ORIGINAL ARTICLE

Effects of mindfulness training programmes delivered by a self-directed mobile app and by telephone compared with an education programme for survivors of critical illness: a pilot randomised clinical trial

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ABSTRACT

Background Patients who are sick enough to be admitted to an intensive care unit (ICU) commonly experience symptoms of psychological distress after discharge, yet few effective therapies have been applied to meet their needs.

Methods Pilot randomised clinical trial with 3-month follow-up conducted at two academic medical centres. Adult (≥18 years) ICU patients treated for cardiorespiratory failure were randomised after discharge home to 1 of 3 month-long interventions: a self-directed mobile app-based mindfulness programme; a therapist-led telephone-based mindfulness programme; or a web-based critical illness education programme.

Results Among 80 patients allocated to mobile mindfulness (n=31), telephone mindfulness (n=31) or education (n=18), 66 (83%) completed the study. For the primary outcomes, target benchmarks were exceeded by observed rates for all participants for feasibility (consent 74%, randomisation 91%, retention 83%), acceptability (mean Client Satisfaction Questionnaire 27.6 (SD 3.8)) and usability (mean Systems Usability Score 89.1 (SD 11.5)). For secondary outcomes, mean values (and 95% CIs) reflected clinically significant group-based changes on the Patient Health Questionnaire depression scale (mobile (−4.8 (−6.6, −2.9)), telephone (−3.9 (−5.6, −2.2)), education (−3.0 (−5.3, 0.8)); the Generalized Anxiety Disorder scale (mobile −2.1 (−3.7, −0.5), telephone −1.6 (−3.0, −0.1), education −0.6 (−2.5, 1.3)); the Post-Traumatic Stress Scale (mobile −2.6 (−6.3, 1.2), telephone −2.2 (−5.6, 1.2), education −3.5 (−8.0, 1.0)); and the Patient Health Questionnaire physical symptom scale (mobile −5.3 (−7.0, −3.7), telephone −3.7 (−5.2, 2.2), education −4.8 (−6.8, 2.7)).

Conclusions Among ICU patients, a mobile mindfulness app initiated after hospital discharge demonstrated evidence of feasibility, acceptability and usability and had a similar impact on psychological distress and physical symptoms as a therapist-led programme. A larger trial is warranted to formally test the efficacy of this approach.

Trial registration number Results, NCT02701361.

Key messages

What is the key question?

► Is a novel, self-directed app a feasible and acceptable approach to overcoming barriers to addressing psychological distress among intensive care unit (ICU) survivors—and work similarly to telephone-based therapy?

What is the bottom line?

► A self-directed mobile mindfulness programme was feasible, well accepted and appeared to reduce psychological and physical symptoms similarly to a telephone-based mindfulness programme and better than an education programme.

Why read on?

► This study highlights numerous issues in the design and conduct of trials designed to reduce psychological distress among ICU survivors that are relevant to both clinicians and researchers alike.

INTRODUCTION

As survival from cardiorespiratory failure has increased over time, so has the recognition that millions of patients who require treatment in intensive care units (ICU) are left with physical symptoms[1–3] and with psychological long-term distress.[4] As many as 66% of acute respiratory distress syndrome (ARDS) survivors report clinically important symptoms of depression, anxiety and post-traumatic stress disorder (PTSD) at 1 year postdischarge.[5–8] Patients have described these symptoms in their own words as daily sources of stress, fear and foreboding, emotional disability and social disruption.[1] However, there are no effective approaches to treating this prominent component of ICU survivors' personal experience of critical illness.[1 9]

In response, we recently developed a telephone-delivered mindfulness-based training programme for ICU survivors, finding in an uncontrolled pilot that it was associated with improved symptoms of depression, anxiety and PTSD.[10] Mindfulness is a learnt practice of non-judgemental awareness that aims to alleviate distress by uncoupling emotional reactions and habitual

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behaviour from unpleasant symptoms, memories, thoughts and emotions.[11 12] Standard mindfulness training, typically provided face-to-face in group settings, has proven efficacious in improving psychological distress in various medical patient populations such as cancer, cardiovascular disease and chronic pain.[13 14] Our telephone-based approach overcame numerous feasibility barriers to in-person therapy presented by ICU survivors' new disabilities, financial distress and great distance from many referral centres.[1 2 15 16] However, recent multicentre trials have demonstrated the challenges of scheduling and delivering psychosocial therapy effectively by telephone,[17] prompting our extension of the mindfulness programme to delivery through a self-directed mobile web app.

