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Providing general practice needs-based care for carers of people with advanced cancer:

a randomised controlled trial

Abstract

Background
Carers of patients with advanced cancer often have health and psychosocial needs, which are frequently overlooked.

Aim
To meet the needs of carers through a GP consultation directed by a self-completed carer needs checklist.

Design and setting
Randomised controlled trial in general practice with recruitment through specialist oncology clinics, in Brisbane, Australia.

Method
Intervention was (a) carer–GP consultations directed by a self-completed checklist of needs at baseline and 3 months; and (b) a GP-Toolkit to assist GPs to address carer-identified needs. Control group received usual care. Outcome measures were intensity of needs, anxiety and depression, and quality of life.

Results
Total recruitment 392. Overall, no significant differences were detected in the number or intensity of need between groups. Compared to controls, intervention participants with baseline clinical anxiety showed improvements in mental wellbeing ($P = 0.027$), and those with baseline clinical depression had slower development of anxiety ($P = 0.044$) at 6 months. For those not anxious, physical wellbeing improved at 1 month ($P = 0.040$). Carers looking after patients with poor functional status had more physical needs ($P = 0.037$) at 1 month and more psychological and emotional needs at 3 months ($P = 0.034$). Those caring for less unwell patients showed improved mental wellbeing at 3 months ($P = 0.022$).

Conclusion
The intervention did not influence the number or intensity of needs reported by carers of people with advanced cancer. There was limited impact in people with pre-existing clinical anxiety and depression. For the carer of those most severely affected by advanced cancer, it drew attention to the needs arising from the caregiving role.

Keywords
Cancer; carers; general practice; palliative care; randomised controlled trial; self-assessment.

INTRODUCTION

Individuals suffering from life-limiting illnesses have clearly recognisable needs, and these are the primary focus of the efforts of health professionals, close family and friends. Their primary carers have lower quality of life (QOL)-impairment in physical functioning, general health, and vitality, and worse overall physical health than carers of patients receiving curative or active treatment. As patients deteriorate physically, carer QOL worsens.[1,2] Further, while many carers feel positively about this role, caregiving may also elicit significant emotional reactions and may increase the risk of psychiatric morbidity and complicated grief.[3] They may also suffer reduced social contact and face significant financial burdens.[3]

Carers whose needs are met are more likely to provide adequate support to enable patients to remain at home as close to death as possible.[4]

GPs usually have important contextual knowledge of the family and of the patient's illness. However, patient needs are the primary focus of the carer and health professionals, and carer needs and distress may be overlooked.[5]

The GP role in multidisciplinary cancer care is not well defined, and in practice it varies widely according to the interplay of factors including patients' expectations and GPs' motivation.[6] General practice consultations provide an opportunity to address carers' legitimate needs as patients in their own right, if both parties are willing,[7] and may provide a formal role for GPs in the multidisciplinary cancer team.

A randomised controlled trial (RCT) was conducted to assess the hypothesis that the efficacy of a GP-based intervention incorporating a carer-reported needs checklist and a supporting GP Toolkit of resources, reduces the reported number and intensity of unmet carer needs, compared with usual care.

METHOD

This trial was conducted in Brisbane, Australia. GPs act as gatekeepers to the health system, and 90% of all Australians see a GP at least once a year.[8] Cancer treatment services are usually conducted by multidisciplinary teams comprising oncologists, radiologists, surgeons and a range of nursing and allied health staff.

A detailed description of the trial design is presented elsewhere.[9]

Carers were recruited through three oncology services and one palliative care service between April 2009 and March 2011. Participants were adult (≥18 years) carers of patients with locally invasive or metastatic disease, who were capable of providing informed consent. They were

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How this fits in

The care of people with advanced cancer rightly focuses on the patient, but carers have significant needs that are often overlooked. Most carers have a GP who is well placed to provide care for the carer. There is no proven means of providing formal assessment of care through general practice. This study reports on a randomised controlled trial of a self-completed carer needs checklist which is used to guide the consultation between the carer and their GP.

recruited through the waiting rooms of oncology services, in day oncology clinics, or on admission to a community palliative care service. Once recruited, participants were randomised.

Intervention group process

The GPs of intervention patients were notified that their patient had agreed to participate in the trial. They were personally visited and introduced to the intervention resources using academic detailing. They were invited to participate at that point.

