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An eHealth System Supporting Palliative Care for Patients with Non-Small Cell Lung Cancer: A Randomized Trial

An eHealth System Supporting Palliative Care for Patients with Nonsmall Cell Lung Cancer: A Randomized Trial

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Abstract

Background—This study examined the effectiveness of an online support system (CHESS) versus the Internet in relieving physical symptom distress in patients with nonsmall cell lung cancer (NSCLC).

Methods—285 informal caregiver-patient dyads were randomly assigned to standard care plus the Internet or CHESS for up to 25 months. Caregivers agreed to use CHESS or the Internet and complete bimonthly surveys; for patients, these tasks were optional. The primary endpoint, patient symptom distress, was measured by caregiver reports using a modified Edmonton Symptom Assessment Scale (ESAS).

Results—Caregivers in the CHESS arm consistently reported lower patient physical symptom distress than caregivers in the Internet arm, with significant differences at 4 months ($P = .031$, Cohen's $d = .42$) and 6 months ($P = .004$, $d = .61$). Similar but marginally significant effects were observed at 2 months ($P = .051$, $d = .39$) and 8 months ($P = .061$, $d = .43$). Exploratory analyses showed that survival curves did not differ significantly between the arms (log rank, $P = .172$),

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although a survival difference in an exploratory subgroup analysis suggests an avenue for further study.

Conclusions—An online support system may reduce patient symptom distress. The effect on survival bears further investigation.

Keywords

lung cancer; symptom distress; palliative care; quality of life; survival; eHealth; communication and information technology

Introduction

Palliative care aims to relieve distress and control symptoms for patients with life-threatening illnesses such as advanced cancer.[1] Although randomized controlled trials testing the effectiveness of palliative care are scarce,[2] several organizations—including the American Society of Clinical Oncology[3] and the Institute of Medicine[4]— advocate that palliative care be routinely integrated into standard cancer care. A study by Movsas et al[5] suggested that nonsmall cell lung cancer (NSCLC) patients might benefit from interventions such as those that help manage symptoms and provide social support. A study by Temel[6] found that NSCLC patients who received early palliative care with standard oncologic care had less symptom distress and depression. An exploratory analysis in Temel showed that patients receiving early palliative care also survived longer by 2.7 months compared to patients who received only standard care.

Psychosocial interventions also have been used to improve the lives of patients with advanced cancer.[7] Both group and individual interventions have been shown to improve physical functioning and reduce psychological symptoms.[7] Some interventions have demonstrated an effect on survival,[8–10] while others have had less positive results.[11–13]

Online interventions that include palliative care and psychosocial support have rarely been studied; even less studied are online interventions aimed at family caregivers.[14] This paper examines the potential benefit of an online information, communication, and coaching system called CHESS (Comprehensive Health Enhancement Support System)[15] that was designed to support informal caregivers of NSCLC patients. CHESS is a non-commercial website created by clinical, communication, and systems scientists at the University of Wisconsin.

We hypothesized that advanced NSCLC patients in caregiver-patient dyads receiving standard care plus CHESS would have less symptom distress than those receiving standard care plus the Internet. We also explored the effect of CHESS compared to the Internet on patient survival.

Methods

Study Design

This paper reports on a multisite, non-blinded randomized trial. Caregiver-patient dyads were recruited at 4 cancer-center hospitals in the East, Midwest, and Southwest U.S. between September 2004 and April 2007; data collection ended in May 2009. The study was approved by the institutional review boards of all centers.

Participants

Eligible dyads consisted of English-speaking adult patients with NSCLC at stage IIIA, IIIB, or IV and a patient-identified primary caregiver willing to participate in the study. Patients had to have a clinician-perceived life expectancy of at least 4 months; if patients had brain metastasis, it had to be stable. Caregivers provided instrumental, emotional, and/or financial support for the patient and were at least 18 years old. Dyads were identified by their oncologist and invited to participate by the enrollment coordinator at each site. After providing informed consent, caregivers and patients completed pretests eliciting demographic data and assessing their physical and emotional well-being. Dyads were randomized to standard care plus either the Internet or CHESS. Caregivers agreed to complete follow-up surveys every 2 months about their own and the patient's health. Completing the surveys and using the computer were optional for patients.

