

Original Article

Improving Outcomes for People With Progressive Cancer: Interrupted Time Series Trial of a Needs Assessment Intervention

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Abstract

Context. Improving the effectiveness of cancer care delivery has become a major focus of research.

Objectives. This study assessed the uptake and impact of the Palliative Care Needs Assessment Guidelines and Needs Assessment Tool: Progressive Disease—Cancer (NAT: PD-C) on the outcomes of people with advanced cancer.

Methods. Given widely varying survival in people with advanced cancer, an interrupted time series design was used, with data on unmet needs, depression, anxiety, and quality of life collected from 195 patients using telephone interviews every two months, for up to 18 months. Patients completed at least two baseline interviews before health professionals were academically detailed in the use of the Palliative Care Needs Assessment Guidelines and NAT: PD-C. Health professionals completed the NAT: PD-C with patients approximately monthly for the remainder of the study. Changes in patients' outcomes were compared prior to and following the introduction of the NAT: PD-C using general estimating equations.

Results. Moderate to high needs across all domains were frequently seen in the preintervention phase. The use of the NAT: PD-C was associated with a significant reduction in *health system and information* and *patient care and support* needs.

Conclusion. These resources have the potential as an efficient and acceptable strategy for supporting needs-based cancer care. Further work is required to

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Key Words

Needs assessment, NAT: PD-C, cancer, patient outcomes

Introduction

The need for improvements in the quality and effectiveness of cancer care delivery in Australia has become a major focus.¹ Despite the demand for people to have access to care that matches the needs they encounter, disparity exists between these expectations and current experiences.² It is argued, “creative solutions are necessary to address the escalating health care demands of chronic conditions.”³ Care should be provided according to the individual needs of the patient, their caregivers, and family so that the type and level of care provided, and the setting in which it is delivered, are dependent on the complexity and severity of individual needs.⁴ The challenge is in determining how “need” is defined and assessed.⁵

Advanced cancer is associated with a significant burden of morbidity as patients are polysymptomatic and often have higher levels of unmet need than those with localized disease, with needs varying throughout the disease trajectory.^{4,6,7} For example, as patients may not seek advice for symptoms, expressed need may be far less than actual need; and research has shown that patient needs are more likely to be detected through systematic assessment than through patient self-report.⁸ The importance of assessment methods that are responsive to changes in the needs experienced across the complete trajectory of illness has been emphasized.^{9–11}

The Palliative Care Needs Assessment Guidelines (Guidelines)¹² and the Needs Assessment Tool: Progressive Disease—Cancer (NAT: PD-C)^{11–13} were developed to inform and facilitate a more efficient approach to the ongoing assessment and management of unmet needs of people with advanced cancer and their caregivers. The NAT: PD-C operationalizes recommendations from the Guidelines to assist health professionals in matching the types and levels of need with the most appropriate

person or service to address that need.¹¹ The tool can be used by health professionals in both generalist and specialist settings to refer patients to a multitude of services, including general practitioners, medical and radiation oncologists, social workers, and other allied health professionals, and specialist palliative care services (SPCSs). This prospective, multi-site, longitudinal study aimed to evaluate the systematic use of these resources on patient outcomes. Process outcomes data, including rates of completion of the NAT: PD-C, its impact on consultation length, and the types of needs and follow-up care to address these needs, have been reported elsewhere.¹⁴ Patient outcomes are reported in this publication.

Aim

The aim of this study was to assess the impact of the systematic and ongoing use of the Guidelines and NAT: PD-C on patient outcomes including level of need, quality of life, anxiety, and depression. It was hypothesized that using the Guidelines and NAT: PD-C would result in reductions in the unmet needs, clinical anxiety and depression of participants, and an increase in their quality of life.¹⁵

Methods

Ethical Approval

Ethical approval was obtained from the Human Research Ethics Committees of the University of Newcastle, Hunter New England Area Health Service, Sydney South West Area Health Service and South East Sydney and Illawarra Area Health Service.

Sample

Eligibility criteria included: 1) a diagnosis of advanced cancer, no longer amenable to cure, with either extensive local, regional, or metastatic disease; 2) age 18 years or older; 3) able

to understand English sufficiently well to complete questionnaires and telephone interviews; and 4) emotionally and cognitively capable of participating, as judged by clinic staff.¹⁵

Study Design

Using an interrupted time series design, data were collected at multiple time points before and after the intervention was introduced to determine whether the intervention had an effect significantly greater than the underlying secular trend.^{16,17} This design allows both the short-term and long-term effects of the intervention to be examined more akin to an effectiveness study than a more limited efficacy study, and is highly suited for use in smaller populations and complex interventions.¹⁸ The unpredictable prognosis of participants with advanced cancer made this design particularly suitable.