The primary purpose of this pilot randomised clinical trial (RCT) was to test the feasibility, acceptability and usability of a novel self-directed mobile mindfulness training app in comparison to both our previous telephone-based approach as well as an ICU education programme control. A secondary goal was to explore the intervention's impact on psychological distress, including symptoms of depression, anxiety and PTSD, as well as distress associated with physical symptoms. Determining if a more flexible and logistically simpler self-directed app approach has a similar impact compared with a more effort-intensive therapist-led approach is critical to planning next-step trials and also to scaling mind-body interventions for widespread use among larger populations.

METHODS

Setting, governance and oversight

Study methodologies and reporting are guided by the 2016 Consolidated Standards of Reporting Trials statement extension to randomised pilot and feasibility trials.[18] The institutional review boards of the participating sites approved the study protocol (online supplement 1). An independent data safety monitoring board approved the protocol and reviewed safety at 6-month intervals.

Enrolment

Between 1 March 2016 and 6 February 2017, research coordinators screened electronic health record systems daily to identify consecutive eligible patients from adult medical, cardiac and surgical ICUs. Inclusion criteria were age ≥18, ICU management for ≥24 hours and cardiorespiratory failure as defined by ≥1 of these criteria: mechanical ventilation via endotracheal tube for ≥12 hours; non-invasive ventilation for acute respiratory failure for ≥4 hours in a 24-hour period; high flow nasal cannula ≥15 L/min or face mask oxygen with a fractional inspired oxygen content ≥0.5 for ≥4 hours; or use of vasopressors, inotropes or an aortic balloon pump for shock for ≥1 hour. Exclusions included pre-existing or current cognitive impairment, treatment for severe mental illness within 6 months of current admission, hospitalised within 3 months of current admission, active substance abuse at admission, expected survival <6 months per ICU attending physician, ICU length of stay ≥30 days, expected discharge to a location other than home, complex medical care expected soon after discharge, poor English fluency and lack of either a reliable smartphone with a data plan or internet plus telephone access (see online supplement 2, pp 1–2).

After obtaining permission from the medical team, research coordinators approached patients for written informed consent after transfer from the ICU to the ward but prior to discharge home. A self-produced 3 min informational video was used to standardise the consent process. Patients were assigned to treatment groups immediately after completion of postdischarge interview 1 (which included a cognition screen), targeted for completion within the first week of arrival home. A computer algorithm allocated participants at a 1.75:1.75:1 ratio (mobile, telephone, education) using simple randomisation for the first 18 participants and then dynamic allocation via a method of minimisation approach[19] to ensure balance across strata including: baseline Patient Health Questionnaire 9-item depression scale (PHQ-9) score (<15 vs ≥15; representing a cut-off of 'moderately severe depression symptoms'), severity of current physical symptom distress (Interview 1 Patient Health Questionnaire 15-item physical symptom scale (PHQ-15) score <10 vs ≥10; representing a cut-off of 'high somatic severity'), age (<50 vs ≥50), ICU service most proximate to enrolment (medical, surgical, cardiac, neurological) and study site. An unequal allocation ratio was used to provide more experience delivering mobile and telephone mindfulness; our education programme has been evaluated in a recent RCT.[17] The three interventions (see online supplement 2, pp 3–4) were targeted to begin immediately after group assignment.

Telephone-based mindfulness training

The goal of both mindfulness programmes evaluated was to help users to be better able to manage distress related to any number of stressors, including their recent critical illness. Each week for a month, a trained psychologist (TG) delivered an ~30 min-long telephone call composed of four previously piloted elements: brief discussion about participants' major current stressor(s); explanation of a didactic element and the rationale for its use; practice and review; and discussion about participant's use of mindfulness skills, challenges in applying the skills and how to maintain progress.[10] The didactic elements included: Session 1: *awareness of breathing*, a core meditation technique that begins to cultivate skills of mindful, non-reactive observation; Session 2: *awareness of body systems* that are working well or less well as a way to continue to cultivate skills of observing, describing and non-judgemental attention; Session 3: *awareness of emotion* and *mindful acceptance*, designed to acknowledge difficult emotions and cultivate feelings of kindness and compassion towards oneself and others; and Session 4: *awareness of sound*, a practice of systematically broadening awareness of senses of sound designed to be an external context to cultivate skills of observing one's experience, letting go and practising non-judgemental awareness. Participants were able to access group-specific complementary video and audio resources on a password-protected study website, as well as a packet of printed information.

