

Online Supplement 2: Effects of mindfulness training programs delivered by a self-directed mobile app and by telephone compared to an education program for survivors of critical illness: a randomized clinical trial

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*Exploratory; not referenced in manuscript.

A. eMethods

1. Inclusions and exclusions

We will target patients at high risk for psychological distress.

Patient inclusion / eligibility criteria:

- age ≥18 years
- acute cardiorespiratory failure managed in an intensive care unit for at least 24hrs*

Acute cardiorespiratory failure defined as:

Respiratory failure	≥1 of these: - mechanical ventilation via endotracheal tube for ≥12 hours - non-invasive ventilation (CPAP, BiPAP) for >4 hours in a 24-hour period provided for acute respiratory failure in an ICU (not for obstructive sleep apnea or other stable use) - high flow nasal cannula (≥15L/min) or face mask O2 with FiO2 ≥ 0.5 for ≥4 hours
Circulatory failure	≥1 of these: - use of vasopressors for shock of any etiology for > 1 hour - use of inotropes for shock of any etiology for > 1 hour - use of aortic balloon pump for cardiogenic shock

- reside at home before hospital admission (i.e., not in a facility)

Other issues relevant to the consent process:

- unable to approach patient for logistical reasons (e.g., off ward in test at time of approach, etc)
- patient discharged before consent could be obtained
- patient dies before consent obtained

Patient exclusion / ineligibility criteria (present before consent): Patients will be excluded if they have characteristics that would prohibit adequate participation including:

- pre-existing significant cognitive impairment (e.g., dementia)
- treated for severe or unstable mental illness within 6 months preceding current admission*
- hospital inpatient within 3 months before current admission
- active substance abuse at the time of admission
- lack decisional capacity**current significant cognitive impairment (≥3 errors on the Callahan cognitive status screen; see below)
- need for a translator because of poor English fluency [many study instruments are not validated in other languages]
- expected survival <6 months per attending physician
- ICU length of stay >30 days
- lack of either:
 - reliable or sufficient smartphone with cellular data plan or
 - reliable computer online access plus telephone access
- unable to complete study procedures as determined by study staff***
- discharge to a location other than a home setting
- complex medical care expected soon after discharge****

*e.g., depression with psychosis, suicidality, schizophrenia (as per medical record)

**We define “decisional capacity” as the ability to participate in effective decision making and provide informed consent. That is, in the judgment of the examiner, the patient—after reading the IRB approved patient consent document (or having it read to them):

--Can generally understand the terms of participation in the study

- the purpose of the study
- what will be required of study participants
- the potential risks, benefits and alternatives of study participation
- pros & cons of study involvement

--Can communicate a choice in his/her own words (or write on a communication board)

***e.g., expectation to be discharged to a home (not their own) and report that they were either staying with friends or family temporarily and had further housing plan, report of substance abuse issues to study staff that were not disclosed in EHR documentation at admission, expected to travel out of the area, etc.

****e.g., multiple planned surgeries, transplantation evaluation (including outpatient daily cardiopulmonary rehabilitation), extensive travel needs for hemodialysis, disruptive chemotherapy/XRT regimen, etc.

Patient exclusion criteria present after consent but before randomization: After providing informed consent, patients will become ineligible if any of the following are present:

- they become too ill to participate (or die)
- they exhibit significant cognitive disability
- they exhibit suicidality
- patient was unexpectedly discharged to location other than a home setting and then did not arrive home within 1 month from hospital discharge

2. Detailed explanation of interventions

After randomization, a coordinator called to explain group assignment and next steps. Also, introductory emails relevant to the study arm were sent to each participant that included instructions for accessing a password-protected, treatment group-specific website hosting videos and other content.

Telephone-based mindfulness training: The development and piloting of the telephone-based mindfulness program was described in past work (Cox CE, et al. *Ann Am Thor Soc.* 11:173-181, 2014). Each ~30-minute therapist-delivered telephone mindfulness training session was composed of four parts: (1) brief discussion about participants' major current stressor(s); (2) rationale and discussion of the didactic focus; (3) practice and review, and (4) discussion about participant's use of mindfulness skills, challenges in applying the skills, and how to maintain progress. The didactic elements of telephone mindfulness included: In **Session 1**, subjects will be provided with a rationale for mindfulness and learn to use awareness of breathing, a core meditation technique that begins to cultivate skills of mindful, non-reactive observation. **Session 2** will introduce awareness of body systems that are working well or less well as a way to continue to cultivate skills of observing, describing, and non-judgmental attention. During **Session 3**, participants will practice awareness of emotion and mindful acceptance, which is designed to acknowledge difficult emotions and cultivate feelings of kindness and compassion towards oneself and others. **Session 4** introduces awareness of senses, a practice in which patients will learn to systematically broaden awareness of senses of sound, sight, smell, and touch. Sensory awareness practice simultaneously builds the skills of attention, concentration, observation, non-judgment, and non-reactivity. Overall, the plan is a blueprint for therapy that can be adapted in the moment to address stress or crises experienced by participants. In general, approximately 10 minutes of each session were spent with a guided meditation, with the remainder spent in discussion with the therapist.



Self-directed mobile mindfulness training:

Rationale: This program is a response to feedback we received from some patients who participated in a recent coping skills training program designed for ICU patients in which they stated a preference for a simpler, less task-oriented treatment approach. The population-specific focus informed design in the targeted manner in which participants are led in practicing and applying the mindfulness skills that themselves are tailored to address stress associated with common challenges for ICU patients, therefore increasing the likelihood of uptake. In contrast to other available mindfulness apps, the ICU patient app is time-limited and purposefully brief—a design element we felt was important given past challenges with engagement and retention observed in post-discharge interventions. This approach contrasts with most generic mindfulness apps that are open-ended in their approach (e.g., you can do as much or as little as you want with no prescribed elements or dose). A final issue was the importance of building a digital solution that included robust security features and could be tightly integrated with a secure data system, features that no app store app can offer.

Development: The self-directed mindfulness app was developed to simulate as completely as possible the experience of the telephone-based mindfulness program described above. First, the content chosen was identical for each weekly session to the original. The same therapists who delivered the telephone-based intervention (Drs. Gremore and/or Greeson) recorded scripted audio meditations that were provided as the weekly centerpiece for the intervention (participants could choose from either therapist's narration for their weekly session). Dr. Gremore also narrated each week's short video, the text of which was taken from the original intervention treatment manual. Content and user experience experts evaluated the app by reproducing expected user tasks, providing feedback that led to iterative revisions before deployment in the clinical trial. We used standard procedures for ensuring app security and integrity of app-data system integration. Additionally, the first two enrolled study participants were used to pilot the intervention and detect any possible errors or inconsistencies. Because they reported no

issues in open-ended query (and also stated that they enjoyed the app), we proceeded to full enrollment with no additional revisions.

Operationalization: Self-directed mobile mindfulness (delivered via a web or app version as preferred) contained all the features of therapist-directed telephone program, with the added features shown in the [Figure](#). There was an added inclusion of web access or smartphone availability. Also, participants viewed a short mMT video in the hospital that familiarizes them with the study procedures (e.g., they will know to expect a weekly text or email reminder with a link to the relevant web-based information starting within 1 week of arrival home) and provided an introduction and rationale. After CRCs verify that the patient had arrived home, the participant began the mobile mindfulness program guided by written handouts, the study website, and a brief review by the CRC.

Delivery	Telephone calls only if needed based on symptoms measured by ePROs* 
Content	also includes app version 
Features	ePRO system automates stepped therapy based on symptom severity & trajectory patient dashboard for symptoms / progress tracking

*ePRO = electronic patient reported outcomes

Patients completed the PHQ-9 weekly via a secure password-protected ePRO system after text or email prompting from our study data entry and management system. For each weekly session, the video required ~4-5 minutes, the meditation lasted ~6-8 minutes, and the remaining app content (e.g., suggestions for including meditations during daily routine) were expected to take ~10 minutes of the user's time for a total of ~20-25 minutes. Therapists only called patients who requested contact via the app. The study PI called all patients who endorsed suicidal ideation based on the relevant PHQ-9 item.

Self-directed education program control. The goal of the education program condition, developed and piloted by our group, is to provide subjects with a level of therapist attention, along with educational information about the nature and treatment of critical illness, but none of the mindfulness training provided to mindfulness recipients. Education program participants received 2 brief check-in calls at the beginning of weeks 1 and 3 to answer questions or troubleshoot issues accessing web content (see topics in [Figure](#)). This educational program was used successfully in another multi-center RCT.(1, 2) Education group participants were given access to an education website with identical capabilities as the mMT website, allowing viewing of education handouts and videos we developed. Hard copies of materials were mailed also. Mindfulness group participants could not access the password-protected education website.

1. Acute respiratory failure: causes and diagnosis	4. Exercise and critical illness
2. Hospital & post-discharge treatments	5. Internet resources for ICU survivors
3. Neuromuscular weakness	6. Nutrition and critical illness

Study website and resources for each treatment group.

The study website, LIFTstudy.duke.edu, was built for three purposes:

- to describe the study for potential participants
- to provide resources (text, video, audio) for participants' use from each treatment group
- to provide transparency to the general public with information about this study that was funded by a government-associated entity

Each treatment group had a tab reserved for their use (i.e., 'Blue Group,' 'Green Group,' and 'Yellow Group'). Group members could access only their group's materials using a unique password that was provided to them after randomization.

Mobile mindfulness group participants' resources included a series of 4 videos (~10-15 min in length each) produced by study staff that largely mirrored the general planned content for the 4 telephone sessions shown above. Handouts in PDF format were available for download that served to augment each session. Links to contact the study team were also present.

Telephone mindfulness group participants' resources included a web app presentation (available from lift.duke.edu) that included 4 videos (~10-15 min in length each) produced by study staff that largely mirrored the general planned content for the 4 telephone sessions shown above. Audio file links for each weekly session were prompted by the app. Also, a different plan for implementing the skills in participants' daily routine was displayed. Handouts in PDF format were available for download that served to augment each session. Links to contact the study team were also present.

Education program group participants' resources included a series of 6 videos (~10-15 minutes in length each) produced by study staff that described topics shown in the Table above. Handouts in PDF format were available for download that served to augment each session. Links to contact the study team were also present.