There were two resources. The Needs Assessment Tool — Carers (NAT-C) is a self-completed checklist for assessing carers' unmet needs across informational, physical, psychological, spiritual, existential, social, financial and legal domains (Box 1). The authors developed the NAT-C based on a comprehensive literature review to identify key issues related to carers' health concerns and the caregiving context, and 25 interviews, including current and recently bereaved carers (n = 6), GPs (n = 6), palliative care (n = 5), and oncology (n = 2) specialists and other informants (n = 6). Prior to finalisation, the NAT-C was pilot-tested by practicing GPs with actor-patients.[10] The NAT-C was also designed to protect the GP from multiple presenting needs in one visit. The NAT-C is modelled on an assessment completed by health professionals, the Needs Assessment Tool: Progressive Disease – Cancer, which has been extensively validated and trialed.[11–14] The NAT-C allows carers to identify and prioritise their own needs, and aims to focus the GP consultation quickly onto relevant matters. The carer and/or patient aimed to book a long appointment and present with a completed NAT-C within a week of the introductory GP interview.

NAT-C-guided consultations were conducted at baseline and 3 months to account for changing needs as patients became more ill. The content of the consultations was independent of the study, guided only by the identified needs and the GP's response to them, including further interventions as required.

The second resource is the GP Toolkit, a compendium of materials presented in both paper-based and electronic forms. It is organised into the domains in the NAT-C, and provides links to evidence–based information, resources and services that might help address identified problems. The Toolkit was reviewed by a reference group of practising GPs for relevance and utility before being finalised.

Control group process

Control carers received no intervention other than whatever was spontaneously offered to them by their or their patient's care team. They were informed that they would be surveyed to track their needs over time. Control group GPs were not contacted.

Outcome measures

Unmet needs: The Supportive Care Needs Survey — Partners and Carers (SCNS-P&C) is a 44-item measure, which assesses the level of unmet needs in the domains of health care service needs, psychological and emotional needs, work and social needs, and information needs in carers of cancer survivors.[14]

The mean change in domain score from baseline to the reference time point was calculated. The total number of needs is the sum of needs reported as 4 or 5 on a scale of need of 0–5 (that is, high levels of need described for that item).

Anxiety and depression: The Hospital Anxiety and Depression Scale (HADS) is a 14-item survey that classifies participants' anxiety and depression levels as low, borderline or clinically significant.[15]

Health-related quality of life: The Short Form Health Survey (SF-12v2) is a 12-item measure evaluating quality of life (QOL) across eight health concepts: physical functioning, role limitations because of physical health problems, bodily pain, general health perceptions, vitality (energy/fatigue), social functioning, role limitations because of emotional problems, and general mental health.[16]

The death of the patient before 6 months was also an endpoint, to prevent confounding by the different issues arising from bereavement.

Sample size calculation

The number and intensity of unmet needs

at 6 months was the primary outcome measure. A sample of 200 in each group at 6 months would identify a difference of between 4.2% and 6.7% in each domain of the SCNS-P&C with $\alpha = 0.05$ and $1\text{-}\beta = 80\%$.[14] Allowing for 8% attrition at each time point, recruitment of 520 patients was required. In a trial of similar design,[17] 101 GPs cared for 159 patients, with 88 GPs caring for 116 of these patients. Therefore a cluster design was not considered necessary.

Randomisation

Participants were randomised with 1:1 block randomisation, using random allocation of patterns in block sizes of four. Randomisation was conducted by research staff remote from the recruitment sites. Participants whose GP had a participant previously randomised were non-randomly allocated to the same study group to prevent contamination.[9] Potential participants were informed that their care needs would be assessed, without reference to testing an intervention, in order to blind their allocation. Intervention group participants were informed of the nature of the intervention following randomisation. Intervention GPs and participants were aware of their allocation, but control participants and their GPs were not.

Data collection

Participants were surveyed at baseline, 1 month, 3 months, and 6 months by trained telephone interviewers, who were blind to the allocation. The interviews were scripted and delivered in an identical fashion to all participants. A small number of participants (*n* = 11, 2.8%) chose to self-complete and return at least one questionnaire by mail.

