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Psychosocial Outcomes of an Electronic Self-Report Assessment and Self-Care Intervention for Patients with Cancer: Randomized Controlled Trial

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Abstract

Objective: The use of Web-based technology to facilitate self-care and communication with healthcare providers has the potential to improve psychosocial outcomes for patients undergoing cancer treatment. This study reports an analysis of psychosocial outcomes of the Electronic Self-Report Assessment for Cancer (ESRA-C-II) study.

Methods: Adult patients starting cancer therapy were randomized to receive usual education about symptoms and quality of life (SxQOL) topics (control) or usual education plus self-care instruction for SxQOL issues, communication coaching, and the opportunity to track SxQOL between clinic visits (intervention). Depression (Patient Health Questionnaire-9) and social, emotional, and role functioning (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 subscales) were measured before treatment (T1), 3–6 weeks after starting treatment (T2), 2 weeks later (T3), and 2–4 weeks after treatment ended or at the next restaging visit for participants who continued to receive treatment (T4). Clinicians received summaries of participant reports at each time point in both groups.

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Results: In multivariable analysis, the depression scores were significantly lower ($p=0.04$) and there was a trend to higher social and role functioning ($p=0.07$) in the intervention group compared to the control. Working status was significantly associated with lower depression and better social and role functioning.

Conclusions: A patient-centered, Web-based intervention that facilitates self-care and communication can improve psychosocial outcomes in the cancer setting.

Keywords

cancer; oncology; psychosocial; depression; quality of life; outcomes

Background

Depression is one of the most common psychosocial problems encountered in cancer patients[1] and rates vary widely by oncology clinical setting,[2] underscoring the importance of vigilance for mood symptoms in patients at different stages of cancer treatment. Depression is frequently comorbid with other problems such as anxiety, pain, fatigue, and suicidal ideation, leads to decreased functioning and quality of life,[3] and is associated with decreased acceptance/tolerance of and adherence to cancer therapy[4] and shorter survival.[5]

Within the context of newly mandated universal distress screening and provision of comprehensive psychosocial care that is integrated into the routine care of cancer patients, [6] the American Society of Clinical Oncology (ASCO) has recently established clinical practice guidelines for the management of depression and anxiety.[7; 8] The convergence of healthcare and health system complexity and increasing clinical demands requires the development of integrated systems of psychosocial care that are cost-effective and adaptable to diverse cancer care systems. Patient-centered technologies to facilitate screening for and communication of symptoms have shown feasibility, acceptability and effectiveness for improving patient-provider communication regarding cancer symptoms and quality of life issues[9; 10] and reduced depression, anxiety and symptom distress.[11–14] However, as reviewed by Agboola,[15] findings have not been consistent across studies.

Our program of research, focused on cancer symptom and quality of life experiences, has been conducted in two randomized controlled trials, the most recent being Electronic SelfReport Assessment for Cancer (ESRA-C-II).[14] We evaluated the effect of Web-based, selfreport assessment and monitoring, self-care instruction, and communication coaching on symptoms and quality of life during cancer treatment. Analysis of the primary outcome, Symptom Distress Scale-15 scores,[14; 16] indicated that intervention group participants reported significantly lower symptom distress than those in the control group. Further analyses have documented the significant impact of the ESRA-C on enhancing patients' verbal reporting of symptoms[10] and the direct relationship between use of the intervention and symptom distress outcomes.[17] Our methods and secondary outcomes papers have documented minimally important clinical differences for the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (QLQ-C30) used

in our first randomized trial[18] and relationships between oral cancer medication adherence, depression and demographic variables.[4]

In this paper we report a secondary analysis of psychosocial outcomes of the ESRA-C-II study by examining the effects of the intervention on depression and on social, emotional and role functioning.