3. Other variables of interest collected during study

In addition to the outcomes described in the main manuscript, we also collected information on potential covariates including:

Study outcomes measures and timing	
Outcomes for all study aims	Timing
Feasibility: Enrollment, randomization, retention, adherence to telephone sessions	Interview 1, 2, 3
Acceptability and usability: Client Satisfaction Questionnaire,(3) Systems Usability Scale,(4) semi-structured open-ended exit interview	Interview 2
Depression and anxiety symptoms: PHQ-9 (5) and GAD-7 (6) ^a	Interview 1, 2, 3
Post-traumatic stress disorder symptoms: The Post-Traumatic Stress Scale (PTSS)(7)	Interview 1, 2, 3
Physical symptoms: The PHQ-10(8)	Interview 1, 2, 3
Mindfulness Measures (Mechanistic Factors)	
Mindfulness: Cognitive and Affective Mindfulness Scale-Revised (9)	Interview 1, 2, 3
Mindful coping: Brief COPE active coping, emotional support, positive reframing, planning, and acceptable domains (10)	
Sociodemographic and Clinical Variables	
Sociodemographics: Age, gender, race/ethnicity, employment, insurance, education level, marital status	Hospital
Clinical characteristics at enrollment: prior functional status, comorbidities, psychiatric medication use, illness severity, ICU delirium (CAM-ICU), Callahan cognitive screen, diagnosis, duration of ventilation, ICU & hospital LOS, disposition.	Hospital
Post-discharge factors: quality of life (Global health scale),(11) functional status, use of psychiatric medications, cognitive function (TICSm),(12) frequency of mindfulness skills use, social support, hospitalizations/clinic visits/days at home, daily caregiving requirement, severity of stress associated self-rated issue of greatest importance	Interview 1, 2, 3
Financial distress (response of either #1 or #2 below): At the end of an average month, what describes how you usually feel when you are paying the bills? 1. Short on money and need more to pay bills 2. Barely have enough to pay bills and for basic needs 3. Have enough for just a few extra things 4. Completely comfortable	Interview 1, 2, 3
Electronic patient-reported outcomes: PHQ-9, GAD-7, PTSS, numerical quality of life visual scale	Interview 1, 2, 3
Objective physical measures: functional status, key physical symptoms	Interview 1, 2, 3

^a also in hospital

4. Statistical analysis, expanded

Methods and SAS Code

In the following code for the psychological distress outcome models, the analysis dataset – intdata – is stacked and sorted, in ascending order by patient (variable name=record_ID) and time point (variable name=interview), such that there is one record per patient per time point.

In the model, FOLLOW1 and FOLLOW2 are indicator variables for the two follow-up interviews, respectively; arm_mm is the indicator variable for the mobile mindfulness group, and tm_arm is the indicator variable for the telephone mindfulness group, with education group as the referent category.

SAS Code for the following outcomes (presented in [Table 2](#) and [eTable 4](#)):

```
proc mixed data = intdata;
class record_ID int;
model outcome= Follow1 Follow2 arm_mm arm_tm arm_mm*Follow1 arm_mm*Follow2
arm_tm*FOLLOW1 arm_tm*FOLLOW2 /ddfm=kr solution residual cl;
repeated interview/subject = record_ID type = cs rcorr;
estimate 'ED Intercept' intercept 1/cl;
estimate 'ED at Follow1' intercept 1 follow1 1/cl;
estimate 'ED at Follow2' intercept 1 follow2 1/cl;

estimate 'MM baseline' intercept 1 arm_mm 1 /cl;
estimate 'MM at follow1' intercept 1 arm_mm 1 Follow1 1 arm_mm*Follow1 1/cl;
estimate 'MM at follow2' intercept 1 arm_mm 1 Follow2 1 arm_mm*Follow2 1/cl;

estimate 'TM baseline' intercept 1 arm_tm 1 /cl;
estimate 'TM at follow1' intercept 1 Follow1 1 arm_tm*Follow1 1/cl;
estimate 'TM at follow2' intercept 1 Follow2 1 arm_tm*Follow2 1/cl;

estimate 'ED at Follow1 differential from baseline' Follow1 1/cl;
estimate 'ED at Follow2 differential from baseline' Follow2 1/cl;

estimate 'MM at Follow1 differential from baseline' Follow1 1 arm_mm*Follow1 1/cl;
estimate 'MM at Follow2 differential from baseline' Follow2 1 arm_mm*Follow2 1/cl;

estimate 'TM at Follow1 differential from baseline' Follow1 1 arm_tm*Follow1 1/cl;
estimate 'TM at Follow2 differential from baseline' Follow2 1 arm_tm*Follow2 1/cl;

estimate 'MM vs ED change from baseline to follow1' arm_mm*Follow1 1/cl;
estimate 'MM vs ED change from baseline to follow2' arm_mm*Follow2 1/cl;
estimate 'TM vs ED change from baseline to follow1' arm_tm*Follow1 1/cl;
estimate 'TM vs ED change from baseline to follow2' arm_tm*Follow2 1/cl;

contrast "Overall treatment test for FOLLOW1" arm_mm*FOLLOW1 1 ,
arm_tm*FOLLOW1 1;
contrast "Overall treatment test for FOLLOW2" arm_mm*FOLLOW2 1 ,
arm_tm*FOLLOW2 1;

run;
```


5. Study amendments and protocol modifications

There were 12 amendments made to the study between November 16, 2015 and April 4, 2017, after the protocol's initial approval on June 5, 2015 by the Duke Coordinating Center Institutional Review Board (see screenshot from Duke eIRB user interface).

There were 2 protocol amendments made before participant enrollment began:

- On November 16, 2015, we removed patient caregivers from the protocol and added the self-directed mindfulness app arm (at the direction of NIH).
- On December 22, 2015, we added a small usability sub-study to evaluate the usability and acceptability of the new mobile app among patients.

The remaining 10 amendments made after enrollment began were not directly relevant to the study protocol or delivery of interventions:

- N=5: Study personnel changes
- N=3: Related to updated study materials (e.g., videos, websites, postcard templates).
- N=2: Related to clarifications about study instrument scripting
- N=2: Related to compensation amount for participants (n=1) and clinicians (n=1) for a usability substudy.

ID	Name	State	Last State Change
Amd012_Pro00064250	AMD #12 - Study Personnel Change	Approved	4/4/2017 5:22 PM
Amd011_Pro00064250	AMD #11 - Study Personnel Change	Approved	1/18/2017 10:31 AM
Amd010_Pro00064250	AMD #10 - Mobile Mindfulness	Approved	10/21/2016 8:03 PM
Amd009_Pro00064250	AMD #9 - Study Personnel Change	Approved	6/1/2016 7:11 AM
Amd008_Pro00064250	AMD #8 - Mobile Mindfulness	Approved	5/3/2016 9:40 AM
Amd007_Pro00064250	AMD #7 - Mobile Mindfulness	Approved	3/21/2016 2:11 PM
Amd006_Pro00064250	AMD #6 - Mobile Mindfulness	Approved	2/25/2016 12:39 PM
Amd005_Pro00064250	AMD #5 - Mobile Mindfulness	Approved	2/2/2016 1:28 PM
Amd004_Pro00064250	AMD #4 - Study Personnel Change	Approved	1/14/2016 7:58 AM
Amd003_Pro00064250	AMD #3 - Study Personnel Change	Approved	12/29/2015 8:09 AM
Amd002_Pro00064250	AMD #2 - Mobile Mindfulness	Approved	12/22/2015 12:25 PM
Amd001_Pro00064250	AMD #1 - Mobile Mindfulness	Approved	11/16/2015 11:10 AM

B. eResults

eTable 1: Additional baseline characteristics of patients and their family members

	Overall n (80)		Mobile mindfulness n (31)		Telephone mindfulness n (31)		Education program n (18)	
Age , mean (SD), years	49.5	(15.1)	48.7	(15.3)	48.1	(16.1)	53.3	(12.6)
Female gender , no. (%)	35	(43.8)	12	(38.7)	15	(48.4)	8	(44.4)
Race , no. (%)								
White	53	(66.3)	23	(74.2)	20	(64.5)	10	(55.6)
Black	18	(22.5)	4	(12.9)	9	(29.0)	5	(27.8)
Asian	1	(1.3)	1	(3.2)	0	(0.0)	0	(0.0)
Native Hawaiian or Other Pacific Islander	3	(3.8)	1	(3.2)	1	(3.2)	1	(5.6)
American Indian/Alaskan Native	4	(5.0)	2	(6.5)	0	(0.0)	2	(11.1)
Missing / Unknown	1	(1.3)	0	(0.0)	1	(3.2)	0	(0.0)
Hispanic ethnicity , no. (%)	5	(6.3)	0	(0.0)	4	(12.9)	1	(5.6)
Missing / Unknown	1	(1.3)	0	(0.0)	1	(3.2)	0	(0.0)
Religion / faith , no. (%)								
Christian	55	(68.8)	21	(67.7)	22	(71.0)	12	(66.7)
Jewish	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muslim	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hindu, Buddhist, Taoism, or other Eastern/Asian	1	(1.3)	0	(0.0)	1	(3.2)	0	(0.0)
None	23	(28.8)	9	(29.0)	8	(25.8)	6	(33.3)
Other	4	(5)	1	(3.2)	3	(9.7)	0	(0.0)
Marital status , no. (%)								
Married or live with partner	39	(48.8)	16	(51.6)	13	(41.9)	10	(55.6)
Divorced or separated	11	(13.8)	5	(16.1)	2	(6.5)	4	(22.2)
Widowed	2	(2.5)	0	(0.0)	2	(6.5)	0	(0.0)
Single	28	(35.0)	10	(32.3)	14	(45.2)	4	(22.2)
Highest level of education , no. (%)								
Grade school or junior high	2	(2.5)	2	(6.5)	0	(0.0)	0	(0.0)
Some high school	5	(6.3)	2	(6.5)	3	(9.7)	0	(0.0)
High school graduate or equivalent	14	(17.5)	4	(12.9)	5	(16.1)	5	(27.8)
Trade, technical, or vocational school	7	(8.8)	1	(3.2)	4	(12.9)	2	(11.1)
Some college	21	(26.3)	9	(29.0)	7	(22.6)	5	(27.8)
College degree or higher	22	(27.5)	10	(32.3)	9	(29.0)	3	(16.7)
Post-graduate work or degree	9	(11.3)	3	(9.7)	3	(9.7)	3	(16.7)