Statistical analysis

For demographic characteristics, *P*-values for differences between means were calculated using an unpaired *t*-test, differences between medians were calculated using Wilcoxon Rank Sum test and differences between percentages were calculated using the χ^2 test.

Change scores for each time point compared to baseline were calculated within each group and are reported as means and standard deviations. The difference in the change between groups was tested using Analysis of Covariance (ANCOVA). The ANCOVA models were fitted using linear regression. The outcome in the model was the value of the outcome variable of interest at the follow-up time point, the main predictor variables were the treatment group and the level of function measured by the Australian-modified Karnofsky Performance Scale (AKPS).[18] The baseline level of the outcome variable was included as a covariate. Analyses were on an intention–to-treat basis, using the principles enunciated by White *et al*.[19] All analyses were conducted in SAS version (9.2).

RESULTS

Participants

Between April 2009 and March 2011, 392 participants were recruited (Figure 1).

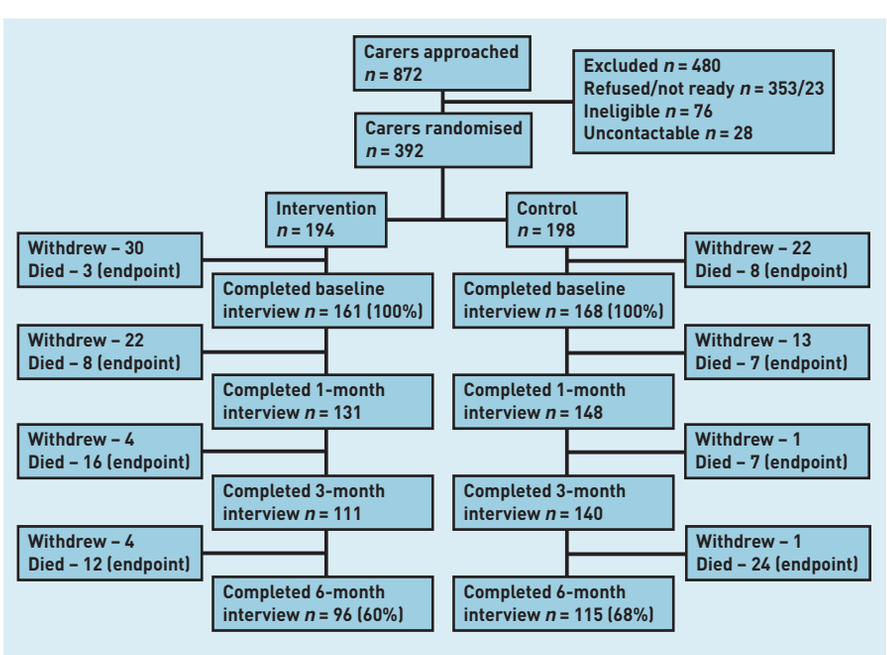

Figure 1. Participant flow diagram.

