



Published in final edited form as:

Psychooncology. 2009 January ; 18(1): 62–70. doi:10.1002/pon.1365.

Effects of a nursing intervention on quality of life outcomes in post-surgical women with gynecological cancers

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Abstract

Objective—Women with gynecological cancers have reported poor health-related quality of life (QOL), with complex physical and psychological needs post-surgery and during chemotherapy treatment. There are no studies reporting interventions addressing these needs post-hospital discharge in this population.

Methods—Patients were randomized into two groups. The intervention group received 6 months of specialized care by an Advanced Practice Nurse (APN); in addition, women with high distress were evaluated and monitored by a psychiatric consultation–liaison nurse (PCLN). The attention control group was assisted with symptom management by a research assistant. The effects of the 6-month intervention were evaluated using self-report questionnaires at baseline (24–48 h after surgery), 1, 3, and 6 months post-surgery. QOL assessments included the Center for Epidemiological Studies–Depression Scale, the ambiguity subscale of the Mishel Uncertainty in Illness Scale, the Symptom Distress Scale, and the Short-Form Health Survey (SF-12). The sample for the longitudinal analysis included 123 who completed QOL outcome measures across three occasions post-surgery.

Results—The APN intervention resulted in significantly less uncertainty than the attention control intervention 6 months after surgery. When the sub-group who received the APN plus PCLN intervention was compared with the total attention control group, the sub-group had significantly less uncertainty, less symptom distress, and better SF-12 mental and physical QOL over time.

Conclusion—Nurse tailored interventions that target both physical and psychological aspects of QOL in women recovering from cancer surgery and undergoing chemotherapy produce stronger outcomes than interventions that target solely one QOL aspect.

Keywords

gynecological cancers; post-surgical; advanced practice nurse; tailored intervention; quality of life

Introduction

Women with gynecological cancers, especially ovarian cancer, often receive complex and aggressive treatments. Typically, the primary treatment is surgery, minimally involving hysterectomy, bilateral salpingo-oophorectomy, lymph node dissection, omentectomy, and resection of surrounding tissue [1]. Common post-operative complications include development of thrombotic and embolic events, prolonged ileus, and wound infection and dehiscence [2]. Shortly following surgery patients are encouraged to initiate chemotherapy.

The seminal work of Weisman and Worden [3] introduced the concept of existential plight to the cancer literature, recognizing a predominance of existential concerns in the first 100 days after diagnosis. Several phenomenological studies corroborate and further define existential plight to include uncertainty, perceived lack of control, feelings of isolation, loss of self-identity, hopelessness, futility, and demoralization [4–6].

The connection between physical symptoms and existential concerns was explored by McCorkle and Quint-Benoliel [7], and later confirmed by Taylor [8]. Despite an apparent inter-dependence between physical and existential burden, there have not been intervention studies to address these patient concerns.

As documented by Zabora *et al.* [9], patients receiving multi-modal therapy, such as the treatment for gynecological cancers, are at risk for prolonged psychological distress that can affect their overall quality of life (QOL). Despite heightened risk for existential crisis and psychological distress, women who have undergone surgery for gynecological cancers do not receive optimal post-discharge care to facilitate their physical recovery while maintaining their QOL. Care in the clinic setting instead focuses on disease management and preparation for chemotherapy; patients' existential concerns and psychological needs are considered secondarily if at all [10–12].

The single-blind randomized clinical trial presented here was designed to test the following hypothesis: By 6 months, women with gynecological cancers randomized to the nursing intervention group will demonstrate higher QOL as assessed by depressive symptoms, uncertainty, symptom distress, and overall QOL, compared with women randomized to the attention control group. Effects of the 6-month intervention were evaluated using questionnaires administered at baseline (24–48 h after surgery), 1, 3, and 6 months post surgery. The study was approved by the Institutional Review Boards at Yale University School of Nursing and the participating hospital.

Methods and patients

Post-surgical women suspected of having a primary diagnosis of ovarian cancer were recruited from a northeastern teaching hospital associated with a comprehensive cancer center. Inclusion criteria were (1) a suspected primary diagnosis of ovarian cancer following abdominal surgery; (2) prognosis of at least 6 months; (3) to be discharged from hospital with a plan to initiate chemotherapy; (4) aged 21 years or older; and (5) living within the State of Connecticut.