Employment status in month prior to hospitalization, no. (%)								
Working full time	37	(46.3)	14	(45.2)	17	(54.8)	6	(33.3)
Working part time	10	(12.5)	4	(12.9)	3	(9.7)	3	(16.7)
Homemaker full time	1	(1.3)	0	(0.0)	0	(0.0)	1	(5.6)
Unemployed	5	(6.3)	2	(6.5)	0	(0.0)	3	(16.7)
Retired	19	(23.8)	8	(25.8)	7	(22.6)	4	(22.2)
Disabled	7	(8.8)	3	(9.7)	3	(9.7)	1	(5.6)
Student	1	(1.3)	0	(0.0)	1	(3.2)	0	(0.0)
Caring for children at home, no. (%)	23	(28.8)	6	(19.4)	10	(32.3)	7	(38.9)
Do you have a caregiver, no. (%)	76	(95.0)	29	(93.5)	29	(93.5)	18	(100.0)
<i>if yes, what is relationship to you:</i>								
Spouse or partner	40	(52.6)	18	(62.1)	13	(44.8)	9	(50.0)
Child	6	(7.9)	0		4	(13.8)	2	(11.1)
Parent	13	(17.1)	4	(13.8)	6	(20.7)	3	(16.7)
Brother / Sister	10	(13.2)	3	(10.3)	5	(17.2)	2	(11.1)
Other family	3	(3.9)	2	(6.9)	0	(0.0)	1	(5.6)
Friend	4	(5.3)	2	(6.9)	1	(3.4)	1	(5.6)
<i>if yes, do they live with you:</i>								
Yes	59	(77.6)	23	(79.3)	21	(72.4)	15	(83.3)
Insurance status, no. (%)								
Medicare	17	(21.3)	5	(16.1)	8	(25.8)	4	(22.2)
Medicaid	15	(18.8)	8	(25.8)	4	(12.9)	3	(16.7)
Commercial	40	(50.0)	15	(48.4)	16	(51.6)	9	(50.0)
None	5	(6.3)	2	(6.5)	2	(6.5)	1	(5.6)
Other	3	(3.8)	1	(3.2)	1	(3.2)	1	(5.6)
Financial distress, no. (%)								
Short on money and need more to pay bills	6	(7.5)	3	(9.7)	1	(3.2)	2	(11.1)
Barely have enough to pay bills and for basic needs	15	(18.8)	6	(19.4)	7	(22.6)	2	(11.1)
Have enough money for just a few extra things	35	(43.8)	13	(41.9)	12	(38.7)	10	(55.6)
Completely comfortable	23	(28.8)	9	(29.0)	11	(35.5)	3	(16.7)
Missing / Unknown	1	(1.3)	0	(0.0)	0	(0.0)	1	(5.6)
How do you learn new things best, no. (%) ¹								
Read on internet	39	(48.8)	15	(48.4)	15	(48.4)	9	(50.0)
Read book / brochure	27	(33.8)	13	(41.9)	10	(32.3)	4	(22.2)
Watch video on internet	48	(60.0)	18	(58.1)	18	(58.1)	12	(66.7)
Listen to CDs	10	(12.5)	3	(9.7)	5	(16.1)	2	(11.1)

Watch DVDs	15	(18.8)	4	(12.9)	8	(25.8)	3	(16.7)
Telephone someone who knows about it	17	(21.3)	3	(9.7)	9	(29.0)	5	(27.8)
By myself at home	22	(27.5)	8	(25.8)	8	(25.8)	6	(33.3)
With a family member	20	(25.0)	8	(25.8)	9	(29.0)	3	(16.7)
In a group of people who are not family	18	(22.5)	6	(19.4)	9	(29.0)	3	(16.7)
Do you practice meditation, no. (%)	14	(17.5)	8	(25.8)	4	(12.9)	2	(11.1)
Taking at the time of hospital admission, no. (%) ¹								
Antidepressants	15	(18.8)	6	(19.4)	6	(19.4)	3	(16.7)
Anxiolytics	9	(11.3)	3	(9.7)	4	(12.9)	2	(11.1)
Other psychiatric medication	1	(1.3)	0		0	(0.0)	1	(5.6)
Narcotics	12	(15.0)	4	(12.9)	5	(16.1)	3	(16.7)
Prescribed at the time of hospital discharge, no. (%) ¹								
Antidepressants	18	(22.5)	6	(19.4)	7	(22.6)	5	(27.8)
Anxiolytics	11	(13.8)	3	(9.7)	5	(16.1)	3	(16.7)
Other psychiatric medication	1	(1.3)	0	(0.0)	0	(0.0)	1	(5.6)
Narcotics	50	(62.5)	19	(61.3)	21	(67.7)	10	(55.6)
Treated for psychiatric condition since hospital discharge, no. (%)	16	(20.0)	5	(16.1)	8	(25.8)	3	(16.7)
<i>If yes, psychiatric condition, no. (%) ¹</i>								
Depression	7	(43.8)	1	(20.0)	4	(50.0)	2	(66.7)
Anxiety	9	(56.3)	2	(40.0)	6	(75.0)	1	(33.3)
PTSD	3	(18.8)	2	(40.0)	1	(12.5)	0	
<i>If yes, taking medications, no. (%)</i>	15	(93.8)	4	(80.0)	8	(100.0)	3	(100.0)
<i>If yes, under care of psychiatrist, psychologist or counselor, no. (%)</i>	7	(43.8)	3	(60.0)	2	(25.0)	2	(66.7)
Health literacy, mean (SD)	6.1	(3.1)	6.3	(3.3)	6.2	(3.1)	5.6	(2.8)
Chronic medical comorbidities, mean (SD)	3.1	(3.3)	2.7	(2.7)	3.0	(3.2)	4.2	(4.3)
Treating ICU at time of eligibility, no. (%)								
Medicine	12	(15.0)	4	(12.9)	5	(16.1)	3	(16.7)
Cardiology	10	(12.5)	5	(16.1)	3	(9.7)	2	(11.1)
Neurology	3	(3.8)	1	(3.2)	1	(3.2)	1	(5.6)
Trauma	16	(20.0)	6	(19.4)	6	(19.4)	4	(22.2)
General Surgery	35	(43.8)	15	(48.4)	14	(45.2)	6	(33.3)
Cardiac Surgery	1	(1.3)	0	(0.0)	1	(3.2)	0	(0.0)
Neurosurgery	3	(3.8)	0	(0.0)	1	(3.2)	2	(11.1)
APACHE II score on day of enrollment, mean (SD)	17.9	(6.8)	18.2	(6.7)	16.9	(5.5)	18.9	(8.9)

Inclusion criterion met								
Mechanical ventilation ≥12 hours	51	(63.8)	19	(61.3)	21	(67.7)	11	(61.1)
Mechanical ventilation days, mean (SD)	4.2	(5.2)	4.5	(4.0)	4.4	(7.0)	3.2	(1.9)
Non-invasive ventilation ≥ 4 hours	8	(10.0)	3	(9.7)	2	(6.5)	3	(16.7)
Non-invasive ventilation days, mean (SD)	6.6	(14.5)	0.4	(0.2)	3.6	(3.1)	14.9	(23.6)
High flow oxygen ≥ 4 hours	13	(16.3)	5	(16.1)	4	(12.9)	4	(22.2)
High flow nasal cannula days, mean (SD)	1.7	(1.1)	1.3	(0.8)	2.8	(1.2)	1.1	(0.3)
Face mask oxygen (>=50% O2) (≥4 hrs), mean (SD)	0.1	(0.3)	0.2	(0.4)	0.0	(0.0)	0.0	(0.0)
Vasopressors for shock ≥ 1 hour	44	(55.0)	19	(61.3)	16	(51.6)	9	(50.0)
Vasopressor days, mean (SD)	2.3	(3.4)	2.7	(3.9)	2.5	(3.7)	0.9	(0.7)
Inotropes for shock ≥ 1 hour	5	(6.3)	3	(9.7)	2	(6.5)	0	(0.0)
Inotrope days (> 1 hour), mean (SD)	8.3	(9.5)	1.5	(1.1)	18.5	(2.9)		
Aortic balloon pump for shock	3	(3.8)	0	(0.0)	3	(9.7)	0	(0.0)
Aortic balloon pump days, mean (SD)	4.4	(3.5)			4.4	(3.5)		
Enthusiasm for study, pre-randomization								
very high	23	(29)						
high	33	(41)						
neutral	20	(25)						
low	4	(5)						
very low	0	0						
Interest in learning about mindfulness, pre-randomization								
very high	21	(26)						
high	30	(38)						
neutral	25	(31)						
low	2	(3)						
very low	2	(3)						
Interest in getting information about critical illness, pre-randomization								
very high	36	(45)						
high	28	(35)						
neutral	9	(11)						
low	3	(4)						
very low	4	(5)						
TICS-m total score on arrival home	14.1	(4.1)	13.9	(4.5)	14.6	(3.9)	13.7	(3.8)
¹ Multiple responses possible								

eTable 2: Clinical characteristics during hospitalization

	Overall n (80)		Mobile mindfulness n (31)		Telephone mindfulness n (31)		Education program n (18)	
Hospital length of stay, mean (SD)	12.3	(8.2)	13.6	(10.1)	12.5	(7.6)	9.7	(4.0)
Intensive care unit length of stay, mean (SD)	5.7	(4.1)	6.1	(5.6)	5.8	(4.4)	4.9	(2.2)
Mechanical ventilator days, mean (SD)	4.2	(5.2)	4.5	(4.0)	4.4	(7.0)	3.2	(1.9)
CAM-ICU positive during first 48 hours of ICU stay, n (%)	7	(8.8)	2	(6.5)	4	(12.9)	1	(5.6)
Lowest RASS during first 48 hours of ICU stay, mean (SD)	-2.1	(1.5)	-2.1	(1.3)	-2.1	(1.6)	-2.1	(1.7)
Acute comorbidities acquired during hospitalization, no (%)								
Shock requiring vasopressors	13	(16.3)	8	(25.8)	2	(6.5)	3	(16.7)
Acute (new) renal failure requiring dialysis	5	(6.3)	2	(6.5)	2	(6.5)	1	(5.6)
Acute respiratory distress syndrome	3	(3.8)	3	(9.7)	0	(0.0)	0	(0.0)
Cardiac arrest	1	(1.3)	0	(0.0)	0	(0.0)	1	(5.6)
Acute myocardial infarction	1	(1.3)	0	(0.0)	1	(3.2)	0	(0.0)
Major surgery during hospitalization	57	(71.3)	22	(71.0)	22	(71.0)	13	(72.2)
Hospital Discharge Disposition, no (%)								
Home, independent	69	(86.3)	28	(90.3)	26	(83.9)	15	(83.3)
Home with home health care services (paid)	9	(11.3)	2	(6.5)	5	(16.1)	2	(11.1)
Inpatient rehabilitation facility	2	(2.5)	1	(3.2)	0	(0.0)	1	(5.6)
Hospital Readmission during follow-up, no (%)	23	(28.7)	8	(25.8)	11	(35.5)	4	(22.2)

