Feasibility, Acceptability, and Preliminary Efficacy of
VidaTalk™ Communication Application with Family Caregivers
of Mechanically Ventilated ICU Patients

Dissertation

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Abstract

Background & Purpose: Family caregivers of critically ill patients are at high risk of developing adverse psychological outcomes such as anxiety, depression, and post-traumatic stress disorder (PTSD). Family caregivers of mechanically ventilated (MV) patients in the ICU also experience difficulty communicating with MV patients. However, little is known about patient-family communication in the ICU and the associated emotional distress. The goal of this pilot study was to assess the feasibility, acceptability, and preliminary efficacy of a newly developed evidence-based electronic communication application, VidaTalk™ among ICU family caregivers and explore family member communication experience, perceptions of the VidaTalk™, and emotional reactions to the communication.

Methods: This study used a mixed-methods design with repeated measures nested within an existing randomized controlled trial (RCT). The intervention group received the VidaTalk™ application whereas the attention control (AC) group received a standard electronic tablet format during the patient's MV treatment in the ICU. Participants completed Family Visitation Logs during the study period to track their ICU visits and tablet usage during each visit. Family caregiver perceived communication difficulty (Family Communication Scale [FCS]), anxiety (Hospital Anxiety and Depression Scale [HADS] – anxiety subscale), and depressive symptoms (HADS-depression) were measured at baseline, at extubation/ICU discharge, and 1-, 3-, and 6-months post-ICU discharge. PTSD-related symptoms (Impact of Event Scale-revised [IES-R]) were measured at 1-, 3-, and 6-months post-ICU discharge. Semi-structured qualitative interviews were performed with family caregivers in the VidaTalk™ group. Feasibility was determined by recruitment rate, retention rates, and number of ICU visits (≥ 3 days per week).

Acceptability was measured by reported use of VidaTalk™ and qualitative evaluation of the VidaTalk™. t-tests were used for group comparisons for anxiety and depression, and Mann-Whitney U tests were used for PTSD-related symptom comparisons.

Results: Thirty four family caregivers of MV ICU patients participated in the study. Analyses indicated that the VidaTalk™ was feasible and acceptable for family caregivers during the ICU stay. The VidaTalk™ and AC groups were not significantly different regarding anxiety, depression, and PTSD-related symptoms across all time points. Although no statistically significant difference was found, the VidaTalk™ application was associated with medium effect size in anxiety symptom reduction ($d = 0.42$) at 1-month. The VidaTalk™ group had lower PTSD-related symptoms with a medium-to-large effect size ($\eta^2=0.09$) at 3-months. The qualitative data indicated that, overall, the families had a positive experience with the VidaTalk™, found it helpful to communicate with MV patients, and experienced both positive and negative emotions while communicating with the patients. Family's perceptions of the VidaTalk™ clustered into seven main themes: 1) satisfaction with the VidaTalk™, 2) communication message content, 3) difference in communication before and after using the VidaTalk™, 4) conditions for using VidaTalk™, 5) other communication methods, 6) barriers to using the VidaTalk™, and 7) suggestions.

Conclusions: VidaTalk™ was found to be both feasible and acceptable as a patient-family communication tool during the ICU stay. Families had overall positive perceptions of communication with nonvocal ICU patients during MV treatment using the VidaTalk™.

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Chapter 1: Introduction

Introduction

A stay in an intensive care unit (ICU) can be a highly stressful event, for both patients and their family caregivers. Family members of ICU patients are at high risk of developing adverse psychological outcomes including anxiety, depression, stress-related disorders, and complicated grief (Davidson, Jones, & Bienvenu, 2012). A recently developed term, post-intensive care syndrome–family (PICS-F), refers to a cluster of symptoms that are common among informal caregivers of intensive care unit (ICU) patients. (Davidson, Hopkins, Louis, & Iwashyna, 2013). Among those psychological problems, depressive symptoms are most commonly reported with estimated prevalence ranging from 16 to 90% (van Beusekom, Bakhshi-Raiez, de Keizer, Dongelmans, & van der Schaaf, 2016). Reported prevalence of symptoms of anxiety and PTSD in family caregivers are also high at 42-80% and 35-50% respectively (Petrinec & Daly, 2016; van Beusekom et al., 2016).

Critical illness is characterized by unpredictability, uncertainty, and the instability of patient condition. While the exact etiology of PICS-F in the process of exposure to critical illness remains unclear, its development is likely dependent on a number of factors. Communication difficulty is one of the most common burdens reported by ICU patients during MV (Nelson et al., 2004; Rotondi et al., 2002). Communication difficulty during MV is associated with negative feelings such as anger, frustration, fear, anxiety, insecurity, and powerlessness for patients (Carroll, 2004; Engstrom, Nystrom, Sundelin, & Rattray, 2013; Karlsson, Forsberg, & Bergbom, 2010; Khalaila et al., 2011; Menzel, 1998; Patak, Gawlinski, Fung, Doering, & Berg, 2004; Patak et al., 2006; Rotondi et al., 2002; Tolotti et al., 2018) and anxiety, feelings of loss, and

frustration for family caregivers (Broyles, Tate, & Happ, 2012; Dreyer & Nortvedt, 2008; Engstrom & Soderberg, 2004; Happ, 2000). These feelings may induce or worsen the adverse psychological outcomes such as anxiety, depression, and PTSD. Despite the importance of family communication, no studies to date have explored the relationship of communication between ICU patients and their family caregivers and psychological outcomes for family caregivers.

Communication is an important interaction between patients and family caregivers. However, little is known about communication between nonvocal ICU patients and their family caregivers. Few qualitative studies to date have explored the family caregiver communication experience with nonvocal MV patients in the ICU (Agard & Harder, 2007; Alasad & Ahmad, 2005; Broyles et al., 2012; Engstrom & Soderberg, 2004; Hupcey & Penrod, 2000). Family caregivers have only simple, low-tech tools, if any, available in the ICU (Broyles et al., 2012). Despite a lack of evidence or support for patient-family communication, clinicians report relying on family caregivers to provide interpretation of nonvocal communication when ICU patients are unable to speak (Engstrom & Soderberg, 2007; Happ, 2000; Magnus & Turkington, 2006). Therefore, there is a need for effective communication tools to promote communication between MV patients and family caregivers and to test the effect of the tool on family caregiver's adverse psychological outcomes.

This PhD dissertation study was a longitudinal pilot study using a mixed-methods design nested within a Phase II small business technology transfer research (STTR) study (Happ, 2016-2018). In the Phase I study, Happ and colleagues successfully defined the basic user requirements and product specifications for a prototype iPad version of VidaTalk™ (Happ, Walaszek, et al., 2014). VidaTalk™ is a touchpad communication application (app) that is

designed to provide MV patients an evidence-based solution to communicate their needs to care providers and family caregivers. The Phase I study confirmed the feasibility of VidaTalk™ as a potential solution for selected MV patients to communicate their needs. The Phase II STTR study aimed to test acceptability, usability and clinical efficacy of an updated, android version of VidaTalk™ with MV patients. The primary goal of this dissertation study, designed as a companion study to the clinical trial, was to test the effect of the VidaTalk™ patient communication app for android tablet computers on adverse psychological outcomes in family caregivers of MV patients in the ICU.

Specific Aims

This study addressed the following specific aims:

Aim #1 Determine the feasibility and acceptability of VidaTalk™ communication intervention in family caregivers of MV patients during their ICU stay. Completion of this aim provided important data on feasibility of recruitment, retention, and family participation in this intervention research and the acceptability of VidaTalk™ as an intervention for ICU family caregivers during and following ICU stay.

Aim #2 Test preliminary efficacy of VidaTalk™ compared to attention control (AC) on anxiety and depression symptoms in family caregivers during the ICU stay and post-discharge (1-mos; 3-mos; 6-mos) and PTSD-related symptoms post-discharge. Completion of this aim provided preliminary evidence regarding the potential efficacy of VidaTalk™ as an intervention to prevent or alleviate adverse psychological outcomes such as anxiety, depressive symptoms, and PTSD-related symptoms in family caregivers following the ICU admission and MV of a family patient.

Aim #3 Examine the role of the family caregiver's perceived communication difficulty in moderating the effects of VidaTalk™ on the caregiver's psychological symptoms. Completion of this aim was intended to provide preliminary evidence about the moderating effect of communication difficulty between MV patients and their family members on adverse psychological outcomes such as anxiety, depressive symptoms, and PTSD-related symptoms in family caregivers.

Aim #4A Explore the family caregiver's perceptions of communication with VidaTalk™ app. Completion of this exploratory aim via qualitative analysis of family caregivers' narratives provided better understanding of the family caregiver's communication experience with the patient using the VidaTalk™, and how the VidaTalk™ influenced their communication with a family member/patient in the ICU.

Aim #4B Explore the family caregiver's emotional experience in communicating with a patient family member during critical illness and MV treatment. Completion of this aim via qualitative data analysis provided an understanding of the family caregiver's emotional reactions to communication with the family patient before and after using the VidaTalk™.

Theoretical Framework

The Facilitated Sensemaking Model

This study is guided by the Facilitated Sensemaking Model (FSM) which is a recently developed middle range theory that provides a basis for the design of family-centered interventions in the ICU (Davidson, 2010). The FSM was derived deductively from a

combination of Roy's Adaptation Model (RAM) (Naga & Al-Atiyyat, 2009) and Weick's Organizational Sensemaking Theory (WOST) (Weick, 1995). Table 1 shows the theoretical underpinnings of the FSM. The roots of sensemaking are also evident in social and cognitive psychology, specifically self-regulation theory (Leventhal & Johnson, 1983). The FSM was also developed through inductive methods including review of evidence from the literature, consultation with content experts and family members during the development of the intervention set, and input from doctoral students, professors, and clinical nurse specialists during the validation process (Davidson, 2010).

The primary goal of the model is to guide nursing interventions to prevent adverse psychological outcomes in family members of ICU patients. The FSM assumes that exposure to critical illness is a life crisis for family members (Davidson, McDuffie, & Kay, 2018). Due to the unplanned and serious nature of critical illness, family caregivers encounter coping challenges. After the disruption, family caregivers need a compensation period to overcome the challenges in the new situation. They need to make sense of what has happened and discover their new roles as ICU caregivers (Davidson, 2010; Davidson, Daly, Agan, Brady, & Higgins, 2010). During this compensation period, family caregivers desire information and the nurse can engage in and facilitate the sense-making process through directed interventions. The nurse can assist the family with understanding the ICU environment, identifying and meeting their unmet needs, providing family support, and engaging them in bedside activities (Davidson, 2010; Skoog, Milner, Gatti-Petito, & Dintyala, 2016).

According to the model, a facilitated sensemaking intervention has two main goals: 1) to help the family understand what is happening in the new situation and 2) to coach what the

family should do as a caregiver of ICU patients. The nurse engages the family caregivers in the sensemaking process through a series of specific nursing interventions. Such sensemaking interventions include identifying the family members' needs, providing information about the prognosis or care plan, providing family support, coaching the family how to meet their own needs, and guiding bedside activities that they can perform while they visit their loved one in the ICUs (Skoog et al., 2016). Family members may be healthier and able to adapt to the situation in the positive way if they meet the sensemaking goals. The FSM assumes that how nurses deal with ICU family caregivers may have a long-term impact on them and structured nursing intervention for family caregivers may minimize negative feelings such as fear and helplessness in families, further, decrease PICS-F (Davidson et al., 2018).

The FSM provides suggestions on bedside activities in two categories (Davidson, 2010): 1) personal care/healing, and 2) bringing normalcy into the room. Personal care activities include applying lip balm, giving a massage, assisting in passive range-of-motion exercises, praying, and engaging in cognitive exercises. The other group of activities includes reading aloud, talking about daily events, bringing in cards/pictures from home to bring normalcy into the room which may help the patient feel relieved as a distractor or re-engaging the patient in life outside of the critical illness. The sensemaking process will finally lead to adaptation which is described in the model as lower adverse psychological outcomes. Sensemaking should be an iterative process. A nurse must readdress the sensemaking process as the patient's condition changes over time, and make sure that the family caregivers are receiving consistent messages from the care providers (Davidson, 2010).

Application and Adaptation of the FSM in Communication Intervention

My application of the FSM to the problem of communication difficulty is depicted in Figure 1. The FSM has not previously included a patient-family communication component in the model, but it is a logical extension. Thus, this application of the FSM to patient-family communication during MV represents an adaptation of the model to address this identified gap and important patient-family care need. The rationale and theoretical substruction for this study are presented below (table 2) and in a paper currently under review for publication (Shin, Tate, & Happ, in review).

Communication difficulty due to MV treatment is an unplanned and sudden event that may cause psychological distress in family caregivers of nonvocal MV patients. The VidaTalk™ communication app is an intervention developed to improve communication between nonvocal patients and others. A communication intervention may facilitate the family caregiver's sensemaking process to compensate for the disruption and adapt to the new situation. Communication distress is expected to be relieved in nonvocal ICU patients and family caregivers by providing strategies to allow the patients and their families to communicate with each other.

The FSM has not been tested for the impact of patient-family caregiver communication on psychological outcomes in family caregivers. I hypothesized that the VidaTalk™ communication intervention will reduce the incidence of adverse psychological outcomes in the family caregiver and/or alleviate those symptoms through two main mechanisms. First, the VidaTalk™ intervention will help family caregivers meet the first sensemaking goal: *to make sense of what has happened in the ICU*. The VidaTalk™ may help family caregivers meet their

own needs for effective communication with the patient to understand the patient's situation, feelings/thoughts, and what they are experiencing. This will help families adapt to the new situation. Second, the VidaTalk™ tablet app may serve as a bedside activity (second sensemaking goal) that family caregivers can perform while visiting their loved one in the ICU. More effective communication may facilitate the family caregiver's bedside activities as they better understand the patient's expressed needs. Moreover, the VidaTalk™ app contains several prepared messages pertaining to *personal care and healing* activities such as patients' basic needs, symptoms, feelings, and emotions. This feature of the VidaTalk™ may facilitate family caregiver's bedside activities while communicating with the patient using the tool. This tool may also allow the family caregivers to *bring normalcy into the room* by talking about daily events with more effective conversational communication with VidaTalk™ than with usual nonvocal communication methods.

Summary

The FSM is the only model that considers specific interventions to improve ICU family caregivers' adverse psychological outcomes. Although previous studies revealed the significance of those psychological outcomes in family caregivers, there has not been an adequate model describing this phenomenon. The FSM is the first model explaining this phenomenon and guiding nursing actions to improve family caregivers' coping and adjustment. The FSM, as a middle range theory, is directly applicable to patient-family communication in the ICU. Since the FSM did not originally address communication between patients and family caregivers, I extended the model by adding a patient-family communication component. Because of its

testability, clarity, and comprehensive consideration of crisis, experience, interventions, and psychological outcomes specifically for the population of ICU family caregivers, it is valuable to guide research on short- and long-term psychological outcomes in family caregivers of ICU patients.

The FSM has not been tested for a communication intervention and the mechanisms between communication difficulty and psychological outcomes in family caregivers are not explicated in previous studies. Therefore, I included a qualitative portion in my study to explore family caregivers' experiences with VidaTalk use, and their emotional reactions to communication with their nonvocal patient during care in the ICU. The results may confirm or suggest further revisions in the model for future use of the theory in communication research.

Innovation and Significance

This dissertation study will fill a gap in family-centered care in the ICU by exploring an understudied phenomenon, the communication experience between nonvocal patients and family caregivers during MV. This is important considering the frequency and magnitude of psychological distress experience by ICU family caregivers. Family- patient communication is an essential interaction for the family caregivers to interpret their loved one's experience of critical illness and understand emotional reactions and thoughts of the family patient. VidaTalkTM was specifically developed to help MV patients effectively communicate with care providers and family. When a patient touches one of the icons, the message is produced audibly via digital speech and the text of the message is displayed on the screen, which enables two-way communication between the patient and others.

To date, there has been no published study to investigate a communication intervention to improve ICU patient-family communication or to examine the impact of communication difficulty perceived by family caregivers on their psychological symptoms. This dissertation study was designed to address this gap by providing a high-tech communication tool for ICU family caregivers to effectively communicate with patients. To our knowledge, this study is the first to test the effect of a communication tool as a potential solution to help family caregivers reduce PICS-F.

Table 1. Theoretical Underpinnings of the FSM

	Central Propositions		Adaptation to the FSM
Combination of RAM and WOST by Davidson while developing the FSM	Roy's Adaptation Model (RAM)	<ul style="list-style-type: none">· The goal of nursing is to promote a person's adaptation whose life is disrupted such as illness.· Illness can cause a disruption in life, and adaptation occurs when people respond to the new environment in a positive way.	<ul style="list-style-type: none">· The FSM follows the adaptation theory premise that family caregivers experience a life disruption which requires a compensatory process to adjust to the disruption and adapt to the new circumstances of a family member's critical illness and their role as ICU family caregivers.
	Weick's Organizational Sensemaking Theory (WOST)	<ul style="list-style-type: none">· Leaders help others form a perception of a crisis event and make sense out of the situation.· Leaders can help others in the workplace with cue sorting to shape a positive impression of the situation.	<ul style="list-style-type: none">· Nurses proactively take cues from the environment and help the family caregivers sort those cues appropriately to make sense of what is going on.
Sensemaking in psychology social and cognitive	Self-regulation Theory	<ul style="list-style-type: none">· Concrete, clear objective information facilitates coping by affecting the person's schema formation about stressful events such as illness.· A schema based on concrete objective information can focus a person's attention away from the emotional dimensions of an impending experience leading to reduced emotional distress during the stressful experience.	<ul style="list-style-type: none">· The FSM follows the self-regulation theory premise that facilitated sensemaking help family caregivers reduce psychological symptoms by making sense out of what happened and their new roles as caregivers in the ICU environment.

Table 2. Theoretical Concepts and Measurements

Concepts	Variables	Measurements / Tools	
Disruption	Critical Illness (ICU admission)	·ICU length of stay / MV days ·Severity of illness	·Medical Records
	Communication Difficulty	·Family perceptions of communication difficulty	·Family Communication Survey (FCS)(Happ, Roesch, & Garrett, 2004)
Compensation (Facilitated Sensemaking)	Communication Intervention (VidaTalk™ tablet communication app)	·Intervention exposure/dose ·Family's experience of the intervention	·Family Visitation Log ·Qualitative interview
Adaptation	Adverse psychological outcomes	·Anxiety ·Depression ·PTSD-related symptoms	·Hospital Anxiety and Depression Scale (HADS) (Snaith, 2003) ·Impact of Event Scale – revised (IES-R)(Weiss & Marmar, 1995)

Figure 1. Facilitated sensemaking concept map for the effect of communication intervention on adverse psychological outcomes in family caregivers of MV patients.