Table 1. Demographic characteristics of participants

Characteristic and category	Treatment group		
	Control (*n* = 168)	Intervention (*n* = 161)	*P*-value
Age			
Mean (SD)	56.6 (13.0)	58.3 (12.6)	0.230
Median (minimum, maximum)	57.0 (23.0, 83.0)	60.0 (25.0, 85.0)	0.242
Sex			
Male	58 (35%)	52 (32%)	0.669
Female	110 (65%)	109 (68%)	
Marital status			
Married/ De facto	144 (85.4%)	135 (83.7%)	0.152
Separated/ Divorced	13 (7.7%)	17 (11%)	
Single/ Widowed	11 (6.5%)	9 (5.6%)	
Relationship to person being cared for			
Spouse/partner	114 (68%)	109 (68%)	0.686
Parent	16 (9.5%)	12 (7.5%)	
Adult child	22 (13%)	28 (17%)	
Sibling	4 (2.4%)	2 (1.2%)	
Other	12 (7.2%)	10 (9.0%)	
Living arrangements of ill person			
With you	141 (84%)	135 (84%)	0.891
By themselves	14 (8.3%)	10 (6.2%)	
Other	13 (7.8%)	16 (9.9%)	
Highest level of education			
Primary school	9 (5.4%)	7 (4.3%)	0.843
Secondary School	92 (55%)	84 (52%)	
Certificate or diploma	43 (26%)	48 (30%)	
University degree	24 (14%)	22 (14%)	
Private health insurance			
Medicare only[a]	111 (66%)	85 (53%)	0.030
Private health insurance	57 (33.8%)	76 (46.9%)	
Employment previous			
Full time	53 (32%)	52 (32%)	0.813
Part time	33 (20%)	28 (17%)	
Self employed	13 (7.7%)	12 (7.5%)	
Retired	40 (24%)	40 (25%)	
Household duties	17 (10%)	14 (8.7%)	
Other	12 (7.2%)	15 (9.3%)	
Employment current			
Full time	36 (21%)	33 (20%)	0.883
Part time	21 (13%)	20 (12%)	
Self employed	11 (6.5%)	9 (5.6%)	
Household duties	21 (13%)	16 (9.9%)	
Retired	51 (30%)	50 (31%)	
Other	28 (16.8%)	33 (21.5%)	
Gross household income per week			
<$300[b]	15 (9.6%)	11 (7.5%)	0.746
$300–499	34 (22%)	26 (18%)	
$500–799	54 (34%)	50 (34%)	
$800–1000	19 (12%)	23 (16%)	
>$1000	35 (22%)	37 (25%)	
Supportive Care Needs Survey - Partners and Caregivers (SCNS-P&C)[c]			
Health care service needs, mean (SD)	2.2 (0.9)	2.4 (0.9)	0.027
Psychology and emotional needs, mean (SD)	2.1 (0.8)	2.3 (0.9)	0.007
Work and social needs, mean (SD)	1.9 (0.8)	2.2 (0.8)	0.006
Information needs, mean (SD)	2.1 (0.8)	2.4 (0.9)	0.004
Total number of unmet needs, mean (SD)	5.8 (7.8)	8.4 (9.4)	0.007
Hospital Anxiety and Depression Scale (HADS)			
HADS anxiety score, mean (SD)	8.0 (4.7)	9.3 (4.3)	0.010
HADS depression score, mean (SD)	5.3 (4.0)	6.3 (4.2)	0.021

... continued

Recruitment ceased to ensure complete data collection within the project timeframe. At baseline, significantly more intervention group participants had private health insurance, had more needs, and were statistically but not clinically more anxious and depressed than the control group (Table 1).

More intervention group participants dropped out of the study between baseline interview and study endpoint (29% intervention versus 15% control) (Figure 1). There was no statistical difference in attrition rate between groups at any timepoint, although the number of intervention participants who stated they were too busy to continue after their initial interview was statistically significant (intervention = 8, control = 0; $P = 0.01$).

Of 158 GPs who were invited to participate because their patient had agreed to participate in the study, only three refused to conduct NAT-C consultations. The proportion of allocated and randomised participants was virtually identical in each group (Intervention — 35 [18%]; Control —38 [19%]). There were no differences in the participants allocated to a treatment group compared with those randomised.

Outcomes: Numbers and intensity of needs, anxiety, depression and QOL at 6 months.

There were no between-group differences in the change from baseline to six-month scores in any of the subscales of the SCNS-P&C, level of anxiety or depression, or in the SF-12 score. Indeed, there were no differences in the changes from baseline to any timepoint. (Table 2)

Subgroup analyses

For carers who were clinically anxious at baseline (Table 3), the intervention was associated with a significant improvement in the mental component of the SF-12 at 3 months ($P = 0.027$). For participants clinically depressed at baseline (Table 3), control participants demonstrated significantly worsened anxiety at 6 months; intervention group participants did not ($P = 0.004$). There was no significant change in depression score at any time point.

Intervention group carers whose baseline anxiety score was normal (HADS<8) demonstrated a significant improvement in their physical SF-12 score at 1 month ($P = 0.040$). By contrast, intervention group carers with pre-existing clinical anxiety or depression reported a non-significant deterioration in their physical SF-12 score at 3 months ($P = 0.053$). (Table 3) The above analyses were adjusted for baseline anxiety