eTable 3: Clinical outcomes during 3-month follow-up period

Outcome and time point	Mobile mindfulness <i>n</i> =31 n (%) or mean (SD)	Telephone mindfulness <i>n</i> =31 n (%) or mean (SD)	Education program <i>n</i> =18 n (%) or mean (SD)
Readmitted to hospital			
1 month	3 (10)	2 (6)	2 (11)
3 months	2 (6)	7 (23)	0
Employment status, 3 months			
Working full time	5 (16)	8 (26)	3 (17)
Working part time	3 (10)	5 (16)	1 (6)
Unemployed, looking for work	5 (16)	4 (13)	3 (17)
Homemaker full time	0	0	1 (6)
Retired	4 (13)	4 (13)	5 (28)
Disabled	5 (16)	7 (23)	3 (17)
Missing	9 (29)	2 (6)	2 (11)
Days until return to work / school / full household duties	44 (23)	60 (33)	34 (30)
Current psychiatric treatment, 1 month			
Treatment for any issue	2 (6)	5 (16)	3 (17)
Depression	0	3 (10)	3 (17)
Anxiety	1 (3)	3 (10)	1 (6)
PTSD	1 (3)	1 (3)	0
Medication?	2 (6)	5 (16)	2 (11)
Under care of mental health professional?	1 (3)	2 (6)	2 (11)
Current psychiatric treatment, 3 months			
Treatment for any issue	4 (13)	5 (16)	4 (22)
Depression	1 (3)	5 (16)	4 (22)
Anxiety	1 (3)	4 (13)	2 (11)
PTSD	2 (6)	2 (6)	0
Medication?	3 (10)	5 (16)	2 (11)
Under care of mental health professional?	2 (6)	1 (3)	4 (22)
Self-rated stressor, pre-intervention			
Physical concerns / symptoms	12 (39)	9 (29)	7 (39)
IADLs / independence	9 (29)	9 (29)	6 (33)
Financial stress	3 (10)	5 (16)	4 (22)

Worry, stress, depression, or traumatic memories	1 (3)	3 (10)	1 (6)
Social stresses (family and loved ones)	1 (3)	2 (6)	0
None	5 (16)	3 (10)	0
Intensity of stressor, baseline	77 (20)	79 (21)	80 (18)
Intensity of stressor, 1 month	78 (22)	79 (15)	72 (20)
Intensity of stressor, 3 months	80 (21)	76 (23)	76 (18)

IADL=instrumental activities of daily living; PTSD=post-traumatic stress disorder

eTable 4: Feedback in participant's own words from the mobile mindfulness training group. Note that each row reflects the feedback from a single user.

Could you provide any comments about specific ways the program helped you?	In what specific ways could the more helpful?	In what specific ways could the videos or the website be more helpful?	In what specific ways could the videos be more helpful?	What, if anything, do you feel you still need help with? (This does not have to be related to the study)	What would be most helpful for a recent ICU patient/family member to get from the hospital, doctors, or others?	How could we improve the app (only asked for app group)?	What did you like most about the app (only asked for app group)?
<p>SUMMARY Positive comments 47 (85%)</p> <p>Neutral comments 3 (5%)</p> <p>Negative comments 5 (10%)</p>	<p>SUMMARY Constructive feedback 22 (42%)</p> <p>No other suggestions 30 (58%)</p>	<p>SUMMARY Constructive feedback 20 (63%)</p> <p>No other suggestions 12 (37%)</p>	<p>SUMMARY Constructive feedback 20 (63%)</p> <p>No other suggestions 12 (37%)</p>	<p>SUMMARY Physical concerns 8 (17%)</p> <p>Depression / anxiety / PTSD 6 (13%)</p> <p>Nothing 17 (35%)</p> <p>Other 17 (35%)</p>	<p>SUMMARY Hospital 5 (9%)</p> <p>Doctors 3 (6%)</p> <p>Post-ICU care 14 (26%)</p> <p>Others 26 (49%)</p> <p>None 5 (9%)</p>	<p>SUMMARY Constructive feedback 6 (37%)</p> <p>No other suggestions 10 (63%)</p>	<p>SUMMARY Usability 17 (81%)</p> <p>Results 3 (14%)</p> <p>Flexibility / time required 1 (5%)</p>
							Easy to follow
The tools were helpful and I applied them at points when I was in particular distress.					I believe that it is most important that there be clarity about who has responsibility for what tasks, roles, etc. The ICU at Duke is a special place. When you move from there to a general med-surg floor your role as a patient increases	I would suggest regarding content that the text be reduced and more quiet/blank time be used to allow the user to follow and practice the instructions provided.	

					significantly. You are taken care of in the ICU.		
The program motivated me to direct my focus away from my traumatic experience by giving me tools to take more control of my situation. In short, it empowered me.	Additional exercises would be most helpful.		A live person guiding the process would be comforting and more encouraging.	Acceptance of the lifelong changes my medical condition brought about.	Clear information about their medical condition based on a holistic view of the person and not just the primary illness.	While the exercises were simple and easy to follow, and expansion of the exercises would be most helpful.	Convenience and easy-to-use format.
It really helped me to relax and my favorite was the breathing exercise	Explain how to do each exercise a little more detailed or maybe add a visual demo				After care	Maybe add some visual	User friendly
Taking a ten minute 'time out' during the day.	none		none	Study groups, FAQs are helpful	What has happened. What is going on now. Is there a treatment plan? What are the possible 'what ifs'.	The instructions are too vague.....What day of the week do you do what.	The 10-15 minute time involved.

No; My time spent in prayer and meditation every morning is what helped me.	More one on one phone conversations.		I don't know; I didn't get much out of them, Especially the video about imagining your problems on leaves floating down the stream	Last week I started having flashback memories of my experience that disturbed me.	Can only speak for me..But I would really like to shake every Doctor, Nurse And Specialist that cared for me and say THANK YOU!	I was satisfied with the webapp	Easy to understand
just helped me focus, not so much to relieve stress but to focus where i am	none		delightful, some time voice on female tones faded(maybe my phone)	will continue to focus on current situations and not worry alot	maybe someone just to talk with regarding questions, they do not necessarily need physician	not anything,	easy to follow, tone of presenter
						I don't have any issues with the webapp.	It provided me with ways to relieve stress and anxiety. Ways in which I could alleviate anger.
Helped me yo find a way to prsctice calmness.	Offer other sites to read about mindfulness.		Xx	Xx	Xx	Xxxx	Easy to follow.
I used it when I walked	None		None		Know that they care. I felt that from all		How they talked you through each assignment
Helped locate and relieve stress and pain. Really helped getting to sleep at night, and still does. Although now, I	Can't think of any ways.		Enjoyed the videos; still prefer the voice-only section.	Doing rather well for this part of recovery. Wish I could regain my strength and stamina more quickly, but that's	Reassurance that recovery will happen, don't rely on others' experiences to gauge your own response and to be		Easy to use and very intuitive. Loved both the male and female voice, although

just need to think about the lessons rather than listen to them.				just the time my body takes to heal.	aware of your own limitations; don't push it!		I preferred the male.
							over all peaceful ambiance
No specific ways provided.	No specific ways, pretty simple to understand.		Can't think of any.	Nothing, can continue to use the website and revisit after the study.	To be able to have a support system to call for questions and encouragement.	Didn't see anything that needed to be changed.	It was easy to follow and explained things well. Voices were good to listen to on the webapp.
It helped me be more calm, especially when I'm going through so much right now.	Its helpful enough		Be more realistic with certain things.	My patience and self love	Strongness	No need to.	It was easy and very simple to use
It provided immediate support and served as a great tool. I could utilize it on a daily basis whenever I needed simply by picking up my phone.	Having some sort of reminder seeing as I had a severe concussion, which caused some temporary memory issues				This program.		I liked the ease-of-use and the application process.
Helped me with pain on going to sleep at night.	I think the program is helpful.		The videos are good.	Nothing.	To get into this study.	I can not think of anything.	Using mind over matter.
I think it really helped with the tightening around my neck.	I think I had some questions about letting stresses go, especially		again I think weeks 3 and 4 needed to be more separate	I don't think so.	I am still struggling trying to figure out recovery time period, what I can	I think for weeks 3 and 4 they seem to be similar, so I think	I liked the video in combination with the

<p>Breathing was very helpful. I think especially at night time, implementing step 2 and letting myself relax before sleep. My neck tightens without me realizing it and I am more aware of that now.</p>	<p>when they were important to me. I would rather deal with them rather than ignoring them. I had questions about how to do that or if I should do that.</p>		<p>and focused on.....they seemed to be mixed together.</p>		<p>expect? Does it have long term effects with disability, do I need to get Social Security early? At the time I discharged I didn't know what to ask? And then who to get in touch with to discuss them now that I know better what I don't know.</p>	<p>finding a way to separate them out somehow, they both seemed to be thoughts and feelings in the present moment, hard to know what exactly was the difference between these two weeks.</p>	<p>practice with somebody talking. I thought it was helpful to have both of them. Good combination. I did like weeks one and two better than 3 & 4. Weeks 1 and 2 were more tangible I think, it was something I could latch on to. Weeks 3 and 4 were more about thought and feelings and it was less helpful for me. I could incorporate the ideas in weeks 1 and 2 better into my life.</p>
<p>It helped me relax but didn't take any of the depression away. It's not the study, it's the fact that I have more going on than my health issues.</p>	<p>I'm not sure</p>		<p>They could actually play all the way through, video #3 stopped in the middle and wouldn't let me get to the survey at the end</p>	<p>Finances.....lol.....but my depression is a big factor that I'm not sure if anything could actually help me with</p>	<p>Great support.....mostly because I'm sure they wouldn't have the extra issues I have</p>		