Recruitment

Recruitment took place from December 2003 to June 2006. Potential patients were identified at daily gynecological oncology rounds by a nurse recruiter. Initial contact was made in the hospital by the Project Director who obtained consent and administered baseline questionnaires. Subsequent data collection visits were completed as in-person interviews by trained research assistants in the patient's home. After baseline data were obtained, consented patients were randomized into the intervention or attention control group using the sealed envelope technique.

A total of 281 women were identified as eligible to participate. Sixty-two were lost to follow-up because they were not scheduled for additional cancer treatment (and therefore did not meet inclusion criteria) or they followed up at another treatment center. Of the remaining 219 women, 149 enrolled, yielding a response rate of 68%. Although detailed statistics were not available for the 70 women who chose not to participate, our sample did not differ from the general population of women on the hospital unit who presented for the same types of gynecological surgery as identified by the Diagnostic Related Groups.

Of the 149 patients who enrolled, 4 were excluded for lack of complete baseline data, 123 patients of 145 completed three outcome measures at 6 months. Twenty-two women did not complete the study; reasons included died during study ($n = 19$), not feeling well ($n = 2$), and too anxious/overwhelmed ($n = 1$). Complete description of study recruitment and attrition are described elsewhere, including the demographic and clinical data of the total sample [13].

Nursing intervention

Patients in the nursing intervention group received 6 months of tailored specialized care by an oncology Advanced Practice Nurse (APN). The primary objective of the intervention was to assist patients in developing and maintaining self-management skills post-operatively and to facilitate their active participation in decisions affecting their subsequent treatment, which included chemotherapy. APN activities included symptom management and monitoring, emotional support, patient education, coordination of resources, referrals, and direct nursing care. Services included 18 patient contacts during the first 6 months after hospital discharge. The plan of care and intervention strategies were individually tailored to each patient's needs and personal priorities and were determined jointly by the nurse and patient. For example, while all patients received post-surgical wound care and medication management, at the first contact one patient might need detailed instruction about nutrition while another might prioritize spiritual concerns. At subsequent contacts, patient needs and priorities might, for example, shift to concerns about family members, issues of sexuality, pain management, and/or side effects of chemotherapy. See Table 1 for schedule of contacts for the intervention and attention control groups.

At baseline assessment, patients were screened for emotional distress using the Distress Thermometer (DT) [14]. Women randomized to the intervention group who scored four or greater on the DT, indicating significant distress, received an evaluation by the psychiatric consultation–liaison nurse (PCLN). The PCLN assessed the patient's emotional needs and

screened for psychiatric disorders as recommended by the National Comprehensive Cancer Network (NCCN) guidelines [15]. After the first PCLN contact, the APN and PCLN reviewed the plan of care in collaboration with the patient.

Patients in both the intervention and attention control groups received the Symptom Management Toolkit (SMT) [16], a manual written at the 6th grade level with information on 16 symptoms commonly experienced post-surgically or with chemotherapy. Each section describes causes of symptoms, strategies for managing symptoms, and when to call the oncologist.

Patients in the attention control group were assigned to a consistent research assistant who was trained in use of the SMT. Initial contact took place at patients' homes where instruction on the use of the SMT was given. At subsequent contacts, research assistants inquired about the presence of symptoms and the utility of the proposed strategies in the SMT in managing the symptom. Successful strategies were retained and reinforced. Patients who had questions outside the content of the SMT were encouraged to call their oncologist. The services of the research assistant included one home visit and 3 weekly telephone calls during the first month after hospital discharge and monthly telephone calls for the remaining 5 months of the intervention period for a total of eight contacts (Table 1). Telephone calls lasted an average of 20 minutes.

Measures

Standardized measures with strong psychometric properties, including validity and reliability were used to measure the variables judged to be central to QOL: depressive symptoms, uncertainty, symptom distress, and overall QOL.

Depressive symptoms were measured by the Center for Epidemiological Studies–Depression Scale (CES-D) [16], which consists of 20 items. The total score may range from 0 to 60, with a score of 16 or more indicating impairment. Original reporting of Cronbach's alpha of the CES-D ranged from 0.84 to 0.90 along with concurrent and predictive validity [17].