Table 1 continued. Demographic characteristics of participants

Characteristic and category	Treatment group: Control (*n* = 168)	Treatment group: Intervention (*n* = 161)	*P*-value
Short Form 12			
SF-12 Physical component score, mean (SD)	47.6 (10.8)	48.8 (11.1)	0.323
SF-12 Mental component score, mean (SD)	46.0 (10.9)	42.2 (11.7)	0.003
Anxious (HADSa >70) N (%)	88 (52%)	102 (63%)	0.044
Depressed (HADSd >70) N (%)	42 (25%)	57 (35%)	0.040
Australia — modified Karnofsky Performance Scale (AKPS) How well is patient functioning			
AKPS 80–100	55 (33%)	55 (34%)	0.960
AKPS 30-70	110 (65%)	103 (64%)	
AKPS 10-20	3 (1.8%)	3 (1.9%)	

[a]Medicare is the Australian national universal health insurance scheme. [b]Income in Australian dollars ($A1 = $US 1.03 in October 2012). [c] SCNS-P&C scores normalised to scores of 0–100.

and depression scores, respectively.

For carers of people severely ill at baseline (AKPS 10–50), intervention participants reported significantly escalated psychological and emotional needs from baseline to 3 months (P = 0.033) and a significant worsening of the SF-12 physical functioning score from baseline to 1 month (P = 0.037) compared to control carers. Intervention carers of less unwell patients (AKPS 60–70), experienced significant improvements in mental health at 3 months (P = 0.022) (Table 4).

DISCUSSION

Summary

This study is the first to test an intervention to address carer needs by seeking to take advantage of a GP's contextual and personal knowledge of the carer developed over time.

The study did not demonstrate improvements in the primary outcome, intensity of needs, at the study endpoint of 6 months or death. However, carers who

Table 2. Mean change in the domain scores of the SCNS-P&C, HADS and SF12 compared to baseline within each treatment group and differences between groups

Characteristic	Follow-up, months	Treatment group Mean change (SD): Control	Treatment group Mean change (SD): Intervention	Absolute difference between groups LSM[a] (95% CI): Difference between groups	Absolute difference between groups LSM[a] (95% CI): *P*-value
SCNS-P&C[b] Health care service needs	1	-0.6 (6.5)	-1.2 (6.2)	0.19 (-1.19 to 1.56)	0.791
	3	-0.8 (8.2)	-2.4 (6.5)	0.45 (-1.13 to 2.04)	0.575
	6	-1.5 (8.4)	-2.5 (8.1)	0.23 (-1.65 to 2.10)	0.811
SCNS-P&C Psychology and emotional needs	1	-0.6 (7.1)	-0.8 (7.0)	0.65 (-0.98 to 2.28)	0.434
	3	-1.4 (7.6)	-2.0 (7.2)	0.33 (-1.39 to 2.05)	0.709
	6	-2.5 (9.7)	-2.0 (8.3)	1.45 (-0.80 to 3.69)	0.205
SCNS-P&C Work and social needs	1	0.1 (3.9)	-0.6 (3.9)	0.06 (-0.80 to 0.92)	0.892
	3	-0.0 (4.3)	-1.0 (3.9)	0.32 (-0.60 to 1.24)	0.497
	6	-1.2 (4.8)	-1.5 (4.4)	0.36 (-0.72 to 1.44)	0.516
SCNS-P&C Information needs	1	-0.4 (4.7)	-0.9 (4.2)	0.12 (-0.86 to 1.11)	0.804
	3	-0.5 (5.2)	-1.7 (4.5)	0.51 (-0.62 to 1.64)	0.373
	6	-1.3 (5.6)	-2.2 (5.7)	0.01 (-1.24 to 1.27)	0.981
SCNS-P&C Total number of unmet needs	1	-0.3 (5.0)	-1.1 (6.0)	0.18 (-1.06 to 1.42)	0.772
	3	-0.8 (6.0)	-2.3 (4.9)	0.49 (-0.76 to 1.73)	0.441
	6	-1.6 (6.8)	-2.6 (6.4)	0.16 (-1.40 to 1.72)	0.841
HADS[c] anxiety score	1	-0.5 (2.8)	-0.8 (3.0)	0.05 (-0.63 to 0.73)	0.886
	3	-0.4 (3.2)	-1.0 (3.8)	0.33 (-0.51 to 1.18)	0.437
	6	-1.1 (4.0)	-0.7 (3.8)	0.82 (-0.18 to 1.82)	0.109
HADS depression score	1	0.3 (2.7)	-0.1 (2.5)	0.22 (-0.39 to 0.83)	0.473
	3	0.4 (3.5)	-0.0 (3.2)	0.21 (-0.62 to 1.03)	0.624
	6	-0.1 (3.9)	0.3 (3.9)	0.73 (-0.28 to 1.74)	0.154
SF-12[d] Physical component score	1	0.0 (6.6)	-0.7 (8.2)	0.61 (-1.09 to 2.31)	0.482
	3	-0.0 (7.3)	-1.0 (8.0)	0.85 (-0.99 to 2.70)	0.362
	6	0.1 (7.6)	-0.0 (9.4)	0.14 (-2.03 to 2.30)	0.902
SF-12 Mental component score	1	-0.4 (9.1)	1.2 (8.4)	0.45 (-1.56 to 2.46)	0.662
	3	-0.4 (9.0)	2.4 (9.3)	1.49 (-0.68 to 3.66)	0.178
	6	0.6 (10.9)	2.1 (9.8)	0.13 (-2.50 to 2.76)	0.924

