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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.

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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

Table 2
Baseline Demographics for intervention and control groups.

	Control group	Intervention group	P
Characteristic	($n=51$)	($n=49$)	
Age (mean)	64.1	65.8	0.54
Male gender (%)	35.3	28.6	0.47
Married/cohabiting (%)	58.8	51.0	0.43
White/white British (%)	98.0	95.9	0.38
Diagnosed in last 12 months (%)	39.2	30.6	0.58
Antidepressant in previous 2 weeks (%)	19.6	22.4	0.73
Depression or stress-related disorder before cancer diagnosis (%)	31.4	36.7	0.54

Table 3
Site of primary cancer.

	Control group	Intervention group
Site	($n=51$) N (%)	($n=49$) N (%)
Breast	11 (21.6)	12 (24.5)
Lung	6 (11.8)	5 (10.2)
Bowel	8 (15.7)	8 (16.3)
Brain	1 (2.0)	1 (2.0)
Cervix	0	1 (2.0)
Head/neck	2 (3.9)	2 (4.1)
Kidney	2 (3.9)	2 (4.1)
Liver	1 (2.0)	1 (2.0)
Lymphoma	3 (5.9)	5 (10.2)
Oesophageal	2 (3.9)	1 (2.0)
Ovarian	0	1 (2.0)
Myeloma	0	1 (2.0)
Melanoma	1 (2.0)	1 (2.0)
Pancreatic	4 (7.8)	1 (2.0)
Prostate	3 (5.9)	4 (8.2)
Stomach	1 (2.0)	2 (4.1)
Uterus	1 (2.0)	1 (2.0)

Of the 100 patients who completed baseline measures, 73% completed 2 week follow-up; 57% 4 week follow-up and 56% completed 8 week follow-up with 43% of patients completing all four follow-up measures (see attached flow chart Fig.1). At baseline the VAS suffering score inter quartile range was 1–7 and the median score for the VAS for intervention group was 4. As can be seen from Table 4 there was no difference at any timepoint in VAS scores between intervention group and control group.

At baseline the median score on the BEDS was 6 (indicating probable depression) with an interquartile range of scores of 2–9. At 4 weeks, a non significant improvement in mean change of 0.2 in scores was observed in the intervention group, but this was not continued at 8 weeks and no other changes were observed in BEDS score over the time of the study. At each time point patients undergoing the intervention demonstrated improvement in mean changes in scores for depression and anxiety on ESAS – the greatest changes for both depression and anxiety were seen at 4 weeks where there was a mean change improvement of 1.0 in anxiety score and a mean change improvement on 0.8 in depression scores – whilst the mean change improvement in anxiety score persisted at1.0 for anxiety, the mean change improvement in depression score reduced to 0.18 for depression at 8 weeks. Patients randomised to the intervention group demonstrated a statistically significant improvement in pain at 8 weeks ($p < 0.01$).

8. Discussion

This pilot randomised controlled trial of a focussed narrative intervention suggests a beneficial effect in anxiety and depression but the intervention did not impact on the primary outcome of global suffering scores as measured by a Visual Analogue Scale.

Patients were recruited into this study from hospices in the North West of England and included patients of all ages and diagnoses. Patients were in the end stages of their disease and 25% of patients died within the study period. It is also of note that median survival in the usual care group was 99 days whereas the median survival was 58.5 days (range 10–262 days) in the intervention group – although not statistically different it suggests intervention group were more unwell with greater physical symptom burden than those patients randomised to the usual care group (Selby et al., 2011).

Patients in the study did not experience high rates of suffering and it may not have been possible to observe changes in VAS scores at the three follow-up time points due to floor and ceiling effects. There was a trend for suffering scores to reduce in both groups during 8 week follow-up. In the UK Hospice day care offers a range of services and interventions (mainly based around creative and diversional activities) all centred on a holistic model of care and it is possible that these interventions offered to all patients in our study reduced suffering scores. The FACIT-Sp was used to determine if the intervention would impact on spirituality scores – there were no observable differences at any time point. This is similar to Chochinov et al. (2011), where baseline FACIT-Sp scores in their population were similar to those recorded in this study and no changes in spirituality scores were seen.

