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Project Onward: An Innovative E-health Intervention for Cancer Survivors

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Abstract

Objective—This study examined the feasibility and acceptability of an Individual Internet Intervention (III) embedded and integrated into an Internet Support Group (ISG) with the ultimate goal of enhancing adherence and learning, compared to an individual internet intervention alone.

Method—Thirty-one post-treatment cancer survivors were randomized in groups of seven to nine to either the 8-week III+ISG intervention or the 8-week III condition. Seventeen participants met HADS criteria for depressive symptoms (HADS \geq 8).

Results—Among all participants, the mean number of logins over 8 weeks was 20.8 \pm 17.7 logins for the III+ISG compared to 12.5 \pm 12.5 in III-only (p=0.15). Two participants in the III+ISG dropped out, compared to 5 in III (p=0.39). Among the 17 participants with depressive symptoms at baseline, both the Onward and the III-only condition showed large reductions in the HADS-dep ($d=1.27$ & 0.89, respectively). Improvement over time and time \times treatment effects only reached trend significance levels (ps=0.07 & 0.12) as this pilot was not powered to detect these differences.

Conclusion—Both the III+ISG and III-only demonstrated pre-post reductions in depressive symptoms and high rates of utilization compared to other web-based treatments for depression. While it is premature to make any determination as to the efficacy of the interventions tested in this feasibility study, these results indicate that pursuing the III+ISG model as well as standard IIIs, may be fruitful areas of future research.

Keywords

Cancer; Oncology; E-health; Internet; Depression; Collaborative Learning

Introduction

A meta-analysis found that depression is common among cancer survivors, with 16.3% of cancer patients meeting criteria for major depressive disorder and an additional 19.2% with minor depression[1]. The Institute of Medicine has called for improving access to psychological treatments for cancer survivors, including developing Internet-based treatment[2].

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Numerous Internet interventions have been developed to treat depressive symptoms but have not been tested in cancer populations[3, 4]. Within Internet interventions, there are two broad classes: Individual Internet Interventions (IIIs) and Internet Support Groups (ISGs). IIIs provide patients with access to web-based self-management programs that typically include text-based didactic material and tools for the completion of homework. However, high rates of attrition plague IIIs, which decreases their efficacy[5]. IIIs guided by a therapist via email or telephone typically produce larger effect-sizes than unguided interventions[3, 4]. It is believed that the greater improvement seen with guided IIIs is at least partially the result of greater adherence and use of the intervention site produced by the therapist[5]. Surprisingly, no trials of IIIs for depression among cancer survivors have been reported.

While cancer survivors often use ISGs, the data on their efficacy is mixed, at best. RCTs have shown inconsistent results, with at least 3 RCTs of unmoderated ISGs showed no benefit[7–9].

To explain how human support enhances adherence to Internet interventions, we developed a theoretical model called “Supportive Accountability”[10]. It suggests that III users are more likely to adhere if accountable to another person. Accountability is defined as knowing that one will have to justify use or non-use to another individual at some future time. The effects of accountability are enhanced when goal-setting and progress expectations are clear and monitored. The model also suggests that those to whom users are accountable should have legitimacy, which is defined as having some expertise (even through personal experience), and those individuals should be trustworthy and benevolent. Social bond also improves the effects of accountability on adherence. Accordingly, it is conceivable that the architecture of ISGs could structure online relationships among peers to create and foster components of supportive accountability among group members, thereby enhancing adherence and outcomes.

In the current study we report on the development and beta-testing of an online intervention called *Onward* that integrates an III with skills management training for distress with a Supportive Accountability based ISG to increase efficacy and adherence of the intervention. Feasibility is tracked using adherence and depressive symptoms among patients receiving *Onward* or the unguided III portion alone.

Methods

Study Design

Participants were randomized in groups of seven to nine to either *Onward* (III+ISG) or the III with identical content and tools. Participants had an initial 10-minute phone call with study staff to ensure site functionality. Outcomes were assessed at baseline, mid-treatment (week 4), and end of treatment (week 8). Participants were paid up to \$100 for completion of assessments. Payment was for assessment completion only and not use of the website. This study was approved by the Northwestern University Institutional Review Board.

