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## Development and preliminary evaluation of a telephone-based coping skills training intervention for survivors of acute lung injury and their informal caregivers

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## Abstract

**Purpose**—Survivors of acute lung injury (ALI) and their informal caregivers have difficulty coping with the physical and emotional challenges of recovery from critical illness. We aimed to develop and pilot test a telephone-based coping skills training intervention for this population.

**Methods**—58 participants were enrolled overall. 21 patients and 23 caregivers participated in a cross-sectional study to assess coping and its association with psychological distress. This also informed the development of an ALI coping skills training intervention in an iterative process involving content and methodological experts. The intervention was then evaluated in 7 patients and 7 caregivers in an uncontrolled, prospective, pre-post study. Outcomes included acceptability, feasibility, and symptoms of psychological distress measured with the Hospital Anxiety and Depression Scale (HADS) and Post-Traumatic Symptom Scale (PTSS).

**Results**—Survivors and their caregivers used adaptive coping infrequently, a pattern that was strongly associated with psychological distress. These findings informed the development of a 12-session intervention for acquiring, applying, and maintaining coping skills. In the evaluation phase, participants completed 77 (92%) of a possible 84 telephone sessions and all (100%) reported that the intervention's usefulness in their daily routine. Mean change scores reflecting improvements in the HADS (7.8 units) and PTSS (10.3 units) were associated with adaptive coping (r=0.50–0.70) and high self-efficacy (r=0.67–0.79).

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**Conclusions**—A novel telephone-based coping skills training intervention was acceptable, feasible, and may have been associated with a reduction in psychological distress among survivors of ALI and their informal caregivers. A randomized trial is needed to evaluate the intervention.

#### Keywords

coping; acute lung injury; behavioral therapy; quality of life

### INTRODUCTION

Acute lung injury (ALI) is a common critical illness associated with long-term multisystemic disability and compromised life quality.[1–3] As a component of this dysfunction, ALI survivors experience clinically important symptoms of psychological distress including depression, anxiety, and post-traumatic stress disorder (PTSD) at rates that exceed population averages by 5 to 10 fold.[4–7] As many as 70% of their informal caregivers (family or friends) also experience symptoms of distress as well.[8, 9] However, there are few treatments designed to address this population's distress and barriers to conventional post-discharge face-to-face follow up including distance, financial stress, and physical disability.[3, 10]

Coping is as an adaptive response aimed at diminishing the physical, emotional, and psychological burden that is linked to stressful life events and daily challenges such as the lived experience of ALI survivorship.[11] Although ALI survivors describe coping ability as central to their overall well being,[3] it is unclear how frequently they use adaptive coping skills such as relaxation, cognitive restructuring, positive reframing, problem solving to alter illness-relevant thoughts, and seeking social support (Online Table 1). Similarly, seriously ill patients often report low self efficacy, defined as confidence in one's ability to perform a specific behavior or task such as coping.[12] Because maladaptive coping and low self-efficacy are associated with psychological distress, these may be important intervention targets for critical illness survivors.

Coping skills training programs have been successful in reducing psychological distress.[13, 14] However, to our knowledge, they have not been tested in the setting of critical illness. Therefore, we aimed to explore the use of coping among ALI survivors and their informal caregivers, develop an ALI-specific coping skills training program informed by these findings, and then prospectively evaluate the program's feasibility, acceptability, and impact on symptoms of psychological distress.

#### METHODS

#### Overview

This study had two components, a development phase and an evaluation phase (Figure 1). In the *development phase*, we assessed coping and its associations with distress in a cross-sectional study of critically ill patients and their caregivers. This information was subsequently used to develop an ALI-specific coping skills training program. In the *evaluation phase*, we explored the coping skills training program's feasibility, acceptability, and clinical impact in an uncontrolled, pre-post design prospective study. All study participants were recruited between 2009–2010 from Duke University Hospital, Durham Regional Hospital, the Hospital of the University of Pennsylvania, and Harborview Hospital at the University of Washington. Each patient and caregiver was compensated US \$25 (( $\in$  20) for the time spent in the study.