Intervention

Caregiver-patient dyads received the intervention for 25 months or 13 months after patient death, whichever was less. For example, if a patient died after 4 months in the study, the caregiver could stay in the study to use bereavement resources for up to 13 months, making 17 months the total time in the study.

Participants in the Internet arm received training on using the Internet and a list of Internet sites about lung cancer, such as www.lungcanceralliance.org, http://cancernet.nci.nih.gov/cancertopics/types/lung, and www.lungcanceronline.org. Those in the CHESS arm received password-protected access to the CHESS "Coping with Lung Cancer" website. CHESS was designed to be easy to use and: (1) provide well-organized lung cancer, care-giving, and bereavement *information;* (2) serve as a channel for *communication* with and support from peers, experts, clinicians, and users' social networks; (3) act as a *coach* by gathering information from users and providing feedback based on algorithms (decision rules); and (4) provide *tools* (e.g., a program to organize support from family and friends) to improve the caregiving experience. CHESS included a Clinician Report that summarized caregiver and patient ratings of the patient's health status[15] and listed their questions for the next clinic visit. Clinicians received e-mail alerts before a scheduled visit and whenever a symptom rating exceeded 7 on a 0-to-10 scale. CHESS services are described in more detail elsewhere.[15]

Dyads in both arms received computers and Internet service if needed and were reimbursed for the cost of Internet service during the study. All were offered phone-based technical assistance to set up the computer and use CHESS or the Internet. At study end, participants could keep the computers and those assigned to CHESS could continue to use CHESS, but data collection and reimbursement for Internet service stopped.

Randomization

The study protocol called for 3 arms consisting of standard care plus (1) CHESS with the Clinician Report, (2) CHESS without the Clinician Report, and (3) the Internet. Because of low accrual, arm 2 was dropped after 37 dyads were assigned to it to retain the power needed for analysis and complete the study within the funded timeframe. Those 37 dyads are not included in this analysis.

A total of 285 caregiver-dyads were randomly assigned to the Internet or CHESS arm (1:1 ratio), with assignment determined at the University of Wisconsin by random numbers. Each site used a separate randomization schedule. Randomization was blocked by caregiver-patient relationship (spouse or partner versus other) and minority status (Caucasian versus

non-Caucasian). Four patients died and 35 dyads withdrew before completing the pretest, leaving 246 of the 285 randomized dyads to receive the intervention (Figure 1).

Outcomes Examined

Caregiver surveys reporting patient symptom distress were used for two reasons. First, patients may not have had the energy to complete bimonthly surveys as their health deteriorated and having a consistent data source throughout the study was important. Second, while some research suggests that caregivers tend to overestimate patient distress,[16–17] the clinical trial focused on caregivers and how they perceived the situation.

A longitudinal examination of patient symptom distress and patient and caregiver QOL was planned for the clinical trial. This paper addresses patient symptom distress while the analysis of caregiver QOL is reported elsewhere.[18] We have not analyzed patient QOL because caregivers felt uncomfortable completing the measure (the McGill Quality of Life Questionnaire) on behalf of patients given that questions focus on a patient's internal psychological experiences.

Pretest and bimonthly follow-up surveys asked caregivers to rate patient symptom distress, the primary outcome, on a scale of 0 (absence of symptom) to 10 (worst possible symptom) using a modified Edmonton Symptom Assessment Scale (ESAS).[19] The original ESAS comprises 7 physical and 2 psychological items. Based on feedback from study oncologists, 3 of the original physical symptoms (activity, drowsy, and well-being) were replaced with common lung cancer symptoms: fatigue, constipation, and diarrhea. Because research has indicated that the two psychological symptoms (depression and anxiety) may not represent the full range of patients' emotional symptoms,[20–22] a separate subscale summed responses for only the 7 physical symptoms. The range of values for the overall ESAS was 0 to 90; for the physical subscale, it was 0 to 70, with a Cronbach's α of .722 at pretest. Analyses are reported on the physical subscale.