Participants

Recruitment occurred from April to December 2010 through the Northwestern University Robert H. Lurie Comprehensive Cancer Center (RHLCCC). Those who were interested contacted the study directly, or completed the online screener. A research assistant contacted potential participants over the telephone to be consented and screened. The participant’s physician confirmed the participant’s cancer diagnosis and treatment completion.

Inclusion criteria for this study were: (1) Any cancer diagnosis, (2) completed radiation and/or chemotherapy and currently in full remission, (3) no history of psychiatric hospitalization for within the past 5 years, (4) access to a telephone, e-mail account, computer, and broadband Internet, (5) ability to navigate a website, (6) able to speak and read English, and (7) at least 19 years of age. Participants were excluded if they (1) had a hearing, voice or visual impairment that would prevent participation in the site or assessments, (2) specific cancer diagnoses or treatment histories that are inappropriate for the study intervention (e.g., history of stem cell transplant, neuro-oncology or other cancer diagnoses with a treatment likely to impact depressive symptoms), (3) had a severe psychiatric disorder as measured by the structured interview Mini International Neuropsychiatric Interview (MINI)[11], (4) reported severe suicidality (e.g., plan and intent) or had a history of suicide attempt in the past five years, (5) were currently receiving or planning to receive psychotherapy during the 8-week treatment, (6) had initiated treatment with an antidepressant in the past 10 days, or (7) planned to be out of town for 2 weeks or more during the 8-week treatment phase.

Inclusion criteria initially included a Hospital Anxiety and Depression Scale (HADS)[12] score of eight or above on the depression scale. Recruitment with this criterion was slow and there was considerable interest in the project from non-distressed survivors, so this criterion was removed.

Randomization

Patients were accumulated until a group had been formed. Groups were then randomized by a biostatistician.

Procedures

The Website—The III website was an 8-week treatment based on moodManager, an III for the treatment of depression[13, 14] based on cognitive behavioral principles[15]. See Table 1 for a chart of the intervention. New lessons and corresponding tools were released twice each week on a unique topic and participants were notified by email. The lessons, which required 10–15 minutes to complete, covered basic cognitive behavioral concepts. Content included text and video. Interactive tools were designed to support implementation of cognitive behavioral skills, required only a few minutes to complete, and were intended to be completed every day or two. The site included self-monitoring features for mood and other personalizable treatment goals.

The Onward version of the site also included a discussion board that featured elements designed to enhance Supportive Accountability. On initial login, participants were encouraged to create a profile sharing details about their cancer experience, as a way of providing personal credibility. Discussion questions related to the content were posted twice a week along with the new content. Participants were encouraged to respond to the questions, each other, and to post their own topics. Postings were monitored for participant safety but there was no posting by study staff. Time since last login was publically posted for each participant to encourage group accountability. Group members could “buzz” each other, which sent a pre-formatted email message to the member, requesting they return to the site. To support group cohesion, “buzzes” contained no content and there was no private messaging feature, thus funneling all communication through group formats. The “buzz” feature was primarily intended as a tool for group participants to exert supportive accountability to non-adherent participants. Expectation for the frequency of logins was made clear during the initial staff phone calls and also in the Getting Started lesson.

Content and layout was identical on the Onward and III versions of the site, except that the Onward site included the discussion board and accountability features. The site also

contained a provider interface that allowed the study team to monitor participants' site activity.

Measures

Self-reports were administered online via SurveyMonkey.com. Interview based assessments were conducted over the telephone at baseline by research assistants supervised by a PhD-level clinical psychologist.

Adherence to this intervention was defined by the number of logins. Participants were considered dropouts if they failed to login after week 4 of the intervention.

Depressive symptoms were measured using the depression scale of the Hospital Anxiety and Depression Scale (HADS-dep)[12].

Psychiatric diagnosis was measured using the Mini International Neuropsychiatric Interview (MINI)[11], a structured interview to evaluate Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) Axis I disorders. The full MINI was administered by telephone at baseline.