Methods

The detailed procedures of the ESRA-C-II trial are reported elsewhere.[14] A total of 752 ambulatory, adult (age ≥ 18 years), English speaking patients diagnosed with cancer of any stage who were about to start a new cancer therapy (did not have to be first-line) were randomized to receive usual education about SxQOL topics (control) or usual education plus self-care instruction for SxQOL issues, communication coaching on how to report troublesome SxQOL to clinicians, and the opportunity to track SxQOL between clinic visits (intervention). The Institutional Review Boards of the participating sites, comprehensive cancer centers in Seattle and Boston, approved the study protocols.

The validated ESRA-C-II questionnaires were used to screen for cancer-related SxQOL issues before treatment (T1) and at specific time points throughout therapy for both groups. Participants completed a second assessment (T2) approximately 3 to 6 weeks after starting treatment. A third assessment (T3) was scheduled 2 weeks later and the final assessment (T4) was planned 2 to 4 weeks after treatment ended, or at the next restaging visit for participants who would continue to receive treatment indefinitely (e.g., palliative therapy).

In both groups, clinicians received a two-page, color-keyed summary of the patient report, and research staff verbally notified the provider of any severe levels of depression and/or pain reported at the time of the clinic visit. Usual education varied between treatment units, but all included the use of nurse assessment and education regarding common side effects. Self-care instructions and coaching in the intervention focused on three messages for each SxQOL reported above an *a priori* threshold: 1) why and how often the SxQOL issue happens, 2) what can be done about the issue between clinic visits, and 3) how and when to report the SxQOL to the clinical team.[14] For example, if a participant completed the PHQ-9 at a study time point, and the score was ≥ 10, the depression teaching tip was autodisplayed (Figure 1). Participants in the intervention arm could also self-monitor their SxQOL by viewing and annotating graphs of their SxQOL scores over time and keeping a journal of SxQOL and self-care activities. Participants in the intervention group accessed the ESRA-C remotely 76% of the time, versus 24% in the clinic.[23]

Psychosocial variables were measured at each time point using the Patient Health Questionnaire-9 (PHQ-9) for depression[19] and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (QLQ-C30)[20] for social function (SF), emotional function (EF), and role function (RF). We also assessed the related domains of cognitive and global function. The 9-item PHQ-9 depression questionnaire assigns scores of 0, 1, 2, and 3 to the response categories of “not at all,” “several days,” “more than half the days,” and “nearly every day,” respectively, over the past two weeks.

The PHQ-9 total score ranges from 0 to 27, where lower scores correspond to less depression. If one or two of the nine items were not answered, we imputed values by assigning the mean of the answered items to the missing items.[2] The QLQ-C30 has 2, 4, and 2 items for SF, EF and RF, respectively. The functional scale summary scores were transformed to range from 0 to 100 according to published methods for version 3,[21] where higher scores correspond to a higher (better) level of function.

Statistical analysis

Our primary measures of psychosocial outcomes were the end-of-study scores. If a patient had finished treatment before T3, T4 measures were not administered, and the T3 scores were used. All eligible, randomly assigned patients with complete outcome data were included according to the intent-to-treat principle, regardless of whether patients utilized the provided usual education or study intervention. The end-of-study scores, adjusted for baseline scores, for the PHQ-9 and QLQ-C30 domains were compared between study groups using analysis of covariance (ANCOVA). The estimated intervention effect was plotted together with a 95% confidence interval (CI). Covariates previously identified[14] as influencing symptom distress (i.e., age, clinical service in which treatment was planned when the participant enrolled in the trial [medical oncology, radiation oncology, stem cell transplant], working status) were adjusted in a multivariable analysis to improve precision of the intervention effect, and possible two-way interactions were checked. Type III p-values were used to assess the overall covariate significance in each model. The change in PHQ-9 score from baseline to end-of-study was calculated, and nonparametric smoothing techniques were used to explore the impact of baseline PHQ-9 on the score change. Additionally, the intervention effect on depression was assessed on the pattern of no/mild or moderate/severe depression (PHQ9 8) using McNemar's Test.[22] All p-values were twosided for which a value of <0.05 was considered statistically significant and a value of 0.05 to 0.1 was considered a nonsignificant trend. Due to the exploratory nature of this analysis, no multiple comparison adjustments were performed.