This pilot trial suggests that the focussed narrative can improve anxiety and depression scores as measured by the Edmonton Symptom Assessment Scale and the Brief Edinburgh Depression Scale. The ESAS is a numerical scale and previous research has suggested a cut off threshold of 2 for Depression on ESAS scale (Vignaroli et al., 2006; Bagha et al., 2012). For depression the effect of the narrative intervention was greatest at 4 weeks post intervention as measured by both the BEDS and ESAS however for anxiety mean point improvement continued at 8 weeks post intervention. These results are encouraging as patients in our study were clearly very unwell and close to the end of life when interventions are more complex to deliver and more difficult to observe results. A trial of cognitive behaviour therapy in patients with advanced cancer (Moorey et al., 2009) found CBT lowered anxiety scores over time but had no effect on depression scores. Our intervention which can be delivered by a member of health care staff with training and supervision could be cost-effective as beneficial effects are seen at 4 weeks post intervention. Additionally an unexpected finding was that patients randomised to intervention arm reported a significantly improved pain score on ESAS at 8 weeks compared to usual care which could be a correlate of patients in intervention group experiencing an improvement in their anxiety and depression scores (Laird et al., 2011).

9. Strengths and limitations of the study

A key strength of this study is a randomised trial within a hospice day care setting with patients of all ages and diagnostic groups, and follow-up for 8 weeks. A number of validated tools were used however these tools may not have been sensitive to change and also the floor and ceiling effects observed. Additionally we did not "screen out" patients with low levels of suffering.

10. Conclusions

We believe that a simple focussed narrative intervention may have a role in treatment of depression and anxiety which are both