Uncertainty was measured using 13 items of the ambiguity subscale of the Mishel Uncertainty in Illness Scale (MUIS). The ambiguity subscale scores range from 13 to 65 with higher scores indicating more uncertainty and have been reported to have acceptable levels of internal consistency and concurrent validity [18].

Symptom distress was measured by the Symptom Distress Scale (SDS) that contains 13 symptoms commonly experienced by patients with cancer. Total symptom distress is obtained as the unweighted sum of the 13 items, a value that can range from 13 to 65. Internal consistency and test–retest reliability estimates indicated the scale was reliable and valid [7].

Overall QOL was measured by the Short-Form Health Survey (SF-12) [19] that consists of 12 items that represent two components: physical and mental health. Scores for the two QOL dimensions, each standardized to the range 0–100, are generated, higher scores represent better health status. Test–retest reliability of the physical and mental subscales has

been reported as 0.89 and 0.76, respectively. The scale has been extensively tested and validated and found to be internally consistent, reliable, and valid.

The DT is a rapid method to evaluate patients' distress endorsed by the NCCN [15]. The DT was administered at baseline as a screening tool to determine which patients in the intervention group would be evaluated by the PCLN. Patients were asked, 'How would you rate your emotional distress today on a scale of 0 to 10'? A score of 4 or above indicated distress requiring further evaluation [20]. Initial psychometric testing has confirmed that the scale is a valid and reliable measure of psychological distress [21].

Data analysis

Statistical analyses were conducted using SAS software version 9.1 [22]. Descriptive statistics were computed for demographic and clinical variables. Means, medians, and standard deviations were calculated for quality of life outcomes at Wave 1 (baseline measure), Wave 2 (1-month from baseline measure), Wave 3 (3-months from baseline measure), and Wave 4 (6-months from baseline measure) for the total sample and by group assignment, by patients who withdrew, and patients not used in these analyses.

The main goal of the analyses was to examine patients' QOL outcomes over time in order to quantify the effects of the interventions longitudinally using mixed effect regression models. One variable feature of the APN intervention was assignment of a PCLN when high emotional distress was assessed by the DT ($n = 32$). To determine impact of the PCLN component, three longitudinal models were constructed: (a) ignoring the PCLN component and focusing on the APN intervention only, (b) treating the PCLN component as a higher 'dose' of the nursing intervention, thus quantifying the groups as three levels of care, and (c) using the PCLN component as a separate factor for analysis.

Preliminary analyses were done to determine which covariates needed to be adjusted for in the final longitudinal analyses. To this end, multiple *a priori* linear regression models were built (stepwise model building) to detect the dependences, if any, of each QOL measure at baseline on demographic and clinical variables. Simple regression models were computed by patient to obtain individual rates of change, with respect to time, of each QOL measure. These QOL rates of change were then regressed against the demographic and clinical variables to determine if additional covariates were needed.

Additional analysis was done in preparation for the final model building. Since distributions of the QOL measures appeared in most cases highly skewed to the right, scores were transformed using the logarithm function. A simple linear regression line was fitted through each patient's QOL measure as a function of time. We then weighted on the reciprocal of the resulting mean-squared error to correct for heteroscedasticity in the mixed effect model. As a result of this weighting protocol, only patients with three or more observations were included in the analysis.

Mixed effects regression models with covariates were built using a backward elimination algorithm. All applicable covariate variables (age less than 60 or greater than and equal to 60, White race or not, recurrent cancer or not, education less than or equal to high school or

greater than high school, early or late stage, married or not, number of comorbidities, combined income less than or equal to \$30 000 or greater than \$30 000, emotional distress score equal to or greater than 4 or not, PCLN or not, and adjusted QOL baseline scores) identified in the preliminary analyses were included as well as their interactions with time. The with-inpatient correlation structure was modeled as a Toeplitz matrix (correlation as a function of time-lag) to account for the time-lag effect. To simplify the models, only main effects and two-way interactions with time were considered. At each step of the algorithm, interactions were retained that had a *P*-value less than 0.05, and main effects (other than those involved in retained interactions) were retained that had a *P*-value less than 0.15. Of course, main effects that were involved in retained interactions were always retained.