Results

Demographic and clinical characteristics of the eligible analytic sample were balanced between study groups in the original trial.[14] A total of 581 eligible participants (292 in the control and 289 in the intervention) who completed the study per protocol comprised this analytic sample.

Table 1 summarizes the available sample and scores on the PHQ-9 and QLQ-C30 SF, EF, and RF scales for each time point. Missing data were negligible and baseline scores were balanced between the two groups. Baseline PHQ-9 scores reflected low levels of depression overall, with means of 3.54 and 3.59 in the control and intervention groups, respectively.

Figure 2 displays the estimated intervention effects together with 95% CIs from the ANCOVA analysis. Ten cases (5 controls, 5 intervention) with missing PHQ-9 scores at baseline or at the end-of-study were removed from the analysis. On average, significantly lower depression scores were observed at the end of the study in the intervention group

compared to the control group. The PHQ-9 score was lower by an estimate of 0.60 (95% CI, 0.08 to 1.12, $p=0.02$) in the intervention group versus the control group. There was a trend toward higher functional scores in SF and RF in the intervention group, suggesting that the intervention group improved functional scores by estimates of 3.01 (95% CI, -0.63 to 6.66 , $p=0.10$) in SF and 3.40 (95% CI, -0.30 to 7.10 , $p=0.07$) in RF. No significant difference in EF score was observed between the two study groups ($p=0.43$). (QLQ-C30 cognitive (estimate= 1.67 , $p=0.20$) and global scores (estimate= 1.79 , $p=0.20$) were nonsignificant, data not shown.)

Table 2 lists results from the multivariable regression, including the covariates age, clinical service (medical oncology, radiation oncology or transplant), and working status. In the adjusted model, the significant difference in depression and trend toward higher social and role functioning remained. Additionally, baseline working status was significantly associated with end-of-study depression, SF and RF, with a trend for EF. Participants who were working at baseline were less depressed and have better functioning. Age and clinical service had no effect on these psychosocial outcomes.

The pattern of change in depression from baseline to end-of-study revealed that in the control group, 25 of 255 (10%) participants with no/mild depression (PHQ-9 < 8) at baseline shifted to moderate/severe depression (PHQ-9 ≥ 8), while 17 of 35 (49%) participants with moderate/severe depression at baseline shifted to no/mild depression by the end of the study ($p=0.22$, McNemar test). In the intervention group, 14 of 251 (6%) shifted to higher depression and 19 of 37 (51%) shifted to lower depression ($p=0.38$, McNemar test). The pattern was not significant in either group.

Visual inspection of results from the smoothing techniques (Figure 3) suggested that the higher the baseline depression (PHQ-9) score—beginning at a baseline PHQ-9 of about 8, indicating moderate or greater severity[22] -- the greater the reduction in PHQ-9 score by end-of-study. Among 71 participants whose baseline PHQ-9 score was 8 or higher, a greater reduction in the score was observed in the intervention group (11.94 [SD 3.62] to 8.10 [SD 4.69]) compared to the control group (11.88 [SD 4.36] to 9.03 [SD 4.91]), with an estimated difference between groups of 1.03 (95%CI, -0.89 to 2.96) by ANCOVA. However, the difference did not reach statistical significance ($p=0.29$) in this smaller subset.

Conclusions

This analysis of psychosocial data from the ESRA-C-II randomized trial indicated a significant and beneficial effect on depression and a trend toward beneficial effects on social and role functioning among those receiving the intervention. Participants who had moderate or more severe depression (PHQ-9 ≥ 8) experienced a greater decrease in depression from the intervention. Patients who were working reported significantly less depression and better functioning than those not working.