Chapter 2: Literature Review

Background

Due to the sudden nature of critical illness and its long-term sequelae, family caregivers of critically ill patients experience various challenges during and after the ICU hospitalization. There are several possible etiologies for psychological distress in ICU family caregivers such as the potential loss of a loved one, emotional burden associated with an integral role in decision-making and patient care, insufficient information and lack of communication, and the social and economic impact of hospitalization (Azoulay et al., 2005; Long, Kross, & Curtis, 2016; Myhren, Ekeberg, & Stokland, 2011; Wendler & Rid, 2011). In this challenging situation, family caregivers may misinterpret events, experience undue stress, fear, or grief, and tend to stop taking care of their own emotions or health (Davidson et al., 2010).

Post-intensive care syndrome – family (PICS-F) is defined as new onset or worsening physical, cognitive, or psychological impairments in family caregivers arising after their loved one's critical illness and persisting after ICU care (Davidson et al., 2018). Among those impairments, psychological symptoms are common adverse outcomes in family caregivers of critically ill patients. Investigators first recognized that family caregivers of the ICU patients could have clinically diagnosable psychological problems in the early 1990s (Pérez-San Gregorio et al., 1992). Since then, there has been growing interest in the impact of critical illness on family caregivers. The keys to family-centered care are a beneficial relationship between family caregivers, patients, and the care providers, family presence, and family involvement in decision making and patient care (Davidson et al., 2018). Clinical practice guidelines for support of family-centered care in the ICU (Davidson et al., 2017; Davidson et al., 2007) address a need

for more structured family support interventions to reduce anxiety, depression, and post-traumatic stress in ICU family caregivers.

Family Caregiver's Psychological Burden

Previous research examining the short- and long-term adverse psychological outcomes in family caregivers of critically ill patients support that the impact of critical illness on family caregivers can be profound and may last for years. Table 2 shows the reported prevalence of depression, anxiety, and PTSD-related symptoms among ICU family caregivers (Haines, Denehy, Skinner, Warrillow, & Berney, 2015; Johnson et al., 2019; Petrinc & Daly, 2016; van Beusekom et al., 2016).

Table 3. Summary of reported prevalence of adverse psychological outcomes among ICU family caregivers

Adverse Psychological outcome	During ICU	3 months	6 months	1 year	2 years
Depression ^a	16 – 97%	12 – 26%	5 – 36%	23 – 44%	
Anxiety ^a	42 – 81%	24 – 63%	15 – 24%		
PTSD ^b	33 – 81%	30 – 52%	35 – 57%	32 – 80%	12 – 14%

^aHaines et al., 2015; van Beusekom et al., 2016; Johnson et al., 2019

^bHaines et al., 2015; van Beusekom et al., 2016; Petrinc et al., 2016; Johnson et al., 2019

The reported prevalence of psychological symptoms varied within a wide range, which may be due to multiple factors such as small sample sizes, convenience samples, different settings, different study designs, different measurement tools with various cut-offs, patient eligibility criteria, or the definition of family caregivers. Despite these limitations, the reported prevalence of adverse psychological outcomes in family caregivers of ICU survivors was high compared to other populations. The reported short- and longer-term prevalence of post-ICU depressive symptoms in ICU families (25-41.3% at two months and 22.8-43% at one year after the ICU discharge) was higher than the lifetime prevalence in the general population (8-15%) (Richards, 2011). The prevalence of short- and longer-term anxiety symptoms (47.9-73.4% during the ICU admission; 15% at six months after the discharge) were comparable with the estimated prevalence of anxiety in dementia caregivers, ranged between 3.7-76.5% (Cooper, Balamurali, & Livingston, 2007). Although the PTSD diagnostic criteria require precedence of a traumatic event and at least one-month duration of symptoms after the traumatic event (American Psychiatric Association, 2013), several studies measured PTSD-related symptoms during the ICU stay as an indication of traumatic stress or baseline for comparison with longitudinal measurements. The prevalence of PTSD was also much higher than the estimated lifetime prevalence of PTSD among adult Americans (6.8%) (Kessler et al., 2005).

Several studies identified patient and/or caregiver-related factors associated with adverse psychological outcomes for ICU family caregivers. More depressive symptoms in family caregivers were associated with younger patient age, severe illness referring to a high Simplified Acute Physiology Score II (SAPS II), patient death, and residence of the patient after the ICU discharge (i.e., institutionalization) (Choi et al., 2012; Douglas, Daly, Kelley, O'Toole, & Montenegro, 2005; Pochard et al., 2005). Caregiver factors associated with high level of

depressive symptoms include female gender, younger age, lower educational level, being a spouse, less social support, and more perceived burden (Cameron et al., 2016; Choi et al., 2013; Choi et al., 2012; Pochard et al., 2005). Identified risk factors associated with higher anxiety symptoms in family caregivers of ICU patients include being a spouse of a patient, female sex, younger patient age, and higher SAPS II scores (McAdam, Dracup, White, Fontaine, & Puntillo, 2010; Paparrigopoulos et al., 2006; Pochard et al., 2005). Factors associated with high level of PTSD-related symptoms included female sex of family caregiver, younger family caregiver age and younger patient age, patient's death, and patient receiving mechanical ventilation during the ICU care (Azoulay et al., 2005; Dithole, Thupayagale-Tshweneagae, & Mgutshini, 2013; Garrouste-Orgeas, Coquet, Perier, et al., 2012). Severe PTSD-related symptoms were associated with higher levels of anxiety and depression (Azoulay et al., 2005; de Miranda et al., 2011; Paparrigopoulos et al., 2006). A cross-sectional study conducted by Azoulay and colleagues (2005) examined prevalence and risk factors for PTSD using multivariate linear modeling. They found a higher level of PTSD-related symptoms in families who thought information regarding the patient's condition provided in the ICU was incomplete, those who shared in end-of-life decisions, and those whose relative died in the ICU or after an end-of-life decision (Azoulay et al., 2005).

Most previous studies relied on standardized self-report measurement tools as screening instruments, rather than valid methods for obtaining a clinical diagnosis. Moreover, time frames used to measure the symptoms were inconsistent across studies, which makes it difficult to compare and synthesize the findings. Despite limitations, the findings still indicate that family caregivers of ICU patients experience high levels of psychological symptoms including depression, anxiety, and PTSD-related symptoms throughout the ICU stay and long after the ICU

discharge. A standardized tool to assess PICS-F needs to be developed. Knowing that psychological symptoms are prevalent in ICU family caregivers, early signs of adverse psychological outcomes should be screened routinely in the early period of ICU care. Some caregiver-related risk factors such as female gender, being a spouse, and younger age were commonly reported across studies and also similar to other populations (Schoenmakers, Buntinx, & Delepeleire, 2010). Identifying those factors will help screen for the family caregivers who are at high risk of development of adverse psychological outcomes and develop an effective intervention for family caregivers in future studies.

Interventions for Family Caregivers' Psychological Symptoms

Despite alarming data on the high prevalence of the adverse psychological outcomes including anxiety, depression, and PTSD in family caregivers of ICU patients, only a few interventions have been developed and tested to improve those outcomes. To date, three types of interventions have been tested to prevent or reduce psychological symptoms in family caregivers of ICU patients: ICU diary, information and educational program.

An ICU diary is one strategy developed and implemented to reduce the psychological distress in ICU survivors. ICU diaries are designed to provide a story of the patient's ICU stay, including background on the cause of the patient's ICU admission and day-to-day activities in narratives (Aitken et al., 2013; Egerod, Schwartz- Nielsen, Hansen, & Lærkner, 2007). Diaries are generally written by nurses, other hospital staffs or family caregivers during the ICU care. As a focus for family empowerment and family-centered care in the ICUs, several studies involving ICU diaries encouraged the participation of the family caregivers. Several studies investigated

the effect of an ICU diary on family caregiver's psychological outcomes as well as patients' outcomes, yet the results are mixed. Kloos and Daly (2008) conducted a quasi-experimental study to determine the effect of a family-maintained progress journal (FMPJ) on the level of anxiety symptoms in 160 family caregivers of patients in the ICU. The diary (FMPJ) was designed for family members to record information and write about feelings. Family members in this study ($n = 78$) maintained the FMPJ as well as received the usual care information from care providers (control group condition). The results showed a significant reduction in anxiety scores from pre-test to post-test for all participants, however, there was no significant difference between the intervention and control groups (Kloos & Daly, 2008).

Garrouste-Orgeas and colleagues (2012) assessed the impact of an ICU diary written by both family members and ICU staff on the psychological well-being of patients and family members using a prospective three group sequential cohort design: pre-diary (control), diary (intervention group) and post-diary(control) (Garrouste-Orgeas, Coquet, Perier, et al., 2012). The results indicated a high prevalence of PTSD-related symptoms in family caregivers in all three study groups at 12-month follow-up, however, the variation across three groups was statistically significant. The intervention group showed a significant reduction in PTSD-related symptoms compared to other two controls. In a pilot study to test whether providing an ICU diary to patients and their relatives reduced the level of PTSD-related symptoms in the close relatives (Jones, Backman, & Griffiths, 2012), all patients in the study had an ICU diary written by the staff with contributions of family members during the ICU care. The intervention group ($n=15$) received their diary as soon as they wanted before two months after ICU discharge, whereas the control group ($n=15$) received their diary after completion of the 3-month follow-up post-ICU discharge. The family members of the patients who received their diary between one and two

months after the ICU discharge (intervention group) had decreased PTSD-related symptoms compared with the equivalent controls. The results of this pilot study suggest that an ICU diary outlining the patient's ICU stay on a day to day basis and delivered to patients and family caregivers within 2 months after discharge may help reduce the level of PTSD-related symptoms in their close family members. Possible explanations for the effectiveness of a diary include: the diary may help the patient and their family members fill in the gap in their memories, facilitate communication about the treatment of the patient and family members, and allow family members to express their feelings by writing in the diary during the ICU stay (Jones et al., 2012).

Several information-related interventions were developed and tested to inform family caregivers about the care, diagnosis, or prognosis of their family in the ICU. A randomized controlled trial to test the effectiveness of a 6-week self-help ICU recovery manual on psychological distress in close families of patients following ICU care (Jones et al., 2004). The participants in the intervention group (n=58) were introduced jointly to the ICU rehabilitation manual which contains advice on areas such as nutrition, what to expect when the patient goes back home, and exercise, as well as relaxation and stress coping for family members. The control group (n=46) received general verbal information about recovery from critical care. The results showed a high incidence of psychological distress in family caregivers, but there was no statistically significant difference in depression, anxiety, and PTSD-related symptoms between study groups. A prospective randomized controlled trial compared the effectiveness of information about the prognosis of critically ill patients delivered to family caregivers by junior (n= 92) versus senior physicians (n=93) (Moreau et al, 2004). The primary outcome was comprehension of information, and the secondary outcomes included satisfaction and anxiety and depression symptoms in family caregivers. The results showed no significant difference in

comprehension, satisfaction, and psychological outcomes between two groups. (Moreau et al., 2004).

A more recent RCT investigated the impact of proactive nurse participation in physician-led ICU family conferences on psychological symptoms in family caregivers of ICU patients (n=42) compared to a control group (n=44) who participated in physician-led ICU conferences without a nurse (Garrouste-Orgeas et al, 2016). In the intervention group, the physician explained information about the patient's diagnosis, care plan, and prognosis while the nurse described the patient's condition at the bedside, information about pain, and other sources of distress. The results showed significantly lower levels of anxiety and depression in the intervention group compared to the control, but no difference in prevalence of PTSD-symptoms (Garrouste-Orgeas et al., 2016). A recent study conducted by Curtis and colleagues (2016) tested the effect of a communication-facilitator intervention on family caregivers' psychological symptoms, patients' ICU and hospital length of stay and costs of care. In this study, a trained nurse or social worker was involved as a communication facilitator or navigator to improve communication about goals of care and palliative care discussions between the ICU team and families of critically ill patients (Curtis et al., 2016). The intervention was associated with a reduction in depression symptoms among family caregivers at six months after the ICU discharge. However, there were no significant differences in depressive symptoms at three months or anxiety or PTSD symptoms at both three and six months after the discharge (Curtis et al., 2016).

Among the seven studies reviewed, three used quasi-experimental study designs (Garrouste-Orgeas, Coquet, Perier, et al., 2012; Jones et al., 2012; Kloos & Daly, 2008) and the other four studies were randomized controlled trials (Curtis et al., 2016; Garrouste-Orgeas et al.,

2016; Jones et al., 2004; Moreau et al., 2004). Most studies were cross-sectional with one time point assessment, and no sustained effects were examined. The hypothesized mechanism of the use of ICU diaries is reducing patients' PTSD symptoms by helping patients to make sense of memory gaps and ICU experience following ICU discharge (Jones et al., 2010), however, the impact of diaries on family caregivers' psychological symptoms is unclear. In this review, all three studies examining the effect of ICU diaries on psychological symptoms in family caregivers used quasi-experimental designs with convenience samples. Moreover, different psychological symptom outcomes were measured across the three studies, making it difficult to compare findings (Garrouste-Orgeas, Coquet, Perier, et al., 2012; Jones et al., 2012; Kloos & Daly, 2008). More effective interventions to prevent/alleviate adverse psychological outcomes in family caregivers of ICU patients need to be developed and tested in future studies. Also, future research may need to use more rigorous study designs, larger samples, and longitudinal data. Most previous research about family caregiver's communication in the ICU focused on communication between families and healthcare team on surrogate decision making and/or families' information needs to enhance their satisfaction with the ICU care (Azoulay & Sprung, 2004; Kynoch, Chang, Coyer, & McArdle, 2016; Lautrette et al., 2007; Scheunemann, McDevitt, Carson, & Hanson, 2011). To date, no intervention targeting improvement of communication between families and patients in the ICU had been developed or tested.

Communication Difficulties and Family Caregivers

Communication between ICU patients and family caregivers is seriously impaired during treatment with MV due to multiple factors, most prominently, the placement of an oral

endotracheal or tracheostomy tube which prevents voice production and impedes communication with vocal speech (MacAulay et al., 2002). In a retrospective descriptive study, medical records were reviewed to identify communication methods and content of communications in 50 non-speaking, non-surviving patients who received MV in the ICU. Findings showed that communication with family caregivers often took the form of emotional expressions (Happ, Tuite, Dobbin, DiVirgilio-Thomas, & Kitutu, 2004). In a feasibility study of speech generating devices (SGDs) as an alternative communication method for MV patients (n=11), the primary content of SGD-constructed messages were “I love you” and questions about home/family (Happ, Roesch, & Garrett, 2004). These findings suggest that communication between family members and patients may be more complex and stressful than simple, standard yes-no questions, and may require more strategic communication methods.

Findings of previous studies suggest possible impact of the family caregiver involvement on the patient outcomes. Family members’ verbal encouragement and coaching could reduce the patient’s fear (Happ et al., 2007). Similarly, patients reported feeling more secure and protected by knowing that their family caregivers were sitting beside them (Bergbom & Askwall, 2000). In other qualitative studies, the patients described that a specific family member with exceptional ability to communicate took the time to understand the patient’s current condition, help the patient to talk, and make the patient understood to their care providers during MV treatment in the ICU (Engstrom & Soderberg, 2007; Magnus & Turkington, 2006). Families’ lack of communication skills and inability to understand patients’ needs or feelings may induce or worsen the patient’s distress rather than comfort them. Families also expressed their wish to help the patients and to protect them by calming and encouraging (Agard & Harder, 2007; Hupcey & Penrod, 2000), but they often did not know what to do. They often disregarded their own needs,

and the uncertainty of critical illness caused high levels of stress and anxiety (Agard & Harder, 2007).

Family caregivers often serve the role as interpreters for persons requiring MV. Patients and clinicians tend to rely on family members interpretation to communicate with patients (Engstrom & Soderberg, 2007; Happ, 2000; Magnus & Turkington, 2006; Tolotti et al., 2018). However, inability or unwillingness to be present consistently at bedside limits family caregiver's role as interpreter as does their skill in understanding the patient's nonvocal communication under extremely stressful, high stakes conditions (Happ, 2000). Several qualitative studies explored family caregivers' perceptions of communication with MV patients. In the studies, family members often express emotional distress, feelings of loss, and frustration with communication difficulty during MV treatment (Alasad & Ahmad, 2005; Broyles et al., 2012; Dreyer & Nortvedt, 2008; Engstrom & Soderberg, 2004; Happ, 2000). Broyles et al. (2012) conducted a qualitative secondary analysis of enrollment notes, intervention logs, and observation records from the SPEACS study (Happ et al., 2014) to identify which augmentative and alternative communication (AAC) tools families used and to describe family members' and nurses' perceptions of communication between family caregivers and MV patients. The results showed that families were generally unprepared for the MV patient's inability to communicate and they experienced negative feelings, such as frustration, with unsuccessful communication. Generally, family caregivers were not familiar with AAC tools and strategies, but they expressed interest in learning about AAC strategies and desired the highest level of communication possible with their critically ill family patients (Broyles et al., 2012). These results support the premise that more effective communication methods may help reduce/alleviate family caregivers reduce their psychological symptoms.

Despite evidence of the communication difficulties expressed by family caregivers and their desire to improve communication, to date, families of MV patients have only simple and low-tech tools to overcome communication difficulties and these are not consistently available at the ICU bedside (Broyles et al., 2012). Previous research demonstrated a strong association between higher psychological distress and negative feelings such as fear and anger in ICU patients and indicated that perceived communication difficulty was the strongest predictor of psychological distress (Khalaila et al., 2011). However, information on the communication challenges between ICU patients and family caregivers is sparse and its impact on psychological outcomes family caregivers has not been addressed in previous studies. Interventions to improve communication between family caregivers and patients might moderate or alleviate families' distress, therefore, prevent or reduce adverse psychological outcomes.