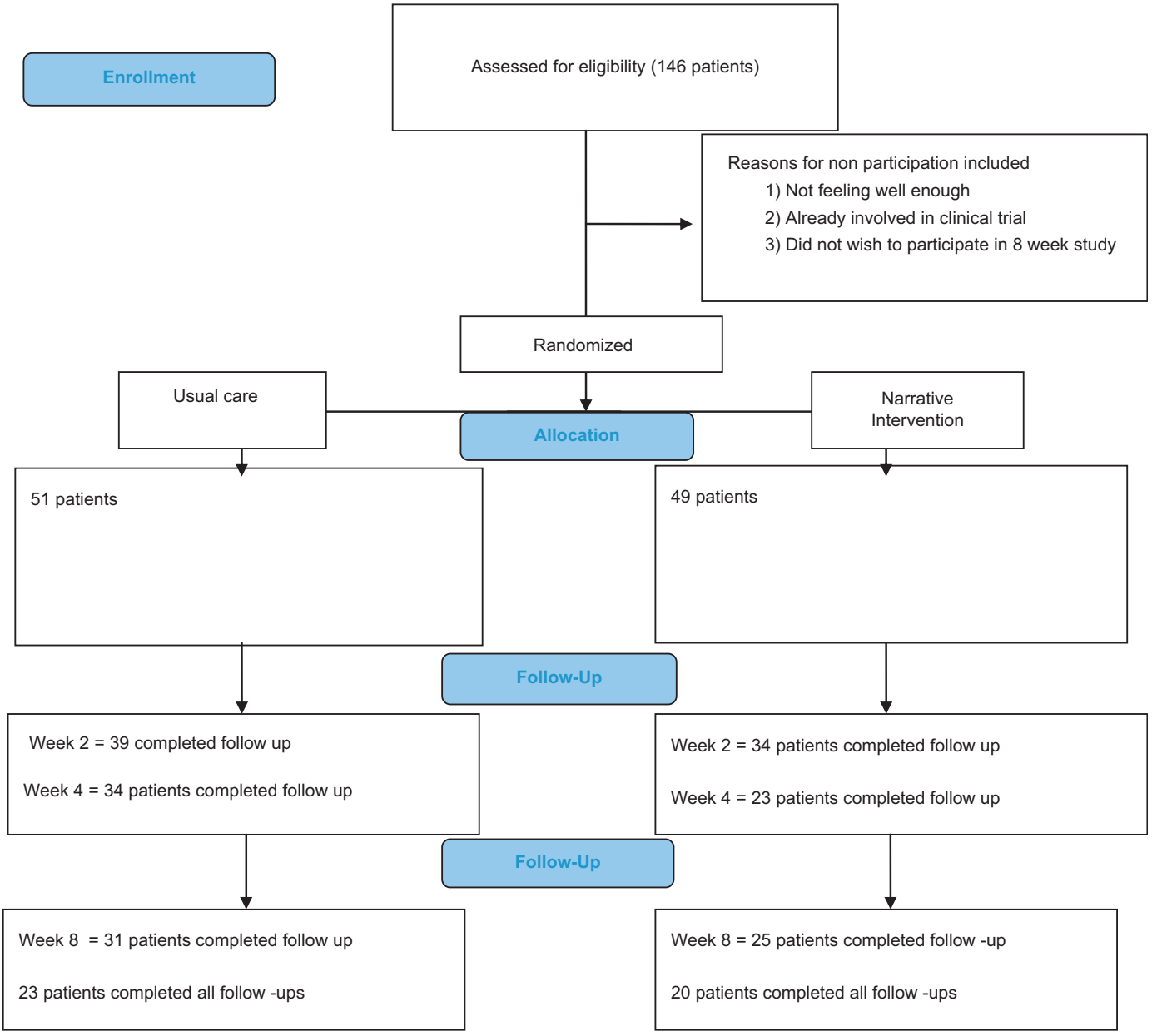

Fig. 1. Flow chart.

Table 4
Median outcome scores for control and intervention groups at baseline, 2, 4 week and 8 week follow-up.

	Baseline	Intervention	2 week follow-up		4 week follow-up		8 week follow-up	
	Control		Control	Intervention	Control	Intervention	Control	Intervention
Baseline measure								
BEDS score *median*	6.0	6.0	4.0	5.0	3.5	6.0	4.0	7.0
ESAS scores:								
Pain *median*	4.0	4.0	4.0	4.0	4.0	3.0	2.0	4.0
Tiredness *median*	5.0	7.0	6.0	6.5	6.0	7.0	5.0	6.5
Nausea *median*	1.5	1.0	1.0	1.0	2.0	2.0	1.0	1.0
Depression *median*	1.5	2.0	1.0	2.5	1.0	2.0	1.0	2.0
Anxiety *median*	3.0	4.0	2.0	4.0	3.0	3.5	2.0	3.5
Drowsiness *median*	3.0	5.0	3.0	5.0	3.0	4.5	3.0	4.0
Appetite *median*	4.0	5.0	3.0	5.0	4.0	5.0	3.0	5.0
Wellbeing *median*	4.0	5.0	3.0	5.0	4.5	5.0	4.0	5.0
Breathlessness *median*	3.5	4.0	3.0	4.0	2.0	3.0	2.0	4.0
Will to live *median*	8.5	9.0	9.0	9.0	9.0	8.0	9.0	8.0
FACIT scores:								
Spiritual well-being *median*	32.0	32.0	30.0	29.0	30.0	27.0	34.0	31.0
VAS Suffering scale *median*	5.0	4.0	3.0	3.0	3.5	3.0	3.0	3.0
No of patients	51	49	39	34	34	23	31	25

symptoms that affect many patients within palliative care. We would wish to replicate this intervention a larger trial prior to supporting its widespread utilisation.

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Conflict of interest

No conflict declared.

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