#### **Development phase**

**Participants**—Clinical research coordinators screened medical and surgical ICUs daily for eligible consecutive patients, defined as those who received ventilation for 4 days and were

18 years of age. Exclusions were lack of informal caregiver, baseline dementia, brain injury or acute stroke, need for a translator because of poor English fluency, or expected survival <3 months by the attending ICU physician. We enrolled one informal (i.e., unpaid) caregiver per patient, defined as the person 18 years of age who expected to provide the most post-discharge patient assistance. Caregiver exclusions were cognitive disorder, dementia, and English fluency poor enough to require a medical translator.

Data collection and study variables—We gathered clinical data from medical charts. [15] Questionnaires administered by telephone were used to assess study outcomes. We assessed psychological distress using the Hospital Anxiety and Depression Scale (HADS). [16] Depression or anxiety domain scores 7 reflect significant symptoms and a change in score of ~2 units reflects the minimal clinically important difference.[17, 18] Post-traumatic stress disorder symptoms were assessed using the Post-Traumatic Symptom Scale (PTSS). [19] Scores 34 reflect clinically significant symptoms. We used the Brief COPE to measure the frequency of adaptive coping skills (active coping, self-distraction, humor, planning, positive reframing, instrumental support, use of emotional support) and maladaptive coping (denial, substance use, behavioral disengagement, venting, acceptance, and self-blame).[20] We measured self-efficacy with a standard scale in which participants rate their ability to self-manage (for patients) or assist in managing (caregivers) psychological distress, symptoms, and function.[21] Quality of life was assessed with a 100-point visual analog scale.[22] We measured acceptability for a future coping skills intervention by asking patients and informal caregivers if they believed such a program would be a useful way to address their post-discharge concerns about physical and psychological stresses (agree/ disagree). Additionally, development phase participants responded to open ended questions about general themes that should be included in a potential "supportive telephone treatment program" and provided feedback on preferred ways to optimize the participation of caregivers in such an intervention.

**Derivation of the coping skills training program**—We aimed to develop a coping skills training intervention to: (a) teach participants a variety of coping strategies for managing the emotional distress and multisystemic symptoms (e.g., weakness, dyspnea, pain) related to ALI and (b) teach the caregiver how to help the patient acquire, apply, and maintain coping skills.[23, 24] We based the intervention's format and content on coping skills interventions with proven efficacy,[13, 14, 24, 25] ALI outcomes studies,[26–28] our past qualitative study of the critical elements of ALI survivors' and families' post-discharge lived experience, and input from development phase study participants.[3] Through an iterative feedback process involving multiple face to face and electronic meetings, investigators summarized common themes related to emotional distress in ALI and used these themes to develop an ALI coping skills training treatment manual, a therapist telephone script, a participant guidebook, and handouts. The intervention was structured in a way that ensured the patients were taught how to apply learned skills to deal with specific thematic issues.

#### **Evaluation phase**

**Participants**—In this prospective evaluation of the coping skills training program, we screened study ICUs for patients in a manner identical to the development phase, with the exception that we limited patient enrollment to consensus-defined ALI with mechanical ventilation for 48 hours; caregiver criteria were identical.[29] By limiting enrollment to ALI, we aimed to focus on a population that shared a similar clinical problem (i.e., severe

**Intervention**—The coping skills training intervention was initiated within two weeks of arrival to home, a period of time that ranged from two weeks to six weeks post-discharge. Our development phase suggested that this strategy would successfully address concerns about early, reversible cognitive deficits. Interview sessions were conducted throughout the 12-week period by one registered nurse at the Duke study site with extensive experience providing both clinical care and similar interventions among medical populations with serious illnesses. Patients and caregivers participated in weekly sessions together, either with a speaker phone or three-way calling, and at various times of the day or early evening when most convenient for them. The interventionist received additional coping skills instruction by two experienced coping skills training providers (LSP, FJK) as well as training in ALI outcomes. Study investigators reviewed selected audio recordings of sessions to assess treatment adherence and provide feedback to the interventionist.