Study Setting

Patients were recruited from medical oncology, radiation oncology, and hematology outpatient clinics at three major cancer centers; from two private gynecological oncologists; and from the gynecological oncology clinic at a major public hospital in New South Wales (NSW). If participants reported having an appointment with their general practitioner or being referred to a SPCS, these health care providers also were engaged in the study.

Procedure

Patients completed computer-assisted, telephone interviews (CATIs) every two months over a period of 18 months, or until their death or withdrawal. The academic detailing visit to introduce the NAT: PD-C and the Guidelines to health professionals was done after patients had completed at least two baseline CATIs to ensure sufficient preintervention comparison data. Medical, nursing, and allied health professionals at each of the cancer centers were trained in the use of the NAT: PD-C using academic detailing. Both individual and group sessions were used, depending on the availability of health professionals and their perceived degree of patient involvement. Individual sessions were preferred for medical staff (oncologists, hematologists, and palliative care physicians). For clinic nurses and allied health staff, group sessions were more widely used.

Where possible, training was scheduled on the same day for all health professionals at a particular site. In training, the purpose and structure of the Guidelines and NAT: PD-C, the potential barriers to using these resources, and strategies to address these barriers were discussed.

Trained clinic staff completed NAT: PD-Cs approximately monthly during their patients' consultations. Staff members from SPCSs also completed NAT: PD-Cs on participating patients referred to them during the study period, at initial assessment and monthly thereafter. Patients' general practitioners also were requested to complete a NAT: PD-C at participating patients' next appointments. To prevent contamination, the study was undertaken in sites where there was no geographic overlap of staff or patients. Academic detailing also was undertaken at different times at each of the sites; in March 2008 at Calvary Mater Newcastle, in May 2008 at St. George and in September 2009 at Liverpool Hospital. Patients continued to complete bimonthly CATIs following the introduction of the intervention. Outcomes were compared pre- and postintervention.

Materials

*The Palliative Care Needs Assessment Guidelines*¹² (Guidelines) aim to educate and inform health professionals about the issues that affect people with advanced cancer, their families, and professional carers to facilitate timely referral to SPCSs if required. The Guidelines cover all aspects of patient, caregiver, and primary health care provider characteristics that may influence the decision to provide more specialist palliative care to a particular patient or family.¹² Chapters describe the utilization and referral patterns of SPCSs in Australia, and the physical and daily living, psychological, cultural and social, spiritual, financial/legal, caregiver/family, and health professional issues that people with advanced cancer and their caregivers may experience.

NAT: PD-C.^{11,13} The NAT: PD-C is a one-page, health professional-completed tool assessing patient well-being, the ability of the caregiver/family to care for the patient and caregiver well-being. It includes four sections:

- Section 1 includes three items to fast-track a review by a SPCS: that the patient has a caregiver available to them if needed;

that the patient or caregiver has requested a referral to a SPCS; or the health professional needs assistance in managing care;

- Section 2 includes seven items to assess the patient's well-being across the physical, daily living, psychological, information, spiritual/existential, cultural and social, financial, and legal domains;
- Section 3 includes six items to assess the ability of the caregiver/family to care for the patient across the physical, daily living, psychological, information, financial, and legal, and family and relationship domains;
- Section 4 includes two items to assess the caregiver's well-being in relation to their own physical, psychological, and bereavement issues.

For Section 1, response options were "Yes" or "No." Items in Sections 2–4 were assessed according to the level of concern ("none," "some/potential for," "significant") they were causing. Prompt questions for each item were included on the back page to facilitate consistency and comprehensiveness in item assessment. Each item had a set of check boxes to indicate the action taken ("directly managed," "managed by another care team member," "referral required") to address any identified concerns. Finally, should a referral be required, a section was included at the bottom of the form detailing the type of referral made (e.g., to SPCS, social worker, general practitioner, medical oncologist), the urgency of the referral ("urgent," "semiurgent," "nonurgent"), and client knowledge of the referral. The psychometric qualities of the NAT: PD-C, including reliability, validity, and clinical feasibility, were confirmed in a simulated setting using filmed consultations, and in a clinical palliative care setting.^{11,13,15} The NAT: PD-C was completed by health professionals during their usual consultation with participants, approximately monthly.