Results

Demographic and clinical characteristics

The sample is described in Table 2. Our goal was to recruit consecutively all women scheduled for gynecological surgery suspected of having ovarian cancer. The final sample of 123 included women with a primary diagnosis of ovarian cancer (61.8%) and other cancers with metastasis to the ovaries and abdomen who were scheduled and received chemotherapy. Seventy-three percent were newly diagnosed and 27% had recurrent disease. Thirty-three percent were diagnosed with early stage (I or II) and 66% with late stage (III or IV) cancer according to the International Federation of Gynecology and Obstetrics staging system. Fifty-nine percent of patients reported two or more comorbidities and 77.2% reported a family history of cancer. Patients in the intervention and attention control groups did not differ significantly in terms of demographic and clinical characteristics, including stage, primary ovarian site, and new or recurrent disease. This sub-sample of patients did not differ on any demographic or clinical variables when compared with the total sample.

Quality of life measures

Total unadjusted scores for the total sample at each wave for each outcome measure are reported in Table 3. At baseline, there were significant differences between the two groups on three outcome variables (CES-D, uncertainty, and SF-12-mental), with the nursing intervention group reporting poorer QOL. However, baseline scores for both groups were adjusted for model testing and were consistent with reports in the literature documenting high psychological and physical impact in high-risk populations [23–27].

The results for the mixed effect regression models are summarized in Tables 4–6. For each model, the coefficient estimates (and respective standard errors and *P*-values) for the wave, intervention, and wave by intervention interaction are reported. Table 4 reports the mixed-effect regression models with covariates and interactions considering only the nursing intervention (ignoring the PCLN factor) and attention control groups. In Table 5, the intervention was modeled as three ordinal levels of ‘dose’. In Table 6, the intervention under consideration was assignment of the PCLN as an additional factor to the nursing intervention. Results for the estimates of the coefficient of the ‘wave’ term contain the estimates of the wave coefficient in the model with all interaction terms deleted. This gives an estimate of the overall time trend. The ‘intervention’ term (‘group’ in Table 4, ‘dose’ in

Table 5, and 'PCLN' in Table 6) gives an estimate of the difference in intercept terms of the intervention group, i.e. the adjustment at baseline. Most importantly, the results for wave by group interaction give the estimates of the difference in time trends between intervention groups (or increment in time trend per increment of dose in the case of 'dose')—in other words, the effect of the intervention on the rate of QOL improvement.

In each model, for each QOL measure (with the exception of the SF-12-mental), QOL improved over time for the total sample, before taking time-interaction terms into account. The corresponding *P*-values and slope estimates can be found in the first column of each of Tables 4, 5, and 6. For SF-12-mental, the *P*-value for the slope coefficient was not significant, indicating that there was no evidence of an overall time trend for either group.

The second column of Tables 4–6 indicates the mean differences in QOL at baseline between the groups. These are obtained as the estimates of the intervention group intercept (main effect) terms when the mixed-effect regression model is fitted. The key features communicated by Tables 4–6 are the estimates of the time-intervention interactions (displayed in the third column). In the case of nursing intervention only versus attention control (Table 4), the rate of improvement in MUIS was significantly greater for the intervention group ($P = 0.0006$). However, in the case of CES-D, SDS, and the SF-12-physical scores, the attention control group appeared to perform better over time. When the intervention was modeled as three levels of increasing 'dose', then the intervention contributed to a significantly better improvement over time in the case of MUIS ($P < 0.0001$) and SF-12-mental ($P = 0.0023$), but less improvement over time for CES-D ($P = 0.0033$) scores. The final model is reported in Table 6 with the PCLN intervention considered as a separate factor. The PCLN component was found to significantly increase the rate of improvement over time for MUIS ($P = 0.0181$), SDS ($P < 0.0001$), SF-12-mental ($P = 0.0001$), and SF-12-physical ($P < 0.0001$) scores. For the CES-D, there was no significant effect of the PCLN component ($P = 0.64$).

The covariates that remained significant during the model-building process are noteworthy. Of particular interest are the covariates that had a significant interaction with time (wave), as this gives us information about factors that affect the rates of improvement of the various QOL outcome measures over time. Covariates that remained in the model included age, marital status, number of comorbidities, disease status (recurrence or not), and education level. Specifically, patients who were younger than 60 years, educated at a high school level or less, married, had fewer comorbidities, and newly diagnosed with cancer had less improvements on QOL outcomes over time.