[a]LSM = Least Squares Mean. [b]SCNS-P&C domain scores normalised to range of 0–100 . [c]HADS Anxiety and Depression scores range 0–21. Scores ≥8 indicate clinical anxiety or depression. [d]SF-12 score range from 0–100. Higher score indicates better health related quality of life.

Table 3. Mean changes from baseline to follow-up time points in selected domains of the SCNS-P&C, HADS and SF-12, adjusted for baseline anxiety (HADS Anxiety scale >8 and ≥8) and Depression (HADS Depression scale >8 and ≥8)

		Treatment group mean change (SD) from baseline		Absolute difference between groups LSM (95% CI)	
Characteristic	Follow-up, months	Control	Intervention		*P*-value
Mental and Social Health			HADS Anxiety ≥8		
SCNS-P&C[a] Psychology and emotional needs	1	-0.1 (0.5)	-0.1 (0.5)	0.06 (-0.10 to 0.23)	0.443
	3	-0.1 (0.6)	-0.1 (0.6)	0.05 (-0.13 to 0.23)	0.597
	6	-0.4 (0.7)	-0.2 (0.6)	0.20 (-0.01 to 0.42)	0.063[b]
SCNS-P&C Work and social needs	1	0.0 (0.6)	-0.1 (0.6)	0.00 (-0.18 to 0.18)	0.984
	3	0.0 (0.6)	-0.2 (0.6)	0.16 (-0.02 to 0.35)	0.087[d]
	6	-0.3 (0.7)	-0.3 (0.7)	0.05 (-0.17 to 0.28)	0.631
SF-12[c] Mental component score	1	-0.8(10.6)	2.1 (9.8)	1.79 (-1.23 to 4.80)	0.244
	3	-1.4 (10.0)	3.6 (10.4)	3.59 (0.41 to 6.77)	0.027[d]
	6	1.9 (11.5)	3.4 (11.1)	0.39 (-3.33 to 4.11)	0.835
			HADS Depression ≥8		
HADS[e] anxiety score	1	-1.5 (3.2)	-1.2 (3.7)	0.30 (-1.30 to 1.91)	0.708
	3	-1.6 (3.7)	-1.9 (4.1)	0.24 (-1.69 to 2.18)	0.801
	6	-3.9 (5.2)	-1.2 (4.8)	2.67 (0.07 to 5.26)	0.044[d]
SF-12 Mental component score[a]	1	-0.8 (6.9)	-1.3 (7.5)	0.15 (-3.11 to 3.41)	0.927
	3	-3.4 (7.0)	-1.8 (7.2)	1.95 (-1.45 to 5.35)	0.255
	6	-7.5 (9.1)	-3.0 (8.2)	4.15 (-0.63 to 8.93)	0.087[d]
Physical characteristics			HADS Anxiety <8		
SF-12 Physical component score	1	-0.6 (6.1)	1.7 (4.5)	2.15 (0.10 to 4.20)	0.040[d]
	3	-0.4 (5.9)	1.7 (6.7)	1.98 (-0.35 to 4.31)	0.094[d]
	6	-0.2 (6.5)	2.3 (5.9)	2.38 (-0.12 to 4.88)	0.062[d]
			HADS Anxiety ≥8		
SF-12 Physical component score[c]	1	0.6 (7.0)	-2.0 (9.4)	2.07 (-0.47 to 4.61)	0.110
	3	0.4 (8.5)	-2.8 (8.4)	2.70 (-0.03 to 5.44)	0.053[b]
	6	0.4 (8.5)	-1.4 (10.8)	1.15 (-2.19 to 4.50)	0.495