Statistical Analysis

Patient symptom distress was examined using ESAS physical symptom distress scores reported by caregivers at pretest and 2, 4, 6, and 8 months after the intervention started. With α of .05 and power of .80, a sample of 128 patients would be sufficient to detect a moderate effect of .5 SD difference in ESAS scores between arms.

A linear mixed-model regression, performed on repeated ESAS scores using IBM SPSS 20, compared patient symptom distress between arms over time controlling for pretest ESAS score and site, caregiver-patient relationship, and race. In addition, the model included effects for arm (CHESS versus Internet), month (2, 4, 6, and 8 months after intervention start), and arm-by-month interaction. A first-order autoregressive covariance structure was used for the repeated measure. Fixed effects were calculated using restricted maximum likelihood estimation, with between-arm tests of estimated marginal means conducted at each time point.

During the study, we observed that caregivers from the Internet arm were transitioning to bereavement status more frequently than CHESS-arm caregivers, which prompted an exploratory survival analysis. Survival was measured from the day the dyads received the intervention until patient death. Participant were censored if they dropped out of the study (censored at the drop date), if no further contact with the patient or caregiver could be made (censored at the last traceable date, e.g., the last medical appointment), or if they lived more than 2 years (censored at 2 years). Cumulative survival rates were estimated using Kaplan-Meier analysis. The Cox proportional hazards model was used to understand the influence

on survival of age, gender, cancer stage, treatment history, and the interval between diagnosis and intervention.

While the study focused on intention to treat, some participants randomized to the CHESS arm did not use it. We defined *use* as proceeding beyond the disclaimer page to something of value (e.g., discussion group, personal stories), as well as median minutes of CHESS use, pages viewed, and logins. We did not have data on Internet-arm use.

To explore patient suffering before death, we used the same mixed effects model from the primary analysis, but with the outcomes being physical ESAS scores from surveys completed 2, 4, 6, and 8 months before patient death.

RESULTS

Baseline characteristics for each arm are shown in Table 1. Between the randomized arms, only caregiver's Internet comfort was significantly different ($P = .044$), with the CHESS group being less comfortable.

Primary Analysis: Symptom Distress

Table 2 shows caregiver-reported patient symptom distress. CHESS caregivers reported significantly lower physical symptom distress than those in the Internet arm ($P = .005$, Cohen's $d = .46$). Comparisons at each survey month showed this pattern consistently, with significant differences at 4 ($P = .031$, $d = .42$) and 6 months ($P = .004$, $d = .61$) and marginally significant differences at 2 ($P = .051$, $d = .39$) and 8 months ($P = .061$, $d = .43$).

To examine whether any individual item drove the results of the physical subscale, we repeated the analysis separately for each symptom. While significant group differences were observed for all items except nausea, no single item dominated the results.

Exploratory Analyses: Survival, Use of CHESS, and Distress Before Death

Figure 2 shows the Kaplan-Meier survival curves over 24 months. During the 2-year intervention, 77 of 124 CHESS-arm patients (62%) died and 89 of 122 Internet-arm patients (73%) died. Median survival was 10.1 months (SE = 1.5) for the Internet arm and 14.8 months (SE = 1.2) for the CHESS arm (log rank, $P = .172$). A marginally significant difference in survival was found after adjustment for age, gender, cancer stage, treatment history, and interval between diagnosis and intervention (adjusted HR, .75; 95% CI, .55–1.04; $P = .083$).

In accordance with the CONSORT eHealth checklist,[23] we looked at CHESS use among those with access to it. CHESS was used at least once by 73.4% of caregivers and 50% of patients, and 51.6% of caregivers and 34.7% of patients used CHESS 5 or more times. The median number of minutes of CHESS use was 103 for caregivers and 146 for patients; the median number of pages viewed was 147 for caregivers and 243 for patients; and the median number of logins was 8 for caregivers and 12 for patients.