I'm always thinking ,so when I'm down ,sad about things, lift	Reminder once a month or every other month		Show videos often . Once a week or every other week	I need help if they can close my wound on my left buttocks.	I'm trying to stay off my wheelchair ,really want to heal my wound	Sometime I forget, more reading	The apps always remind you something about lift.
It made me more aware of my environment, of my surroundings, it helped me pay closer attention to details and how that affects my mood. Before I wasn't thining about it and now it crosses my mind. It does help me feel calm when I use it, it doesn't last forever though.	I don't know, have people available if you need them.		thought the videos were fine.	I really don't think I need help with anything, the recovery time takes a while, it may have been helpful to know how long revoery would take, maybe to communicate with the physician.	Communication is the main thing that patients want. They sent me home and said see you in three months, they didn't communicate what my restrictions were, or what I'd be going through, you may go through depression, boredom and pain.	I am not sure. I didn't pay a pay a ton of attention to the web app. It was a little boring.	I thought it was fairly easy to navigate and you could always find help if you need it.
In times of stress i found it easy to use and very effective to redirect my thoughts to more pleasent thoughts and to ease any negative feelings which came up during the day or in the evening.	Works very effective for me. i see very few ways it could be more helpful.			N/A	Information on ICU patient care at home and reasons why this is important to the future health of said patient not only for the patient but also for the family who has daily contact with the patient at home.	Good as is for me	Very straight forward to use and easy to navigate thru to get to each section.
Nothing	Not really		Great videos	Depression and ptsd	Dealing with feelings	Nothing	Interactive
Help me clear my mind	I felt it was just fine		They were fine	Not really sure how I want to answer that one	Support i guess	I felt it worked just fine for its purpose	Simple to understand and easy to use

helped me problems with sleep and it helped alot most beneficial	nothing I can think of	website and videos very helpful		still tire very easily -	I can't think of anything - they were so courteous and helpful.		
The study helped me by causing me to be more aware of my body and my thoughts	I am not sure	It is not very relaxing to sit at a desk in front of computer and focus on the mind study--- I think the calls are more beneficial.		N/A	The after transplant information before the transplant- so some of the questions could already be answered.		
Did not use the website as she doesn't have internet Helped to keep focused, and brought you back to where you should be when you were getting off track	can't think of anything	Did not use the website as she doesn't have internet		worried about kids	nothing they could have done to make it any better		
The study provided support and a voice to express my concerns/issues.	If possible, relay any concerns/issues to healthcare providers. Also provide resources to those who might need ongoing support after the participation in the studt has been completed.	The videos were very helpful, no recommendation for improvement.		None at this time	Information about how to help about how to help care for and support the patient.		

I appreciated the body scan exercise, in particular. This helped me to really access how I was feeling, relaxed me, and helped me better deal with my pain and live in the moment.	I am not sure. I, personally, do not enjoy speaking on the phone- so that was the most difficult part for me.	It would be helpful for the first recording to have a second session that did not include all the intro talking for the repeat listens. Also- for the exercise in reflecting on thoughts and emotions, a second recording being available that were a little longer with more space between speech would be helpful to allow time for deeper thought.		I am still finding it difficult to carve enough space, quiet, and structure to process some of my thoughts and emotions around my transplant. I need guidance and prompting- but also to be quiet and alone!	A guide for dealing with common problems like fatigue, breathing issues, etc- with ways to work with these and not feel failure or undue stress.		
It helped me calm down and helped control me from snapping at loved ones	working more with the person on the phone	i think that maternal was great					
Gave me a peace of mind through my illness	No complaints	No complaints		Financial help due from not working because of illness	Encouragement		
relaxed me, especially when she talked with me on the phone	more time to complete it--I had so much going on with back and forth to drs appointments			my health is better though I'm still wearing my wound vac.			

The real-time discussions w/ the person that called me for this program. I did not use the website but chose to practice of various items that we talked about online each week.	I do not have any specific ways the program could be more helpful.	Did not use the videos or website.		The program enhanced the way I already have thought my entire life. For me, the glass is always half full not half empty. Our three boys are out of our home and Mary. I am 74 years old and at this point my work habits and beliefs in God are already established.	And awareness of the important points taught by this program.		
Has helped to be able to relax both mentally and physically.	Cannot think of any ways. Good program.	None that I can think of		How to limit or not over exert myself	As much information as possible about what to expect as far as recovery, limitations and long term effects of the illness		
It helped me to have a more positive perspective on my situation following a near-death situation.	I found the telephone sessions to be very helpful. If there was anything that could be improved, I would say it would have to be my own consistency in availability.	I actually didn't use the website very much, so I have no input.		I feel as if I was helped adequately.	Support.		
Helped me with my pain. The controlled breathing really helped.	Make 6 weeks.	Make them, especially the audio part. It was sometimes difficult to get it to play.		I'm doing great right now. Just have to keep doing the skills I learned.	For the attending doctors to introduce themselves. I only had two attending doctors introduce themselves to me.		

The techniques provided allowing me to relax more	I think the mindfulness program will be helpful not only for coping with illness but helpful with coping with a lose as well. I had to deal with both at the same time and it has been very usefull	i had no issue with the videos		n/a	the program should be referred to the patients upon release		
It was difficult for me to participate in. I didn't see the value.	I'm not sure. I'm not a person who does meditation.	I don't know. I just really couldn't relate to this program.		nothing.	It was a horrible experience. I try not to think about it.		
Relaxing for me	It would be nice if we could have the study twice a week	That would be great		Just taking my time in everything I try to do	Just slow down. Take time for themselves		
Learning to relax		A CD mabey it helped me relax		I was very happy my experience was very easy compared to others	I was able to relax myself and lower my BP and pulse		
I found the sessions very helpful in learning how to breath and tune into my breathing.	no comment	no comment		no comment	do not know how to answer that question other than more sleep but we know constant monitoring is necessary so sleep is impossible to obtain		
Helped me cop with thinking more rationally.	It could be more helpful by having someone who had gotten into the same injury as the patient to relate more.	Videos could be longer and could be more visual.		I need help with getting my mind off letting myself down. I need to get my mind off how I am going to pay for my bills.	Get someone who'll help handle your diet. Someone who can help and make sure you eat and can get some food.		

Tina was so supportive and really let me vent and then helped me see past my emotions and anxiety.	More! More phone sessions. The meditation is great but just being able to talk to someone who is willing to listen and understands that what you went through was extremely difficult. I think when you have something like ptsd, most people don't take it seriously. They think you're making it up because it didn't happen at war so it's not a valid symptom.	The videos were great. They were clear and easy to understand. Some of the visualization exercises didn't work for me but Tina really helped me find an exercise that did work for me.		I think I need help with my physical goals. Getting as far back to normal as I can. Also, occasional emotional support. I have my family but sometimes it is just easier to talk to someone outside your situation to gain perspective.	Permission to be upset. Everyone is always telling you to stay positive and not to cry and not to say things like I might die. I was lucky in the sense that my surgeon never sugar coated anything for me and always gave me all the information about all my labs and didn't try to be aggressively happy or force hope into the situation. That's worked for me because I'm a realist.		
No not really ... time heals all wounds	It's a lil weird already ... wouldn't change anything ...	Idk ... didn't visit the web sight		Not at all	Uninterrupted sleep lol		
It can help patient openly talk about their problems with the staff in the phone.		The video helps the breathing practice and reminded me how to do it correctly.			Transportation would help since family members are sometimes not able to drive patient to follow up appointments n parking is limited.		

focusing on the breathing, i liked that, blocking everything out	Maybe having twice a week telephone calls, more interaction with psychologist, everyone is so busy during the week, a session at the beginning and the end of the week	I honestly don't know, the website wasn't that important, I liked the interaction with areal person, she was pleasant and real nice, like a mom		After the accident, it was real, real humbling, I am not superman, I am not invincible, family is everything, without family the days will drag on, working on my patience, take it one day at a time, thankful to be here	I thought they were pretty thorough, I knew very well what I needed to upon discharge, that's important		
it helped with overcoming what happened and accepting the circumstances and moving on.	I don't think it could be more helpful.	I don't have an answer.		Really just overcoming the things that have happened and moving on.	No answer.		
It really helped to make me feel like I had other support besides at home.	I thinks it was very helpful	Since this was new to me I thought it did a very good job		nothing really	to make sure they have follow up Drs set up		
Helped me to focus, and relax. It was great. Kept my mind from wondering off.	Few more sessions on the telephone would be helpful.	Video could be more helpful if they were longer.		Nothing.	More information about the study.		
info to take better care of health and be aware of	no	more info		not at this time	make sure that follow up with doctor is set up soon within wk of leaving hospital		
It helped me to better understand some procedures and medical terms.					Explanation of what occurred to require your stay in ICU		

It confirmed for me that it was expected that I would be weak when I came home from the hospital.	The nature of and reasons for the study could be more clearly explained when people are asked to participate.			I need an ileostomy take-down and reconnection.	It might be helpful to have printed information relating to any research study one may have agreed to participate in.		
NO	Be specific for reason in ICU	Don't know		Workout regiment after transplant	No idea		
Not really.	It was pretty complete, covers everything.	It was pretty complete, covers everything.		Nothing comes to mind health wise.	Nothing other than better parking.		
It was helpful upon my discharge to talk to someone about my experience and to read information about what happened while I was in ICU since I had no recollection of what occurred.	It would be helpful to discuss more about the psychological aspects of what happens when recovering after being in ICU and the different emotions you may experience afterwards.	I think the videos were helpful.		Transportation, since I am unable to drive because of experiencing a seizure during my procedure.	In my situation, it would be helpful to find out what resources might be available if you are told you are not able to drive for 6 months. I also think it is helpful to get a phone call from someone possibly a week out to see how they are doing/coping. It takes some time to process all that has happened initially. It feels overwhelming what may occur afterwards in terms of follow up visits, tests, and learning if you may have to start taking new medications.		