Patient CATI Questions. Trained interviewers telephoned participants every two months during the study period to undertake a CATI to assess unmet needs, depression, anxiety, and quality of life (questions are listed in Table 1).

Sample Size

As the primary outcome was level of need, sample size was based on the changes in the

percentage of people reporting at least one moderate or high need in each of the Supportive Care Needs Survey (SCNS)¹⁹ domains pre- and postintervention. Secondary outcomes included depression, anxiety, and quality of life. Assuming a maximum prevalence of 50% (chosen as the worst case scenario) at preintervention for each domain, using a 5% significance level and having a minimum of 407 patients would give the study 80% power to detect a reduction in prevalence of 10% in each of the need domains postintervention.

Statistical Methods

The data were analyzed using SAS version 9 (SAS Institute Inc., Cary, NC). Descriptive statistics of patient characteristics at baseline and summary measures of levels of need, anxiety, depression, and quality of life at each time point were presented as means and 95% confidence intervals (CIs) for continuous variables, and as percentages and 95% CIs where the data were categorical. The recruitment site, demographic, and disease characteristics of the sample were compared with a NSW cancer population.²⁰ Where significant Chi-squared comparisons were found, *z*-tests were used to determine the level of the demographic variable at which the difference occurred. Statistical significance for patient outcomes was assessed using Chi-squared tests for categorical variables and *t*-tests for continuous outcomes ($\alpha = 0.05$).

For each of the SCNS domains, five-point Likert scales for each item in the domain were dichotomized into two categories: no need ("no need/not applicable," "no need/satisfied," and "low need") vs. need ("moderate" or "high need"). This method is described in the SCNS Users Guide and has been used in a number of studies assessing unmet needs.²¹ Similarly, the anxiety and depression subscales of the Hospital Anxiety and Depression Scale (HADS) were dichotomized into normal/borderline (score of 0–10) and clinically positive (score of 11+).²² Quality of life scores remained a continuous variable.

Each participant was allocated an individual intervention date, that is, the date of the first appointment after his/her oncologist had received training in the use of the Guidelines and NAT: PD-C. Based on this date, every CATI completed for a patient was allocated

Table 1
Measures Used to Assess Needs, Depression, Anxiety, and Quality of Life in Patients' CATIs

| Instrument | Items and Domains | Question Format |
|------------------------------|--|--|
| Demographic information | Nine items assessing: <ul style="list-style-type: none"> • Age • Gender • Marital status • Level of education • Type of health insurance • Gross income • Employment • Type of diagnosis • Time since initial diagnosis | |
| SCNS-SF34 ^{7,19,21} | 34 Items mapped to five domains: <ul style="list-style-type: none"> • Physical and daily living • Psychological • Patient care and support • Health system and information • Sexuality | Assesses level of need over the preceding month using a five-point Likert scale: <ul style="list-style-type: none"> • "No need/not applicable" • "No need/satisfied" • "Low need" • "Moderate need" • "High need" |
| NA-ACP ³⁸ | 132 items: Only the six items assessing spirituality were included | Assesses level of need over the preceding month using a five-point Likert scale: <ul style="list-style-type: none"> • "No need/not applicable" • "No need/satisfied" • "Low need" • "Moderate need" • "High need" |
| HADS ²² | 14 items assessing depression (seven items) and anxiety (seven items) | A score out of 21 is obtained for each subscale and is used to classify people as: Normal (score 0–7) Borderline (score 8–10) Clinically anxious or depressed (score 11–21) |
| EORTC QLQ-C30 ²⁴ | Two global questions assessing overall health and overall well-being | Assesses quality of life during the week preceding the interview using a Likert scale (1–7). Two item scores were summed, averaged, and scaled out of 100, with a higher score indicating a greater quality of life. |

CATI = computer-assisted telephone interview; SCNS-SF34 = Supportive Care Needs Survey—Short Form; NA-ACP = Needs Assessment for Advanced Cancer Patients; HADS = Hospital Anxiety and Depression Scale; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire.

to either a preintervention or postintervention time point. The last preintervention CATI was allocated Time 0 (T0). CATIs prior to this date were allocated to preintervention time points (T −3, T −2, and T −1 are approximately six, four, and two months preintervention); and CATIs after this date were allocated as postintervention (T1, T2, and T3 are approximately two, four, and six months postintervention).