Augmentative and Alternative Communication Methods

Communication is essential to understand patients' needs and detect patients' symptoms, which may help improve the quality of care and safety. MV patients generally use natural communication methods such as gestures, head nods, mouthing words, and writing with paper and pen to communicate with nurses (Happ et al., 2011). However, those natural methods are time-consuming and can be unreliable. Augmentative and alternative communication (AAC) refers to all forms of communication used to supplement or replace oral speech including all ways to express messages such as facial expressions or gestures, body language, and aided low- and high- tech tools for those with speech or language impairment (American Speech Language Hearing Association (ASHA), 2018). Alternative communication methods developed and tested to improve communication for MV patients in the ICUs include low-tech tools such as

communication boards and speaking valves for patients with tracheostomy and high-tech tools such as computerized communication tools, and other AAC strategies. Table 3 summarizes several low- and high-tech communication tools available and tested for nonvocal patients in the ICUs (Ten Hoorn, Elbers, Girbes, & Tuinman, 2016).

Table 4. Summary of low- and high-tech communication tools for nonvocal patients

	Features	Weaknesses/Barriers
Low- Tech Tools		
Communication Boards	<ul style="list-style-type: none"> • Usually consist of an arrangement of the alphabet, words/phrases, icons, or pictures. • Icons and pictures represent common messages in which patients can easily point with fingers 	<ul style="list-style-type: none"> • Boards are prefabricated and cannot be personalized. • Optimal positioning may be difficult. • A board may contain too much information on a page for some patients.
Tracheostomy Speaking Valves	<ul style="list-style-type: none"> • Can be placed in the tracheostomy tube to allow phonation. • Facilitate verbal communication for tracheostomized patients. 	<ul style="list-style-type: none"> • Common malfunction includes occlusion of air vent port, cuff leaks, and kinking of the airflow. • The use is limited to few tracheostomized patients in the ICU who meet criteria.
High-tech Tools		
Speech Generating Devices (SGDs)	<ul style="list-style-type: none"> • Electronic AAC devices that produce pre-recorded voice messages or computer-generated voice when touching specific locations on the device screen or keyboard. • SGDs can be simple such as recorder devices or specialized computer systems. 	<ul style="list-style-type: none"> • Barriers to use include deterioration of patient's cognitive function and muscle strength or coordination, sedation, restraint, and unfamiliarity of health care providers with SGDs. • Poor device positioning also limits usage. • Hardware and software for SGDs can be costly.

Communication Computer Applications (apps)	<ul style="list-style-type: none"> • Communication apps may or may not speech-generating. • Several software apps for tablet computers or smartphones are commercially available. • Contain messages/icons like communication boards. • Most apps provide keyboard feature which allows the user to create novel messages 	<ul style="list-style-type: none"> • Usability of the tools is not well tested yet. • Barriers to use the tool include insufficient muscle power to use the device or coordination of the upper extremities.
Eye Tracking Devices (ETDs)	<ul style="list-style-type: none"> • Can be used for paralyzed patients or others with restricted use of upper extremities. • Integrate the data by detecting eye-movement and position to create a gaze point for selections on a computer screen. • Allow patients to use their eyes to operate a speech-generating device using eye-gaze control technology. 	<ul style="list-style-type: none"> • Barriers include patient's short attention span, sedation, and limited technology in a hospital environment. • Care provider's lack of familiarity with communication technology.

As communication technology advances, more technology-based communication strategies have been developed and introduced. Computerized AAC devices are specialized computers containing a database of phrases voiced out by a speech synthesizer (Ten Hoorn et al., 2016). The ICU-Talk, a computer-based communication aid containing a database of pre-stored phrases, was developed and evaluated specifically for intubated patients in the ICUs (MacAulay et al., 2002). The ICU-Talk was easy to use and required very little training, however, participants had a significant problem with the organization and navigation of the database of phrases in this study. Another pilot study to evaluate a computerized communication system, the LifeVoice™, was conducted for nonvocal ICU patients. The LifeVoice™ consisted of a medical grade hardware and software computer system which enables a patient-tailored method of

communication controlled by the eye-blink detector, touch buttons, or a touch-sensitive screen (Miglietta, Bochicchio, & Scalea, 2004). Thirty-five (35) ICU patients who were mostly blunt trauma victims (97%) participated in this pilot study over a 3-month period. Patients' ability to use of the device, comfort and ease of use, and clinical usefulness were measured on the first day, days 3 and 7 using patient and staff surveys. Almost all patients were able to use the device within minutes of instruction, they felt that the device assisted them in obtaining their needs (94-97%) over the study period. Hospital staff also reported that the device improved patient care (96%), and approximately 91% of staff felt that the device helped patients feel more comfortable (Miglietta et al., 2004). However, generalization may be limited since this study involved young patients with the mean age of 36 years who may be more familiar and adapt more easily to high-tech, computer devices, and most ICU patients are older. The patient's reduced attention span and level of sedation were reported barriers to use of the LifeVoice™. There were no further published reports on the use of LifeVoice™ in the 14 years since this paper was published.

More recently, a programmable SGD, a multifunctional software incorporated in a tablet computer, was evaluated for its feasibility and usability for hospitalized, suddenly speechless patients in a pilot study by Rodriquez et al. (2012). Among eleven patients who participated in this study, over 72% demonstrated independent use of the communication tool and most patients were strongly satisfied with the use of the tool during the hospital stay. Reported difficulties encountered by participants included the inability to push icons physically, limited visual acuity, sedation, restraints, and having a pulse oximeter on the dominant hand (Rodriguez et al., 2012). Expanding their previous work, Rodriquez et al. (2016) conducted a quasi-experimental study with repeated measures involving a larger sample (n=115) of suddenly speechless patient in the ICUs. The intervention group (n=52) was provided with the SGD containing three

communication functions including touch selection of pictorial hot-buttons, hand-writing on a screen, and typewriting using a keyboard, whereas the control group (n=63) received usual care with an urgent button that announces “I need help” when activated. The intervention group reported lower levels of frustration and higher mean satisfaction scores compared to the control group. Although the perceived communication difficulty was not significantly different between the two groups, the intervention group reported a consistent increase of perceived ease of communication over the hospital stay (Rodriguez et al., 2016).

Technology has rapidly changed and become more common in our lives. Electronic tablets and mobile communication devices - are becoming more available and common in healthcare settings. Speak for Myself (SFM), an android tablet computer application (app), was developed for nonvocal hospitalized patients by Koszalinski et al. (2015). The SFM was developed from the perspective of patients with communication impairment due to cerebral palsy, and it contains various messages including patient’s needs, emotions, and requests for certain providers, an analog pain scale, typing features, as well as a text-to-speech generation when the ‘speak’ button is selected. This app is also programmed with word prediction as well as customizable to the user’s history where the user’s selection is store in the “recent” menu. The SFM was tested for feasibility with nonvocal ICU patients (n = 20) in a pilot study using a quasi-experimental design. During the feasibility testing, the participants, their nurses, and anyone at the bedside received a 5 to 10 minutes training to use the software. Participants answered four open-ended questions about their experience with the use of SFM at the end of shift or the following day. As a result, 95% (n=19) participants found the SFM helpful for communication (Koszalinski, Tappen, & Viggiano, 2015). Qualitative findings suggested that patients felt less frustrated with the inability to communicate, expressed pain, needs, and preferences more clearly

and had greater opportunity to participate in care decisions after receiving the SFM (Koszalinski, Tappen, Hickman, & Melhuish, 2016).

Several other communication apps such as Society Critical Care Medicine (SCCM)'s Patient Communicator, Greenhouse Publication's Health Care Communication, and Vidatak's VidaTalk™ are now commercially available. Although the number of messages and message categories contained in each tool, menu pages, and a way to operate tools are different across those apps, the main features are similar. The communication apps contain pictures and phrases pertaining to needs and well-being, pain scales, pictures of the body to indicate needs in a certain area, and type feature which allows the patient to generate novel messages. However, the other two tools have text-to-speech generation for the messages selected, whereas the SCCM's Patient Communicator does not have that feature. Compared to the other tools, the VidaTalk™ additionally has a finger drawing feature in which patients can write messages on the screen using their fingers. Nilsen et al. (2018) tested these three apps and three different commercially available communication boards (VidaTak's EZ Board™, VidaTak's Picture Board™, and Greenhouse publications' Health Care Communication Board) for the usability and acceptability of those tools among older adults in a controlled setting. A total of 30 adults > 60 years old (15 without cancer history and 15 who had undergone surgery for head and neck cancer) participated in this study (Nilsen et al., 2018). Participants were provided with six communication tools (three communication boards and three computer apps) in a private room and explored them without special instructions or guidance. Then, they were asked to complete six tasks using the tool to communicate 1) pain, 2) frustration, and 3) the need to use the bathroom as if they were unable to speak during hospitalization. After completion of tasks for each tool, participants completed a questionnaire on ease and perceived usefulness of the tool and were asked to select

their most preferred tool. The results showed that more patients successfully completed most tasks with communication boards than apps and ease of use scores were significantly better for the communication boards than apps ($p = .002$). However, patients most preferred the Picture Board™, VidaTalk™ app, and EZ Board™ in descending order, and one patient reported that any of the apps would be more useful than a communication board. Difficulty navigating the pages and finding all available features in the communication apps was the biggest issue in using the apps. Importantly, participants commented that the apps could be used more effectively, given more time and training (Nilsen et al., 2018). Considering that any instructions or guidance were not provided to the participant in this study, these findings suggest that high-tech AAC tools such as communication apps could be more useful for effective communication for older adults with appropriate training in the future.

Numerous studies emphasized the importance of effective communication in the ICUs and several AAC tools are available, most previous studies testing communication tools are small pilot studies, case series, or quasi-experimental designs rather than larger RCTs (Ten Hoorn et al., 2016). Also, only a few studies investigated different communication tools within a study to compare the usefulness of the tools on nonvocal ICU patients. More studies are needed to examine the usability and efficacy of communication tools with a larger sample using more rigorous study designs such as RCTs. Moreover, future studies need to compare different tools to test one tool's superiority over the other and/or identify which tool will be more beneficial for a specific group of patients with certain conditions. Newer technology-based communication tools such as communication apps might be more beneficial since those are easy to use and might be less expensive, considering more people possess tablet computers or smartphones nowadays and

those apps can be easily downloadable. More studies need to be conducted to test those new innovative high-tech tools in a hospital setting to determine its efficacy and barriers to use.

Although multiple AAC methods/tools are available for nonvocal patients in hospital settings, very little is known about communication between nonvocal MV patient and family caregivers in the ICU. Happ and colleagues investigated multimodal communication intervention, SPEACS and SPEACS-2 trial, between nurses and patients (Happ et al., 2010; Happ, Garrett, et al., 2014; Happ et al., 2015; Trotta, Hermann, Polomano, & Happ, 2019). The involvement of family caregivers in assisted communication strategies with nonvocal ICU patients and the use of AAC tools in patient-family communication in the ICU has not been systematically investigated and remained unknown. Family involvement needs to be accounted for in the studies about AAC methods and tools in the ICU. Moreover, effectiveness of the use of AAC tools on communication between nonvocal ICU patients and their family caregivers need to be examined in the future.

Chapter 3: Methodology

Research Design

This dissertation study used a sequential mixed-methods design with repeated measures to study the effects of the VidaTalk™ patient communication application for android tablet computers on psychological symptoms of family caregivers of nonvocal, ICU patients. Mixed-methods design involves combining quantitative and qualitative research approaches and data types in a single research study (Creswell, Plano Clark, Gutmann, & Hanson, 2003). The sequential mixed methods approach involves two distinct phases: quantitative investigation followed by qualitative exploration. This approach is quantitative phase dominant (QUAN > qual) and qualitative phase is connected to the quantitative results. The overall intent of this design is to have the qualitative data help explain in more detail the initial quantitative results (Creswell et al., 2003).

This study was conducted as a companion study to a randomized controlled trial (RCT) designed to test the clinical efficacy of the VidaTalk™ application with MV patients compared to attention control (AC) (android tablet with MyChart Bedside (EPIC), games, and educational applications). An interventionist either oriented enrolled patients to the VidaTalk™ application or introduced a simple game application (AC) based on the random assignment. This study explored the intervention effect in a different group (i.e., family caregivers). In this study, the quantitative phase entailed examining the feasibility and acceptability of the VidaTalk™ with ICU family caregivers (Aim 1), testing the preliminary effect of the VidaTalk™ app on family caregivers' psychological outcomes (Aim 2), and identifying the role of family caregivers' perceived communication difficulty as a moderator of psychological outcomes (Aim 3). The

qualitative phase of the study was primarily devoted to exploring family caregivers' experience of communication with VitaTalk™ app while they were visiting the patient in the ICU (Aim 4) and their emotional reactions to communication with a family member- patient during critical illness and MV (Aim 5). Part of qualitative data was also used to determine acceptability of the VitaTalk™ to ICU family caregivers (Aim 1).

Figure 2. Visual model of Mixed-Methods Design Procedure

Description of the Parent Study

The parent study tested the clinical efficacy of VidaTalk™ on ICU patient's clinical outcomes by conducting an RCT with AC. A total of 63 alert, non-delirious, intubated adult patients receiving MV in the ICUs was included in the parent study sample. Inclusion and exclusion criteria for the parent study are presented in Table 5.

Table 5. Summary of Parent Study- Patient Inclusion/Exclusion Criteria, Variables

Inclusion Criteria	Exclusion Criteria	Variables
1) ≥ 18 years old,	1) pre-existing severe communication or memory impairments	<u>Covariates</u>
2) able to communicate in English,	2) diagnosis of severe dementia or brain injury limiting communication	<ul style="list-style-type: none"> • Demographic information • Severity of Illness • Physical Restraint Use • Intubation mode
3) awake alert, responding appropriately to commands,	3) Confusion Assessment Method (CAM-ICU) positive for delirium (on enrollment)	<u>Fidelity-Usability</u>
4) normal (aided or unaided) hearing and vision,	4) Pre-existing speech or hearing impairment that limits functional communication	<ul style="list-style-type: none"> • Intervention Exposure/Dose • Usability
5) able to control head, arm and hand movements		<u>Patient Outcomes</u>
6) in no acute distress (per nurse report)		<ul style="list-style-type: none"> • Anxiety • Sedation-Agitation • Sedation exposure (24h) • Delirium / Coma-free days • Communication difficulty & Frustration
7) intubated via oral endotracheal or tracheal tube without speaking valve		

Participants were randomized into two groups: intervention and AC group. Patients in both groups continued to receive the standard of care regarding communication on the unit. Commercially prepared EZ Board™ communication boards (Vidatak, LLC) were available on the unit throughout the study. Android tablet computers (Samsung Galaxy) containing the MyChart Bedside™ application are routinely available for patient/family use on the ICUs,

however, prior to this study, deployment was inconsistent, and relatively sparse to mechanically ventilated ICU patients. Patients randomized to the intervention group (n=31) were provided the Samsung Galaxy Android tablet computer with the VidaTalk™ application as a communication tool. The tablet also contained the MyChart Bedside (EPIC) application, and selected games as standard in the hospital. A protocolized instruction in the use of the VidaTalk™ application, device positioning, and “usage tips” card was provided for those in the intervention group. The device was mounted on table top pyramid stands or held by the patient depending on patient’s preference. The instruction in device use included patient return demonstration of key features, customization of a personal message page if desired, trouble shooting, returning to the home page, and review/ testing to competence conducted by a trained interventionist. The interventionist visited patients each day to check their needs and concerns about the device. All patient interactions with the interventionist were recorded in the interventionist log using the format established in a previous clinical trial (Happ, Garrett, et al., 2014). The Android tablet with VidaTalk™ app was available until the patient was extubated or discharged from the ICU whichever came first. The 32 patients randomized to the AC group received a standard Android tablet loaded with MyChart Bedside (EPIC) and game applications but without VidaTalk™ or any other patient communication application. They received a protocolized introduction to the bedside Android device focused on a simple game application of their choice.

VidaTalk™ Communication Application. VidaTalk™ is a touch pad tablet computer software application developed to provide MV patients an evidence-based solution for communicating their needs to care providers and family. On the VidaTalk™ screen, there are seven different menu bars activated by touch: *home*, *questions*, *I am*, *I want*, *pain*, *draw*, and *keyboard*. The *home* page contains picture icons with words/phrases most commonly used by MV patients. A patient can select a message from categories such as “needs,” “feelings,” and “people to see” by touching a picture icon with word labels related to the message, such as “I am hot”. The *questions* menu is comprised of the most common questions asked by patients identified by labeled picture icons. Words/messages describing how a patient is feeling such as “cold,” “anxious”, and “frustrated” are located within the *I am* page. When a patient touches one of those “buttons,” the message is produced audibly via digital speech and the text of the

message is displayed on the screen. The *I want* menu contains different words/phrases communicating common patient needs in the hospital. For example, a patient can express the need for a bath, bathroom, and comforting, or ask for needed objects such as blanket, eyeglasses, and pain medicine by touching the appropriate icon within the *I want* page. There are three different *pain* menu options for patients to describe pain severity, location, and = the pain quality (e.g., sharp, dull, aching, etc.). The first option is labeled “How bad is the pain” in which a patient is asked to select a number to rate the pain intensity on a zero to ten scale. The second option is “Where is the pain?” Two body figures, frontal and posterior, are divided into several colored body areas or quadrants, like a map, for the patient to indicate pain location. The next feature on the menu, *draw* page, is a finger writing (or drawing) screen for patients to construct novel written messages or pictures with his/her finger. The drawing feature is visual only. It does not include speech generation/voice output. Finally, the *keyboard* screen provides another option to write or type novel messages. A blank box with sentence starters such as “when” and “can I leave?” is located at the top of the *keyboard* screen. A patient can begin to construct a message choosing the appropriate sentence starter followed by typing the remainder of the message, then the typed message will be read aloud via digitized speech.

Setting

This study took place at the Ohio State Wexner Medical Center (OSUWMC), where we recruited from several types of ICUs: two general medical (36 beds), one medical oncology (24beds), one general surgical (24 beds), one surgical oncology (12), one general neuro (16 beds), one neuro oncology (8 beds), one cardiovascular (30 beds), and one coronary care unit (30 beds). The ICU has a nurse-to-patient ratio of 1:2. Standard of care for communication in the ICU at OSUWMC includes writing tools (paper and pen), and occasionally, picture or alphabet communication charts provided for communication at the discretion of the bedside nurse.