**Data collection and study variables**—Research coordinators who were not involved in the intervention administered the HADS, PTSS, Brief COPE, self-efficacy, and acceptability instruments described above by telephone twice to patients and caregivers. The first interview was conducted during the week before the initiation of the intervention, while the second interview was performed within one week after its completion (i.e., 12 weeks after intervention initiation). During the second interview, acceptability was addressed by recording participants' comments to an open ended prompt for general feedback on the intervention and its perceived usefulness to them. The feasibility of the coping skills program was measured using rates of enrollment, retention, and completion of scheduled telephone sessions.

**Statistical analyses**—We present categorical data as numbers (percent) and continuous data as means (SDs) or medians (interquartile ranges [IQRs]). We also performed Pearson's correlations between HADS, PTSS, Brief COPE, and self-efficacy scale scores to explore the association between psychological distress and coping. We used Stata, version 11 (College Station, TX) for all analyses. Institutional Review Boards at all study sites approved the study procedures and all participants provided written consent. Portions of this data have been presented previously in abstract format.[30]

## RESULTS

#### **Development phase**

**Cross-sectional assessment of coping and psychological distress**—A total of 34 medical and surgical ICU survivors and their informal caregivers were assessed for eligibility. A total of 23 ICU survivors (35% with ALI) and 23 informal caregivers completed the development phase of the study (Table 1). Six patients didn't meet inclusions, four patients died before the study interview (causing two caregivers to decline further participation), and two caregivers and one patient refused to participate (Figure 1). Participants were middle aged (median age 58), seriously ill (median APACHE II 25), represented a mix of medical (68%) and surgical (32%) diagnoses, and experienced long hospital stays (median 28 days). Thirteen (57%) caregivers were spouses, 3 (13%) were adult children, 2 were parents (8%), and 5 (22%) were friends or more distant family members. Although patients were discharged from hospital to home (24%), skilled nursing

facilities (24%), inpatient rehabilitation (14%), or transferred to another facility (14%) all were at home at the time of the study interview.

Patients frequently reported significant symptoms of depression (58%), anxiety (66%), and post-traumatic stress (58%) (Table 2). Caregivers reported similar symptoms, though somewhat less frequently. All participants demonstrated low coping ability in at least one Brief COPE domain, while half had low overall coping. Infrequent use of adaptive coping was associated with symptoms of depression (r=0.30–0.75), anxiety (r=0.32–0.72), PTSD (r=0.36–0.80), and quality of life (r=0.39–0.66). Low overall level of coping ability was strongly associated with symptoms of depression (r=0.75), anxiety (r=0.72), and PTSD (r=0.80). These findings supported the validity of targeting coping to reduce psychological distress.

**Derivation of the coping skills training program**—The final coping skills training program consisted of 12 weekly, 30-minute telephone sessions, a dose of caregiver-assisted coping skills training that is generally adequate to demonstrate clinically meaningful reductions in psychosocial distress.[31, 32] The session outline, treatment manual, and participant handouts are shown in the Online Supplement.

#### **Evaluation phase**

We enrolled 10 ALI survivor-informal caregiver dyads in the evaluation component of the study (Figure 1). Three enrolled dyads did not begin the intervention: one patient died before hospital discharge, one was readmitted and withdrew consent, and one was lost to follow up before intervention initiation. All participants lived at home throughout the study period and were diverse in age, race and ethnicity, and gender (Table 1). Most participants were married couples.