More support about what to expect after the operation and how your life may change after living with your illness for many (10) years.	I watched the videos, but that seemed to be the only information. I couldn't find anymore. I feel like I missed something.	Could have had a little more information		Getting back to normal.	Make sure you bring a pen and paper and always write down your questions.		
I did feel very supported.	A little less wordy.	A little less wordy.		I am pretty good. Physical therapy give me good results.	Everyone was very intuitive about what we needing. Better waiting facilities for the family.		
Further understand how ICU helped me live	Links added for therapeutic advice	They are good. Easy to follow		I wasn't ready for pain med withdrawals. That could be talked about	Support and follow up		

<p>Although the information provided by the Lift program was good, it did not apply to my situation at all. The information was about recovery after being on a ventilator and I was not kept on a ventilator after surgery. However, I did read through all the material.</p>	<p>I feel like the information you are trying to provide to the patient is coming a little too late. If I would have gone through being on a ventilator to the point that it would have affected me that much, I would have liked to have had this information in the hospital prior to being released. I feel that this would give the patients an opportunity to be better prepared from day 1 of their release.</p>	<p>This would truly depend on the individual. To me the information provided was a little vague. I knew prior to surgery that I would be on a ventilator throughout the surgery and by looking into it a little bit, I already knew all that you were providing in the videos/website. However, I do understand that with many people they may not be as proactive or educated and therefore a simple form of information would be just fine for them.</p>		<p>I do not really need any additional help. When I have a question, I just call into the spine clinics=c and they have been very helpful in answering my questions.</p>	<p>Once in ICU, the information flowed. Any question my husband had was answered promptly and thoroughly. I on the other hand, don't remember anything more than a few ice chips! The area that I feel is more important to improve upon would be the 'waiting room'. My husband sat for 10 hours without receiving a single update other than I was still in surgery. I think that for the sake of the family members, it would be good to get an update occasionally so that they know that everything is either going well or that there had been complications.</p>		
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Nothing to say	Not really sure, more personable, I enjoyed the questionnaires, but once it got turned on to the on line portion it seemed less personable	I really don't know		I personally am having trouble getting the proper care from physician. I have been trying to see an orthopedist for 8 weeks now. I have been trying for a long time to get more follow up care. Coordination of follow care has not been good. I thought the follow up care would be better. I am pretty proactive in my recovery but I can imagine that others may have much more trouble. Needing more help with L & I.	A nurse case manager probably. A representative who can get them through the hoops. I left the hospital with not a lot of direction or further help. I was very injured and went home with very little help.		
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eTable 5: Model-estimated means and mean differences in psychosocial outcomes over time between treatment groups

Outcome and time point	Model-estimated means (SE)			Mean change from baseline (95% CI)			Between-Group Differences (95% CI)			
	Education	Mobile mindfulness	Telephone mindfulness	Education	Mobile mindfulness	Telephone mindfulness	Mobile mindfulness vs Education	p ³	Telephone mindfulness vs Education	p ³
PHQ-9¹										
Baseline	7.1 (1.1)	8.2 (0.8)	7.6 (0.8)							
1 month	5.8 (1.1)	4.4 (0.9)	4.6 (1.4)	-1.3 (-3.5, 0.9)	-3.8 (-5.6, -1.9)	-2.4 (-4.2, -0.7)	-2.5 (-5.3, 0.4)	0.09	-1.2 (-4.0, 1.6)	0.41
3 months	4.0 (1.1)	3.4 (0.9)	3.1 (1.4)	-3.0 (-5.3, 0.8)	-4.8 (-6.6, -2.9)	-3.9 (-5.6, -2.2)	-1.7 (-4.7, 1.2)	0.25	-0.9 (-3.7, 2.0)	0.55
GAD-7¹										
Baseline	4.5 (1.0)	4.8 (0.7)	5.1 (0.7)							
1 month	4.1 (1.0)	3.4 (0.8)	2.8 (1.2)	-0.4 (-2.3, 1.5)	-1.4 (-3.0, 0.1)	-1.7 (-3.1, -0.2)	-1.0 (-3.4, 1.4)	0.41	-1.3 (-3.6, 1.1)	0.29
3 months	3.9 (1.0)	2.8 (0.8)	2.9 (1.2)	-0.6 (-2.5, 1.3)	-2.1 (-3.7, -0.5)	-1.6 (-3.0, -0.1)	-1.5 (-3.9, 1.0)	0.24	-1.0 (-3.3, 1.4)	0.43
PTSS¹										
Baseline	21.4 (2.4)	22.1 (1.8)	21.9 (1.9)							
1 month	20.4 (2.5)	20.5 (2.0)	19.7 (3.0)	-1.0 (-5.4, 3.5)	-1.7 (-5.3, 2.0)	-1.7 (-5.2, 1.7)	-0.7 (-6.5, 5.0)	0.80	-0.8 (-6.4, 4.8)	0.78
3 months	17.9 (2.5)	19.6 (2.1)	19.2 (3.0)	-3.5 (-8.8, 1.0)	-2.6 (-6.3, 1.2)	-2.2 (-5.6, 1.2)	-0.9 (-4.9, 6.8)	0.75	1.3 (-4.4, 7.0)	0.65
PSS-4¹										
Baseline	6.3 (0.8)	5.4 (0.6)	4.4 (0.6)							
1 month	4.8 (0.8)	4.5 (0.6)	7.2 (1.0)	-1.5 (-3.1, 0.2)	-0.9 (-2.1, 0.4)	0.88 (-0.4, 2.1)	0.6 (-1.5, 2.7)	0.56	2.4 (0.3, 4.4)	0.02

3 months	4.8 (0.8)	4.1 (0.6)	6.3 (1.0)	-1.5 (-3.1,0.1)	-1.3 (-2.7, 0.05)	0.02 (-1.2,1.2)	0.2 (-1.9, 2.3)	0.85	1.5 (-0.5, 3.6)	0.1 4
PHQ-10¹										
Baseline	11.0 (0.9)	10.1 (0.7)	10.1 (0.7)							
1 month	7.6 (0.9)	6.9 (0.8)	8.4 (1.2)	-3.4 (-5.4, 1.5)	-3.1 (-4.8, -1.5)	-2.6 (-4.1, -1.1)	0.3 (-2.3, 2.8)	0.66	0.8 (-1.7, 3.3)	0.5 2
3 months	6.3 (1.0)	4.7 (0.8)	7.3 (1.2)	-4.8 (-6.8, 2.7)	-5.3 (-7.0, -3.7)	-3.7 (-5.2, 2.2)	-0.6 (-3.2, 2.0)	0.52	1.1 (-1.5, 3.6)	0.4 1
QOL VAS²										
Baseline	71.8 (4.3)	80.4 (3.3)	74.3 (3.3)							
1 month	72.5 (4.4)	72.9 (3.7)	72.6 (5.7)	0.7 (-8.6, 9.9)	-7.5 (-15.1, 0.2)	0.8 (-6.4,8.0)	-8.1 (-20.2, 3.9)	0.18	0.1 (-11.7, 11.9)	0.9 9
3 months	72.5 (4.5)	77.6 (3.8)	75.0 (5.7)	0.7 (-8.9, 10.1)	-2.7 (-10.6, 5.1)	3.2 (-4.0,10.4)	-3.4 (-15.7, 9.0)	0.59	2.5 (-9.4, 14.5)	0.6 7
CAMS-Mindfulness²										
Baseline	30.1 (1.5)	31.9 (1.1)	31.2 (1.1)							
1 month	30.0 (1.5)	31.0 (1.2)	28.7 (1.8)	-0.1 (-2.9, 2.6)	-0.9 (-3.2, 1.3)	-1.4 (-3.5, 0.8)	-0.8 (-4.4, 2.8)	0.7	-1.2 (-4.7, 2.3)	0.5
3 months	28.8 (1.5)	32.6 (1.3)	29.2 (1.8)	-1.3 (-4.1, 1.5)	0.7 (-1.7, 3.0)	-0.9 (-3.1, 1.3)	1.9 (1.7, 5.6)	0.3	0.4 (-3.2, 3.9)	0.8
Brief COPE²										

Baseline	13.8 (1.0)	14.5 (0.7)	13.0 (0.7)							
1 month	13.1 (1.0)	14.6 (0.8)	15.2 (1.2)	-0.8 (-2.5, 1.0)	0.05 (-1.4,1.5)	1.4 (0.04, 2.7)	0.8 (-1.4,3.1)	0.47	2.2 (-0.04,4.4)	0.0 5
3 months	13.6 (1.0)	14.1 (0.8)	15.2 (1.2)	-0.2 (-2.0, 1.6)	-0.5 (-1.9, 1.0)	1.3 (-0.03, 2.7)	-0.2 (-2.6, 2.1)	0.83	1.5 (-0.7, 3.8)	0.1 8

¹ Negative scores represent improvement

² Positive scores represent improvement

³ Based on general linear models

eTable 6: Mobile mindfulness training group app use as quantified by web analytics

	Mean (SD)	Median (IQR)	Range
Overall			
Number of sessions	15.1 (12.8)	11.0 (5.5, 22)	1 - 46
Session duration, minutes	8.5 (4.5)	7.1 (5.3, 10.5)	0.2 - 20
Average pages/per session	6.2 (3.3)	4.8 (2, 8.7)	3 - 17
Average time on page, minutes	2.0 (1.6)	1.5 (1.2, 2.3)	0.1 - 8
Average screen clicks	188.4 (220.8)	122.5 (57, 251.5)	3 - 1,109
Week 1 audio			
Page views	5.9 (4.8)	4 (2, 7)	1 - 19
Time on page	6.3 (5.4)	4.3 (1.9, 8)	0.4 - 18
Week 2 audio			
Page views	4.0 (3.7)	2 (1, 6)	1 - 15
Time on page	13.1 (23.8)	5.3 (0.3, 9.9)	0.3 - 104
Week 3 audio			
Page views	4.0 (3.1)	3 (0.3, 9.9)	1 - 11
Time on page	11.0 (12.7)	7.6 (5.6, 9.5)	2 - 53
Week 4 audio			
Page views	3.8 (2.1)	3.5 (2, 5.3)	1 - 7
Time on page	10.4 (10.9)	6.9 (4.9, 11.2)	1 - 44

eTable 7: Pearson's correlations between study outcomes and mobile mindfulness group app use characteristics derived from web analytics procedures. *indicates $p < 0.05$.