Mobile mindfulness training

The therapist (TG) made one introductory telephone call during the patient's first week home to explain the study rationale and to lead a brief (~10 min) mindfulness exercise. Thereafter, the mobile app delivered all the content of the telephone mindfulness programme through a four-session guided series of videos, audio files and interactive text features. Each weekly session included a short (4–5 min) background video, a 6–8 min guided mediation (users could choose either a female or male voice) and interactive suggestions for how to apply mindfulness within their daily routine (~10 min). At the end of each study week, the participant was automatically prompted via email or text (as preferred) to complete the PHQ-9 depression scale survey via a secure electronic patient-reported outcome (ePRO) system integrated with the study data system.[20]

Education programme comparator

The goal of the self-directed web-based education programme, developed and tested by our group,[17] was to provide educational information about the nature and treatment of critical illness, yet no content relevant to psychological distress (see online supplement 2). Education participants received two brief phone calls from a research coordinator at 1 and 3 weeks postrandomisation to answer general questions (eg, troubleshooting the website).

Data collection

Participants were encouraged to self-complete all study surveys via an ePRO system accessible from automated text or email links generated by the study data system. After six emails (1 per 48-hour period) without completion of a 1 or 3-month follow-up survey, the participant was called for its completion by a clinical research coordinator. Participants were compensated $25 for each completed study procedure. Follow-up was completed in June 2017.

Outcome measures

The primary outcomes included feasibility, acceptability and usability. Feasibility was assessed by comparison of observed frequencies to a priori-specified targets of informed consent among eligible patients (70%); randomisation of consented participants (60%)[17]; retention (80%); and among participants who neither dropped out nor died, who completed all interviews (75%), completed all weekly surveys (60%; mobile group only) and completed all intervention sessions (50%). Acceptability was measured with the adapted Client Satisfaction Questionnaire (CSQ),[21] which assesses credibility and satisfaction (range 9 (low) to 36 (highest)). Usability of the mobile app was assessed with open-ended participant feedback and with the 10-item System Usability Scale (SUS; 0 (lowest) to 100 (highest)).[22]

Secondary outcomes included psychological distress symptoms, physical symptoms, mindfulness skills and coping. Depression symptoms were assessed with the PHQ-9, a 9-item scale (range 0 (no distress) to 27 (high distress)); symptom severity is interpreted as mild (5–9), moderate (10–14), moderately severe (15–19) and severe (20–27).[23] Anxiety symptoms were measured using the Generalized Anxiety Disorder 7-item scale (GAD-7; range 0 (no distress) to 21 (high distress)); symptom severity is interpreted as mild (5–9), moderate (10–14) and severe (15–21).[24] The Post-Traumatic Stress Scale (PTSS), a 10-item scale (range 10 (no symptoms) to 70 (high burden of symptoms)), was used to assess PTSD symptoms; >20 represents clinically important symptoms.[25] We assessed quality of life using the EuroQOL 100-point visual analogue scale.[26] The PHQ-15 was used to measure distress associated with physical symptoms (range 0 (none) to 30 (very troublesome)).[27] To evaluate possible mechanisms of intervention effects, we measured mindfulness skills with the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R), a 12-item measure of mindful qualities (range 12 (low ability) to 48 (highest ability))[28] and coping skills with the Brief coping inventory (Brief COPE) (range 10 (low use) to 40 (highest use)).[29] Participants were also given the opportunity to report their greatest stressor at the time of the baseline interview, and then to rate its severity at each subsequent interview (range: 0 (no stress) to 100 (high stress)). During the final survey, we elicited open-ended feedback from the app group about their experience with the programme (questions shown in online supplement 2).

Statistical analysis

The primary aim of this pilot trial was to explore the feasibility, acceptability and usability of mobile mindfulness to inform a definitive future clinical trial. A pragmatic sample size of 90 was chosen not based on formal power calculations, but rather because it represented a cohort large enough to inform the investigators about the potential challenges of delivering an app-based intervention in the context of postdischarge care. Contextual framing of feasibility success was performed by comparing observed versus a priori-stated benchmark percentages by one-sample z-tests for key study milestones such as rates of attrition, adherence to telephone sessions and interview completion across all treatment groups. Similarly, comparison of observed to benchmark means was performed using one-sample t-tests for acceptability (CSQ) and usability (SUS), as well as examination of participant feedback from postintervention semistructured interviews.