Feedback was obtained through a self-report questionnaire after completion of the intervention. Participants were asked to review the site and provide thoughts about the program. These data were collected to help improve future versions of Onward.

Statistical Analyses

This feasibility study was intended primarily to examine use patterns in a small sample of participants and was not powered to detect significance. Nevertheless, significance testing is presented, including the Wilcoxon test for login data, and mixed model analyses for depressive symptoms. All analyses were conducted on an intention-to-treat basis.

RESULTS

Participants

Of the 91 patients screened, 31 (34%) were enrolled, of whom 29% came through fliers or newsletters, 42% through mailings, 26% through online recruitment, and 3% through physician referral. Table 2 shows the clinical characteristics of the 31 participants enrolled.

Adherence

Adherence data are displayed in Table 2. Data are presented first for participants meeting the HADS-dep ≥ 8 criterion for depressive symptoms as this was the original intended treatment population. Among depressed participants, the mean number of logins over 8 weeks for Onward was 21.5 ± 18.7 compared to 11.3 ± 8.6 in III-only, but did not reach significance ($p=0.20$). Number of logins was similar in the total sample, with mean number of logins for Onward 20.8 ± 17.7 compared to 12.5 ± 12.5 in III-only, with trend-level significance ($p=0.15$). Among depressed participants, dropout did not differ significantly ($p=0.25$), with 1 (10%) dropout in Onward and 3 (42.9%) in III-only. Among all Onward participants, 2 (13.3%) dropped out, compared to 5 (31.3%) in III-only ($p=0.39$).

Outcomes for Depressive Symptoms

The means, standard deviations, and effect sizes are shown in Table 2. Among participants meeting HADS >8 criterion, both the Onward and the III-only condition showed large within treatment reductions on the HADS-dep ($d=1.27$ & 0.89 , respectively). Time \times treatment effects only reached trend-level significance ($ps = 0.07$ & 0.12) as this pilot was not

powered to detect these differences. The full sample, including non-depressed participants, showed a similar pattern, with effect sizes of $d=0.72$ and $d=.38$, which were smaller than the depressed sample primarily because the non-depressed participants did not show change on depressive symptoms. The time \times treatment was not significant ($p=0.15$).

User Feedback

Overall, comments from users were positive. Forty-two percent of participants across both groups noted that they appreciated having access to the information provided and that the CBT framework was a useful perspective. Those in the Onward group found “sharing thoughts with other survivors” to be valuable. Most mentioned talking with other survivors to give and receive support was a main reason for participation. The Relaxation and Mindfulness lessons received the most positive feedback, with 16% noting it as their favorite lesson, and the associated Relaxation Tool was used more than other tools, with 236 hits.

Discussion

This study examined the feasibility of a novel, web-based intervention called Onward, that integrated III and an ISG aimed at providing self-management skills to reduce depressive symptoms among cancer survivors. In contrast to other unmoderated ISGs[7–9], both the III and Onward demonstrated reductions in depressive symptoms and high rates of utilization compared to other web-based treatments for depression[5]. This suggests that properly designed web-based interventions may be effective for reducing depressive symptoms among cancer survivors. If participants had logged in as directed, they would have accessed the site at least 16 times over the course of the intervention. Those in the Onward group surpassed this number, averaging about 21 logins, while those in the unguided III only logged in an average of about 12 times (75% adherence). Despite that, adherence and outcomes to the III appeared better than commonly seen among medically healthy populations, where recent meta analyses have found effect sizes around .24 with adherence of 50–70% login rates in the 4–15 range[4, 5]. While this study was not powered to detect differences in depressive symptoms outcomes, trends suggest that integration of ISGs and IIIs to create collaborative learning environments[16] and enhance supportive accountability[10] may prove useful in enhancing both adherence and outcomes. This suggests that cancer patients may be uniquely suited for web-based care.

While it is premature to make any determination as to the efficacy of the interventions in this feasibility study, these results indicate that pursuing the Onward model, as well as standard IIIs may be fruitful areas of future research. On the basis of these results we have initiated a program of further development and evaluation of Onward, as well as exploring comprehensive recruitment strategies. Future trials should evaluate efficacy among patients with depressive symptoms.