Discussion

Our nursing intervention resulted in significantly less uncertainty than the attention control intervention 6 months after surgery for gynecological cancers. When the APN plus PCLN intervention group was compared with the attention control group only, our results were even stronger and affected other dimensions of QOL. Women had significantly less uncertainty, less symptom distress, and better SF-12-mental and physical QOL over time than women who did receive the attention control. Of note, there were no differences in the

final model between the intervention and attention control groups on changes in depressive symptoms, nor were depressive symptoms responsive to the addition of the PCLN intervention. However, although there were no between groups differences, there were significant within-groups differences in CESD scores over time. The quality of the concerns of this sample of women with gynecological cancers was captured by the MUIS rather than the CESD. In future studies, anxiety may be more reflective of existential concerns over time than depressive symptoms.

Other studies evaluating transitional care interventions for non-cancer populations have also shown beneficial effects on patient outcomes. A review of 94 studies revealed the transition of older adults from hospital to home was associated with high rates of poor outcomes [28]. Emotional problems are identified as one of the factors contributing to negative outcomes. Naylor and colleagues showed that a 3-month APN-directed discharge planning and home follow-up protocol had significant effects on overall QOL in adults with heart failure [29].

Our trial is unique in its design of including a specialized intervention to transition women from the hospital to their homes after surgery with the addition of evaluating the women for emotional distress, and using the services of a PCLN for those with high levels of psychological morbidity. We demonstrated that women who received the nursing intervention and a psychological evaluation by a PCLN had better rates of improvement over time than women in the attention control group. This effect was especially strong among women most emotionally distressed as screened with the DT at entry into the trial. Because this group had higher distress scores, there was also greater room for improvement. We also found that women who did not improve significantly were younger, healthier, and newly diagnosed. This group most likely received more toxic chemotherapy, more often, with recommended higher doses of drugs. Future studies should record these specific treatments and more homogeneous groups need to be compared. Meta-analyses suggest psychotherapeutic interventions are effective in reducing symptoms of cancer or its treatment [30], as well as anxiety, depression, and psychological distress [31]. There have been successful efforts to target patients as they recover physically [32], and only limited efforts to focus on both physical and emotional components of QOL concurrently.

Whether these women were confronting a new or recurrent diagnosis, the findings confirm they were experiencing an existential crisis. Placing the longitudinal results within the context of a 100-day timeframe helps to account for the improvements made by both groups and the application of the ‘tincture of time’; however, the fact that the intervention group improved more implies the intervention exceeds or accelerates the natural resolution of distress and assists in sustaining its effects. We believe the intervention worked so well in reducing uncertainty because it captured the flexibility and tenacity of the APNs as they engaged and followed the women over time teaching them to manage their physical and mental health problems concurrently. Meeting with family members and informing them about management strategies and facilitating communication between patients and medical providers were also vital components.

This study supports meeting both the physical and psychological burdens associated with cancer and its treatment. The nursing intervention with a psychological evaluation by the

PCLN or other professional trained in psychosocial oncology is ideally suited to address these neglected aspects of patient need. This study underscores the recommendation of the recently released Institute of Medicine report that all cancer care should ensure the provision of appropriate psychosocial health services [33]. As more and more people age, cancer will continue to be a major challenge for cancer providers and facilitating patients' recovery after cancer surgery is essential. Minimally, patients must be screened for emotional distress and evaluated for additional services.

There are several limitations that need to be acknowledged. Although our intent was to recruit women who were newly diagnosed with only ovarian cancer, the primary site of their tumor was not always known prior to surgery—so our sample included cancers metastasized in the abdomen and included other gynecological cancers. In addition, to achieve adequate power we expanded our sample to include women who had a disease-free interval and were post-surgical for recurrence of ovarian cancer. The two groups were balanced randomly by these variables and were not retained in our final model as significant; however, these subgroups were small and additional research is needed. The groups were not balanced at baseline on QOL measures. The attention control group had better mental health, less uncertainty, and less depressive symptoms. We have no explanation for these differences and may have occurred by chance. Measures were obtained prior to randomization. The sample was recruited from one cancer center so additional testing of our intervention is needed in other settings. In addition, both groups received interventions. We do not know whether the QOL of the women in the nursing intervention group would have improved with larger significant differences if compared with women in a control group alone. The sample was limited to women so we do not know whether men with aggressive cancers would respond similarly.