For each patient, levels of need, anxiety, depression, and quality of life were measured repeatedly over the study and analyzed using a generalized estimating equation (GEE).²³ GEE analyses allow patients to be compared even when they have different numbers of observations, in this case, the number of CATIs completed. The GEE model fitted time as a factor and also analyzed the number of CATIs completed as an interaction variable. The

GEE analyses were run for both continuous and categorical outcome variables, adjusting for potential confounders including age, gender, time since diagnosis, comorbidity score, and presence of a caregiver, to ascertain whether the intervention had any impact on patient outcomes.

Results

Sample

A total of 219 patients consented to participate, a participation rate of 36% (Fig. 1). Given the patient sample was recruited from a number of clinical settings in metropolitan and regional NSW, the recruitment site, demographic and disease characteristics of the sample were compared with a NSW cancer population, as detailed in Table 2.²⁰

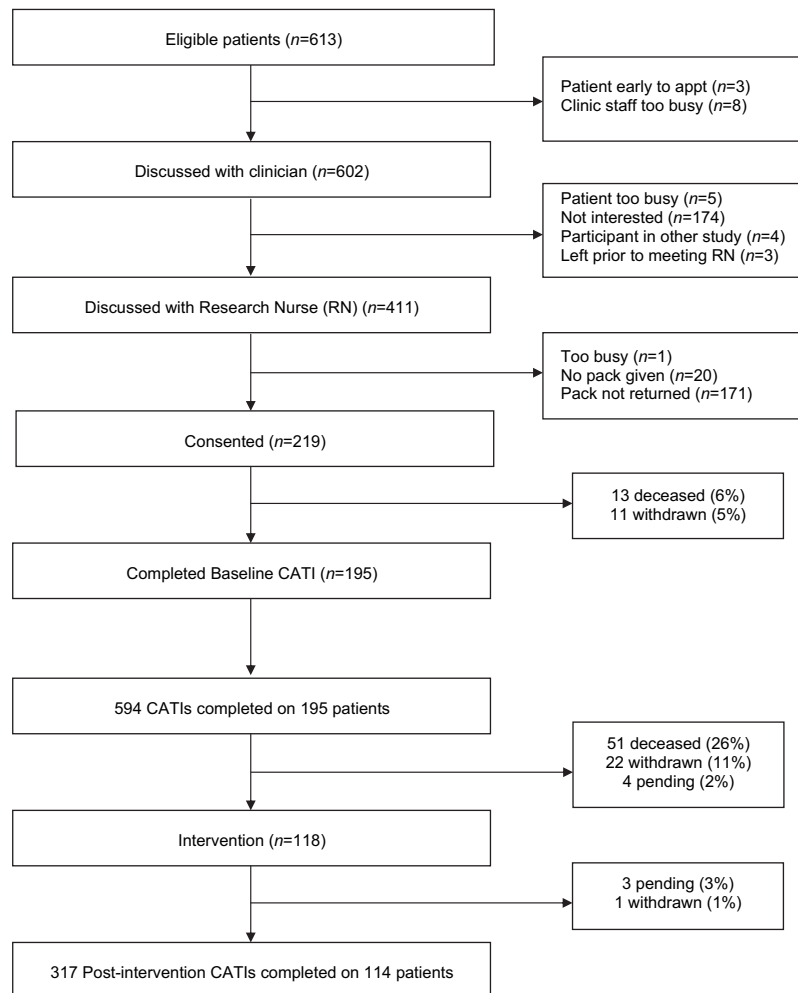


Fig. 1. Summary flowchart of patient recruitment and data collection in a study to assess the impact of a needs assessment intervention on patient outcomes.

Chi-squared comparisons found that the two groups were comparable with respect to gender ($\chi^2 = 1.11$, $df = 1$, $P = 0.29$), but differed in the age profile ($\chi^2 = 19.86$, $df = 5$, $P < 0.01$). Those aged 65–74 years were over-represented in the study sample ($z = 2.02$, $P < 0.05$) and those aged 75 years and older were under-represented ($z = -2.44$, $P < 0.05$). Significant differences also were observed for cancer type ($\chi^2 = 103.8$, $df = 7$, $P < 0.001$): people with lymphoid, hematopoietic diagnoses were over-represented in the study sample ($z = 6.74$, $P < 0.01$), as were breast cancers ($z = 2.51$, $P < 0.05$) and female genital cancers ($z = 6.34$, $P < 0.001$). Males with prostate cancer were under-represented ($z = -2.37$, $P < 0.05$), as were people with diagnoses not represented in

the eight diagnostic categories reported ($z = -6.70$, $P < 0.001$).