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Table 1

Intervention Content Description

	Lesson Content	Associated Tool
Week 1:	Getting Started: An introduction to the basic principles of cognitive behavioral therapy (CBT) and how these ideas could be used to improve quality of life;	Mood Diary: Participants rate their mood at each login and can track it across time with a variety of graphing features
Week 2	Your Activities: Described the relationship between activities and mood, highlighting the importance of increasing positive activities as a method to improve mood.	Activity Diary: Allowed participants to track and rate daily activities and to increase positive activities by scheduling them.
Week 3	Your Thoughts: Described the effects of thoughts on mood and introduced the concept of cognitive restructuring.	Thought Diary: Used to monitor and challenge automatic thoughts. Provided video content and examples to model appropriate use.
Week 4	Relaxation and Mindfulness: Explained the role of relaxation and mindfulness in managing stress and described the basic principles of both concepts.	Relaxation and Mindfulness Tool: a place where participants could listen to audio exercises and record stress levels before and after the exercises.
Week 5	Fear of Reoccurrence: Explored anxiety and fear of reoccurrence while introducing a cognitive conceptualization and response to anxiety.	Anxiety Tool: A variation of the Thought Diary tool that encouraged participants to identify risks or anxiety provoking situations and the resources available to cope with them.
Week 6	Developing Your Care Plan: Participants were able to select from five extra lessons on specific symptoms experienced (fatigue, pain, sleep problems, cognitive changes, and body image/intimacy) and develop strategies to cope with them better.	Survivorship Care Plan: Based on the NCI's "Facing Forward: Life After Cancer Treatment," participants could create a personalized care plan.
Week 7	Maximizing Social Support: Provided ideas to improve social support and how to use it most effectively.	Free Journal: A place for participants to document general experiences and link them to other tools in the program.
Week 8	Valued Living: Explored how values change with cancer diagnosis and ways to increase meaning and value in activities.	Activity Diary was used to schedule activities that increased meaning in daily life.

Table 2

Clinical Characteristics and Outcome Data

	Total Sample (N=31)	Depressed Sample (HADS-Dep >=8) (N=17)
Age	50 (27–68)	46 (32–68)
Gender		
Female	27 (87%)	14 (82%)
Race		
White	27 (87%)	15 (88%)
Af.Am.	3 (10%)	2 (12%)
Asian	1 (3%)	0
Ethnicity		
Hispanic	3 (10%)	3 (18%)
Education		
	N(%)	N(%)
Professional Degree	2 (6%)	0
Masters	10 (32%)	6 (35%)
4yr	13 (42%)	6 (35%)
Some College	4 (13%)	3 (18%)
2yr	1 (3%)	1 (6%)
Some HS	1 (3%)	1(6%)
Cancer Type		
Breast	14 (45%)	8 (47%)
Lymphoma	8 (26%)	4 (24%)
Gynecologic	3 (10%)	1 (6%)
Lung	2 (6%)	1 (6%)
Colon	2 (6%)	1 (6%)
Sarcoma	1 (3%)	1 (6%)
Thyroid	1 (3%)	1 (6%)
Stage		
I	8 (26%)	5 (29%)
II	11(35%)	5 (29%)
III	6 (19%)	3 (18%)
IV	3 (10%)	2 (12%)
none	3 (10%)	2 (12%)
Main Outcomes (Intention to Treat)*		
	Total Sample	Sample with HADS-D>=8
	Onward (N=15) III-Only (N=16)	Onward (N=10) III-Only (n=7)

HADS - Dep	Total Sample (N=31)		Depressed Sample (HADS-Dep >=8) (N=17)	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Baseline	7.73 (4.06)	6.63 (4.24)	10.10 (2.02)	10.43 (2.51)
Post-Tx	5.40 (2.67)	5.14 (3.28)	6.50 (2.51)	7.67 (2.16)
effect size	0.72	0.38	1.27	0.89
Adherence				
Mean logins	20.8 (17.7)	12.5 (12.5)	21.5 (18.7)	11.3 (8.6)
Drop-outs	2 (13.3%)	5 (31.3%)	1 (10%)	3 (42.9%)