Sample

Family caregivers of patient participants enrolled in the parent study were recruited for this dissertation study. Family caregiver was defined as a person who is responsible for the patient's treatment, care decisions and providing care after hospital discharge without financial compensation; the person with whom the patient has a significant relationship; the person did not have to be a blood relative (Cameron et al., 2016). One or more family caregivers for each patient were recruited as identified by the patient and/or by the family caregiver. All family caregivers who were interested in the study and met inclusion criteria were enrolled. Inclusion and exclusion criteria for the family participants in this study are presented in Table 6. No power calculation could be done for the number of family caregivers to be recruited because the power of the study was based on the recruitment of patients, and family caregivers were approached only if the patient was recruited.

Table 6. Study – Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1) Family caregivers of the enrolled patient participants in the parent study as identified by the patient	1) Severe uncorrected hearing loss (inability to hear to the audio recording)
2) ≥ 18 years old	2) Self-reported diagnosis of dementia or Alzheimer's disease
3) Able to read and speak English	3) Self-reported major psychiatric disorder (bipolar disorder, schizophrenia) or substance abuse requiring inpatient treatment within the last 12 months
4) Non-professional, un-paid caregiver	4) Unreliable telephone access (for follow-up assessment)
5) Identified by patient and/or self as providing the majority of support and visitation	
6) Plans to visit > 3 days/week during ICU stay	

Research Protocol

Recruitment. Potential study participants were identified by: (1) the patient, (2) clinicians, or (3) family members themselves when the patient was enrolled in the parent study. When potential family participants were present in the ICU room or waiting area, they were approached by the study principal investigator (PI) or research staff for screening and consent process. When identified family caregivers were not present at patient's enrollment, the researcher's contact information and the study brochure (Appendix A) which contains brief information about the study were left in the room. The PI also asked the patient or the nurse about the family's anticipated visiting date/time and returned to meet the family member. When potential family participants were interested in participating in the study, the PI or research staff informed them about the study purpose and procedures and asked several questions to check caregiver's eligibility (See Table 6). A family caregiver who met the eligibility criteria and agreed to participate were provided detailed information about the study procedures and informed consent was obtained for study participation including follow-up measures and/or optional qualitative interviews.

Participant Consent Procedure. Approval for the study was obtained from the Institutional Review Board (IRB) and the OSUWMC Nursing Department Feasibility Review Committee. All procedures for recruitment, informed consent (Appendix B), and assessments followed the IRB-approved procedures. During the informed consent process, the PI described the study protocol in lay terminology including the nature and duration of the study. The study purpose was described as to test the effect of a tablet computer application provided to patients on the family member's perceptions of communication with the patient and feelings and

emotions during and after the ICU experience. Emphasis was made that the data collected would be for research purposes and refusal to participate in the investigation would have no effect on the patient's routine treatment. Family caregivers were informed that there is no obligation to participate in the study. The family was provided with a written copy of the consent form and ample time to have questions answered prior to enrollment. During the enrollment, the PI asked the family caregivers to provide at least two telephone numbers, a current mailing address, and email addresses for follow-up data collection and optional qualitative interviews. They were asked which method among emails, telephone, and mails they preferred for the follow-up measurements.

Intervention and AC group. The enrolled family participants whose patient was assigned to the intervention group were informed that their patient may communicate with or without the VidaTalk™ while family visit. The bedside Android device with the VidaTalk™ application and a user instruction card (Appendix D) were available for family caregivers to use with the patient in the intervention group until the patient was extubated or discharged from the ICU. The family caregivers whose patient was assigned to the AC group received the standard format Android tablet computer and a user instruction card for the Android tablet. This study was intentionally designed to follow the natural course of family involvement and outcomes not to interfere differentially with the parent study.

Data Collection Procedure. After informed consent, baseline assessment was performed by the PI or trained research associate with the participating family caregiver(s). Baseline

assessment included demographic information, communication difficulty (Family Communication Survey (FCS) (Happ, Roesch, & Kagan, 2004)), anxiety (Hospital Anxiety and Depression Scale – Anxiety (HADS-A) (Snaith, 2003)), and depression symptoms (HADS – Depression (HADS-D) (Snaith, 2003)) in family caregivers. Family caregivers' anxiety, depression, and communication difficulty were measured using the same measurement tools at patient' ICU discharge or extubation whichever came first. Family caregivers in both intervention and AC groups were asked to complete a family visitation log for each visit to the patient's ICU room (Appendix E). The family visitation log obtained information about visiting start/end time, who was visiting, and the use of tablet during the visit (yes or no). At one month after the extubation/ICU discharge, anxiety (HADS-A), depression (HADS-D), and PTSD-related symptoms (The Impact of Event Scale-revised (IES-R) (Weiss, 2007)) were measured by electronic surveys, telephone interview, or mailing surveys depending on the participant's preference. Several options were provided for the participant to choose as participant retention strategy since these people were hard to reach during the post-ICU period. The HADS and the IES-R can be administered via self-report or by interview and have been administered by phone in previous studies in the ICU family caregiver population (de Miranda et al., 2011). Electronic surveys were performed via a secure web application, Research Electronic Data Capture (REDCap) (Harris et al., 2009). Those who preferred electronic surveys were contacted via email first. If electronic surveys were not completed after two reminders within five days, the data collection was conducted by telephone interview. Paper surveys were sent via mail to those who preferred mailed surveys a week before the exact data collection date. If the mailed surveys were not returned, the participant was contacted via telephone. Participants received at least two reminders for survey completion at each follow-up time point. Participants were considered

missing follow-up if they were not responsive to electronic or mailing surveys for first seven days, and additional five calls within additional seven days. Participants missing at one time point were contacted at the next time point unless they requested withdrawal from the study. The same survey procedure was repeated at three and six months after the ICU discharge.

Variables and Measurements

Participant Characteristics

Demographic information. Family participants' demographics included age (years), sex, race, highest education level, occupation, relationship to the patient, previous ICU experience as a visitor or a patient prior to this study (yes or no), history of use of psychoactive medications, and history of psychiatric or psychological support. Demographic information was obtained by self-report at baseline assessment. During the follow-up assessment, additional ICU experience, psychoactive medication treatment, and psychological support were detected at each time point. Whether or not family caregivers received any help from psychiatrists, psychologists, counselors, any institutional services for their psychological problems, and use of psychoactive medications during the study were identified by self-report at each time point. Additional ICU experience and newly started psychoactive medication treatment or psychological support during the post-ICU period were explored descriptively in the analysis and interpretation.

Patient Demographics and clinical characteristics. Patient's demographic characteristics including age, gender, and race and clinical characteristics such as severity of illness, primary diagnosis, ICU length of stay, the length of time on MV were obtained from the

electronic medical record (EMR). This information was accessed from the parent study database. After the ICU discharge, whether or not the patient returned home or transitioned to rehabilitation, long-term acute care or skilled nursing facilities was obtained at ICU discharge and/or one month follow-up time point.

Feasibility and Acceptability

Feasibility was evaluated by recruitment and retention rates. A log of participant screening, enrollment, and retention was kept throughout the study. In addition, the number of ICU visits per week for each family participant and, if available, length of visiting time for each ICU visit were obtained from the family visitation log to examine the feasibility of family participation.

Acceptability was evaluated by examining information from several sources. Use of the tablet during the ICU visit, defined as total number of visits where tablets were used / total number of ICU visits, was obtained from the family visitation log. Written quotes about VidaTalk™ were available from the Family Communication Survey (FCS) which was performed at baseline and extubation/ICU discharge in answer to an open-ended question about their communication experience during the MV treatment in the ICU. As part of the parent study, the interventionist completed the interventionist log and field notes daily during the study period and family member's involvement, if any, in the used of the tablet was recorded on those forms. Qualitative interviews with a subset of participants provided narrative feedback on the VidaTalk™, which helped determine the acceptability of the VidaTalk™ as an intervention for family caregivers.

Family Outcomes

Anxiety Symptoms. The Hospital Anxiety and Depression Scale (HADS) – Anxiety subscale was used to measure symptoms of anxiety in family caregivers. HADS was originally designed by Zigmond and Snaith (1983) for detecting clinically significant depression and anxiety in patients attending outpatient settings, and for discriminating between anxiety and depression (Zigmond & Snaith, 1983). Although HADS contains both anxiety and depression subscales, the developers selected items that could distinguish between anxiety and depression. HADS-anxiety (HADS-A) is a brief measure which evaluates common dimensions of anxiety. The HADS-A consists of 7 items measuring generalized symptoms of anxiety including tension, worry, fear, panic, difficulties in relaxing, and restlessness. Each item is scored on a 4-point Likert scale (0 to 3), and total scores range from 0 to 21. The following guidelines are recommended for the interpretation of scores: 0 –7 for normal or no anxiety, 8 –10 for mild anxiety, 11–14 for moderate anxiety, and 15–21 for severe anxiety (Bjelland, Dahl, Haug, & Neckelmann, 2002). The respondent is instructed to complete the tool indicating how he/she has felt in "the past week" so as to avoid the influence of immediate changes (McDowell, 2006). The psychometric studies observing a two-factor solution supported the use of the anxiety subscale as an independent measure (Bjelland et al., 2002). This instrument has been validated for use in various populations including primary care patients, psychiatric cases, the elderly, adolescents as well as general population (Bjelland et al., 2002; Helvik, Engedal, Skancke, & Selbæk, 2011; Snaith, 2003; White, Leach, Sims, Atkinson, & Cottrell, 1999). It has been widely used as a screening instrument both inside and outside of the hospital setting (Flint & Rifat, 2002). The HADS-A demonstrated high internal consistency (Cronbach's alpha ranging from 0.76 to 0.93) in various populations including community-dwelling adults, psychiatric samples, and medical

samples (Bjelland et al., 2002; McDowell, 2006). Criterion validity, concurrent validity, and discriminant validity for the HADS-A have been established in previous studies in various populations (Bjelland et al., 2002; Helvik et al., 2011; McDowell, 2006; White et al., 1999). The HADS was the most frequently used measure to assess psychological burdens in informal caregivers of adult ICU survivors in previous studies (van Beusekom et al., 2016). The HADS-A typically takes less than five minutes to complete (Snaith, 2003) and easy to understand. Anxiety symptoms were measured at baseline (enrollment), at extubation or ICU discharge, one month, three months, and six months after ICU discharge.

Depressive symptoms. The HADS – Depression subscale was used to measure depressive symptoms in family caregivers. The HADS-Depression (HADS-D) is a brief measure of depression focusing on the concept of anhedonia which is central to depression and is amenable to treatment (McDowell, 2006). The HADS-D consists of 7 items, and each item is scored on a 4 Likert scale (0 to 3). Total scores range from 0 to 21, and higher scores represent more distress. A meta-analysis suggested scores for the interpretation: 0 –7 for normal, 8 –10 for mild, 11–14 for moderate, and 15–21 for severe depression (Bjelland et al., 2002). The HADS-D demonstrated high internal consistency (Cronbach’s alpha ranging from 0.70 to 0.90) in various populations including cancer patients, depressed patients, HIV patients, myocardial infarction patients as well as the general population (Bjelland et al., 2002; McDowell, 2006). Criterion validity, concurrent validity, and discriminant validity for the HADS-D have been established in previous studies in various populations (Bjelland et al., 2002; Helvik et al., 2011; McDowell, 2006; White et al., 1999). In terms of criterion validity, Zigmond and Snaith (1983) reported correlations between patient ratings and clinical ratings during the original development. The results suggested that convergent correlations were significant ($r = 0.79$ between HADS

depression and clinical depression, $p < 0.01$) whereas discriminant correlations were not significant (between HADS depression and clinical anxiety) (Zigmond & Snaith, 1983). Concurrent validity was established in several studies by comparing HADS-D scores with results from other instruments. For hospital outpatients, the correlation between HADS-D score with the Montgomery-Åsberg Depression Rating Scale was 0.77 (Aylard, Gooding, McKenna, & Snaith, 1987), and 0.70 in a sample of psychiatric patients (Bramley, Easton, Morley, & Snaith, 1988). In a general population sample, the HADS-D correlated 0.71 with scores on the Beck Depression Inventory (Lisspers, Nygren, & Söderman, 1997), and 0.78 with the depression scale of the Irritability-Depression-Anxiety (IDA) scale in a mixed sample of psychiatric patients (Snaith & Taylor, 1985). The HADS-D takes only 1-3-minutes to complete (Snaith, 2003) and easy to understand. Depressive symptoms were measured at baseline (enrollment), at extubation or ICU discharge, one month, three months, and six months after ICU discharge.

PTSD-related symptoms. PTSD-related symptoms was measured by the Impact of Events Scale-revised (IES-R). The original version of IES was introduced by Horowitz and colleagues in 1979 (Horowitz, Wilner, & Alvarez, 1979). It was a simple but powerful self-report measure for assessing the magnitude of symptomatic response to a specific traumatic life event during the past 7 days. According to the DSM-5 (American Psychiatric Association, 2013), the diagnostic criteria for PTSD include three symptom clusters: re-experiencing, persistent avoidance and numbing, and hyperarousal. The original IES comprised only two subscales including inclusion and avoidance but did not include the hyperarousal subscale. The IES was revised to accomplish a complete assessment of all three PTSD symptom clusters in 1997 (Weiss, 2007; Weiss & Marmar, 1995).

The IES-R is a 22-item self-report instrument with three subscales including intrusion (8 items), avoidance (8 items), and hyperarousal (6 items). The respondent is asked to report the degree of distress experienced for each item in the past 7 days. Each item is scored on a five-point Likert scale (0, not at all; 1, rarely; 2, occasionally; 3, fairly often; and 4, often) and total scores range from 0 to 88. The IES-R takes approximately 10 minutes to and easy to apply without a special training to administer (Motlagh, 2010). Higher scores are representative of greater distress. Total scores of 22 or more on the IES-R had 92% sensitivity and 57% specificity for PTSD in a population of substance abusers (Rash, Coffey, Baschnagel, Drobles, & Saladin, 2008). Previous research suggested scores of 22 or more as the cutoff indicating a significant rate of PTSD-related symptoms (de Miranda et al., 2011; Garrouste-Orgeas, Coquet, Périer, et al., 2012) and 37 or more as severe to suppress immune system functioning (Kawamura, Yoshiharu, & Nozomu, 2001). There is no sufficient evidence to support the IES-R as a tool confirming a diagnosis of PTSD, rather, it was intended to provide an indication of a general level of distress related to an event (Motlagh, 2010).

Psychometric properties of the IES-R have been established in previous studies (Beck et al., 2008; Creamer, Bell, & Failla, 2003; Rash et al., 2008). Internal consistency for the total scale was high (Cronbach's $\alpha = 0.96$) as well as for the subscales (intrusion: 0.94, avoidance: 0.87, hyperarousal: 0.91). In terms of concurrent validity, the IES-R total score was highly correlated with the PTSD Checklist (PCL) total score (0.84, $p < 0.001$) and correlations for each of the subscale were: intrusion = 0.86; avoidance = 0.66; hyperarousal = 0.79 ($p < 0.001$). The original IES is the most frequently used instrument to measure PTSD-related symptoms in informal caregivers of adult ICU survivors (van Beusekom et al., 2016). The IES-R is the second most commonly used in this population and is comprised of all three subcategories of PTSD

symptoms. According to the diagnostic criteria for PTSD (American Psychiatric Association, 2013), one or more traumatic events should precede the symptoms and the duration of symptoms need to be more than a month. To capture the early sign of PTSD-related symptoms in family caregivers, the IES-R was performed at one month after the ICU discharge. The PTSD-related symptoms were followed up at 3 and 6 months after ICU discharge.

Communication Difficulty. Communication difficulty and satisfaction with communication were measured by a standardized tool, the Family Communication Scale (FCS). The FCS is a self-report survey developed to measure family caregivers' perception of difficulty, satisfaction, and effectiveness in communicating with the MV patient. The FCS was developed and used by investigators in previous work (Happ, Roesch, & Garrett, 2004). This tool contains nine items, and each item is scored on a five-point Likert scale (1, strongly disagree; 2, disagree; 3, not sure; 4, agree; and 5, strongly agree). Total scores range from 9 to 45, and higher scores indicate less perceived communication difficulty. Item 9 score was reversed for a total score. Exploratory factor analysis revealed two factors, explaining 72.2% of the total item variance. Internal consistency of the scale is very good (Cronbach's $\alpha = 0.89$). The FCS was administered at two-time points: at enrollment and at ICU discharge/extubation whichever came first.

Table 7. Measures for Data Collection

VARIABLES	INSTRUMENT / DATA SOURCE	RELIABILITY (Cronbach's alpha)	DATA COLLECTION (TIME POINTS)
Psychological Outcomes			
Anxiety symptoms	Hospital Anxiety and Depression Scale (HADS) – Anxiety	.76-.93*	Enrollment, extubation/ICU discharge, 1-mos, 3-mos, 6-mos
Depressive Symptoms	HADS-Depression	.70-.90*	Enrollment, extubation/ICU discharge, 1-mos, 3-mos, 6-mos
Post-traumatic Stress Disorder-related Symptoms	Impact of Events Scale-revised (IES-R)	.87-.96**	1-mos, 3-mos, 6-mos
Proposed Moderator			
Perceived Communication Difficulty	Family Communication Survey (FCS)	.89***	Enrollment, extubation/ICU discharge
Feasibility/Acceptability			
Recruitment and Retention Rates	Screening and retention log	N/A	From enrollment to study completion
Number of ICU visit per week / Number of tablet use per ICU visit)	Family Visitation Log	N/A	From enrollment to extubation/ICU discharge time point
Perceptions of the VidaTalk application [intervention group only]	Interventionist log/field notes (parent study), Qualitative interviews	N/A	Daily Within 1-month post discharge
Covariates			
Demographics (age, sex, race, education, occupation, relationship to patient)	Demographic Questionnaire	N/A	Enrollment
ICU Experience	Demographic Questionnaire	N/A	Enrollment, 1-mos, 3-mos, 6-mos
Psychological Support	Demographic Questionnaire	N/A	Enrollment, 1-mos, 3-mos, 6-mos
Patient Demographics (age, sex, race)	Parent study	N/A	Enrollment
Patient Clinical Characteristics (APACHE III score, Charlson comorbidity score, primary diagnosis, ICU length of stay (days), length of time on MV(days))	Medical Record	N/A	Enrollment
Discharge Disposition / Death	Demographic Questionnaire	N/A	1-mos, 3-mos, 6-mos

*Bjelland et al., 2002; McDowell, 2006

**Weiss, 2007

***Happ, Roesch, et al., 2004

Qualitative Interview

All family participants who were in the VidaTalk™ group and agreed to be contacted for an optional qualitative interview during the enrollment procedure were invited to participate in the qualitative interview. The invitation was performed via telephone or in-person at a time point after the ICU discharge or patient's death before the 1-month follow-up to be proximal to the family caregiver's experience of communication during MV without losing their ability to recall. The family caregivers who agreed to participate in the interview were asked to answer open-ended questions asking about their perception of communication with VidaTalk™. The interview guide (Box 1) was designed to elicit the family caregiver's ideas and opinions about how the use of VidaTalk™ influenced communication with the MV patient and their emotional reactions. The interview guide ensured that the key issues were addressed and the interview flow was maintained during the interview.