Chi-squared comparisons indicated no significant associations between cancer diagnosis and any of the outcomes at baseline, including quality of life [$F(7, 189) = 1.33$, $P = 0.24$]; the percentage of people with physical and daily living needs ($\chi^2 = 3.89$, $df = 7$, $P = 0.79$), psychological needs ($\chi^2 = 10.89$, $df = 7$, $P = 0.14$), health system and information needs ($\chi^2 = 13.45$, $df = 7$, $P = 0.06$), patient care and support needs ($\chi^2 = 9.19$, $df = 7$, $P = 0.24$), sexuality needs ($\chi^2 = 5.78$, $df = 7$, $P = 0.57$) or spirituality needs ($\chi^2 = 12.35$, $df = 7$, $P = 0.09$); clinical depression ($\chi^2 = 3.98$, $df = 7$, $P = 0.78$); anxiety ($\chi^2 = 3.57$, $df = 7$, $P = 0.83$); or distress ($\chi^2 = 2.51$, $df = 7$, $P = 0.93$). Tests of association were

Table 2
Recruitment Site, Demographics, and Disease Profile of Participants at Baseline Compared With a NSW Cancer Population

| Characteristics | Patient Sample (<i>n</i> = 198 ¹), % | Reference Population, % | <i>P</i> -value |
|--|--|----------------------------|-----------------|
| Recruitment site (of total 219 patients recruited) | | | |
| Calvary Mater Newcastle Hospital | 53.4 | | |
| Cancer Therapy Center, Liverpool Hospital | 25.6 | | |
| Cancer Care Center, St. George Hospital | 16.0 | | |
| Gynecology clinic, John Hunter Hospital | 2.7 | | |
| Private gynecological clinics | 2.3 | | |
| Age (years) (mean = 66.1, SD = 10.7; range 31–89 years) ^a | | | |
| 0–34 | 1.0 | 3.4 | <0.01 |
| 35–44 | 2.0 | 5.0 | |
| 45–54 | 12.1 | 11.6 | |
| 55–64 | 24.8 | 22.2 | |
| 65–74 | 36.4 | 25.9 | |
| 75+ | 23.7 | 31.8 | |
| Gender ^b | | | |
| Male | 53.0 | 56.8 | 0.29 |
| Female | 47.0 | 43.2 | |
| Marital status ^c | | | |
| Married | 66.7 | 49.6 | <0.001 |
| Widowed | 15.2 | 5.9 | |
| Separated or divorced | 13.6 | 11.3 | |
| Never married or single | 3.5 | 33.2 | |
| De facto or living with a partner | 1.0 | - | |
| Gross income (Aus dollars) ^d | | | |
| Less than \$300 per week | 25.6 | 11.2 | <0.001 |
| Between \$300 and \$499 per week | 39.3 | 12.3 | |
| Between \$500 and \$799 per week | 17.3 | 15.3 | |
| Between \$800 and \$1000 per week | 8.4 | 9.3 | |
| More than \$1000 per week | 9.4 | 51.9 | |
| Diagnosis ² | | | |
| Digestive | 22.2 | 18.5 | <0.001 |
| Lymphoid, hematopoietic | 20.2 | 7.5 | |
| Breast | 17.7 | 11.9 | |
| Prostate | 11.1 | 17.5 | |
| Female genital | 7.6 | 1.7 | |
| Urinary | 7.1 | 4.7 | |
| Lung | 6.6 | 8.9 | |
| Other | 7.6 | 29.3 | |

NSW = New South Wales; SD = standard deviation.

^aOf the 219 patients recruited to the study, baseline demographic information was available for 198 patients from the baseline CATI. Only 195 patients completed the entire baseline CATI, including all measures.

^bCompared with sample (*n* = 35,159) from Cancer in NSW Incidence and Mortality 2006.

^cCompared with all Australians (*n* = 19,855,288) from Census of Population and Housing, 2006.

^dCompared with all Australian households (*n* = 7,926,200): Household income and income distribution, 2005–2006.

not undertaken between cancer type and outcomes over time, as the study was not powered for this.

Chi-squared comparison between the study sample and Australian census data found a greater percentage of the study sample was married or widowed ($\chi^2 = 200.26$, *df* = 4, *P* < 0.001). A greater percentage of the study participants had an income of less than AUD\$300 a week, whereas a lower percentage had an income of more than AUD\$1000

a week when compared with all Australian households ($\chi^2 = 215.61$, *df* = 4, *P* < 0.001).