STATA command: pwcorr phq9change gadchange ptsschange phq10change camschange numberofsessionsperuser pageviews sessions hits wk1sessions wk1avgtime wk2sessions wk3sessions wk3avgtime wk4sessions wk4avgtime, star(0.05)

	phq9ch~e	gadcha~e	ptssch~e	phq10c~e	camsch~e	number~r	pagevi~s
phq9change	1.0000						
gadchange	0.4745*	1.0000					
ptsschange	0.3259	0.6757*	1.0000				
phq10change	0.6810*	0.4009	-0.0054	1.0000			
camschange	0.0388	-0.1655	-0.1838	0.0456	1.0000		
numberofse~r	-0.3209	-0.1752	-0.2342	-0.2195	-0.1310	1.0000	
pageviews	-0.5451*	-0.2948	-0.0794	-0.2824	-0.2029	0.6812*	1.0000
sessions	-0.4619*	-0.0762	0.0003	-0.1937	-0.1458	0.8216*	0.8108*
hits	-0.4944*	-0.1678	-0.1810	-0.2107	-0.1645	0.6449*	0.7216*
wk1sessions	0.0234	-0.0045	0.1687	-0.0023	-0.3821	0.4926*	0.5133*
wk1avgtime	-0.1011	0.0921	0.0496	0.1379	-0.0990	0.4685*	0.3312
wk2sessions	0.0195	0.1643	0.1175	0.2804	-0.1848	0.7172*	0.6470*
wk3sessions	-0.4567	-0.0241	-0.0763	0.1782	0.0356	0.5496*	0.6147*
wk3avgtime	-0.4216	-0.0282	-0.0115	-0.0864	-0.1779	0.5050*	0.5250*
wk4sessions	-0.2286	0.0425	-0.0688	0.1870	-0.0657	0.2236	0.4459
wk4avgtime	-0.3271	0.0450	-0.1291	0.0166	-0.0507	0.6428*	0.2766

phq9change: Change in PHQ-9 score between 3 months and baseline

gadchange: Change in GAD-7 score between 3 months and baseline

ptsschange: Change in PTSS score between 3 months and baseline

phq10change: Change in PHQ-10 score between 3 months and baseline

camschange: Change in CAMS-R score between 3 months and baseline

numberofsessionsperuser: Total number of unique app sessions

pageviews: Total page views in app per user

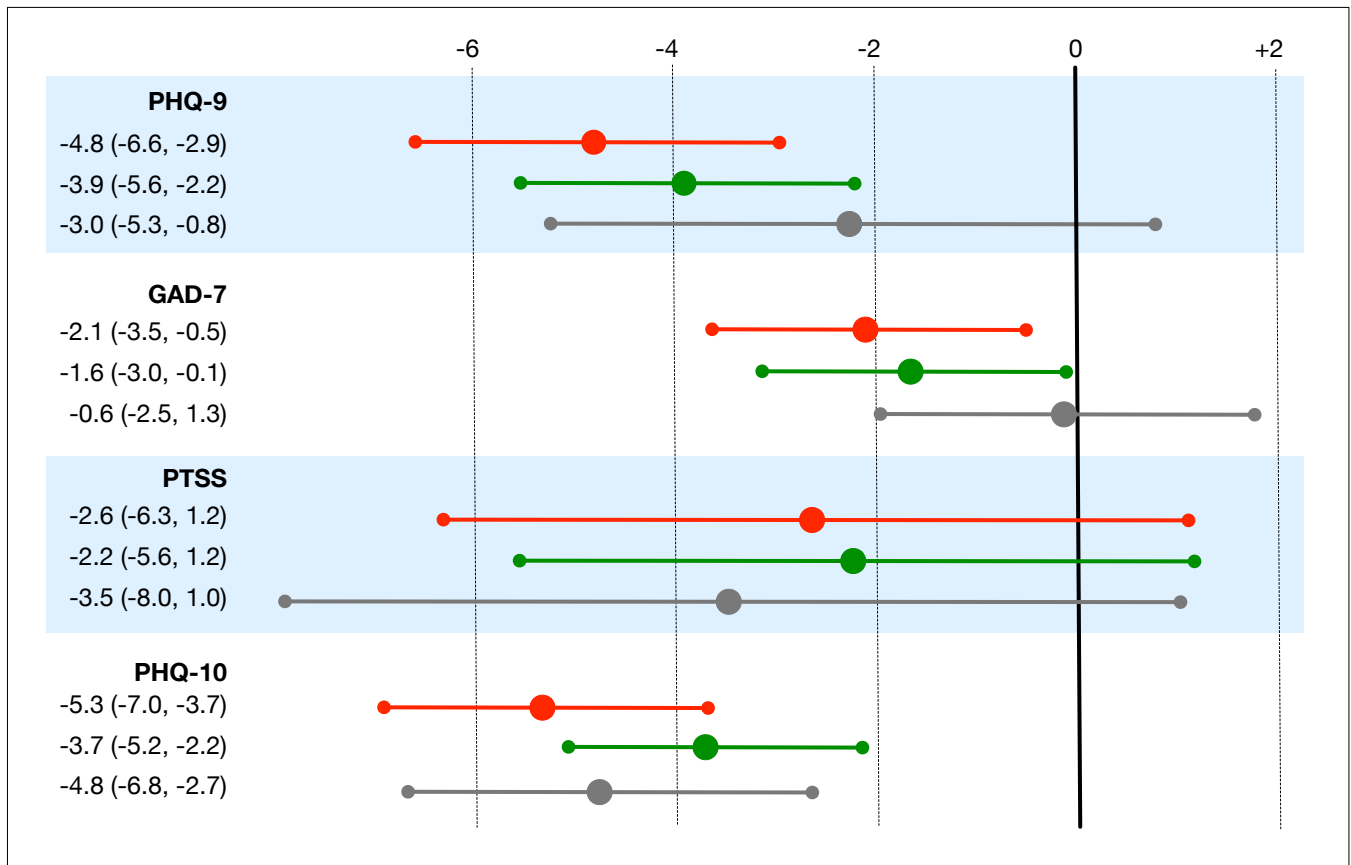
sessions: Time spent with audio sessions

hits: Total number of app pages, sessions, views

wk1sessions (same for weeks 1-4): Total duration of week 1 audio session listened to

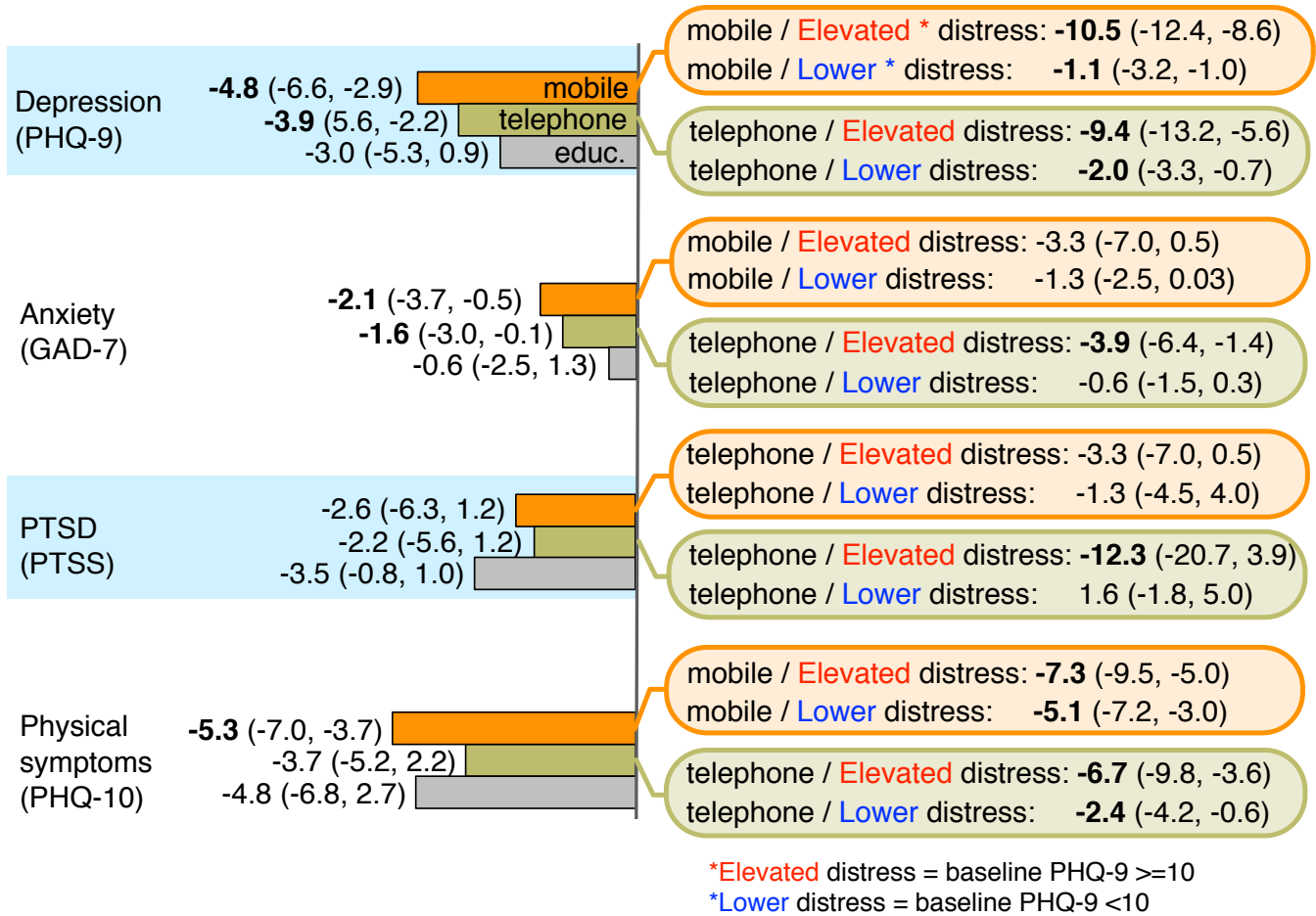
wk1avgtime (same for weeks 1-4): Average duration of week 1 audio sessions per user

eFigure 1: Mean change by group between baseline and 3 months for key secondary outcomes.