Qualitative interviews were performed using e-mail interview method. There are several advantages of e-mail interview method. E-mail interviews cost less than telephone or face-to-face interviews by sending them e-mail messages individually, rather than making long-distance telephone calls, using regular mails, or traveling to the location of participants (Meho, 2006). Also, there is no intrusion of technology such as audiotaping or microphone. Email interviews allow participants to reflect on questions and to participate at times most convenient to them. Participants may be less guarded and more candid when responding in the more "anonymous" online format of email. Moreover, the email interview is the raw data itself, and there is no need for transcription, which eliminates transcription reliability issues (Hamilton & Bowers, 2006). The e-mail interview involved three or four cycles. The initial cycle contained several questions about the general experience of communication with their family member while they were

visiting in the ICU (question 1-3). That was followed by the second cycle with questions about conversations that they had with their family member in the ICU (question 4 & 5) and the last cycle with the question asking their suggestions for the use of the VidaTalk™ for the future family caregivers (question 6). The questions were constructed based on the interview guide, and analysis of participant's answers in each previous cycle allowed the interviewer to ask for more details while developing the next set of questions. To maximize participation, family caregivers who did not use email or had difficulty accessing emails due to their family patient's extended hospitalization were asked if they would like to participate in the interviews using another method, in person or written. The same qualitative interview was performed via paper copies instead of emails during the hospital stay for two participants (n = 2).

Box 1. Semi-structured Qualitative Interview Guide

Questions	
Cycle 1	1. We'd like to know about your experience using the tablet computer and VidaTalk application to communicate with your family member while you were visiting in the ICU. Please tell me about that experience.
	2. How often did your family member use the VidaTalk application to communicate with you or with others while you were visiting? What other methods of communication did you use?
	3. Tell me about how you felt when communicating with [patient's name] after starting to use the VidaTalk?
Cycle 2	4. What messages were communicated using the VidaTalk application?
	5. Tell me about what conversation had the most impact on you? Which conversation was the most meaningful? Which conversation bothered you most?
Cycle 3	6. What suggestions do you have for other family caregivers of patients receiving mechanical ventilation who may use or assist in the use of the VidaTalk application to communicate?

Potential Benefits and Risks

Potential risks to the study participant were minimal. Fatigue or emotional distress could occur during the data collection procedure when answering questions about psychological symptoms. Two family participants became unable to continue during the telephone interview for the post-ICU follow-up, I terminated the data collection session. Both participants' family patients died short after the ICU discharge and they became distressed while answering the questions about their recent feelings and emotions and wanted to end the session. In addition, if a participant was found to be at high risk for major depression (HADS-D score of 15 or greater) or PTSD (IES-R score of 37 or greater), mental health resources were provided, and he/she was encouraged to contact their health care provider to schedule an appointment for an evaluation. Four participants in the AC group and one in the VidaTalk™ group who showed high scores on IES-R or HADS-D were provided with mental health resources at one or three months. We also had an emergency protocol in the event that a participant was identified as suicidal. Fortunately, this did not occur.

As in any research participation, there was also a potential risk of loss of confidentiality. Many strategies were in place to maintain participant confidentiality. Only the consent and contact information forms contained any identifiable information. All other written documentation of data contained study identification numbers only. Patient participants were given study ID numbers within the parent study, and family participants were assigned a separate number. Only one coded identifier linked the family member to the patient participant. All hard copy data obtained were kept in a locked file cabinet in a locked office, and all electronic data were kept in a password-protected computer on a secured research server to ensure confidentiality. Two layers of passwords secured access to the database.

All data were transferred to REDCap (Harris et al., 2009), a secure web application for data management. Participant identifiers were not revealed at any time in any manner, whether in presentation, description, or publication of the research for scientific purposes.

The risks of the study were reasonable in relation to the anticipated benefits.

Participation in this study may provide no direct benefit to participants. They may benefit future family caregivers of MV patients by improving our understanding of the effectiveness of communication intervention on their psychological symptoms. As incentives for participation in this study, participants received a \$5 gift card at baseline, a \$10 gift card at 1-month follow-up, and a \$5 gift card at each 3- and 6-month follow-up data collection. For the subset of participants who participated in a qualitative interview, we provided an additional \$10 gift card.

Figure 3. Study Timeline

Data analysis and Interpretation

Quantitative Data Analysis

The quantitative data were cleaned and descriptive statistics (mean and standard deviation (SD)) for continuous variables and frequency and percentage for categorical variables) were used to describe relevant demographics and characteristics of the sample. Data screening and preliminary analysis were first performed using Chi-square tests for categorical variables and t-tests for continuous variables. The results from this analysis: 1) described data distributions; 2) evaluated the amount and patterns of missing data; and 3) identified the associations between variables such as possible imbalances between groups. We applied a significance level $\alpha = .05$ and the data were analyzed using Statistical Package for Social Sciences, SPSS Version 25, SPSS Inc.

Analysis for Aim 1) *Determine the feasibility and acceptability of VidaTalk™ communication intervention in family caregivers of MV patients during their ICU stay.*

Feasibility. Recruitment rate was determined by proportion of participants screened as eligible and approached who consent to the study. Retention rate was calculated as the proportion (completed/enrolled) of participants remaining to each follow-up time point and study completion (6 months after the ICU discharge). The number of family participant's ICU visits during the ICU stay (from study enrollment to ICU discharge/extubation) documented by family participants in the family visitation log was used to determine the feasibility. Participants in both intervention and AC groups completed Family Visitation Logs during the study period to track their ICU visits and tablet usage during each visit. The written data including number of visits and daily tablet use in the log were transferred to Excel spreadsheets for data management.

Proportion of number of visits to days in the study was calculated for each participant then transformed to number of visits per week. Mean number of visits per week was calculated for each group for group comparison.

Acceptability. The proportion of use of the tablet to the number of ICU visits was calculated for each patient. Mean proportion of tablet use to ICU visit was calculated for each group for group comparison. Participants' written narrative feedback on the VidaTalk™ from the FCS, family caregiver's involvement noted by a researcher in daily interventionist log/field notes, and participants' narrative responses from the qualitative interviews were coded into qualitative themes regarding family caregivers' perceptions of the VidaTalk™, use of the VidaTalk™ while ICU visit, and emotional reactions to the use of the VidaTalk™.

Analysis for Aim 2) *Test the preliminary efficacy of VidaTalk™ compared to AC on psychological symptoms in family caregivers during the ICU stay (baseline, extubation/ICU discharge) and post-discharge (1-mos; 3-mos; 6-mos).*

1) Selection of family member

We selected one family participant for each patient for the analysis for the aim 2 for several reasons: (1) to meet the criterion for independence; (2) when more than one family caregiver was enrolled in the study, we noticed that only one family caregiver had major communication experience with the patient (more ICU visits and more frequent communication with the patient). One family caregiver was identified based on the number of ICU visits and tablet usage recorded in the Family Visitation log form. Six patients had two family caregivers who participated in the study. First, we excluded those who did not meet the threshold number of ICU visit (≥ 3 days per week). As a result, four participants (two from each group) who did not

meet this threshold were excluded. We also excluded participants who had zero or almost zero tablet usage which excluded an additional two participants in the VidaTalk™ group.

2) Anxiety and depressive symptoms.

To test the effect of VidaTalk™ on anxiety and depressive symptoms which were measured at five time points including at baseline, extubation/ICU discharge, 1-mos, 3-mos, and 6-mos post-ICU discharge. Because we noticed that there were many external factors that were not controllable during the post-ICU period, we determined that the 1-month time point which is most proximal to the intervention should be the primary focus in the analysis and interpretation.

To examine the effect of missingness, baseline HADS-A and HADS-D scores, demographics, other variables were compared between those lost to follow-up and those who remained in the study at each time point. Exploratory analysis identified the associations between variables such as possible imbalances between groups. Baseline HADS-A and HADS-D scores, demographics, and other variables that possibly affect the outcomes were compared between the VidaTalk™ and AC groups at each time point.

Due to missing data and multiple dropouts during the post-ICU discharge period for the follow-up assessment, between-group comparisons were used to evaluate the preliminary efficacy of the VidaTalk™ app on family caregiver anxiety and depressive symptoms. Score changes from the baseline were computed for HADS-A and HADS-D at each time point. Those change scores were compared between the VidaTalk™ and AC groups using t-test. Due to the limited number of study participants, effect sizes were computed to quantify the difference between two groups. Effect sizes indicate clinical impact of an intervention which is a simple way of quantifying the difference between two groups. Effect size is important tool in reporting and interpreting effectiveness which emphasizes the size of the difference rather than

confounding this with sample size (Ellis, 2010). The effect size used for t-test in this study was Cohen's d. Cohen suggested that $d = 0.2$ be considered a 'small' effect size, 0.5 represents a 'medium' effect size, and 0.8 a 'large' effect size (Polit, 2010).

3) PTSD-related symptoms

Impact of Events Scale-Revised (IES-R) scores were not normally distributed and displayed a large degree of skewness, therefore, we used nonparametric method to test the effect of the VidaTalk™ on post-ICU PTSD-related symptoms. Mann-Whitney U test was used to conduct non-parametric between-group comparison of 1-mos, 3-mos, and 6-mos IES-R scores. Effect sizes were computed using Eta squared (η^2) for Mann-Whitney U test (Levine & Hullett, 2002). While Cohen's d effect sizes are .20, .50, and .80 (small, medium, and large, respectively), the Eta squared equivalents are .01, .06, and .14, respectively (Polit, 2010). IES-R scores of ≥ 22 indicate a significant rate of PTSD-related symptoms (de Miranda et al., 2011; Garrouste-Orgeas, Coquet, Périer, et al., 2012). The existence of PTSD-related symptoms post-ICU discharge was determined by IES-R scores above the cut-off of 22. We compared the number of participants with PTSD-related symptoms at each time point using Chi-square test. Odds Ratio (OR) was calculated to measure the association between the intervention exposure and the number of participants who had PTSD-related symptoms at 1-, 3-, and 6-month time points.

Analysis for Aim 3) *Examine the role of family caregivers' perceived communication difficulty in moderating the effects of VidaTalk™ on their psychological symptoms.*

Family caregivers' perceived communication difficulty, total scores on FCS, was hypothesized to have a moderating effect on the effect of the communication tool on psychological symptoms. To test Aim 3, we explored the possible effect of baseline perceived communication difficulty, measured by the FCS, on 1-mos anxiety and depressive symptom patterns. The total FCS score at baseline was transposed to a categorical variable using the cut-off score of 27 indicating the most neutral response on perceived communication difficulty.

Subgroup comparisons were conducted. We categorized baseline total FCS scores into two groups: 1) high perceived communication difficulty (scores below 27) and 2) low perceived communication difficulty (scores above 27). We compared the number of participants who had HADS-A and HADS-D scores above the cut-off (≥ 7 for each HADS subscale) at 1-month time point by communication difficulty subgroup as well as the intervention group. Due to small sample size, comparisons were conducted by visual examination of patterns.

Qualitative Data Analysis

Analysis for Aim 4A & 4B) *Explore the family caregiver's perceptions of communication with VidaTalk™ (Aim 4A) and their emotional experience in communicating with a patient family member during critical illness and MV treatment (Aim 4B).*

The qualitative data (e-mail interviews) were transferred into ATLAS_{ti} (Version 7.5.18) for data management. Basic qualitative description and constant comparative techniques were

used to code and analyze the text (Creswell, 2012). This strategy involved taking one piece of data and comparing it with all others that may have similarities or differences to develop conceptualizations of the possible relations between various pieces of data. First, the PI read each interview several times to make sense of the data and to become immersed in the data (Polit & Beck, 2012). Then the comparison was conducted within each interview in a form of open coding. During open coding process, every passage of the interview was studied and labeled with an adequate code (Boeije, 2002). The line-by-line examination was done to label meaning units, and additional codes may be added, or existing codes may be modified as the analysis continues. After open coding, the codes were collected on to coding sheets and categories were generated. The codes and definitions were reviewed and discussed with dissertation committee members who are experts in qualitative data analysis in regular meetings. Then, the comparison was conducted between interviews using axial coding (Boeije, 2002). During this process, fragments from different interviews interpreted as dealing with the same theme were compared and recurring themes across interviews were identified using constant comparison. With the dynamic and cyclic process, recurring patterns, new issues, and the connections linking themes were identified (Gibbs, 2007).

Integration of Qualitative and Quantitative Research Findings

Qualitative and quantitative data were combined to amplify findings and identify within case and between case differences using visual displays (Happ, 2009; Happ, Dabbs, Tate, Hricik, & Erlen, 2006). The frequency of tablet usage from the family visitation log was used to identify high and low user groups. The themes on participants' perceptions of the VidaTalk™ and emotional reactions to the use of VidaTalk™ from qualitative interviews were compared by

tablet usage groups. This between-group comparison showed patterns/differences of their perceptions of the VidaTalk™ and their emotional reactions to communication with the nonvocal patient during the ICU stay among tablet usage groups.

Chapter 4: Results

The study period spanned from February 2018 to June 2019. During this period, participant recruitment, intervention delivery, quantitative data collection, retention, and qualitative interviews were completed.

From February 2018 to November 2018, both patient recruitment for the parent study and family participant recruitment for this study, intervention delivery, and baseline (T0) and extubation/ICU discharge (T1) data collection were completed. Follow-up data collection was conducted at 1-, 3-, and 6-mos after T1 time point and all follow-up data collection was completed by June 2019. A total of 34 family caregivers of 28 patients who were enrolled in the parent study agreed to participate in this study.

Demographics and Baseline Outcomes

Table 8 displays family participants' characteristics for each group and between-group comparison. The sample (n=34) included 30 women (88.2%) and four men, with ages ranging from 24 to 71 years old (mean (SD) = 49.76 (15.65), median = 55.5). Family caregivers were primarily Caucasian (n=25; 73.5%), and more than half (58.8%) were spouses or partners of the patient. Seven of the participants (20.6%) were taking mood-controlling or antidepressant medications for their mood, anxiety, or sleep problems such as Sertraline (Zoloft) (n = 4), Bupropion (Wellbutrin) (n = 1), Escitalopram (Lexapro) (n = 1), and Atarax (Hydroxyzine) (n = 1) at baseline. Six participants (17.6%) had a history of psychiatric or psychological support within a year of the patient's ICU admission such as counseling with a psychologist (n = 3), counseling with a psychiatrist (n = 2), drug/alcohol counseling (n = 1) at baseline. Three

participants had both histories of medication and psychological/psychiatric support. During the post-ICU follow-up period, only one family caregiver newly started taking medication for anxiety (Alprazolam (Xanax)) at 3-month time point.

At baseline (enrollment), more than half (64.7%) of the family caregivers (n = 23) reported dissatisfaction with patient communication, and 38.2% (n = 13) expressed feeling uncomfortable communicating with the patient. Moreover, 76.5% (n = 20) reported that their family patient was not able to say everything that he/she needed to say, and 52.9% (n = 18) did not think that the patient's way of communicating met their current needs.

Five participants (14.7%) showed severe anxiety according to the HADS-A scores (HADS-A $\geq$ 15), and 17 (50%) showed mild to moderate anxiety at baseline (HADS-A= 8-14). Twelve (35.3%) participants reported mild to moderate depressive symptoms based on HADS-D at baseline (Bjelland et al., 2002).

Table 8. Family caregiver Characteristics and Baseline Outcomes

Variables (mean, SD)	Total	Group comparison		
	n = 34	VidaTalk (n = 18)	AC (n = 16)	p values
Age	49.76 (15.65)	48.94 (15.84)	50.69 (15.89)	.88
HADS-A (0-21)	9.24 (4.71)	9.22 (5.02)	9.25 (4.49)	.99
HADS-D (0-21)	5.59 (3.96)	5.89 (3.85)	5.25 (4.17)	.65
FCS total (9-45)	25.47 (5.87)	25.94 (6.24)	24.93 (5.57)	.63
Variables (n, percentage)				
Sex (Female)	30 (88.2)	15 (83.3)	15 (93.8)	.60
<u>Race</u>				.49
Caucasian	25 (73.5)	12 (66.7)	13 (81.3)	
AA	8 (23.5)	5 (27.8)	3 (18.8)	
Asian	1 (2.9)	1 (5.6)	0	
<u>Relationship to patient</u>				.81
Spouse/Partner	20 (58.8)	10 (55.6)	10 (62.5)	
Parent	5 (14.7)	2 (11.1)	3 (18.8)	
Adult child	3 (8.8)	2 (11.1)	1 (6.3)	
Sibling	5 (14.7)	3 (16.7)	2 (12.5)	
Other	1 (2.9)	1 (5.6)	0	
<u>Occupation</u>				.39
Employed	15 (44.1)	7 (38.9)	8 (50)	
Self-employed	1 (2.9)	1 (5.6)	0	
Unemployed	6 (17.6)	3 (16.7)	3 (18.8)	
Retired	9 (26.5)	4 (22.2)	5 (31.3)	
Other (disabled)	3 (8.8)	3 (16.7)	0	
<u>Highest Education</u>				.45
Some high School, no diploma	2 (5.9)	0	2 (12.5)	
High school graduate	8 (23.5)	5 (27.8)	3 (18.8)	
Some college credit, no degree	5 (14.7)	2 (11.1)	3 (18.8)	
College graduate	15 (44.1)	8 (44.4)	7 (43.8)	
Advanced degree	4 (11.8)	3 (16.7)	1 (6.3)	
<u>Previous ICU Experience</u>				
As caregiver	17 (50.0)	7 (41.2)	10 (62.5)	.17
As patient	3 (8.8)	0	3 (18.8)	.09
History of treatment with psychoactive agents	7 (20.6)	3 (18.8)	4 (25.0)	.55
History of psychological/psychiatric Support	6 (17.6)	2 (11.1)	4 (25.0)	.29

Legend: HADS = Hospital Anxiety and Depression Scale; HADS-A= Anxiety subscale; HADS-D= Depression subscale; FCS= Family Communication Scale; AA= African American

The patient sample included 21 men (75%) and seven women, with ages ranging from 27 to 80 years old (mean (SD) = 51.39 (16.04)). Patients were severely ill with high mean Acute Physiology and Chronic Health Evaluation (APACHE) III scores (66.35, SD = 25.48) with multiple co-morbidities with mean Charlson Comorbidity Scores of 3.71 (SD = 2.54). Fourteen patients (50%) were admitted to medical units, ten patients (35.7%) were in Cardiovascular, and four (14.3%) were in Surgical units. The most frequent diagnosis on the ICU admission was respiratory problems (n = 12, 42.9%), followed by cardiovascular problems (n = 6, 21.4%), sepsis (n = 5, 17.9%), and surgery (n = 5, 17.9%). Mean ICU length of stay was 32.57 days (SD = 23.87, median = 25.01) and the mean number of MV days was 21.7 days (SD = 15.18, median = 19.00).