Unmet Needs

At baseline, 63% of the sample reported a moderate or high need in at least one of the domains. The highest levels of need overall were reported in the *physical and daily living* and *psychological* domains, including “Not being able to do the things you used to” and

Table 3
Top Ten Items for Which Participants Reported a Moderate or High Need for Help in the Month Preceding the T0 CATI (n = 195)

| SCNS Items | % With Moderate/High Need | Domain |
|---|---------------------------|---------------|
| Not being able to do the things you used to do | 33.0 | Daily living |
| Concerns about the worries of those close to you | 27.9 | Psychological |
| Lack of energy, tiredness | 26.2 | Daily living |
| Work around the home | 23.0 | Daily living |
| Uncertainty about the future | 21.4 | Psychological |
| Pain | 20.9 | Daily living |
| Worry that results of treatment are beyond your control | 19.4 | Psychological |
| Fears about the cancer spreading | 18.8 | Psychological |
| Feeling unwell a lot of the time | 17.3 | Daily living |
| Anxiety | 15.3 | Psychological |

CATI = computer-assisted telephone interview; SCNS = Supportive Care Needs Survey.

“Concerns about the worries of those close to you” (Table 3).

The number and percentage of people who reported having at least one moderate or high need in any of the need domains, from six months preintervention to six months postintervention, were examined. The time at which the intervention was introduced is represented by T0. The percentage of people reporting at least one moderate or high need was 64% at the time of the intervention, 61% at two months postintervention and 51% at four months postintervention. Although the percentage decreased to 52% six months

postintervention, this was not significant because of the differences in sample size ($z = 1.73$, $P = 0.08$).

Table 4 presents the change in the percentage of people who reported having at least one moderate or high need in each of the domains, from six months preintervention to six months postintervention. The percentage of patients with moderate or high *health system and information* needs remained highest prior to the intervention, with a statistically significant reduction at two, four, and six months postintervention. Although few participants in the sample had *patient care and support* needs, a progressive decline in the percentage of people with these needs was observed over the course of the study; and significantly fewer people reported needs six months postintervention.

The percentage of participants reporting moderate or high *physical symptom and daily living* needs was significantly lower at six months preintervention than at the intervention point. Although the percentage decreased immediately postintervention, changes were not statistically significant. The percentage of people with at least one *psychological* need decreased between four months preintervention and six months postintervention, but not significantly so. The percentage of people with *sexuality* needs began to decline significantly during the preintervention period and leveled off in the postintervention period. *Spirituality* needs were least frequently reported by participants throughout the study period.

Quality of Life

The study sample's mean quality-of-life score was significantly lower at baseline than the

Table 4
Percentage of Participants Reporting at Least One Moderate or High Need in Each SCNS Domain and the NA-ACP, From Six Months Pre- to Six Months Postintervention

| SCNS Domain | Time -3 (n = 70) | Time -2 (n = 122) | Time -1 (n = 160) | Time 0 (n = 192) | Time 1 (n = 103) | Time 2 (n = 85) | Time 3 (n = 67) |
|-----------------------------------|---------------------|----------------------|----------------------|---------------------|---------------------|--------------------|--------------------|
| Physical symptom and daily living | 40.2 ^a | 46.9 | 52.1 | 51.0 | 46.0 | 47.2 | 48.8 |
| Psychological | 37.1 | 46.4 | 44.7 | 38.8 | 37.4 | 35.3 | 33.1 |
| Health system and information | 32.9 | 28.8 | 26.2 | 28.3 | 18.8 ^a | 19 ^a | 15.8 ^b |
| Patient care and support | 13.2 | 18.3 | 12.6 | 13.6 | 12.3 | 10.6 | 4.9 ^a |
| Sexuality | 12.5 | 14.6 ^b | 7.4 | 6.3 | 8.4 | 7.3 | 6.4 |
| Spirituality (NA-ACP) | 13.8 | 10.4 | 10.7 | 8.8 | 9.2 | 8.8 | 9.3 |

SCNS = Supportive Care Needs Survey; NA-ACP = Needs Assessment for Advanced Cancer Patients.

^a $P < 0.05$.

^b $P < 0.01$.