Our findings are consistent with other studies showing that patients with more severe depression often respond more strongly to interventions aimed at mitigating depression.[23; 24] In an analysis of exposure to the ESRA-C intervention, working participants tended to

be more likely to use the remote intervention.[17] Not surprisingly, a similar significant relationship was found between working and better role function, as being able to work is a feature of role function as measured in the QLQ C-30. Social functioning, or level of interference with family life and social life, tended to be better in the intervention group and was significantly related to work status, suggesting that less symptoms/ depression and working may have increased opportunities for social interactions. Although there was only a trend toward better social and role functioning in the intervention vs. control group, the between group difference of greater than 3 suggests a potentially clinically meaningful difference.[18]

While screening alone for depression has not consistently been shown to improve clinical outcomes,[25] screening coupled with self-monitoring and coaching on self-management and communication with providers and peers shows more promise. In a systematic review of the effect of technology-based interventions on depression, Agboola et al.[15] found only 4 of 9 studies focused on depression reported statistically significant effects, two of which were Internet-based. Borosund et al.[26] reported that an Internet-based patient-provider communication tool plus WebChoice, which facilitates symptom monitoring, selfmanagement and communication with other patients, improved depression. Stanton et al. [27] reported that a personalized website in which breast cancer patients could journal cancer experiences and share content with their social network improved depressive symptoms, positive mood, and life appreciation. Basch et al. found that symptom self-reporting via tablet computers among advanced solid tumor patients improved overall HRQOL as well as anxiety/depression, compared to usual care.[28] Other remote approaches, such as those that use telephone and mobile technologies, have also shown promise in improving psychosocial outcomes.[15; 29]

The clinical implications of these findings are that a Web-based, self-report assessment and monitoring, self-care instruction, and communication coaching program can identify patients with depressive symptoms and provide a first step in empowering patients to manage and communicate these symptoms to their providers. A follow-up assessment for those who endorse depression is important to identify and treat patients who remain depressed and require more intensive treatment, such as pharmacotherapy or psychotherapy.[7; 8]

The findings of this analysis are limited by the lack of racial, ethnic and socioeconomic diversity in the original trial.[14] There were too few participants in each diagnostic category to stratify analysis by cancer type. Data were collected only through the end of therapy or shortly thereafter, precluding the study of longer term effects of the intervention. Depression was assessed using self-report, so there may have been under-reporting of symptoms. Although depression was significantly lower in the intervention group compared to the control group, the effect was modest; there was likely a „floor effect” due to the non-selective nature of study inclusion and low baseline scores. Despite baseline mean depression scores being in the „minimal” severity range, the control group”s PHQ-9 score increased by 0.62 (17.5%), whereas the intervention group”s PHQ-9 score increased by 0.05 (1.4%), resulting in a between-group difference in depression of 16.1%. Applying previously proposed criteria,[30; 31] the intervention provided a clinically meaningful benefit by preventing even minimal depressive symptoms from worsening. While the absolute

between-group difference was larger among participants with moderate or more severe depression at baseline, our small sample size in this subgroup limited statistical power; future studies should examine the impact of the intervention on a larger sample of depressed individuals. Although we previously reported that patients in the intervention group discussed depression symptoms more often than patients in the control group,[10] which may have enhanced clinical management of depression, a formal mediation analysis was beyond the scope of this paper.

While screening patients for psychosocial distress has received primary focus, the subsequent steps, such as what to do with the information to best benefit the patient, pose the most challenges. The results from this study suggest that a patient-centered, Web-based self-care intervention, accessed at a patient's convenience, improves depression and may improve psychosocial function. Future studies should examine potential mechanisms for these effects. While the ESRA-C is not designed to be a stand-alone therapy for psychosocial distress, its self-assessment and monitoring, self-care instruction and communication coaching may be used as an important adjunct to an integrated program to manage psychosocial distress in the cancer setting.[32]

Acknowledgments

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Depression

Some of our patients have had concerns about depression as a result of their treatment.