An additional aim was to provide meaningful 95% CIs for estimates of effect. For all distress outcomes, we estimated mean changes and corresponding CIs from baseline to each follow-up for each treatment group using general linear models in SAS PROC MIXED (SAS Institute, Cary, NC). Model parameters included treatment arm, indicator variables for the two follow-ups and the treatment arm by time indicator interactions. Models were fit with a compound symmetry correlation between patients' repeated measures. All participant data collected were included in models and analysed according to the original group allocation. Further details, including the statistical code, are provided in online supplement 2, p 6.

RESULTS

Of 121 potentially eligible patients, 90 provided informed consent during hospitalisation and 80 were randomised (site 1 n=48, 60%; site 2 n=32, 40%) after discharge home to mobile mindfulness (n=31, 39%), telephone mindfulness (n=31, 39%) and education (n=18, 22%) (figure 1). The cohort was middle aged (mean age 49.5 (SD 15.1)) and mostly male (n=45, 56%), white (n=53, 66%), previously employed (n=47, 59%), admitted for a surgical or trauma diagnosis (n=55, 69%) and had a mean Acute Physiology and Chronic Health Evaluation II score that approximated a 30% expected hospital mortality rate (table 1; see also online supplement 2 eTables 1 and 2). Though the mean ICU length of stay is similar across groups, there was a greater frequency of shock and ARDS diagnoses in the mobile group.

A total of 190 (88%) of 215 possible data collections were done online via self-report, while the remainder were completed by telephone interviews. Observed primary outcome metrics of feasibility, acceptability and usability met or exceeded benchmark targets (table 2). A total of 66 randomised patients completed the study, representing 83% overall and 89% of those with any postdischarge contact with study staff. Loss to contact and withdrawal were more common in the mobile mindfulness group, although seven (78%) of the nine lost to contact never initiated the intervention (figure 2). Among the 24 mobile mindfulness patients who initiated the app, 93 of 96 (97%) possible weekly app sessions were completed; 22 (92%) completed all four app sessions and all four weekly surveys as determined by app analytics. Similarly, 27 (93%) of telephone and 17 (94%) of education patients completed all intervention sessions. Mean CSQ (27.6 (SD 3.8)) and SUS (86.5 (SD 13.3)) scores demonstrated strong acceptability and usability, findings complemented by generally positive participant feedback (online supplement 2 eTable 4).