Table 5
Changes in Mean Quality-of-Life Score as Assessed by the EORTC QLQ-C30 and the Percentage of People Classified as Clinically Depressed or Anxious Using the HADS, From Six Months Pre- to Six Months Postintervention

| Outcome | Time -3 (n = 70) | Time -2 (n = 122) | Time -1 (n = 160) | Time 0 (n = 192) | Time 1 (n = 103) | Time 2 (n = 85) | Time 3 (n = 67) |
|---|---------------------|----------------------|----------------------|---------------------|---------------------|--------------------|--------------------|
| EORTC QLQ-C30 (mean quality-of-life score 0–100) | 64.5 ^a | 61.2 | 61.2 | 58.0 | 57.5 | 56.5 | 57.5 |
| Clinical depression (% of participants with HADS score 11+) | 9.9 | 8.4 ^a | 10.2 | 13.5 | 9.5 | 10.9 | 13.8 |
| Clinical anxiety (% of participants with HADS score 11+) | 8.8 | 8.1 | 8.5 | 9.2 | 9.2 | 13.5 | 8.1 |

EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire; HADS = Hospital Anxiety and Depression Scale.

Higher scores represent higher quality of life for the EORTC QLQ-C30.

^a $P < 0.05$.

published general population reference data²⁴ (61.8 vs. 71.2, $t(7995) = 5.80$, $P < 0.05$). Table 5 presents the changes in the mean quality-of-life score of participants, from six months preintervention to six months postintervention. Quality of life was significantly higher at T-3 compared with T0. However, no significant changes were found following the introduction of the intervention.

Depression and Anxiety

When compared with the general Australian population,²⁵ a significantly greater percentage of our study sample was classified as clinically depressed (HADS score 11+) at baseline (11% vs. 6.2%; $P < 0.05$); the difference between the proportions was 5% (95% CI = 1% to 10%). A significantly lower percentage was classified as clinically anxious (7% vs. 14.4%; $P < 0.05$); the difference between the proportions was 7% (95% CI = -10% to -3%).

Table 5 presents the changes in the percentage of participants with clinical levels of depression and anxiety, from six months pre- to six months postintervention. Whereas the percentage of clinically depressed participants increased significantly in the preintervention period, the postintervention changes were not statistically significant. No significant changes occurred in the percentage of clinically anxious participants.

Comparison of Baseline Outcomes: T3 Completers vs. Participants Who Withdrew Prior to T3

Comparisons were made on baseline (T0) measures of outcomes of interest in the 67 participants who completed the study (T3) vs.

those who had withdrawn prior to T3. A significantly higher percentage of participants who withdrew prior to T3 reported at least one moderate/high need at baseline (69.6% vs. 50.8%; $\chi^2 = 6.65$, $df = 1$, $P < 0.01$); and they also reported a significantly lower baseline quality-of-life score (54.1 vs. 65.3; $t(189) = -3.22$, $P < 0.01$). The two cohorts had a comparable percentage of people reporting clinical depression (7.5 vs. 16.1; $\chi^2 = 2.87$, $df = 1$, $P > 0.09$) or anxiety (4.5 vs. 11.3; $\chi^2 = 2.49$, $df = 1$, $P = 0.12$).

Discussion

This study examined whether the use of the Guidelines and NAT: PD-C could prompt a more comprehensive assessment of patient concerns, potentially bringing about a reduction in the level of unmet needs, depression, and anxiety and an increase in patient quality of life. The NAT: PD-C had a high rate of completion, identified needs consistent with those self-reported by patients in interviews, and did not alter consultation length.¹⁴

The most notable study results are in relation to a number of domains of need and in quality of life. Clinically and statistically significant reductions in *health system and information* needs and *patient care and support* needs were observed. Health system and information needs related to the treatment center and obtaining information about the disease, diagnosis, treatment, and follow-up, for example, "Having one member of hospital staff with whom you can talk about all aspects of your condition, treatment, and follow-up."⁷ Patient

care and support needs related to health care providers showing sensitivity to physical and emotional needs, privacy, and choice, for example, "More choice about which cancer specialists you see."⁷ Furthermore, whereas participants' quality-of-life scores did not significantly increase over the course of the study, importantly, they did not deteriorate either, and remained higher than published scores for other populations in the terminal phases.^{26,27}

There are a number of possible explanations of these results. First, they may represent a true intervention effect. Previous research has shown that early provision of palliative care can result in improved quality of life in people with lung cancer.²⁸ In this study, rather than the intervention leading to improvements in quality of life, use of the NAT: PD-C may have, in fact, minimized the decline in quality of life that may be encountered as the disease progresses.^{29,30} Similarly, *physical and daily living* needs may increase in complexity and severity over the course of the disease, and the intervention may have minimized the worsening of anticipated symptoms. As the focus of palliative care is on enhancing the quality of life and comfort of patients, their caregivers and families, if this is a true intervention effect, it is an important finding, particularly as statistical significance may not reflect a change that is important to the person.²⁹

However, these observed effects cannot be confirmed because of the absence of a control group with which to compare the trajectory of these outcomes. Second, the effect may reflect a response shift, with patients' quality of life (and potentially unmet needs) self-normalizing as they adjust to their situation.³¹ Third, the observed effects may have been a result of a "healthier" cohort remaining to the end of the study. Comparisons between the 67 participants who remained active at T3 and those who had withdrawn from the study prior to T3 show that those who withdrew had significantly higher needs and significantly lower quality of life at baseline compared with the 67 participants who completed the study. Hence, the observed effects may have been because these people were less ill and experiencing less need than those who had withdrawn or died prior to their T3 CATI.