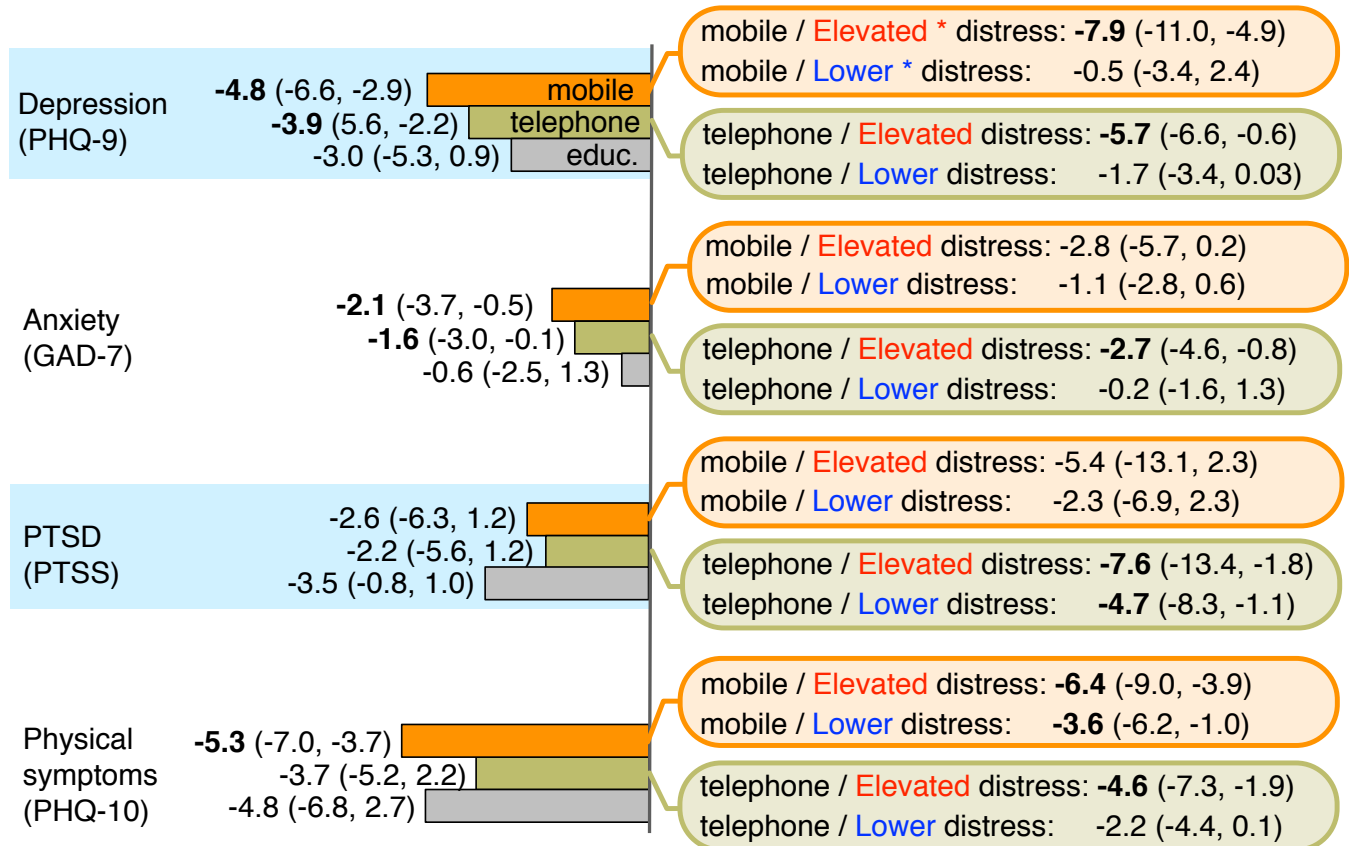


- Mobile mindfulness
- Telephone mindfulness
- Education program

eFigure 2: Exploratory analysis of secondary outcomes by level of baseline distress. For these exploratory descriptive analyses, 'elevated distress' was defined by a baseline PHQ-9 score ≥ 10 . Mean change scores (95% confidence intervals via t statistic) between baseline and 3 months post-randomization. For mobile mindfulness, there were 8 participants with elevated baseline distress and 14 with lower distress. For telephone mindfulness, there were 7 participants with elevated baseline distress and 21 with lower distress.



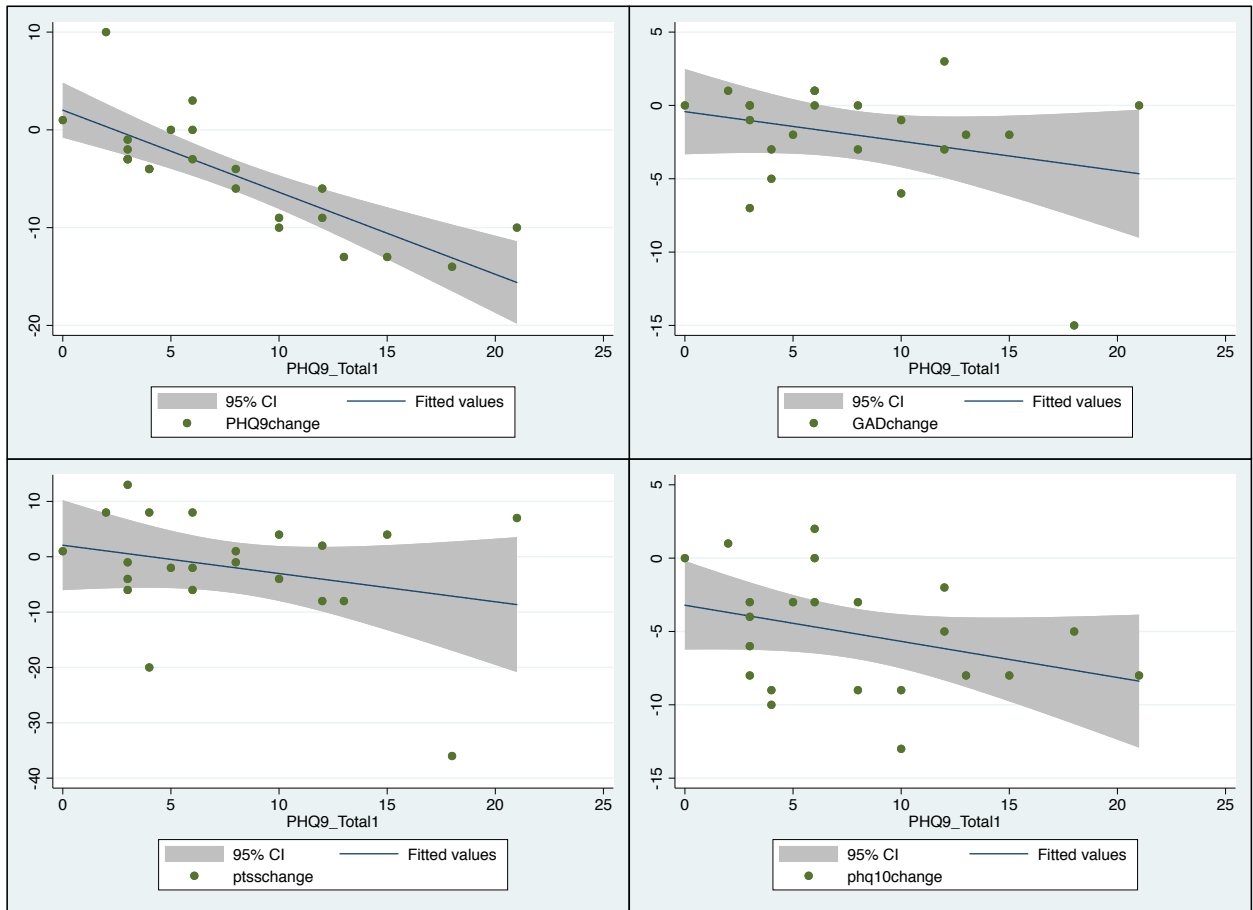
eFigure 3: Exploratory analysis of secondary outcomes by level of baseline distress. For these exploratory descriptive analyses, 'elevated distress' was defined by a baseline PHQ-9 score ≥ 10 or a GAD-7 score ≥ 10 or a PTSS score ≥ 20 . Mean change scores (95% confidence intervals via t statistic) between baseline and 3 months post-randomization. For mobile mindfulness, there were 12 participants with elevated baseline distress and 10 with lower distress. For telephone mindfulness, there were 15 participants with elevated baseline distress and 13 with lower distress.



*Elevated distress = baseline PHQ-9 ≥ 10 or GAD-7 ≥ 10 or PTSS ≥ 20

*Lower distress = baseline PHQ-9 < 10 and GAD-7 < 10 and PTSS < 20

eFigure 4: Two-way scatterplot of baseline PHQ-9 score (x axis) and mean score change between baseline and 3 months (y axis) for secondary psychological distress outcomes measures among mobile mindfulness training group recipients.



C. eReferences

References

1. Porter LS, Keefe FJ, Baucom DH, et al. Partner-assisted emotional disclosure for patients with gastrointestinal cancer: results from a randomized controlled trial. *Cancer* 2009;115:4326-4338.
2. Porter LS, Keefe FJ, Garst J, et al. Caregiver-Assisted Coping Skills Training for Lung Cancer: Results of a Randomized Clinical Trial. *J Pain Symptom Manage* 2010.
3. Attkisson CC, Zwick R. The Client Satisfaction Questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. *Eval Program Plann* 1982;5:233-237.
4. Brooke J. A quick and dirty usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, McClelland AL, editors. *Usability evaluation in industry*. London: Taylor and Francis; 1986.
5. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-613.
6. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-1097.
7. Stoll C, Kapfhammer HP, Rothenhausler HB, et al. Sensitivity and specificity of a screening test to document traumatic experiences and to diagnose post-traumatic stress disorder in ARDS patients after intensive care treatment. *Intensive Care Med* 1999;25:697-704.
8. Kroenke K, Spitzer RL, Williams JB. The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. *Psychosom Med* 2002;64:258-266.
9. Feldman G, Hayes A, Kumar S, et al. Mindfulness and emotion regulation: The development and initial validation of the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R). *Journal of Psychopathology and Behavioral Assessment* 2007;29:177-190.
10. Carver CS. You want to measure coping but your protocol's too long: Consider the Brief COPE. *Int J Behav Med* 1997;4:92-100.
11. Hays RD, Bjorner JB, Revicki DA, et al. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res* 2009;18:873-880.
12. de Jager CA, Budge MM, Clarke R. Utility of TICS-M for the assessment of cognitive function in older adults. *Int J Geriatr Psychiatry* 2003;18:318-324.