Conclusion

In summary, these findings substantially inform our understanding of intervention strategies needed to improve QOL outcomes for patients recovering from cancer surgery and undergoing chemotherapy. They suggest the potential benefit of a comprehensive intervention directed by APNs with a PCLN psychological evaluation that spans the existential plight of cancer and bridges the transition from hospital to home, recovery from surgery, and initiation of chemotherapy. Nurse tailored interventions that target both physical and psychological aspects of QOL in women recovering from cancer surgery and undergoing chemotherapy produce stronger outcomes than interventions that target solely one QOL aspect. These findings serve to specify more carefully within the QOL literature the importance of tailoring interventions that focus on the existential plight and its connection to uncertainty and physical and mental health.

Acknowledgments

The work was funded by The National Institutes of Health, National Institute for Nursing Research, 1R01NR07778, R. McCorkle, was the PI.

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Table 1

Schedule of contacts for intervention and attention control groups

Group	Interventionistic qualifications	Number of subjects	Number of contacts	Nature of contacts	Care provided
Specialized nursing intervention program plus	Advanced practice nurse in oncology	63	18 total; 2 per week, month 1; 2 per month, months 2–6	8 home visits, 7 telephone calls, 3 clinic visits	Stabilize post-surgery, Maintain ADLs, Symptom management for chemotherapy side effects, Counseling and support, Community referrals, Teach self-management skills
PCLIN consultation with APN in oncology	Advanced practice nurse in mental health nursing	32 of 63	1 to 2 additional contacts	1 clinic visit/home visit for evaluation telephone follow-up	Psychiatric evaluation for high emotional distress, Collaborative Rx plan developed, Identification of resources and referral
Attention control	Research assistant with BS and MS degrees	60	8 total; 1 per week, month, 1; 1 per month, months 2–6	Contact 1: home visit Contacts 2–8: telephone calls	Symptom management for chemotherapy side effects

Table 2Baseline patient demographic and clinical characteristics by group $N = 123$

Characteristic	Intervention ($N=63$)		Attention control ($N=60$)	
	Mean (\pm SD)		Mean (\pm SD)	
Age	58.4 (11.3)		62.2 (12.7)	
DT	5.68 (2.8)		5.03 (2.7)	
	<i>N</i>	%	<i>N</i>	%
Race				
White	57	90.5	56	93.3
Non-White	6	9.5	4	6.7
Marital status				
Never married	8	12.7	6	10.0
Married/with partner	32	50.8	39	65.0
Divorced	18	28.6	9	15.0
Widowed	5	7.9	6	10.0
Education				
HS	18	29.0	26	33.4
College	28	45.2	23	38.3
<College	16	25.8	11	18.3
Employment status				
Employed	27	42.8	31	51.6
Not working	15	23.8	7	11.7
Retired	21	33.4	22	36.7
Disease status				
New	44	69.8	46	76.7
Recurrent	19	30.2	14	23.3
Comorbidities				
Zero	11	17.5	9	15.0
One-Two	16	25.4	14	23.3
>Two	36	57.1	37	61.7
Income				
0–29999	12	22.2	12	22.2
30000–59999	14	25.9	14	25.9
60000– and above	28	51.9	28	51.9
Family history of cancer	50	79.4	45	76.3

Numbers and percentages may not equal total sample due to missing values.

Table 3

Summary of Unadjusted QOL measures by groups over time $N = 123$

Measure	Baseline		One month		Three months		Six months	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
CESD	18.5±7.6	15.0±8.0	13.7±7.4	10.9±7.2	13.7±8.0	10.0±7.7	12.2±8.0	8.3±5.9
MUIS	39.2±8.8	34.8±9.1	35.3±9.3	32.7±9.3	35.0±9.0	31.8±9.5	31.1±10.6	27.9±10.5
SDS	29.0±6.7	26.8±6.6	25.3±6.9	23.2±6.3	24.7±6.2	22.0±6.4	22.9±6.8	19.9±5.1
SF-12 Mental ^a	43.3±9.9	47.8±9.8	47.9±10.7	51.0±8.7	46.9±9.8	51.0±9.3	48.9±9.7	52.8±8.5
SF-12 Physical ^a	32.8±9.1	33.3±8.9	34.7±8.8	36.9±10.9	39.0±9.9	41.1±10.7	41.0±11.4	44.8±11.9

^a Higher score reflects better health.