[a]SCNS — P&C = Supportive Care Needs Survey — Partners and Carers. Scores normalised to 0-100. [b]Favours control. [c]SF-12 = Short form 12. [d]Favours intervention. HADS = Hospital Anxiety and Depression Score.

were anxious or depressed at baseline experienced some improvement. Further, the intervention was associated with reporting of significantly more identified psychological and emotional needs at 3 months and a significant worsening of the SF-12 physical functioning score in intervention carers caring for a person who was severely ill at baseline, but an improvement in the mental health of individuals at 3 months who were caring for less unwell individuals. The results reflect how carer needs are impacted by factors other than the patient's cancer itself.

Strengths and limitations

This study recruited from oncology treatment centres, where many patients had prognoses measured in months, and some in years. While this provided access to a study population which could be assessed over the 6-month study period, it may be that the intervention was introduced too early to have a measurable impact on many people.

The study recruited a large sample of carers, compared to previous intervention trials in this population.[20] By seeking carers in the waiting rooms of oncology services and day oncology clinics, the burden on clinic staff of having to approach carers who were not actually their patients was reduced. Further, a strong recruitment of GPs was attained, which can be very difficult to achieve.[21] That only three GPs refused to participate indicates both a suitable means of recruiting GPs, and that the nature of the intervention was acceptable. The only thing that prevented recruitment was the funding timeframe. For complex trials such as this, even with a successful recruiting strategy, more realistic funding timelines need to be available. Most research bodies

Table 4. Mean changes from baseline to follow-up time points in selected domains of the SCNS-P&C and SF-12 component scores, adjusted for baseline patient performance status (AKPS 60–70 and 10–50)

		AKPS 60–70				AKPS 10–50			
		Treatment group Mean change (SD)		Absolute difference between groups LSM (95% CI)	*P*-value	Treatment group Mean change (SD)		Absolute difference between groups LSM (95% CI)	*P*-value
Characteristic	Follow-up time	Control	Intervention			Control	Intervention		
SCNS-P&C Psychology and emotional needs[a]	1 Months	-0.8 (7.8)	-0.2 (6.5)	1.12 (-1.22 to 3.46)	0.344	-0.6 (6.7)	-1.6 (7.5)	0.55 (-3.31 to 4.42)	0.775
	3 Months	-0.4 (8.3)	-1.9 (7.1)	0.54 (-2.08 to 3.15)	0.686	-3.7 (7.3)	0.1 (7.6)	4.61 (0.40 to 8.82)	0.033[b]
	6 Months	-2.1 (9.8)	-1.6 (8.2)	1.26 (-2.11 to 4.62)	0.461	-4.9 (11.3)	-0.9 (8.0)	4.17 (-1.91 to 10.25)	0.171
SF-12 Physical component score[c]	1 Months	-0.7 (6.6)	-0.6 (8.3)	0.26 (-2.22 to 2.74)	0.837	2.0 (8.4)	-3.7 (8.1)	5.21 (0.32 to 10.09)	0.037[b]
	3 Months	-1.4 (7.8)	-1.1 (7.8)	0.44 (-2.35 to 3.23)	0.753	4.5 (8.8)	-1.8 (7.1)	4.82 (-0.53 to 10.17)	0.076[b]
	6 Months	-0.5 (7.4)	-0.4 (8.2)	0.22 (-2.74 to 3.19)	0.881	1.2 (10.6)	-2.2 (10.9)	1.96 (-5.89 to 9.81)	0.614
SF-12 Mental component score[c]	1 Months	-0.9 (9.7)	0.9 (8.3)	0.95 (-1.95 to 3.84)	0.520	-2.1 (10.3)	2.3 (9.1)	2.12 (-3.82 to 8.07)	0.476
	3 Months	-1.5 (9.4)	3.2 (8.0)	3.54 (0.52 to 6.56)	0.022[d]	0.7 (8.9)	2.9 (11.1)	1.78 (-4.25 to 7.81)	0.553
	6 Months	-0.0 (12.3)	1.5 (10.6)	0.28 (-3.94 to 4.51)	0.894	3.0 (10.3)	3.8 (10.9)	1.53 (-6.03 to 9.09)	0.682

[a]SCNS-P&C domain scores normalised to range of 0–100. [b]Favours control. [c]SF12 component score range from 0–100. [d]Favours intervention.