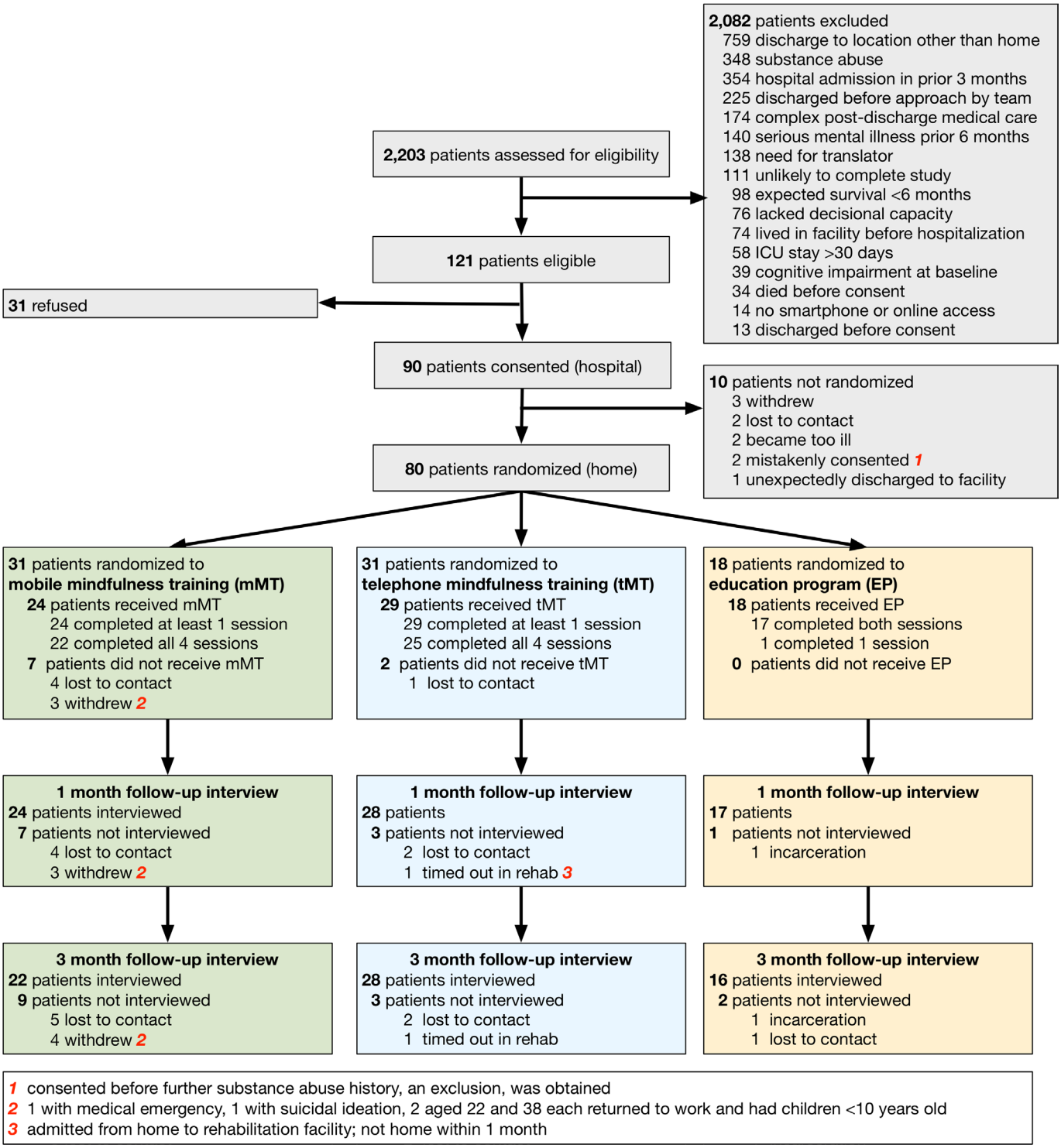

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) diagram for flow of study participants. ICU, intensive care unit.

The full cohort demonstrated mild baseline symptoms of depression and anxiety, as well as mild to moderate PTSD symptoms that did not differ by group assignment (table 3; see also online supplement eTables 5 and 6).[30] In comparison to the education programme (−3.0; 95% CI −5.3 to −0.8), reductions in mean PHQ-9 scores were similar between mobile mindfulness (−4.8; 95% CI −6.6 to −2.9) and telephone (−3.9; 95% CI −5.6 to −2.2) groups at 3 months. This similar impact was consistent across the GAD-7 (mobile mindfulness −2.1 (−3.7 to −0.5); telephone −1.6 (−3.0 to −0.1)), PTSS (mobile mindfulness −2.6 (−6.3 to 1.2); telephone −2.2 (−5.6 to 1.2)) and PHQ-10 (mobile mindfulness −5.3 (−7.0 to −3.7); telephone −3.7 (−5.2 to −2.2)); see also online supplement 2 eFigures 1, 2, 3, and 4. Among education recipients in comparison to the mindfulness groups, there was numerically less impact seen on PHQ-9 (−3.0 (−5.3 to −0.8)) and GAD-7 (−0.6 (−2.5 to 1.3)) scores at 3 months, though similar changes on the PTSS score (−3.5 (−8.0 to 1.0)). The CAMS-R and Brief COPE did not appear responsive to change. Participants' severity ratings for self-named stressors, generally focused on physical and functional concerns, did not improve in any treatment group (see online supplement 2 eTable 3).