Based on your report, you may have some concerns about feeling down, depressed, or blue. This may include having little interest or pleasure in doing things or feeling hopeless. Along with these feelings, people often have trouble with sleep, appetite, energy, or concentration. These symptoms can lead to difficulty with relationships, work, home or social life, or other activities. If you are having thoughts of suicide, call your team/clinic nurse right now.

Why does this happen? Depression can result from the stress of cancer treatment, but may also result from certain medications or medical conditions. At least 19% of patients in our previous research report similar problems after starting treatment.

What can I do about this?

- [Seattle Cancer Care Alliance \(Depression\)](#)
- [The National Cancer Institute \(Depression\)](#)
- [The American Cancer Society \(Depression\)](#)
- [LiveStrong Lance Armstrong Foundation \(Emotional Effects of Cancer\)](#)
- [The American Society of Clinical Oncology \(Depression & Anxiety\)](#)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about depression and ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this:

"I've noticed that _____ (fill in the blank to describe your mood, such as feeling down, depressed, or hopeless). For example _____ (describe how your mood has affected you or interfered with your daily activities). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Figure 1.

Depression communication and self-care education presented on-screen to participants scoring 10 on the PHQ-9 measure

Figure 2.
Estimated intervention effect and 95% confidence interval (95% CI) for PHQ- depression score and QLQ-C30 social, emotional, and role functioning scores

Figure 3.
Effect of baseline PHQ-9 score on PHQ-9 score change between baseline and end-of-study

Table 1. PHQ-9 and QLQ-C30 SF, EF, and RF scores and sample sizes at each time point (N = 581)

		T1 (baseline)			T2			T3/4 (end-of-study)		
		n	Mean	SD	n	Mean	SD	n	Mean	SD
PHQ-9	Control	290	3.54	3.98	289	4.55	3.69	289	4.16	4.09
	Intervention	288	3.59	3.98	287	4.58	4.25	285	3.64	3.65
SF	Control	292	79.17	23.63	289	73.59	23.49	292	74.77	26.56
	Intervention	288	78.07	23.37	287	70.96	27.36	286	77.21	24.98
EF	Control	292	75.04	18.19	289	78.49	18.24	292	79.69	17.60
	Intervention	289	74.31	20.80	288	77.31	20.61	286	80.30	18.58
RF	Control	292	82.93	24.30	290	73.97	25.52	292	74.60	26.63
	Intervention	289	81.49	23.82	288	72.16	27.96	287	77.29	24.47

PHQ-9=Patient Health Questionnaire-9 (range 0–27, lower=less depression), SF=QLQ-C30 social functioning, EF=QLQ-C30 emotional functioning, RF=QLQ-C30 role functioning (QLQ-C30 ranges 0–100, higher=better function)

Table 2.

Multivariable regression analysis of end-of-study PHQ-9 and QLQ-C30 SF, EF, and RF scores

	PHQ-9		SF		EF		RF	
	Estimate	P-value	Estimate	P-value	Estimate	P-value	Estimate	P-value
Group (Intervention vs. Control)	−0.56	0.04	3.49	0.07	0.79	0.54	3.54	0.07
Age	0.01	0.40	−0.03	0.72	0.05	0.34	−0.06	0.51
Clinical Service		0.25		0.11		0.19		0.27
HSCT vs. Radiation Oncology	0.74	0.19	−6.03	0.14	3.28	0.21	−6.36	0.12
Medical Oncology vs. Radiation Oncology	0.43	0.16	−4.09	0.05	−1.16	0.41	−0.31	0.89
Working (No vs. Yes)	0.62	0.05	−5.31	0.02	−2.48	0.09	−5.91	0.008
Baseline score	0.55	<.0001	0.52	<.0001	0.53	<.0001	0.49	<.0001

PHQ-9=Patient Health Questionnaire-9, EF=QLQ-C30 emotional functioning, HSCT=hematopoietic stem cell transplant, RF=QLQ-C30 role functioning, SF=QLQ-C30 social functioning,