group and 51 to usual care. The median age was 66 years age range (31–89 years) and 68% were female. Breast cancer accounted for 33% of diagnosis; colorectal cancer for 16%, Lung cancer 13%, prostate 7% and 30.6% of patients had been diagnosed with cancer within last 12 months. (Tables 1–3) At baseline the ECOG performance was rated as One for 19%; two for 56%; three for 23% and four for 2% and the median survival of all patients was 169.5 days (range 10 days to still alive at end of study). At baseline symptoms of tiredness, drowsiness and appetite were all statistically significantly worse in the intervention group indicating those patients randomised to intervention group were more unwell. Twenty five patients died during the study period – 11 (21.5%) in the usual care group – median survival in the control group was 99 days (range 36–352 days) and 5 patients (9.8%) died within 3 months of recruitment. Fourteen (28.5%) patients died in the intervention group and 10 patients (20.4%) died within 3 months of recruitment – the median survival in the intervention group was 58.5 days (range 10–262 days) – this was not statistically different ($p=0.17$) to that of the usual care group

Table 1
Baseline scores for control and intervention groups.

Baseline measure	Control	Intervention	MW-up
BEDS score *median (IQrange)*	6.0 (4.0–9.0)	6.0 (2.0–9.0)	0.62
ESAS scores:			
Pain *median* (*IQ range*)	4.0 (1.0–6.25)	4.0 (1.0–6.5)	0.91
Tiredness *median* (*IQ range*)	5.0 (3.75–7.0)	7.0 (5.0–8.0)	0.03
Nausea *median* (*IQ range*)	1.5 (0–5.25)	1.0 (0–4.0)	0.95
Depression *median* (*IQ range*)	1.5 (0–5.0)	2.0 (0–5.5)	0.57
Anxiety *median* (*IQ range*)	3.0 (0–6.5)	4.0 (1.5–7.0)	0.24
Drowsiness *median* (*IQ range*)	3.0 (0–6.0)	5.0 (1.0–8.0)	0.07
Appetite *median* (*IQ range*)	4.0 (2.0–5.0)	5.0 (2.5–7.0)	0.09
Wellbeing *median* (*IQ range*)	4.0 (2.0–6.0)	5.0 (4.0–5.0)	0.41
Breathlessness *median* (*IQ range*)	3.5 (0–7.0)	4.0 (0–7.0)	0.66
Will to live *median* (*IQ range*)	8.5(7.0–10.0)	9.0(7.5–10.0)	0.28
FACIT score			
Spiritual concerns score *median* (*IQ range*)	32.0 (25–38)	32.0 (25.5–39)	0.42
VAS Suffering scale *median* (*IQ range*)	5.0 (1.0–7.0)	4.0 (2.5–6.5)	0.85