To explore the effect of CHESS use on survival, we compared patients who used CHESS (n = 62) to patient non-users (n = 62) and Internet-arm patients (n = 122). Estimated median survival for CHESS users was 19.2 months (SE = 3.4) and for CHESS non-users, 9.9 months (SE = 2.7; log rank, $P = .003$). The difference remained significant after controlling for age, gender, cancer stage, treatment history, and interval between diagnosis and intervention (adjusted HR, .49; 95% CI, .28–.84; $P = .009$). Survival differences were also significant when comparing CHESS users to those from the Internet arm (log rank, $P = .007$; adjusted HR = .58; 95% CI, .38–.89; $P = .012$].

CHESS users and non-users were not randomly assigned; they self-selected. We compared baseline patient ESAS scores and found no significant differences between CHESS users, CHESS non-users, and the Internet arm. Between CHESS users and non-users at baseline (Table 1), significant differences were found for caregiver gender ($P = .008$) and treatment history ($P = .021$). A marginally significant difference was found for the percentage of caregivers who were spouses or partners vs. other ($P = .067$). Between CHESS users and Internet patients at baseline, we found one significant difference on caregiver gender ($P = .035$) and one marginally significant difference on treatment history ($P = .058$).

To examine whether the longer survival was accompanied by prolonged suffering, we compared CHESS users to non-users and to Internet patients on symptom distress at points related to patient death (e.g., at 2, 4, 6, and 8 months before patient death). No significant differences between groups were observed, suggesting that longer living patients did not suffer more.

Discussion

The study demonstrates that an online intervention is associated with reduced patient symptom distress in advanced lung cancer. Patients randomized to CHESS had significantly less caregiver-reported physical distress than those in the Internet arm at 4 and 6 months after intervention start and similar but marginally significant results at 2 and 8 months. An exploratory analysis found that the two arms did not differ in 2-year survival rates, but CHESS-arm patients who used the system did survive longer than controls and non-users. Despite living longer, patients who used CHESS did not suffer more in caregiver-reported distress in the months before they died.

To our knowledge, this is the only randomized trial of an online system of information, support, and coaching available 24/7 to lung cancer patients and their caregivers. Project ENABLE II[24] (a telephone-based, nurse-led palliative care intervention) improved QOL in patients with advanced cancer, giving evidence for a distant though not online intervention.

Our study also overcomes methodological problems[2, 7] common in studies of palliative care and psychosocial interventions. Specifically, the study recruited all eligible patients diagnosed with NSCLC, not just those referred to palliative or psychosocial interventions; the sample size provided sufficient power for testing the primary hypothesis; and the symptom distress measure was appropriate to terminal patients and in fact tailored to NSCLC patients.

Why might a system chiefly designed for *caregivers* affect *patients*? Information in CHESS may help caregivers provide better informal care, and the Clinician Report may have allowed both caregivers and clinicians to manage symptoms more effectively.[14] (When caregivers or patients rated patient distress symptoms at 7 or higher, CHESS automatically sent an email message to clinicians.) With better symptom management, patients may have been encouraged to adhere to treatment. The Clinician Report may also have enabled clinicians to better address patient and caregiver concerns during clinic visits. In interviews, some clinicians reported that caregivers using CHESS were more engaged during clinic visits and better able to describe their concerns and the patient's symptoms.[14]