Table 1 Baseline characteristics of patients*

	Overall n=80		Mobile mindfulness n=31		Telephone mindfulness n=31		Education programme n=18	
Age, mean (SD), years	49.5	(15.1)	48.7	(15.3)	48.1	(16.1)	53.3	(12.6)
Female gender, n (%)	35	(44)	12	(39)	15	(48)	8	(44)
Race, n (%)								
White	53	(66)	23	(74)	20	(65)	10	(56)
Black	18	(23)	4	(13)	9	(29)	5	(28)
Asian	1	(1)	1	(3)	0	(0)	0	(0)
Native Hawaiian or other Pacific Islander	3	(4)	1	(3)	1	(3)	1	(6)
American Indian/Alaskan Native	4	(5)	2	(7)	0	(0)	2	(11)
Missing/unknown	1	(1)	0	(0)	1	(3)	0	(0)
Hispanic ethnicity, n (%)	5	(6)	0	(0)	4	(13)	1	(6)
Missing/unknown	1	(1)	0	(0)	1	(3)	0	(0)
Highest level of education, n (%)								
High school graduate or less	21	(26)	8	(26)	8	(26)	5	(28)
Trade school or some college	28	(35)	10	(31)	11	(36)	7	(39)
College degree or higher	31	(39)	13	(42)	12	(39)	6	(33)
Employment status in month prior to hospitalisation, n (%)								
Working, homemaker or student full-time	39	(49)	14	(45)	18	(58)	7	(39)
Working part-time	10	(13)	4	(13)	3	(10)	3	(17)
Unemployed	5	(6)	2	(7)	0	(0)	3	(17)
Retired	19	(24)	8	(26)	7	(23)	4	(22)
Disabled	7	(9)	3	(10)	3	(10)	1	(6)
Caring for children at home, n (%)	23	(29)	6	(19)	10	(32)	7	(39)
Insurance status, n (%)								
Commercial or other	43	(54)	16	(52)	17	(55)	10	(56)
Medicare	17	(21)	5	(16)	8	(26)	4	(22)
Medicaid	15	(19)	8	(26)	4	(13)	3	(17)
None	5	(6)	2	(7)	2	(7)	1	(6)
Financial distress, n (%)†	56	(70)	22	(71)	20	(65)	14	(78)
Chronic medical comorbidities, mean (SD)‡	3.1	(3.3)	2.7	(2.7)	2.9	(3.3)	4.2	(4.3)
Treating ICU at time of eligibility, n (%)								
Medicine	25	(31)	10	(32)	9	(29)	10	(56)
Surgery	55	(69)	21	(68)	22	(71)	8	(44)
APACHE II score on day of enrolment, mean (SD)	17.9	(6.8)	18.2	(6.7)	16.9	(5.5)	18.9	(8.9)
Taking at the time of hospital admission, n (%)§								
Antidepressants	18	(23)	6	(19)	7	(23)	3	(17)
Anxiolytics	11	(14)	3	(10)	5	(16)	2	(11)
Other psychiatric medication	1	(1)	0	0	0	(0)	1	(6)
Narcotics	12	(15)	4	(13)	5	(16)	3	(17)
Prescribed at the time of hospital discharge, n (%)§								
Antidepressants	16	(20)	6	(19)	5	(16)	5	(28)
Anxiolytics	10	(13)	3	(10)	4	(13)	3	(17)
Other psychiatric medication	1	(1)	0	(0)	0	(0)	1	(6)
Narcotics	50	(63)	19	(61)	21	(68)	10	(56)
Treated for psychiatric condition since hospital discharge, n (%)	16	(20)	5	(16)	8	(26)	3	(17)
If yes, psychiatric condition, n (%)†								
Depression	7	(44)	1	(20)	4	(50)	2	(67)

Continued

Table 1 Continued

	Overall n=80		Mobile mindfulness n=31		Telephone mindfulness n=31		Education programme n=18	
Anxiety	9	(56)	2	(40)	6	(75)	1	(33)
PTSD	3	(19)	2	(40)	1	(13)	0	(0)
If yes, taking medications, n (%)	15	(94)	4	(80)	8	(100)	3	(100)
If yes, under care of psychiatrist, psychologist or counsellor, n (%)	7	(44)	3	(60)	2	(25)	2	(67)

*Expanded table in online supplement 2.
†See online supplement section 3 for item wording.[17]
‡From Charlson-Deyo Index.[42]
§Multiple responses possible.
APACHE, Acute Physiology and Chronic Health Evaluation; PTSD, post-traumatic stress disorder.

In the mobile mindfulness group, the frequency and duration of app use correlated with improvement in distress symptoms (see online supplement 2 eTables 6 and 7). For example, depression symptom improvement (ie, PHQ-9 score change) was correlated with number of pages viewed per session (r=−0.54), number of screen clicks per app session (r=−0.49) and number of app sessions viewed overall (r=−0.46). Depression symptom improvement had a stronger correlation with activity in the later stages of the intervention (r=−0.42 (week 4)) compared with earlier stages (r=0.02 (week 1)).

DISCUSSION

In this multicentre pilot RCT, we found support for the feasibility, acceptability, usability and impact on psychological distress of a novel self-directed mindfulness training programme delivered by a mobile app. Importantly, mobile mindfulness performed similarly to therapist-led mindfulness training programme and generally better than an education programme. Mobile mindfulness therefore appears to show promise as a scalable patient-centred approach to addressing ICU survivors' widely prevalent psychological distress that can also overcome many postdischarge access to care barriers these patients experience.