Feasibility was supported by the fact that all 14 subjects who began the intervention protocol completed it, participating in 77 (92%) of a possible 84 intervention telephone sessions. Acceptability was supported by participants' unanimous report that they utilized the coping skills taught and that these skills were useful in addressing their post-discharge concerns about critical illness-associated stresses and disabilities. Mean total HADS and PTSS scores decreased overall, though more among patients than informal caregivers (Figure 2). Mean HADS scores improved 2 units for most participants in depression (6 patients [86%] and 5 [71%] caregivers) and anxiety (5 patients [71%] and 6 [86%] caregivers) domains. The number of patients with a clinically important burden of PTSD symptoms (PTSS 34) decreased from 5 [67%] at baseline to 1 (17%) post-intervention. Although the sole caregiver that had clinically important PTSD symptoms experienced a reduction in PTSS score, the overall PTSS score remained greater than 34. Mean self-efficacy scores improved by 17 units (SD 26) overall, and 18 units (SD 33) and 15 units (SD 20) among patients and caregivers, respectively. Improvement in total HADS and PTSS scores was highly correlated with improvement in self-efficacy (r=0.67-0.79) as well as adaptive coping styles including emotional support (r=0.52-0.59), acceptance (r=0.50-0.62), and active coping (r=0.36-0.62) 0.70).

## DISCUSSION

This study demonstrates two key findings. First, we observed that ineffective coping is common among critical illness survivors and their informal caregivers, confirming our past qualitative research, and is a behavior associated with psychological distress.[3] Second, we found that a novel telephone-based coping skills training intervention was feasible, acceptable, and may have been associated with reductions in psychological distress that

exceeded improvements that critical illness survivors generally experience over a similar time period.[33–36]

As ALI survival improves, there is an increasing number of patients that suffer from physical and psychological disability—disability that is pervasive, persistent, and important. [1, 37] The ability to cope with this disability during the slow process of recovery is a skill that is closely associated with psychological well being and quality of life. However, coping skills may be particularly inadequate in the context of the ALI experience because of complicated factors such as extreme situational stress, the often sudden and overwhelming nature of critical illness, and tendencies toward denial. Although adaptive coping skills have been taught in other serious conditions,[13, 14] our study is novel because it introduces such a training program to survivors of critical illness and their families.

Our coping skills training intervention has several qualities that are attractive in ALI. First, while prior attention has focused on the hospital setting, this intervention shows promise for improving survivorship during the longer post-discharge period in which there are few effective therapies. Second, this intervention can address the significant burden of psychological distress suffered by both patients and their informal caregivers.[8, 9, 38–40] Third, telephone-based interventions are relatively inexpensive, can easily be scaled by insurers and health systems, and do not require participants to leave their homes.[41] Because psychological distress is associated with increased health care costs, days of disability, and lost productivity, psychological interventions have potential to lower healthcare resource utilization by proactively addressing symptoms.[42–46]

This study has several limitations. First, it is an uncontrolled preliminary study without longterm follow up, and as such does not establish the efficacy of coping skills training. These results should be interpreted cautiously because of the relatively small sample size, the limited number of study centers, and the lack of formal qualitative data on the specific benefits that recipients attributed to the intervention. Also, we do not have a complete view of what specific factors (e.g., education level, stress, pre-morbid psychiatric condition, degree of relationship to the caregiver) were related to individuals' maladaptive coping abilities. However, our informal qualitative assessments did not suggest underlying ameliorative factors such as the routine prescription of psychiatric medications during follow up. Also, individuals themselves may differ in their baseline coping skills and disability, and therefore the efficacy of our intervention could vary across participants. Second, the generalizability of these results for practitioners beyond the US is unclear. There may be considerable US-European differences in severity of patient illness, post-discharge state-based support for informal caregivers, cultural expectations, variability in regulation of psychological therapies and provider credentialing, as well as the delivery of critical care itself.[47] Additionally, the outcomes questionnaires we used are not well validated in some languages spoken by the readers of this journal. Although our findings appear promising, a multicenter randomized control trial is needed to test whether coping skills training is both effective for individuals and cost-effective for societies. We estimate that using conservative baseline HADS scores (18, SD 9), it would require between 200 (power=80%, two-sided  $\alpha=0.05$ ,  $\rho=0.4$ ) to 260 (power=80%, two-sided  $\alpha=0.05$ ,  $\rho=0.2$ ) patients to demonstrate a 4unit improvement. Such as sample size would provide a power exceeding 80% to show a 6unit difference in PTSS scores as well (two-sided  $\alpha = 0.05, \rho = 0.4$ ). Further research should explore how cognitive and physical dysfunction may mediate the intervention effect, as well as how the intervention can be efficiently targeted to address particularly stressful symptoms or transition points (e.g., return to work or school) during recovery.[48, 49]