Fourteen (41.2%) patients were discharged to a post-acute care facility including long-term care, skilled nursing facility, hospice, and rehab, eight (28.6%) were discharged to home from the hospital, and five patients (17.9%) expired during the hospitalization. Among those who survived at extubation/ICU discharge (n = 23), ten patients (43.5%) were re-admitted to the ICU. During the post-ICU discharge period, four more patients expired.

Feasibility and Acceptability of VidaTalk™ for ICU family caregivers

Aim 1) Determine the feasibility and acceptability of VidaTalk™ communication intervention in family caregivers of MV patients during their ICU stay.

Feasibility

Feasibility was determined by 1) recruitment rate, 2) retention rate, 3) the number of ICU visits per week (>3 days/week).

1) Recruitment. Figure 4 shows the CONSORT Flow Diagram that summarizes study recruitment, enrollment, retention, and reasons for withdrawal/dropouts at all study time points. Based on previous studies that enrolled ICU patient-family dyads, we expected to enroll family caregivers from approximately 50% of the enrolled study patients (Cox et al., 2018). From 2/19/2018 to 11/4/2018, we identified 49 patients who had family caregivers who regularly visited and 69 family caregivers of 49 patients were screened for eligibility. Among those 69 family members, 22 did not meet inclusion criteria, and the remaining 47 family caregivers were approached. We enrolled 34 family caregivers from 28 enrolled patients (6 patients had two family participants). The number of 28 patients was approximately 44% of patients who were enrolled in the parent study and 57% of the enrolled patients who had family members visiting regularly (n = 49). Seven out of 47 (14.9%) family members approached declined to participate in the study by indicating that they were “not interested in the study” (n = 5) or “too much is going on in the ICU” (n = 2). Six family caregivers became ineligible after they requested additional time to consider participation, because the patient’s participation in the parent study ended due to extubation or ICU discharge. Finally, a total of 34 family caregivers (72.3% of those eligible) of 28 patients (44.4% of patients who were enrolled in the parent study, and 57% of patients who had family caregivers) agreed to participate, signed the informed consent, and completed the initial data collection.

Figure 4. CONSORT Flow Diagram

2) Retention. Retention rate from baseline (T0) to ICU discharge/extubation (T1) was 82.3% (28 out of 34). However, the retention rate dropped dramatically after ICU discharge for follow-up data collection as depicted in Figure 4, Figure 5, and detailed below.

Intervention Period. At baseline, all family participants who agreed to participate in the study completed baseline assessment and began study participation. Five participants withdrew because their family patients' condition deteriorated (n=2) or the patient died during the ICU stay (n=3). All of these five participants were in the VidaTalk™ group. Only one participant in the AC group withdrew and this was due to the family caregiver participant's own health condition. Most participants, n=28 (82.3%), remained in the study until extubation/ICU discharge (T1).

Post-ICU period. At 1-month (T2), there were 5 dropouts from the study (3 in VidaTalk™, 2 in AC) including one requested withdrawal due to the patient's death (VidaTalk™ group) and 4 lost to follow-up with no response to multiple contact attempts. A total of 23 (23/34 = 67.6%) remained in the study at 1-month. At 3-months (T3), four more participants dropped out (2 in VidaTalk™, 2 in AC), two withdrew by request in the VidaTalk™ group: one withdrew because "too much going on" with patient's readmission and another withdrew due to the patient's death. Another two were lost to follow-up in the AC group. Therefore, nineteen (n=19) participants remained in the study at 3-months (19/34 = 55.9%). At 6-months (T4), there were 3 dropouts (one VidaTalk™, two AC group) all were nonresponsive to multiple contact attempts, i.e., lost to follow-up. A total of 16 family caregivers representing 14 patients completed the 6-months follow-up assessment (16/34 = 47.1%).

Figure 5. Retention rate at each time point

3) Number of ICU visits

The proportion of days during the intervention period (from enrollment to extubation/ICU discharge) in which family caregivers visited the ICU was 65.8% for the VidaTalk™ group and 66.5% for the AC group respectively (mean days in study = 10.14 days; mean ICU visit times = 6.11). The number of ICU visits per week was 4.61 days/week for VidaTalk™ and 4.65 days/week for the AC group. Both the VidaTalk™ and AC groups met the acceptability criteria and were well-matched for the number of ICU visits per week (≥ 3 days/week) that was set before the study began. Figure 6 shows the individual number of ICU visits per week and group means. Two participants in each group did not meet the threshold (≥ 3 days/week) (figure 6).

Figure 6. Individual and group mean of the number of ICU visits per week

Acceptability

Acceptability of the tablet communication application to family caregivers was determined by 1) patient-family caregiver tablet usage during ICU visit and 2) participants' qualitative evaluation of acceptability and the experience of the VidaTalk™.

1) Tablet Usage (group comparison)

The mean proportion of tablet use (yes/no) per ICU visit was calculated for each group (25.9% for AC; 59.4% for VidaTalk™ group). Participants in the VidaTalk™ group used the tablet more often than did those in the AC group (figure 7).

Figure 7. Comparison of tablet usage between groups

2) Qualitative Evaluation

The acceptability of the VidaTalk™ to family caregivers of nonvocal ICU patients was also evaluated qualitatively by thematic analysis of participants' narrative comments and feedback on the FCS survey, family visitation log, interventionist log, PI's field notes and qualitative interviews with family participants in the intervention group. In written narrative feedback about the VidaTalk™, participants generally reported positive experiences with the VidaTalk™ app. The following sections provide detail on participant satisfaction and experiences using the app.

Satisfaction with the VidaTalk™. The family caregivers described their experiences of having the VidaTalk™ as an exciting and an overall good experience. The VidaTalk™ helped them communicate with their loved ones during the ICU stay by providing a means for the patients to express their needs/wishes clearly and for the families to understand exactly what the patient was trying to say.

“Our experience with the tablet was overall good experience when we used it. It helped my wife have the capability to tell us what she needed from us while having a trach (tracheostomy). It (VidaTalk™) was a valuable tool that allowed us to understand exactly what she wished to say.” (61-yr-old husband, interview)

“Using VidaTalk™ application is an exciting experience during the difficult time when my husband was admitted in the ICU.” (30-yr-old wife, interview)

“We relied on (before receiving the VidaTalk™ app) info from staff re patient communications; hand gestures, lip reading aren't always clear - we've tried to use pre-pointed

messages but they are not usually successful. The tablet was helpful in expanding our communication.” (50-yr-old wife, narrative comments in the FCS)

Some family caregivers shared their positive experience with others such as visitors or ICU staff and encourage them to use the VidaTalk™ to communicate with the patient.

“Wife was observing wound care and talking with the palliative care DNP. She shared experience with tablet with the DNP; DNP later looked at tablet and gave extremely positive feedback.”

“Spouse showed and demonstrated how the Vidatalk™ app worked with the kidney dialysis nurse. She shared that the patient created a question with the 'texting' /typing portion of the app – usually type sentences to ask questions.”

(63-yr-old wife, observation recorded in the interventionist log)

Family’s supportive role. Families often helped the patient to use the tablet by holding the tablet and coaching them on how to use it. They also encouraged their loved one to use it when the communication was not clear.

“The patient's brother was in the room today. He was very excited to see the Vidatalk™ app and encouraged his sister (patient) to use it rather than the Boogie Board since it speaks for her. He was very thankful that I was able to restore the app to working appropriately.”

(Patient’s brother, observation recorded in the interventionist log)

“Sister is very involved in helping and encouraging the patient with the device. When she is not able to understand what the patient is trying to say, she encourages him to use VidaTalk™. She holds the tablet for him, points (to) messages, and asks if he wants a different menu/message. The sister said that she couldn't understand him, so offered the tablet. He was

able to say "I am in pain", so she went to 'pain description' menu and he described the location of pain and level of pain." (65-yr-old sister, observation recorded in PI's field note)

"After receiving the tablet, we could hold the tablet for [patient] while he either pointed to an icon or typed his questions or answers into the Tablet." (63-yr-old wife, interview)

"I love you" message to the family. Nonvocal patients were able to say "I love you" to their family caregivers using the picture icon or typing within the VidaTalk™ app. Family caregivers commented that the "I love you" message from their loved one was one of the most meaningful conversations to them.

"The patient called her [wife] and said "I love you" using the VidaTalk™ app over the phone before she arrived at the hospital." (35-yr-old wife, observation recorded in PI's field note)

"During enrollment and baseline data collection in the room, the patient wanted to say something. He asked for the tablet, hit the "I love you" icon in the VidaTalk™ app, and smiled at his wife." (30-yr old wife, observation recorded in PI's field note)

"..he pointed to the icon "I Love You" every day which means a lot when you can't hear your spouse's voice." (63-yr-old wife, interview)

Less frustration/less stress. The families also commented about a reduction of frustration and additional stress in both the families and the patients while communicating with each other using the VidaTalk™.

"It was nerve-wracking not to know what my mom was trying to say to us and it also frustrated her. The tablets helped give us a sense of relief to lessen this frustration." (34-yr-old daughter, qualitative interview)

Preliminary Efficacy of VidaTalk™

Aim 2) Test the preliminary efficacy of VidaTalk™ compared to AC on psychological symptoms in family caregivers during the ICU stay (baseline, extubation/ICU discharge) and post-discharge (1-mos; 3-mos; 6-mos).

We selected one participant for each patient for the statistical analysis for the Aim 2. A total of 28 participants were included in the efficacy analysis at baseline. Table 9 shows the number of participants included in the analysis at each time point. Due to dropouts and missing data at each time point, only partial data was available for the analysis. Table 6 shows how many participants were available at each time point.

Table 9. Number of participants at each time point

Group	Baseline (n=28)	Extubation/DC (n=22)	1-mos (n=19)	3-mos (n=16)	6-mos (n=14)
VidaTalk™	14	9	7	6	5
AC	14	13	12	10	9

We compared baseline outcomes, demographics, and other variables that might be associated with outcome variables to assess between-group differences. We compared those between-group differences for a total of 28 patients at baseline (Table 10) as well as for those who remained in the study at each time point. There were no significant differences in baseline HADS-A and HADS-D scores, total FCS scores, demographics, ICU experiences, history of psychoactive medication treatment, or history of psychological/psychiatric support between the VidaTalk™ and AC groups.

Participants who remained in the study were compared, using Chi-square and t tests, with those who dropped out at each time point to identify any differences in baseline HADS-A and HADS-D scores, demographics, and other variables. There were no statistically significant differences between participants who remained in the study and those who dropped out.

Table 10. Family Caregiver Characteristics and Baseline Outcomes

Variables (mean, SD)	Study Group		<i>p</i> values
	VidaTalk (n = 14)	AC (n = 14)	
Age	48.50 (17.24)	53.36 (14.98)	.43
HADS-A	9.14 (5.08)	9.29 (4.83)	.94
HADS-D	5.86 (3.98)	5.50 (3.98)	.82
FCS total	25.50 (5.53)	26.64 (6.64)	.63
Variables (n, percentage)			
Sex (Female)	11 (78.6)	13 (92.9)	.28
<u>Race</u>			.35
Caucasian	9 (64.3)	12 (85.7)	
AA	4 (28.6)	2 (14.3)	
Asian	1 (7.1)	0	
<u>Relationship to patient</u>			.71
Spouse/Partner	10 (71.4)	9 (64.3)	
Parent	1 (7.1)	3 (21.4)	
Adult child	1 (7.1)	1 (7.1)	
Sibling	2 (14.3)	1 (7.1)	
<u>Occupation</u>			.48
Employed	6 (42.9)	6 (42.9)	
Unemployed	3 (21.4)	3 (21.4)	
Retired	3 (21.4)	5 (35.7)	
Other (disabled)	2 (14.3)	0	
<u>Highest Education</u>			.61
Some high School, no diploma	0	2 (14.3)	
High school graduate	4 (28.6)	3 (21.4)	
Some college credit, no degree	2 (14.3)	3 (21.4)	
College graduate	7 (50.0)	5 (35.7)	
Advanced degree	1 (7.1)	1 (7.1)	
<u>Previous ICU Experience</u>			
As caregiver	5 (35.7)	8 (57.1)	.26
As patient	0	2 (14.3)	n/a
History of treatment with psychoactive agents	3 (21.4)	3 (21.4)	1.0
History of Psychologic/psychiatric Support	3 (21.4)	3 (21.4)	1.0

Exploration of Anxiety and Depressive symptoms over time

We explored anxiety and depressive symptoms demonstrated by mean scores of HADS-A and HADS-D over time by group (Figure 8).

Both anxiety and depressive symptoms were similar in both the VidaTalk™ and AC groups at baseline. VidaTalk™ group anxiety symptoms (mean HADS-A scores) decreased dramatically after the ICU discharge/extubation (T1) at the 1-month time point (T2), then increased after T2. The increased scores after T2 are still lower than the level of anxiety during the ICU stay, and stayed nearly constant until T4. On the other hand, the AC group anxiety level remained constant from baseline until T2, then decreased after T2. The mean HADS-A scores after T2 were similar in both VidaTalk™ and AC groups. Depressive symptoms demonstrated by mean HADS-D scores tended to increase after T1 in both VidaTalk™ and AC groups. In the VidaTalk™ group, mean HADS-D scores remained high until T4, whereas mean HADS-D scores decreased over time.

Figure 8. Anxiety and Depressive symptom changes over time by each group

Preliminary effects of VidaTalk™ on Anxiety and Depressive Symptoms

Between-group comparisons were used to evaluate the preliminary efficacy of the VidaTalk™ app on family caregiver anxiety and depressive symptoms. We assessed individual difference in anxiety and depressive symptoms between baseline scores and scores at each time point. By treating means of difference in HADS-A and HADS-D scores between baseline and each time point as outcome variables, we compared group differences to evaluate the impact of VidaTalk™ on patient's anxiety and depressive symptoms. Table 8 displays mean scores of anxiety (HADS-A) and depressive symptom (HADS-D) at each time point for each group, mean of difference in HADS-A and HADS-D scores between baseline and each time point for each group, and between-group comparisons.

Mean difference of HADS-A scores at T1 was close to zero for both groups (.11 for the VidaTalk™ group and -.08 for the AC group). The mean difference of HADS-A scores were negative across all time points after T1 for both groups, which means the participants' anxiety symptom scores were lower than their baseline scores. The biggest between-group difference was found in mean HADS-A scores at T2 (1-mos) in which mean difference of HADS-A scores was - 2.29 for the VidaTalk™ group and -.83 for the AC group. Anxiety symptom scores (HADS-A mean scores) decreased by 1.5 greater in the intervention group than the AC group with a medium effect size (Cohen's $D = -.43$). As our primary endpoints for anxiety and depressive symptoms were T1 and T2 which were more proximal to the intervention, these findings are clinically meaningful, though not statistically significant.

Mean difference of HADS-D scores was negative at T1 in both VidaTalk™ and AC groups. Mean difference of depressive symptom scores was positive for both groups at T2, then it stayed at a positive level at T3 (3-months) and T4 (6-months) for the VidaTalk™ group,

whereas it decreased for the AC group. The biggest between-group difference was found at T4 (6-mos) in which mean difference of HADS-D scores was 0.6 for the VidaTalk™ group and -1 for the AC group with medium effect size ($d = 0.54$).

Table 11. Group comparisons of family caregiver anxiety and depressive symptoms

	Symptom score, Mean $\pm$ SD		Change score from baseline, Mean $\pm$ SD		Effect Size (Cohen's D)	<i>t</i> statistics	<i>p</i> value
Variable (range)	VidaTalk™	AC	VidaTalk™	AC	VidaTalk™ vs Control		
<u>HADS-A</u> (0-21)							
T0	9.14 $\pm$ 5.08	9.29 $\pm$ 4.83	-	-	-	-	-
T1	8.67 $\pm$ 4.44	9.62 $\pm$ 4.86	.11 $\pm$ 3.72	-.08 $\pm$ 2.59	.06	-.14	.89
T2	4.86 $\pm$ 4.06	9.17 $\pm$ 4.80	-2.29 $\pm$ 3.25	-.83 $\pm$ 3.51	-.43	.91	.38
T3	6.83 $\pm$ 4.92	6.80 $\pm$ 5.07	-1.00 $\pm$ 4.29	-2.20 $\pm$ 5.43	.25	-.49	.63
T4	6.80 $\pm$ 5.63	6.22 $\pm$ 6.48	-1.20 $\pm$ 3.70	-2.22 $\pm$ 6.99	.18	-.36	.73
<u>HADS-D</u> (0-21)							
T0	5.86 $\pm$ 3.98	5.50 $\pm$ 4.31	-	-	-	-	-
T1	5.78 $\pm$ 4.32	5.15 $\pm$ 4.43	-.33 $\pm$ 1.66	-.15 $\pm$ 2.41	-.09	.21	.84
T2	7.43 $\pm$ 2.64	6.20 $\pm$ 3.73	.86 $\pm$ 3.18	.08 $\pm$ 2.81	.26	-.55	.96
T3	7.03 $\pm$ 3.98	5.53 $\pm$ 3.93	.67 $\pm$ 2.25	-.20 $\pm$ 3.73	.28	2.11	.17
T4	6.33 $\pm$ 4.27	4.33 $\pm$ 3.67	.6 $\pm$ 2.88	-1.00 $\pm$ 3.43	.54	-.88	.39

T0 = baseline, T1 = Extubation/ICU discharge, T2 = 1-mos, T3 = 3-mos, T4 = 6-mos follow-up

Preliminary effect of VidaTalk™ on Post-ICU PTSD-related Symptoms

To evaluate the preliminary effect of VidaTalk™ on family caregivers' PTSD-related symptoms during the post-ICU discharge period, the Revised Impact of Events Scale (IES-R) was used to capture the early symptoms at 1- and 3-months and late symptoms at 6-months after the ICU discharge.