As mindfulness grows in general popularity and evidence accrues for its efficacy,[31–34] the delivery of mindfulness content by a mobile web app accessible on any digital device could become an attractive approach for providers and patients alike. The self-directed (though app-guided) nature of mobile mindfulness meets many patients' stated preference for convenience and flexibility at a time when they are re-entering home, work

Table 2 Feasibility, acceptability and usability

	Target % or mean	All patients n (%) or mean (SD)	P values*	Mobile mindfulness n (%) or mean (SD)	Telephone mindfulness n (%) or mean (SD)	Education programme n (%) or mean (SD)
Feasibility						
Eligible participants who consented	≥70%	90 (74%)	0.33	NA	NA	NA
Consented participants who were randomised	≥60%	80 (91%)†	<0.0001	NA	NA	NA
Randomised participants who dropped out						
Overall		14 (18%)		9 (29%)	3 (10%)	2 (11%)
Before intervention initiated		9 (64%)		7 (78%)	2 (66%)	0
After intervention initiated		5 (36%)		2 (22%)	1 (34%)	2 (100%)
Participants who completed all interviews‡	≥75%	66 (83%)	0.0984	22 (71%)	28 (90%)	16 (89%)
Participants who completed all weekly surveys‡	≥60%	NA	0.004	17 (89%)	NA	NA
Participants who completed all intervention sessions‡	≥50%	NA	<0.0001	22 (92%)	27 (93%)	17 (94%)
Acceptability						
CSQ score, mean	≥10	27.9 (3.7)	<0.0001	27.6 (3.8)	29.4 (3.3)	25.7 (3.2)
Usability						
SUS score, mean	≥80	NA	0.03*	86.5 (13.3)	NA	NA
Number of participant clicks on website§	NA	NA		188.4 (220.8)	NA	NA

*P values reflect the two-sided test of the difference between target percentages or means for all patients with the exception of the mean SUS score, which reflects comparison to the mobile mindfulness group alone.
†Denominator is 88 because of two consented who mistakenly met exclusion criteria; see figure 2.
‡Among eligible participants who neither dropped out nor died.
§Using Google analytics; also see online supplement 2.
CSQ, Client Satisfaction Questionnaire; NA, not applicable; SUS, Systems Usability Scale.

Figure 2 Patient intervention adherence and study completion by treatment group. This figure displays adherence status as well as reasons for non-adherence by treatment group as well as reasons for missed sessions for all study groups. Each circle represents one patient. The number of sessions completed by each patient is indicated on the horizontal axis.

and family demands while also navigating recovery from a life-threatening condition.[35] It is important to note that adherence and retention for mobile mindfulness was substantially higher than that observed in a recent telephone-based coping skills training programme for ICU survivors of similar length.[17] From the trialist's perspective, a self-directed therapy overcomes logistical barriers associated with telephone-based interventions delivered from unfamiliar area codes to patients spread across multiple time zones.

This RCT also provides numerous lessons about how to improve mobile mindfulness and its delivery. First, though participants' feedback on the app was positive, patients' constructive feedback highlighted targets for further enhancing usability including more interactive features and enhanced visualisation

Table 3 Model-estimated means and mean differences over time in psychosocial outcomes between groups

	Model-estimated means (SE)*			Mean change from baseline (95% CI)		
Outcome and time point	Education†	Mobile mindfulness‡	Telephone mindfulness§	Education†	Mobile mindfulness‡	Telephone mindfulness§
PHQ-9¶						
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 to 0.9)	−3.8 (−5.6 to −1.9)	−2.4 (−4.2 to −0.7)
3 months	4.0 (1.1)	3.4 (0.9)	3.1 (1.4)	−3.0 (−5.3 to 0.8)	−4.8 (−6.6 to −2.9)	−3.9 (−5.6 to −2.2)
GAD-7¶						
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 to 1.5)	−1.4 (−3.0 to 0.1)	−1.7 (−3.1 to −0.2)
3 months	3.9 (1.0)	2.8 (0.8)	2.9 (1.2)	−0.6 (−2.5 to 1.3)	−2.1 (−3.7 to −0.5)	−1.6 (−3.0 to −0.1)
PTSS¶						
Baseline	21.4 (2.4)	22.1 (1.9)	21.9 (1.9)			
1 month	20.4 (2.5)	20.5 (2.0)	19.7 (3.0)	−1.0 (−5.4 to 3.5)	−1.7 (−5.3 to 2.0)	−1.7 (−5.2 to 1.7)
3 months	17.9 (2.5)	19.6 (2.1)	19.2 (3.0)	−3.5 (−8.0 to 1.0)	−2.6 (−6.3 to 1.2)	−2.2 (−5.6 to 1.2)
PHQ-15¶						
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 to 1.5)	−3.1 (−4.8 to −1.5)	−2.6 (−4.1 to −1.1)
3 months	6.3 (1.0)	4.7 (0.8)	7.3 (1.2)	−4.8 (−6.8 to 2.7)	−5.3 (−7.0 to −3.7)	−3.7 (−5.2 to −2.2)
QOL VAS**						
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 to 9.9)	−7.5 (−15.1 to 0.2)	0.8 (−6.4 to 8.0)
3 months	72.5 (4.5)	77.6 (3.8)	75.0 (5.7)	0.7 (−8.9 to 10.1)	−2.7 (−10.6 to 5.1)	3.2 (−4.0 to 10.4)
CAMS-R**						
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 to 2.6)	−0.9 (−3.2 to 1.3)	−1.4 (−3.5 to 0.8)
3 months	28.8 (1.5)	32.6 (1.3)	29.2 (1.8)	−1.3 (−4.1 to 1.5)	0.7 (−1.7 to 3.0)	−0.9 (−3.1 to 1.3)
Brief COPE**						
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 to 1.0)	0.05 (−1.4 to 1.5)	1.4 (0.04 to 2.7)
3 months	13.6 (1.0)	14.1 (0.8)	15.2 (1.2)	−0.2 (−2.0 to 1.6)	−0.5 (−1.9 to 1.0)	1.3 (−0.03 to 2.7)