Given that patients in the two randomized arms were well matched at baseline, they would seem to have had equal potential for survival, and over the 2-year span of data collection, the survival curves did not differ. But within the CHESS arm, those who actually used CHESS were associated with longer survival. It may be that CHESS encourages the qualities sometimes linked to longer survival, such as active rather than depressive coping[25] and high involvement in self-help.[26] The psychosocial support in CHESS—the ability of

patients and caregivers to communicate with peers, 24/7, about others' treatments and decisions—also may reduce stress and physical and psychological symptom burden, thereby leading to improved survival. For example, a CHESS patient (or caregiver) may have communicated with a patient (or their caregiver) who survived longer than expected, inspiring closer adherence to treatment recommendations. Although patients in the two arms had similar symptom distress at baseline, Internet-arm patients had greater symptom distress during the study, perhaps affecting decisions they made about seeking or adhering to treatment or their eligibility for further treatment. CHESS users and non-users differed significantly on treatment history. It may be that users were better off to start than non-users and therefore well enough to use CHESS. However, ECOG status (a measure of patient functioning) did not differ at baseline between users and non-users (or between users and the Internet arm or between randomized arms).

The study has limitations. Patient treatment was not tracked after randomization, and it could be confounding. At baseline, treatment history was significantly different between CHESS users and non-users ($P = .021$) and marginally significantly different between CHESS users and patients in the Internet arm ($P = .058$). Although the analysis used treatment history as a covariate, the survival advantage found for CHESS users may relate to unmeasured prognostic variables rather than to CHESS use. Patients in both arms lived longer than patients with advanced lung cancer generally do, probably because, to be eligible, patients needed a clinician-anticipated survival of at least 4 months. Future studies will also benefit from having ongoing measures of system use in all groups.

Additional rigorous studies are needed to determine whether online emotional and instrumental support for both patient and caregiver can ease distress and lengthen survival. An effective online system of palliative care could offer a low-cost end-of-life intervention that would be relatively easy to distribute widely.

Acknowledgments

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| Enrollment | Recruited | 518 | |
| | Excluded[a] | 233 | |

		CHESS	**Internet**
Allocation	Randomized	144	141
	Deaths	2	2
	Dropouts	18	17
	Received intervention	**124**	**122**

Pretest	Complete[b]	119	114
	Incomplete[b]	5	8
		124	122

2m	Complete	59	65
	Incomplete	3	4
	Deaths[c]	9	9
	Dropouts[c]	3	1
	Missing	50	43
		124	122

4m	Complete	60	58
	Incomplete	1	0
	Deaths	22	25
	Dropouts	6	3
	Missing	35	36
		124	122

6m	Complete	44	54
	Incomplete	5	1
	Deaths	31	33
	Dropouts	8	4
	Missing	36	30
		124	122

8m	Complete	43	42
	Incomplete	1	2
	Deaths	38	47
	Dropouts	11	4
	Missing	31	27
		124	122

Figure 1.
Flow of participants from recruitment to analysis
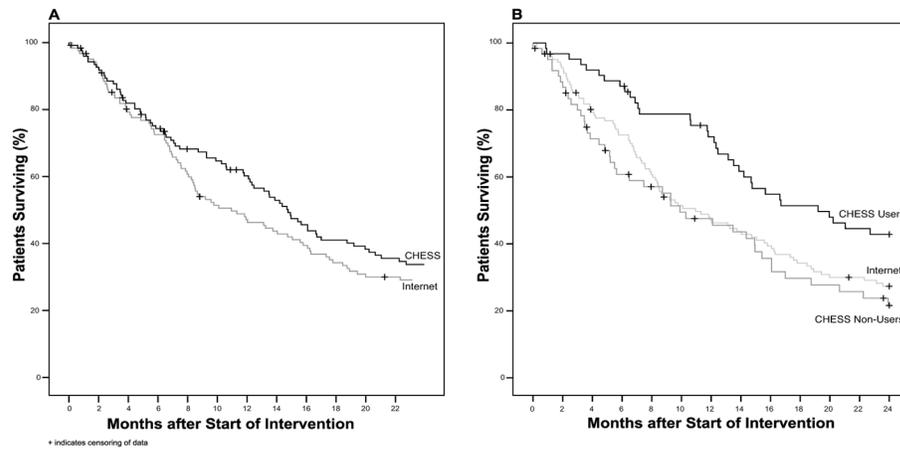
Figure 2.
Kaplan-Meier survival curves are shown for (A) the CHESS vs. Internet arms and (B) CHESS users vs. CHESS non-users vs. Internet participants.