Table 4

Mixed-effect regression models with appropriate covariates and wave-variable interactions considering nursing intervention and attention control groups $N = 123$

Independent variable	Wave (without interactions) ^a	Group (correction at baseline)	Wave* group (interaction) ^b
Dependent variable	Estimate (P-value)±se	Estimate (P-value) ±se	Estimate (P-value) ±se
CESD	-0.08357 (<0.0001)±0.01265	0.1643 (0.0197) ±0.06923	0.06566 (0.0030) ±0.02190
MUIS	-0.03367 (<0.0001) ±0.00764	0.1007 (0.0232) ±0.04362	-0.04847 (0.0006) ±0.01394
SDS	-0.06465 (<0.0001) ±0.00405	0.05823 (0.1705) ±0.04218	0.05092 (0.0021) ±0.01638
SF-12 Mental	-0.00237 (0.6354) ±0.00500	-0.05018 (0.0805) ±0.02841	0.01776 (0.1195) ±0.01138
SF-12 Physical	0.07730 (<0.0001) ±0.01400	0.09373 (0.1421) ±0.06332	-0.07599 (0.0019) ±0.02425

^aOverall time trend in sample.

^bDifference in time trends between groups.

Table 5

Mixed-effect regression models with appropriate covariates and wave-variable interactions considering attention control, nursing intervention, and PCLN care as increasing levels of intervention ‘dose’ $N = 123$

Independent variable	Wave (without interactions) ^a	Dose (correction at baseline)	Wave* dose (interaction) ^b
Dependent variable	Estimate (P-value)±se	Estimate (P-value)±se	Estimate (P-value) ±se
CESD	-0.08269 (<0.0001) ±0.01259	0.08575 (0.0284) ±0.03853	0.03594 (0.0033) ±0.01213
MUIS	-0.03343 (<0.0001) ±0.00767	0.04456 (0.1022) ±0.02700	-0.03917 (<0.0001) ±0.00915
SDS	Poor model fit		
SF-12 mental	-0.00229 (0.6471) ±0.005001	-0.05196 (0.0065) ±0.01869	0.02300 (0.0023) ±0.00748
SF-12 physical	Poor model fit		

^aOverall time trend in sample.

^bIncrement in time trend per increment of ‘dose’.

Table 6

Final Mixed-effect regression models with appropriate covariates* and wave-variable interactions considering PCLN care as a separate factor $N = 123$

Independent variable	Wave (without interactions) ^a	PCLN (correction at baseline)	Wave* PCLN ^b (interaction)
Dependent variable	Estimate (P-value)±se	Estimate (P-value)±se	Estimate (P-value) ±se
CESD	-0.08356 (<0.0001)±0.01266	-0.02553 (0.8450)±0.1302	0.01662 (0.6400)±0.03549
MUIS	-0.03348 (<0.0001)±0.00763	-0.03635 (0.5160)±0.05576	-0.04978 (0.0181)±0.02094
SDS	-0.06490 (<0.0001)±0.00405	0.2680 (<0.0001)±0.05053	-0.1164 (<0.0001)±0.01284
SF-12 Mental	-0.00230 (0.6454)±0.00500	-0.1145 (0.0127)±0.04505	0.06558 (0.0001)±0.01676
SF-12 Physical	0.07681 (<0.0001)±0.01399	-0.1044 (0.3309)±0.1068	0.1948 (<0.0001)±0.03877

* Covariates included age less than 60 or greater than and equal to 60, White race or not, recurrent cancer or not, education less than or equal to high school, or greater than high school, early or late stage, married or not, number of comorbidities, combined income less than or equal to \$30 000 or greater than \$30 000, emotional distress score equal to or greater than 4 or not, PCLN or not, and adjusted QOL baseline scores.

^a Overall time trend in sample.

^b Difference in time trends between groups.