The changes that occurred in the remaining outcomes were less notable. A significant decrease in *sexuality* needs occurred prior to the intervention, not supporting the effects observed being attributable to the intervention. Whereas the percentage of people with *psychological* needs decreased over the study period, these changes were not significant. There were no significant changes in *physical and daily living* needs and *spirituality* needs during the study period.

The intervention did not appear to have any significant impact on psychological morbidity, as assessed by the measures included in this study. The low initial prevalence of clinical depression and anxiety may have reduced the likelihood of detecting significant reductions in these outcomes postintervention, but is consistent with other recent research in advanced cancer populations.³² Reporting of psychological issues is highly context-dependent and participants may have been more willing to report issues to telephone interviewers than to health professionals. However, further work is needed to examine the impact of the resources on psychological morbidity, especially in those people with heightened levels of distress.

Study Design and Limitations

In palliative care, the referral of people to services is dependent on the service, and there is considerable heterogeneity in the design of services and availability of resources. As such, the ideal trial design is an interrupted time series.³³ It has been suggested, "replicated findings from interrupted time series designs by different investigators in different settings may provide convincing evidence that an intervention is effective."³⁴

The response and consent rates for the study were lower than expected. Only 219 patients of the estimated 407 were recruited. Factors contributing to the less than optimal numbers included recruitment staffing issues, gate-keeping by clinicians, lower than expected numbers of eligible patients from all sites, and higher than predicted percentages of patients unable to speak English sufficiently well or deemed ineligible by their treating clinicians because they were unwell, cognitively impaired, or too distressed. Also, of the 195 patients who completed the baseline CATI, only 114 completed postintervention CATIs. This

rate of attrition over the course of the study is not unexpected given the participants all had advanced cancer and, hence, a limited life expectancy. Although lower than some published research with similar populations,³⁵ the attrition rate is not dissimilar to others.³⁶ Even so, it presents a challenge in interpreting the findings, which may be more positive than expected if the participants left at the end of the study are the “healthier” ones.

Aside from the small sample size, our participants differed from the NSW cancer population in terms of age and type of diagnosis. Not surprisingly, given the sites that agreed to participate, gynecological and lymphoid/hematopoietic cancers were over-represented. Given the relatively better prognosis of people with advanced breast cancer, an inverse proportion is understandable. The relative underrepresentation of men with abnormal prostate cancer is a result of their care more often still being in the private practice of urologists rather than multidisciplinary cancer clinics.

Another contributing factor for the lack of significant changes in the aggregate number of the needs may be that the resolution of baseline needs may have been offset by the addition of new needs in that area, thus minimizing reductions in prevalence of overall needs between baseline and follow-up.³⁷ Longitudinal studies defining the actual cause of the perceived needs in each domain and replication studies³⁴ are required to ascertain the unique contribution the developed resources have in improving the outcomes of people with cancer.

This study was prospective and followed a cohort of people with advanced cancer over time, was conducted in large cancer centers, and had minimal eligibility criteria. In this controlled environment, extra support was provided in the form of research nurses who were present in the oncology clinics to oversee the completion of the NAT: PD-Cs by clinicians. Each clinician also received academic detailing training in the use of the Guidelines and NAT: PD-C prior to the introduction of the resources. Hence, there is a need to conduct large-scale studies to assess the effectiveness and applicability within the real-world setting to further support the use of the Guidelines and NAT: PD-C. The impact of using these resources in nonmetropolitan centers, general practice,

and specialist palliative care settings also must be examined further.

Conclusion

In a population of people with advanced cancer, the use of the Guidelines and NAT: PD-C may contribute to reductions in the reporting of unmet needs, in particular, *health system and information* needs, and *patient care and support* needs. Whereas these results are promising, further research is needed to confirm the results. It is important that we ascertain how the resources can be successfully implemented in settings of care, and continue to explore the impact these resources have on patient outcomes and utilization and quality of cancer care.

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