*Based on general linear models; no adjustment for covariates. Model-estimated means are based on all patients, not just those with observations at 1 and 3 months.
†n=18 at baseline, n=17 at 1 month and n=16 at 3 months.
‡n=31 at baseline, n=24 at 1 month and n=22 at 3 months.
§n=31 at baseline, n=28 at 1 month and n=28 at 3 months.
¶Negative scores represent improvement.
**Positive scores represent improvement.
Brief COPE, Brief coping inventory; CAMS-R, Cognitive and Affective Mindfulness Scale-Revised Mindfulness instrument; GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health Questionnaire 9-item depression scale; PHQ-10, Patient Health Questionnaire 10-item physical symptom scale; PHQ-15, Patient Health Questionnaire 15-item physical symptom scale; PTSS, Post-Traumatic Stress Scale; QOL VAS, quality of life 100-point visual analogue scale.

of progress over time. Our data closely linking the frequency, quality and duration of app use with reduction in depression symptoms demonstrate the importance of optimising user engagement as a means to improve adherence, retention, dose and effect.[36 37]

Second, while the self-directed mobile mindfulness programme had a favourable effect on symptoms, uncommon for a comparative web-based therapy,[36 38] the telephone group had slightly better adherence and retention. Though the retention of participants is significantly better than that observed in a similarly structured mobile coping skills training intervention conducted among ICU patients,[17] further study is required to understand the two approaches' possible trade-offs (eg, personalisation, dose, costs, scalability), as well as to determine the value of an initial motivational interview at kick-off or targeted therapist interaction during the mobile intervention (eg, non-responders with persistent or increasing symptoms over time).[39]

Third, some study design elements that may have diluted the comparative effects of mobile mindfulness. Patients were randomised regardless of distress level,[40] similar to recent approaches, because we hypothesised that distress may increase during follow-up due to persistent financial, social and medical stressors. However, in a recent RCT we found a concentration of psychosocial intervention effect among only ICU survivors with elevated baseline distress.[11] That trial also showed that the ICU survivor-specific education control also used in the current mindfulness trial had an active effect on 3-month distress. Furthermore, despite less improvement in distress compared with the mobile mindfulness group, the education group had a lower prevalence of shock and ARDS and returned to normal duties

over 2 weeks earlier. Last, the relatively mild baseline distress across groups may have contributed to an impact-limiting floor effect.

This pilot study has notable limitations. First, the small sample limits the precision and the generalisability of results as well as our ability to understand the impact of clinical and demographic variables. Second, while the results are compelling, this pilot study was not designed to evaluate efficacy. Third, though postrandomisation dropout was higher in the mobile mindfulness group, most of it occurred before patients either had contact with study staff or used the app. While likely due to chance, the small sample size limits a better understanding of differential attrition. Last, while there is not clear consensus about an optimal duration for a mindfulness programme, our strategy that emphasised convenience, a relatively brief period of daily guided meditation (10 min) and a brief intervention duration is shorter than most.[41] However, short durations can be effective[34] and may be an attractive way to foster self-care behaviours for this unique population.

CONCLUSIONS

A self-directed, four-session postdischarge mindfulness programme for ICU survivors delivered by a mobile app was feasible, acceptable and usable, and demonstrated evidence for impact on psychological distress that was similar to a therapist-delivered mindfulness programme. Further study is warranted to understand the mobile app's most impactful elements, to further optimise its usability and to determine its long-term efficacy.

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