Table 12 shows the median of IES-R scores at each time point and the number of participants who had scores above cut-off (IES-R score ≥ 22) indicating that the individual has PTSD-related symptoms for each group. There was no statistically significant difference in median IES-R score and the number of participants who had PTSD-related symptoms between groups at 1-, 3-, and 6-month time points (Table 12).

Although no statistically significant difference was found, the median of IES-R scores was lower in the VidaTalk™ group than the AC group across all three time points (Figure 9). The VidaTalk™ group had lower PTSD-related symptoms with a medium effect size ($\eta^2=0.07$) at one month, and a medium-to-large effect size ($\eta^2=0.09$) at three months. The Odds ratio (OR) results indicate that family caregivers in the AC group are 3 times more likely to develop PTSD-related symptoms than those with VidaTalk™ at 1-month. The odds of development of PTSD-related symptoms was 2.33 higher in the AC group compared to the VidaTalk™ group, and 2.3 at 3-months.

Table 12. Comparisons of PTSD-related symptoms between VidaTalk™ and AC groups

	VidaTalk™	AC	Effect size (η^2)	Odds Ratio	<i>p</i> value
T2 (1-mos)	n = 7	n = 12			
Median IES-R Score [IQR]	21.5 [32]	30.5 [37]	.07		.26
IES-R Score ≥ 22 , n (%)	3 (50)	9 (75)		.33	.29
T3 (3-mos)	n = 6	n = 10			
Median IES-R score [IQR]	21 [26]	27.50 [23]	.09		.25
IES-R score ≥ 22 , n (%)	3 (50)	7 (70)		.43	.42
T4 (6-mos)	n = 5	n = 9			
Median IES-R score [IQR]	23 [22]	26 [34]	.00		.79
IES-R score ≥ 22 , n (%)	3 (60)	5 (55.6)		1.2	.57
Mann-Whitney U test for comparison of median IES-R scores; Chi-square test for comparison of number of participants who had above cut-off IES-R scores

Figure 9. Total IES-R scores at 1-, 3-, and 6-month

Moderating effect of Communication difficulty

Aim 3) Examine the role of family caregivers' perceived communication difficulty in moderating the effects of VidaTalk™ on their psychological symptoms.

To determine if there is a moderating effect of family's perceived communication difficulty on the effect of VidaTalk™ on ICU family caregiver adverse psychological outcomes, we conducted subgroup comparisons. We categorized baseline total FCS scores into two groups: 1) high perceived communication difficulty (scores below 27) and 2) low perceived communication difficulty (scores above 27).

We compared the number of participants who had HADS-A and HADS-D scores above the cut-off (≥ 7 for each subscale) at 1-month time point by communication difficulty subgroup as well as the intervention group. This comparison showed that there are no clearly different 1-month symptom patterns among the participants who reported high communication difficulty at baseline; and the sample is just too small to detect a pattern. Due to the study limitations, aim 3 was not testable.

Table 13. Comparisons of anxiety symptoms at 1 month by communication difficulty subgroup

	VidaTalk™		AC	
	HADS-A ≥ 7	HADS-A < 7	HADS-A ≥ 7	HADS-A < 7
Low communication difficulty	2	3	3	1
High communication difficulty	2	1	4	4

Table 14. Comparisons of depressive symptoms at 1 month by communication difficulty subgroup

	VidaTalk™		AC	
	HADS-D ≥ 7	HADS-D < 7	HADS-D ≥ 7	HADS-D < 7
Low communication difficulty	2	3	1	3
High communication difficulty	2	1	2	6

Qualitative Phase

Aim 4A & 4B) Explore the family caregiver's perceptions of communication with VidaTalk™ and the family caregiver's emotional experience in communicating with a patient family member during critical illness and MV treatment.

Recruitment and participant characteristics

Among 18 family participants in the intervention group, four family caregivers withdrew from the study due to patient's condition change/death during the ICU stay. Out of 14 remaining in the study after the ICU discharge, three family caregivers were unresponsive to additional contacts for the invitation to participate in the qualitative interview. A total of 11 participants were invited to participate in qualitative interviews, and four participants declined. Finally, seven family caregivers of 6 patients agreed to participate in the qualitative interviews; five completed the 3 or 4 cycles of the email interview and two partially completed the interview (one to two cycles).

Most respondents (five out of seven) were female, and their median age was 61 years (range 23 to 71). Four were spouses, two were adult children (daughters), and one was a sister of the patient.

Figure 10. Concept map

The VidaTalk™ opened patient-family communication by allowing clear communication and expanding communication contents. Family caregivers described their experience of communicating with the nonvocal mechanically ventilated patients as difficult and frustrating. After receiving the VidaTalk™ tablet application, they felt relieved, happy, and thankful to communicate with their loved one. Most family caregivers commented about the difference in communication before and after using the VidaTalk™ (Figure 10).

“After having a tracheotomy my wife “OOO”, and those caring for her, found communication quite difficult and frustrating. Attempting to convey the most simplest (sic) of wants and needs by gesture and communication poster were exasperating. OOO began using a Vidatalk tablet approximately July 1, 2018 with immediate positive results. OOO enjoys working on her computer and in little time was able to navigate the various applications. Within a few days the tablet was used constantly to communicate with doctors, nurses and visitors.” (71-yr-old husband)

Perceptions of communication with VidaTalk™

Communication experience before using VidaTalk™

Family caregivers described their experiences communicating with their loved one in the ICU before they received VidaTalk™ as difficult, “guess work,” frustrating, and stressful.

1) Guess work

Family caregivers needed to guess what the patient was trying to say by mouthing words gestures, or writing in the air, but the communication was not always clear.

“Communication before the tablet was at best guess work not sure if wants and needs were met let alone understood.” (71-yr-old husband)

“...He also liked to write out letter in the air and we would try our best to guess which word he was trying to spell.” (23-yr-old daughter)

2) Communication difficulty

The families stated that communication between families and patients before having the VidaTalk™ was difficult. Family caregivers were not able to understand their patient’s needs or wishes and found reading lips and interpreting gestures challenging. They also commented that the patient was not able to express exactly what they wanted to say and that the message topics were not always easily predicted.

“I am not very adept at reading lips and interpreting gestures was a challenge.” (71-yr-old husband)

“OO often asked about things that needed to be addressed at home or with his care which weren’t always clear when reading his lips.” (62-yr-old wife)

3) Family caregiver’s negative feelings

Both families and patients felt frustrated and stressed with inability to communicate. Respondents described the families’ frustration and stress as additional to the stress they felt with situations in the ICU.

“My feeling while communicating, it was kind of very frustrating since he wasn’t able to talk during that time.” (30-yr-old wife)

One family member described the family's position as an observer in the ICU. She stated that witnessing the patient suffering with being unable to communicate adds more frustration and stress in the ICU.

"I can't imagine a more frustrating and stress filled situation than witnessing a loved who is in the hospital ICU and unable to communicate clearly." (62-yr-old wife)

4) Patient's negative feelings

The patients also had negative feelings with the inability to communicate that family caregivers recognized. Respondents perceived that not being understood increased the patient's stress and frustration or exasperation significantly.

"After having a tracheotomy, my wife, and those caring for her, found communication quite difficult and frustrating. Attempting to convey the most simplest (sic) of wants and needs by gesture and communication poster were exasperating." (71-yr-old husband)

The family caregiver's frustration with inability to understand and the patient's frustration with communication difficulty often occurred together. The families described the patient abandoning or withdrawing from further communication attempts when unable to be understood. The worry and stress that this situation engendered in family caregivers was striking and included concern for the patient's safety and mental health.

"It was nerve-wracking to not know what my mom was trying to say to us and it also frustrated her." (34-yr-old daughter)

“Prior to the tablet use, he was frustrated that he couldn’t be understood and we could visibly see his facial disappointment and exasperation as he waived off any additional attempts to try and relay what he was trying to express.” (62-yr-old wife)

“We were all worried about his health and the added stress of not understanding his wishes greatly increased his frustration and our worry for his peace of mind, care and comfort.” (62-yr-old wife)

Perceptions of communication with VidaTalk™

Seven main themes in terms of family caregiver’s perceptions of communication with VidaTalk™ were identified from the analysis of qualitative interviews. Those include: 1) satisfaction with the VidaTalk™, 2) communication contents, 3) difference in communication before and after using the VidaTalk™, 4) conditions when VidaTalk™ was used, 5) other communication tools used, 6) barriers to using the VidaTalk™, and 7) suggestions for future patients and families.

1) Satisfaction with the VidaTalk™

This category refers to family caregiver’s satisfaction with the use of VidaTalk™ that family caregivers voiced about their experience with VidaTalk™ during the MV treatment in the ICU. Families described having VidaTalk™ during the ICU stay as positive experience.

i) Being helpful to communicate: All seven respondents commented that the VidaTalk™ was helpful to communicate with their family patient during MV treatment in the ICU.

“The tablet helped my husband communicate with his family and staff when we weren't able to understand his wishes.” (62-yr-old-wife)

“.. the tablet helped my husband a lot to communicate with me, family, and other visitors using the downloaded app (VidaTalk™) such as needs and wants... during that time, I was thankful and happy that he was able to express his feeling.” (30-yr-old wife)

“While using the tablet I found it to be helpful when the patient is being more willing to use the tablet. I personally liked the tablet because it would give us a better idea as to what he was trying to say.” (23-yr-old daughter)

“The VidaTalk™ app helps you communicate with your loved one, and that was of upmost importance to us!” (34-yr-old daughter)

One family member stated that it would have been more helpful if they would have received the tablet earlier during the patient's period of intubation.

“It would have been more helpful if we would have received tablet while she was intubated. Would definitely have saved her some stress and frustration not being able to communicate. We only got to use it for about a week and it was very helpful.” (61-yr-old sister)

ii) Understanding communication: Most family caregivers commented that VidaTalk™ allowed them to have clear communication with their loved ones. They stated that their family patients were able to express their needs/wishes clearly, and family caregivers were able to understand exactly what the patient wanted to say. They also stated that VidaTalk™ allowed them to know if the patient's needs were being met or not.

“Previous to the use of the tablet his thoughts and concerns were not always clearly understood; afterward we knew exactly what he thought or needed.” (62-yr-old wife)

“The tablet we figured out better ways to communicate and help my mom with what she needed from us.” (34-yr-old daughter)

iii) Allowing two-way communication: In addition to the family member’s ability to understand the patient and the patient’s ability to express their needs/wants, VidaTalk™ allowed more than two-way communication between the patient, families, and care providers. The communication interactions moved from yes – no questions or simple requests to dialogue.

“..The tablet allowed him (the patient) to type his questions to us (families) and we could then answer his questions or relay his wishes to the staff. He asked about bills, insurance, how the kids were doing, pointed to the “I Love You” icon, he asked that the staff adjust his position in bed, let them know the level of his discomfort..” (62-yr-old wife)

iv) Restoring a sense of humor: The ability to communicate with VidaTalk™ provided the patients with a means to express their personality and to lighten the mood with humor.

“With the use of the keyboard, she was also able to joke with those caring for her... Joking was not actually telling jokes per say, but just everyday kidding.” (71-yr-old husband)

v) Communication is crucial: Family caregivers emphasized the importance of family-patient communication while the patient is unable to communicate in the ICU. They also stated communication aid is crucial for the ICU patients and family members.

“..strongly encourage families and staff to use this tool (VidaTalk™ app) as it’s very important to allow the patient to continue participating in their own care and home life.” (62-yr-old wife)

“I think a form of communication is crucial for families and caregivers receiving mechanical ventilation. You have to have a way of sharing your feelings and thoughts and communicating what patients need when they are unable to talk.” (34-yr-old daughter)

vi) Unexpected benefit: Family caregivers described unexpected benefits of using a tablet communication application during the ICU stay in addition to clear communication. Specifically, family caregivers identified the rehabilitative benefits of neuromotor coordination as well as the psychological benefits of improved attitude, confidence, and well-being.

“Other unexpected benefits of the tablet were improvement of hand-eye coordination and other motor skills such as stretching to reach for the tablet, increasing range of motion.”

“It cannot be emphasized enough what this tablet did for communicating, overall self-confidence, and well-being for both OOO and her caregivers. ..Her ability to use the tablet opened up communication, that was the beginning of a more healthy attitude aiding in her recovery..”

“Everyone was aware in her overall abilities improving, all centered around being able to talk through the tablet. Before using the tablet, the frustrations associated with the inability to express wants and needs made other improvements in hand-eye and other motor skills were marginal.” (71-yr-old husband)

2) Communication contents

Family caregivers described the content of messages that were shared during communication with nonvocal family patients using the VidaTalk™. They also mentioned specific features within the VidaTalk™ that were used to communicate a particular message, the

most meaningful conversation with their loved one, and the messages that bothered them the most.

i) Patient's needs/requests: The topic most frequently mentioned by family members was the patient's needs and requests. Patients were able to express clearly their needs such as repositioning in bed, washing face, a need for a fan or massage to their family members or care providers. Family members stated that those messages were expressed using picture icons or keyboard on VidaTalk™ app.

"The keyboard was nice to be able to type out exactly what she needed or wanted from us."

(61-yr-old husband)

"..use the tablet with the icons and the keyboard pertaining to his needs." (62-yr-old wife)

ii) 'I love you' message to the family: Most family members stated that their family patient said, 'I love you' to them using picture icons or the typing (keyboard) feature within the VidaTalk™ app. Several family members stated that the patient's 'I love you' message was one of the most meaningful conversations that they had in the ICU.

"The most meaningful (conversations) were always when we discussed his recuperating, coming home and how much he loved his family. He pointed to the icon "I Love You" every day which means a lot when you can't hear your spouse's voice." (62-yr-old wife)

"He told me he love me so much ♡." (30-yr-old wife)

"She was able to tell me she loved me." (61-yr-old husband)

iii) Patient's emotions/feelings: Another frequent conversation topic was the patient's expressed emotions and feelings. Patients were able to express their positive feelings such as feeling of gratitude as well as negative feelings such as feeling scared, anxiety, or distress about their treatment/care using the VidaTalk™.

One family member commented that the patient's ability to express feeling grateful was the most meaningful to the family member.

"I remember her pressing the button that said she was scared. She (patient) also expressed her feeling of gratitude. She thanked us and told us she loved us on the tablet... Her being able to express feelings of gratitude for those helping her were most rewarding." (34-yr-old daughter)

On the other hand, better understanding the patient's feelings could also be heartbreaking as families learned that patients felt anxious and distressed about their illness and treatment.

"Her ability to tell of her anxiety were heartbreaking." (71-yr-old husband)

"The conversation that bothered me the most was his distress about the surgeries." (62-yr-old wife)

The families provided verbal encouragement and emotional support when the patient expressed their fear, worries, or feeling hopelessness about their treatment/care.

"I was so emotional at that time (when the patient (husband) expressed his concerns on his condition and his feeling of hopelessness), and I encouraged him to be strong and everything's gonna be OK." (30-yr-old wife)

"The conversation with my husband that had the most impact was about his need for a heart transplant. Discussed how strong he was and how the Doctors were so hopeful and impressed with his will and positive mental attitude." (62-yr-old wife)

iv) Symptoms/discomfort: Patients also used the VidaTalk™ to describe their symptoms, discomfort, and pain. One family member commented on how the patient described her pain using pain descriptors within the VidaTalk™ app.

“I remember her pointing to her legs and bottom on the VidaTalk™ to show us what was bothering her. We were able to let the nurses know where her pain was coming from.” (34-yr-old daughter)

v) Home/family: Several family caregivers mentioned conversations about home and family that they had with their loved ones. Patients often asked how their children or other family members were doing and talked about future plans for the family.

“The most meaningful conversation was... We were talking about our plan building our house, going on a vacation, and renewing our wedding vows. I was happy that we talked about it.” (30-yr-old wife)

vi) Treatment/care: Patients also asked about things that needed to be addressed with their care, discussed about their treatment plan with families, and wanted to know test results. Patients often expressed their feelings and emotions related to the conversation about their care and treatment plan.

vii) Finances: Several family caregivers commented that their family patient asked about the bills and insurance. One family member stated that her family patient concerned about his health and recovery first, then he became more concerned about bills and insurance later. While financial topics can restore the patient’s normal social function or role, participants also describe it as a source of stress for patients and/or families.

“The conversation that bothered me the most was his distress about the surgeries. Later it was about his concern for medical bills rather than his thoughts being about his health and recovery.” (62-yr-old wife)

3) Difference in communication before and after using the VidaTalk™

i) Difference in communicated messages: Most family members mentioned the difference in communicated messages with their nonvocal family patients in the ICU before and after they started using the VidaTalk™ app. One family member stated that the VidaTalk™ ‘opened up’ the communication with their loved one, and it allowed all levels of communication between the patient and the family member.

“Her ability to use the tablet opened up communication, that was the beginning of a more healthy attitude aiding in her recovery.”

“After the tablet was in use communication on all levels was achieved, wants, needs humor, financial, legal, the door was once again opened.”

(71-yr-old husband)

Similarly, another family member commented about the difference in the level of communication with the VidaTalk™ compared to without the VidaTalk™. Use of the app enabled an expansion of communication range and functions. The following description shows the “opening up” of the patient’s communication ability as a vehicle of empowerment and engagement.

“Until OO received the tablet, he didn't ask as many questions as he then realized he could communicate. He asked about his care more, relayed requests for meds, repositioning in the bed, needing to go the bathroom, who the staff members were that came in groups, need for the fan, a massage. OO also asked for the music be turned on or off, asked about the bills, insurance, how our boys and family were doing, he pointed to the icon “I Love You” every day..” (62-yr-old wife)

This is contrasted with the same family member’s description of a patient’s disempowerment and withdrawal of attempts to communicate when his wishes were not understood before having the VidaTalk™, literally surrendering to voicelessness.

“There was a great difference in communication after receiving the tablet. We all realized that his exact and more detailed thoughts and questions could be discussed. Prior to the tablet use he was frustrated that he couldn’t be understood and we could visibly see his facial disappointment and exasperation as he waived off any additional attempts to try and relay what he was trying to express.” (62-yr-old wife)

4) Barriers to use the VidaTalk™

Several family members mentioned barriers to use of the VidaTalk™ during their ICU stay. Although they found the tool helpful to communicate, some of them were not able to use the VidaTalk™ app as much as they wished for the following reasons.

i) Patient’s condition: When the patient’s condition deteriorated or they were sedated, using the tablet and/or communicating was difficult. One family member stated that the patient was not able to use it due to a lack of strength.