In summary, we developed a novel telephone-based coping skills training intervention for ALI survivors and their informal caregivers that was feasible, well accepted, and may have

reduced psychological distress. Further research is needed to establish the intervention's efficacy, its applicability to populations of critical illness beyond ALI, its optimal timing of initiation, and its long-term effects on patients, caregivers, and resource utilization.

#### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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#### Figure 1. Study overview

This study consisted of two components, a development phase and an evaluation phase. The development consisted of an assessment of the relationship between psychological distress and coping, as well as the derivation of a coping skills training intervention. The prospective evaluation used an uncontrolled, pre-post intervention design to assess the intervention's feasibility, acceptability, and clinical impact using validated measures of psychological distress. HADS=Hospital Anxiety and Depression Scale, PTSS=Post-Traumatic Symptom Scale, COPE=Brief COPE scale.

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## Figure 2. Preliminary results of pilot prospective evaluation of the coping skills training intervention

In this figure, both pre-intervention (dark bars) and post-intervention (light bars) scores for the HADS (total score as well as anxiety and depression domain scores) and PTSS questionnaires are shown for patients (n=7) and their informal caregivers (n=7).

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#### Table 1

## Characteristics of study population

	Cross-sectional study		Evaluation study	
Characteristic	Patient (n=21)	Caregiver (n=23)	Patient (n=7)	Caregiver (n=7)
Age	56 (47, 74)	66 (43, 80)	50 (43, 67)	52 (45, 64)
Female	12 (57%)	13 (57%)	4 (57%)	4 (57%)
White	14 (67%)	16 (70%)	2 (29%)	3 (43%)
Relationship				
spouse		13 (57%)		6 (86%)
other		10 (43%)		1 (14%)
Education > high school	9 (39%)	9 (39%)	1 (14%)	1 (14%)
APACHE II	25 (18, 31)		26 (24, 38)	
Diagnosis				
medical	11 (52%)		6 (86%)	
surgical	10 (48%)		1 (14%)	
Mechanical ventilation days	10 (6, 21)		9 (7, 19)	
Length of stay, days				
Intensive care unit	19 (10, 25)		12 (9, 20)	
Hospital	28 (18, 50)		22 (17, 45)	

Data in table shown as number (percent) or median (interquartile range).

#### Table 2

Outcomes at six weeks post-discharge in development phase study

	Patients (n=21)	Caregivers (n= 23)
HADS—depression	7 (6, 10)	5 (4, 7)
Significant depression *	12 (58%)	5 (22%)
HADS—anxiety	9 (7, 10)	7 (5, 8)
Significant anxiety $\dagger$	14 (66%)	11 (48%)
PTSS	32 (26, 36)	26 (21, 34)
Significant PTSD symptoms $\ddagger$	12 (58%)	7 (30%)
Quality of life $§$	70 (35, 75)	60 (29, 83)
Poor coping on 1 Brief COPE subscale **	21 (100%)	23 (100%)
Poor coping on 7 Brief COPE subscales **	14 (66%)	12 (52%)

Values are median (IQR) or *n* (percent).

\*Significant symptoms of depression defined by HADS-depression score 7;

 $^{\dagger}$  Significant symptoms of anxiety defined by HADS-anxiety score 7;

 $\ddagger$  Significant symptoms of post-traumatic stress defined by PTSS score 34;

 $^{\$}$  Assessed by visual analog scale ranging from 0 (worst possible quality of life) – 100 (best possible quality of life);

\*\* Brief COPE subscale score <3