Table 1

Characteristics of Patients and Caregivers at Pretest

Characteristics	Internet		CHESS		CHESS Non-Users (Patients Only)		CHESS Users (Patients Only)	
Age	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Patient	122	61.4 (9.7)	122	62.0 (10.6)	61	63.5 (10.5)	61	60.5 (10.6)
Caregiver	117	54.6 (12.2)	117	56.6 (12.9)	58	55.5 (13.2)	59	57.6 (12.6)
Caregiver's Internet comfort[a]	118	2.7 (1.2)	123	2.4 (1.3)	61	2.4 (1.0)	62	2.3 (1.5)
Days from diagnosis to intervention	121	370.5 (470.0)	122	342.9 (440.7)	60	351.1 (472.6)	62	335.0 (411.2)
Cancer stage	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
IIIA	16	13.3	21	17.4	10	16.7	11	18.0
IIIB	23	19.2	21	17.4	9	15.0	12	19.7
IV	81	67.5	79	65.3	41	68.3	38	62.3
ECOG performance status								
0,1	89	74.8	77	66.4	43	71.7	46	78.0
2,3,4	30	25.2	39	33.6	17	28.3	13	22.0
Patient treatment history								
No treatment	4	3.4	8	6.8	1	1.8	7	11.7
Currently receiving first line treatment	44	37.6	55	47.0	27	47.4	28	46.7
Completed first line, now in remission	6	5.1	4	3.4	0	0.0	4	6.7
Failed first line, now on or has had additional treatment	60	51.3	50	42.7	29	50.9	21	35.0
Failed first line, now no additional treatment	3	2.6	0	0.0	0	0.0	0	0.0
Patient and caregiver live together (yes)	94	78.3	96	78.0	45	73.8	51	82.3
Gender (female)								
Patient	59	48.4	62	50.0	27	43.5	35	56.5
Caregiver	86	70.5	82	66.1	48	77.4	34	54.8
Highest level of education (high school diploma or less)								
Patient	45	37.5	37	30.5	21	34.4	16	26.6
Caregiver	27	22.5	24	19.9	14	23.0	10	16.6
Any other major illness or health condition? (yes)								
Patient	73	61.9	66	55.5	32	54.2	34	56.7

Characteristics	Internet		CHESS		CHESS Non-Users (Patients Only)		CHESS Users (Patients Only)
Caregiver	56	46.7	52	42.6	25	41.7	27	43.5

Abbreviations: SD, standard deviation; ECOG, Eastern Cooperative Oncology Group

[a]Internet comfort was measured on a scale from 0 ("not comfortable at all") to 4 ("extremely comfortable").

Table 2

Patient Physical Distress[a]: Mean ESAS Scores[b]

Outcome	Internet Mean (SE)	CHESS Mean (SE)	Difference (95% CI)	P	d[c]
Main effect	22.32 (1.88)	17.04 (1.76)	5.28 (1.60–8.97)	0.005	0.46
Month					
2	21.21 (2.08)	16.75 (2.00)	4.46 (−0.01–8.94)	0.051	0.39
4	21.72 (2.10)	16.89 (1.95)	4.83 (0.44–9.23)	0.031	0.42
6	22.95 (2.13)	16.03 (2.05)	6.92 (2.25–11.60)	0.004	0.61
8	23.39 (2.29)	18.47 (2.17)	4.92 (−0.24–10.08)	0.061	0.43

Abbreviations: SE, standard error; CI, confidence interval.

[a]Patient physical distress is the sum of the caregiver report of 7 patient symptoms: pain, nausea, appetite, shortness of breath, fatigue, constipation, and diarrhea. Range of values: 0 (absence of all symptoms) – 70 (worst possible on all symptoms).

[b]Adjusted for pretest ESAS score, site, caregiver-patient relationship, and caregiver race.

[c]Cohen's d calculated as the mean difference divided by the pooled standard deviation at pretest (11.43).