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Provenance

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Competing interests

The authors have declared no competing interests.

Ethical approval

Approval was received from Human Research Ethics Committees at The University of Queensland, The University of Newcastle, Princess Alexandra Hospital, Mater Health Services and St Vincent's & Holy Spirit Health. The trial registration number is ISRCTN43614355.

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have time-limited or limits of money they will invest, and most will not fund projects that are not considered feasible in their time frame or outside the budget. They will also be reluctant to fund part of a project. This places researchers in the invidious position of estimating recruitment times on the assumption that all will work perfectly, which is the exception rather than the rule.

However, the numbers fell short of the proposed sample size. Recruitment was ceased to adhere to the project timeline and resources, and the negative result may be a type two error.

Some participants were allocated to a group on the basis that their GP already had carer and/or patients randomised to that group. While this introduced a risk of bias, it was believed that contamination was potentially the greater risk.[9] The similarity of the numbers and characteristics of participants indicate this decision did not introduce systematic bias.

Intervention group participants had more psychomorbidity than those in the control group, although differences were not clinically significant. The reason for this apparent systematic bias is unclear. Recruitment staff knew nothing about the carers prior to approaching them in waiting rooms, and subsequent randomisation was conducted off-site using a predetermined randomisation schedule. The possibility that the intervention group, with slightly more psychomorbidity at baseline, may have responded more rapidly than the control group in mental wellbeing items was not upheld in the trial results.

Partial blinding of participants was achieved by partial disclosure to potential participants, so that the control group participants and their GPs were unaware of the nature of the intervention. Further, telephone interviewers were blind to the allocation, and followed carefully constructed scripts.

These results are generalisable to urban carers of patients with advanced cancer, but not necessarily to carers of patients not routinely receiving oncology services such as house-bound older persons and those in rural and remote settings.

Comparison with existing literature

The medical team and carers themselves focus on the patient during this time of severe stress. Carer needs may be overlooked because carers may resist raising their own concerns in the sick person's presence;[6,10] the consultation will focus on the patient unless a separate carer appointment is given;[9] the brevity of consultations makes in-depth consultations difficult though counterbalanced by the GP's knowledge of the patient and carer/patient gained over time;[11] and both the GP and carer may be reluctant to raise carer issues, for different reasons.[7] Carers who dropped out because they were too busy may have felt that the focus should be on the patient's more urgent needs, not on themselves, or that participation in the surveys and the NAT-C was too confronting when the patient was very ill.

These results suggest that, for those caring for very ill people, an intervention which prompts them to reflect on their own needs may in fact draw attention to needs which had previously gone unattended. It is not clear whether this increased awareness constitutes harm or not. It may prompt carers and their GPs to put extra support measures in place, such as extra home help, respite or hospitalisation of the ill person.

This intervention showed limited improvements for people with pre-existing anxiety and depression. Both anxiety and depression are prevalent in one third to one half of carers of people with advanced illness.[1,17,22] In the current study, 57.8% of participants who completed a baseline interview had clinical anxiety, and 30.1% were clinically depressed.

Implications for research and practice

In addition to the formal analysis of this trial, the nature of carer needs and the way these needs change over time were explored. Qualitative in-depth interviews were also conducted to identify the impact of using the NAT-C in clinical practice. These will be reported in future publications.

This approach to the carers of people with serious illness should be tested in non-malignant contexts. While a generic carer needs assessment tool is possible, there are also specific issues around specific conditions like dementia, which may require a specific approach.

While this intervention did not reduce the intensity or number of needs, there may be some benefit in administering it to people with pre-existing anxiety or depression. Further, it impacted positively on the physical wellbeing of non-anxious carers. Raising awareness of the impact of caring on the carers of very ill people may trigger extra help in a timely manner.

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