“..her ability to communicate with her tablet is not an option at this time due to her deteriorated state. This unfortunate circumstance has only served to make me appreciate the tablet more.” (71-yr-old husband)

“My experience with using the tablet is very vague due to my father being (in) a sedation state because of being on and off of the breathing tube. During those times, I wasn’t able to use the tablet as much as I would need to. ... I personally liked the tablet because it would give us a better idea as to what he was trying to say but it would get frustrating because with him having to stay laying down he wasn’t able to hold the tablet up or there could be days where he didn’t have enough strength to move his arms or fingers in order to tap on the icon that he wanted. It became difficult to hold the device up and still be able to see what the icon he wanted to tap.” (23-yr-old daughter)

ii) Other preferred communication methods: One family caregiver stated that they preferred another communication tool, a LCD writing tablet (Boogie Board), which is a 8.5 inch LCD writing screen, because they found it easier for the patient to write using the special pen. Another patient was able to mouth words well, so they did not perceive a need to use the VidaTalk™ tablet app.

“She was pretty good at being able to mouth things and was easy to read her lips so it was not used as much as probably some patients.” (61-yr-old husband)

“The pen with the boogie board was easier to use than the one with the VidaTalk™, especially when using the draw function.” (34-yr-old daughter)

5) Other communication tools

Most family caregivers mentioned other communication methods they used in addition to the VidaTalk™ to communicate with nonvocal family patients during their ICU stay. Some participants described that their family patient tried to use more a simple communication method at first, then selected the VidaTalk™ for more clear communication. For some families, another communication method was the primary method and VidaTalk™ served a supportive role.

i) Unaided communication methods: Four family caregivers stated that they used unaided communication methods including mouthing words/lip reading, head nodding, gestures, and body language in addition to the VidaTalk™ to communicate with their loved ones during MV treatment.

“Gesturing was also used for communication but I would venture to say that the tablet was used 75% to 80% of the time.” (71-yr-old husband)

ii) Writing: Nonvocal patients also wrote messages using a paper and pen or using fingers in the air to communicate with family members and care providers.

“Another method that we used was him spelling things out with his hands or giving him a pen to write. He also liked to write out letter in the air and we would try our best to guess which word he was trying to spell.” (23-yr-old daughter)

iii) LCD writing tablet (Boogie Board): As noted previously, two family caregivers from the same patient found the Boogie Board helpful to communicate as well as the VidaTalk™. They said that they used both. They used VidaTalk™ to express pain/symptoms, but preferred the Boogie board rather than VidaTalk™ for writing.

“We also had already ordered a Boogie Board right before we were introduced to VidaTalk™ so that was used as well. The pen with the boogie board was easier to use than the one with the VidaTalk™, especially when using the draw function.” (34-yr-old daughter)

6) Conditions when the VidaTalk™ was used

Family members identified conditions under which they used VidaTalk™ to communicate. When another communication method was the primary method, the VidaTalk™ tablet app was employed under a specific condition, such as initial failure to be understood or when more complicated communication was needed.

“We used the tablet almost daily if we could not read his lips or understand his simple hand gestures. The majority of the time OO would try to communicate simple word requests via mouthing words or the use of hand gestures, however, for more wordy communications he requested the use of the tablet.” (62-yr-old wife)

“The patient was able to use the tablet, mostly when she couldn't get her point across (with other communication methods).” (61-yr-old sister)

7) Suggestions for future use

Most family caregivers recommended use of the VidaTalk™ app for future patients and families.

“The tablet (VidaTalk™ app) was greatly appreciated and hope they are offered to all patients who cannot communicate.”

One family member suggested a bedside tablet holder to make using the VidaTalk™ app easier for the patients who are in a weakened state.

“A bedside tablet holder would be a wonderful addition to this program as it will allow the patient to have at hand rather than being placed somewhere in the room outside of their reach.”

The same family member also suggested a training system involving ICU staff and strong encouragement of families and ICU staff to use the communication tool.

“Develop a hands on training system and strongly encourage families & staff to use this tool as it’s very important to allow the patient to continue participating in their own care and home life.”

Emotional experience in communicating with nonvocal patient

We also explored family caregivers’ emotional reactions to the communication experience with their loved ones using the VidaTalk™ during the ICU stay.

All seven family caregivers expressed their positive feelings while communicating with their nonvocal family patient with VidaTalk™. Several family caregivers described their experience with the VidaTalk™ as ‘exciting’ experience. The families felt happy and elated that they were able to communicate with their loved one by understanding patient’s needs and requests clearly. Family caregivers also felt relieved while communicating with a reduction of frustration with inability to communicate and additional stress that they would have felt without VidaTalk™ during their loved one’s MV treatment in the ICU. The VidaTalk™ also eliminated

the family's increased worries for the patient's comfort and feeling of being safe with inability to understand communication. Several family caregivers felt thankful and grateful for participating in this study and having VidaTalk™ to communicate with the patient.

At the same time, the families also felt negative feelings such as sadness or distress while the patient was expressing their anxiety, worries, feeling scared about their health and treatment. Family caregivers commented about conversations with the patient that bothered them the most.

Table 15. Families' feelings/emotions while communicating with the patient

Subthemes	Quotes
Feeling elated / happy / excited	<p><i>"Elated, is the best way to describe my feelings of being able to communicate with my wife." (71-yr-old husband)</i></p> <p><i>"It [VidaTalk™] was very effective in providing the communication my wife needed and we were happy with them." (61-yr-old husband)</i></p> <p><i>"Using VidaTalk™ application is an exciting experience during the difficult time when my husband was admitted in the ICU." (30-yr-old wife)</i></p> <p><i>"We were excited to get the tablet and my mom was happy to have a way to communicate with us while having the trach." (34-yr-old daughter)</i></p>
Feeling relieved	<p><i>"Once she was able to communicate and know that she had the tools she needed to make us understand her, we felt a sense of relief." (61-yr-old husband)</i></p> <p><i>"There was a sense of relief when we found ways for her to communicate with us such as using the VidaTalk™ app." (34-yr-old daughter)</i></p>

Feeling thankful / grateful	<p><i>“We thank you for being included in this study and encourage you to share our good fortune with others.” (71-yr-old husband)</i></p> <p><i>“What I feel after using the VidaTalk™ to communicate, my husband and I feel thankful that you guys provide this VidaTalk™. The tablet helps my husband to communicate with me, and during that time, I am thankful and happy that he is able to express his feeling.” (30-yr-old wife)</i></p> <p><i>“The tablet was greatly appreciated and hope they are offered to all patients who cannot communicate.” (62-yr-old wife)</i></p>
Less frustrated / less stressful	<p><i>“We were relieved to have the ability to communicate clearly with my husband -this reduced the additional stress we all felt. I can’t imagine a more frustrating and stress filled situation that witnessing a loved who is in the hospital ICU and unable to communicate clearly. We were all worried about his health and the added stress of not understanding his wishes greatly increased his frustration and our worry for his peace of mind, care and comfort. The tablet eliminated this.” (62-yr-old wife)</i></p> <p><i>“It was nerve-wracking to not know what my mom was trying to say to us and it also frustrated her. The tablets helped give us a sense of relief to lessen this frustration.” (34-yr-old daughter)</i></p>
Feeling sad / distressed	<p><i>“Her ability to tell of her anxiety where heartbreaking.” (71-yr-old husband)</i></p> <p><i>“The conversation bothered me when he said that he’s in pain, he gonna die, he can’t make it.” (30-yr-old wife)</i></p> <p><i>“The conversation that bothered me the most was his distress about the surgeries.” (34-yr-old daughter)</i></p>

Integration of Quantitative and Qualitative findings.

We categorized the qualitative interview participants into two groups based on the recorded number of VidaTalk™ use in the Family Visitation Log form: 1) high user, and 2) low user. We compared the number of participants who commented about each main theme by VidaTalk™ usage group (Table 16).

Both high and low user groups reported satisfaction with the tool in which the tool was helpful to communicate between the patient and the family caregiver and the tool allowed them to understand communication. Both groups reported feelings of relief, less frustration/less stress, and feeling elated/happy while communicating with the tablet.

However, high user group experienced more diverse emotional reactions including both positive (feeling thankful) and negative (feeling sad/distressed) feelings. Low user group reported more barriers to use the VidaTalk™ to communicate with the patient during MV treatment in the ICU.

Table 16. Family caregiver's experience with VidaTalk™ by tablet usage subgroups

Themes		VidaTalk™ usage	
		High (n = 4)	Low (n = 3)
Difference in communication		●●	●
Satisfaction with the tool	Being helpful	●●●	●●●
	Understanding communication	●●●	●●●
Feelings/emotions while communicating using VidaTalk	Feeling elated/happy	●●	●●
	Feeling thankful/grateful	●●●	
	Feeling sad/distressed	●●●	
	Less frustrated/less stress	●●	●●
	Feeling relieved	●	●●
Barriers to use		●	●●●

● = number of participants who mentioned the theme during the individual interview.

Chapter 5: Discussion

This study addresses an understudied phenomenon, communication between MV patient and family caregivers during critical illness. This pilot study explored the use of the VidaTalk™, a patient communication application (app), with the family caregivers of nonvocal ICU patients who were receiving MV treatment. The VidaTalk™ was a novel communication tool for nonvocal ICU patients to communicate with their family caregivers and care providers. To our knowledge, this was the first time that a communication strategy to improve patient-family communication in the ICU was provided and tested with family caregivers of ICU patients.

This study was conducted using a mixed-methods design. The quantitative phase evaluated the feasibility and acceptability of the VidaTalk™ communication app for ICU family caregivers and tested the preliminary efficacy of the VidaTalk™ on adverse psychological outcomes in ICU family caregivers. The VidaTalk™ was newly developed and had not been tested with ICU family caregivers, so the exploratory pilot study approach was used. The qualitative phase examined the family caregiver's communication experience with the VidaTalk™, their perceptions of the VidaTalk™, and their emotional reactions to communication with the patients in their narratives.

Discussion of study results considers strengths, limitations, and its scientific contribution.

Feasibility and Acceptability

VidaTalk™ was found to be feasible as a patient-family communication tool during the ICU stay. Specifically, the recruitment rate (defined as the number recruited from the number

eligible) was 72.3% (34 out of 47). This rate is higher than reported recruitment rates for other studies in the ICU family caregiver population ranging between 60-63% (Anderson, Arnold, Angus, & Bryce, 2008, 2009; Barnato et al., 2017). We expected to enroll family caregivers from approximately 50% of the enrolled study patients based on previous studies that involved patient-family co-enrollment (Cox et al., 2018). We enrolled 34 family caregivers of 28 patients which, 57.1% of patients who had eligible family caregivers, but 44.4% of the total number of patients who were enrolled in the parent study. The rate of 44.4% is slightly lower than the projected rate of 50%. The main reason for not being eligible in this study was our exclusion criterion of “visiting or planning to visit less than 3 days per week” (n = 17). Because prior studies used different inclusion/exclusion criteria for family caregiver participants and different enrollment procedures, it is challenging to compare recruitment rates between studies. For example, this study has a unique participant inclusion criterion or threshold for the number of ICU visits (3 visits/week) because we wanted to insure exposure and opportunities for patient-family communication. Future studies could maximize family caregiver participation by not limiting the opportunity to participate in the study according to this threshold but controlling for intervention exposure and number of visits statistically.

Our retention rate during the ICU stay (from baseline to ICU discharge/extubation) was 82.3% (28 out of 34), which was acceptable. However, the retention rate dropped dramatically after the ICU discharge. The retention rates for this study were 67.6% at 1-mos, 55.9% at 3-mos, and 47.1% at 6-mos follow-up. In the ICU family caregiver population, the retention rates reported in previous studies involving long-term follow-ups vary widely across studies. In intervention studies, some reported rates were similar to those in this study. For example, a large RCT assessed family participant symptoms at 3-mos and 6-mos after the ICU discharge, and

49.6% (n = 113 of 268 enrolled) remained at 3-mos, and 46% (n = 122 of 268) remained at 6-mos follow-up (Curtis et al., 2016). Our study retention rates are similar to those in the Curtis et al. study, although the sample size is different. In other intervention studies, the reported retention rates were higher: 83% (n = 30 of 36 enrolled) at three months (Jones et al., 2012) and 76% (n = 66 of 86 enrolled) at six months (Cox et al., 2018). The retention rates in prospective observational studies were 57% at two months (Douglas, Daly, O'Toole, & Hickman, 2010) and ranged between 50 and 63% at six months (Van Pelt et al., 2007; Van Pelt, Schulz, Chelluri, & Pinsky, 2010).

The long-term retention rates during the post-ICU period in this study were similar to or lower than reported retention rates in previous studies involving ICU family caregivers. Several potential factors may have affected the low retention in this study. First, participation in this study required relatively little involvement from or with family caregivers. This was a purposeful methodological choice to avoid interference with the parent study treatment. Therefore, we did not provide an active intervention such as communication training or instruction with the tablet to family caregivers beyond a simple instruction sheet. Despite best practices for participant retention strategies such as reminders, incentive payments, clear expectations of follow-up, and same interviewer used in throughout the study (Abshire et al., 2017; Chhatre et al., 2018; Dilworth-Anderson & Williams, 2004), our long-term retention rates were low. Family caregivers likely had competing priorities and this was confirmed during phone conversations with retained participants in which they revealed multiple caregiving responsibilities, serious financial concerns, rehospitalization, etc. More participants might have remained in the study if they received more contact, attention, and study benefits, and formed a closer relationship with the research staff (Abshire et al., 2017).

An additional marker of study feasibility that should be considered is the number of ICU visits during study participation. In this study, mean number of ICU visits per week met our preset threshold (3 days/week) in both groups. This threshold was determined during the study planning period considering that family caregivers needed enough exposure to patient-family communication that occurs during the family's ICU visit.

In summary, our recruitment and retention rates and the number of ICU visits support that the VidaTalk™ is feasible as a tool for patient-family communication during the ICU stay. However, our low retention rates over time during the post-ICU period show that it is challenging to follow-up ICU family caregivers and future research needs to improve strategies for participant retention.

The acceptability of the VidaTalk™ was determined by tablet usage and qualitative evaluation by the study participants in the VidaTalk™ group. Participants in the VidaTalk™ group used the tablet (VidaTalk™) more than twice as often than did those in the AC group, although the mean number of ICU visits per week was similar between the two groups.

Overall, participants in our study evaluated their experience with VidaTalk™ during the ICU stay as positive. The VidaTalk™ was helpful and useful for the families to communicate with their loved one by allowing the patient to express their needs/wishes clearly as well as allowing the families to better understand what the patient was trying to say. Family caregivers had positive perceptions of the VidaTalk™, reducing their frustration and additional stress with the inability to communicate. Some families voluntarily took a supportive role for the patient to use the VidaTalk™ to communicate with care providers and other visitors. They encouraged the patient to use the VidaTalk™ rather than other communication methods/tools, held the tablet for the patient to see the tablet screen, and coached the patient how to use it. Sometimes, they shared

their positive experience with the VidaTalk™ with nurses or other care providers and demonstrated how the tool worked for them. This suggests the importance of family involvement in communication strategies to improve communication for nonvocal MV patients in the ICU.

Our qualitative and tablet usage data demonstrate that the VidaTalk™ is an acceptable tool for ICU family caregivers, particularly in light of positive perceptions of the VidaTalk™ in the families' narrative evaluation, and observations by the research staff.

Preliminary Efficacy of VidaTalk™ on adverse psychological outcomes in ICU family caregivers

The results of this pilot study of the preliminary effect of the VidaTalk™ are encouraging for short-term anxiety in ICU family caregivers. Due to the small sample size included in the analysis, we focused on effect sizes to interpret the data analysis results. Although we did not find a statistically significant difference in anxiety symptom changes between groups across all time points, the results indicate that the VidaTalk™ was associated with medium effect size in anxiety symptom reduction ($d = 0.42$) at 1-month time point. In prior studies, reported prevalence of post-ICU discharge anxiety symptoms was 21% at one month (Anderson et al., 2008) and ranged between 24-63% at three months (de Miranda et al., 2011; Lemiale et al., 2010; McAdam, Fontaine, White, Dracup, & Puntillo, 2012; Young et al., 2005). Those prevalence statistics indicate that family caregivers still suffer from anxiety symptoms after the ICU discharge. Our primary purpose of this study was to test whether the use of the VidaTalk™ help family caregivers reduced post-ICU adverse psychological outcomes or not. Because we noticed that there were many external factors that were not controllable during the post-ICU

period, we determined that the 1-month time point which is most proximal to the intervention should be the primary focus in the analysis and interpretation. Considering that the 1-month follow-up was our primary endpoint for anxiety symptoms and that the between-group difference in anxiety symptom scores is the greatest at the 1-month follow-up, these findings were clinically meaningful.

Preliminary effects on PTSD-related symptoms are also encouraging. Although not statistically significant, the median of IES-R scores was lower in the VidaTalk™ group than the AC group across all time points. When we compared the difference in median of IES-R scores between two groups, the VidaTalk™ had lower PTSD-related symptoms with a medium effect size ($\eta^2=0.07$) at one month, and a medium-to-large effect size ($\eta^2=0.09$) at three months. We were also interested in the number of participants who had scores above cut-off (IES-R score ≥ 22) indicating existing PTSD-related symptoms at each time point. Although it was challenging to conduct group comparisons due to small sample size and different number of participants between groups, the VidaTalk™ group had lower proportion of participants who had PTSD-related symptoms at one and three months. These findings suggest that future studies may need to focus on the short-term effect on anxiety symptoms and post-ICU PTSD-related symptoms in family caregivers. Also, future studies can consider testing the immediate effects of a communication tool on families' anxiety symptoms by including daily measures of state anxiety.

The family caregivers' depressive symptoms increased from baseline to 1-month in both VidaTalk™ and AC groups, which is inconsistent with the previous study findings (Choi et al., 2012). Choi et al. (2012) explored the patterns of response in depressive symptoms over time from the ICU admission to 2 months post-ICU discharge in caregivers of critically ill MV patients. They found that depressive symptoms in family caregivers were initially high and

decreased over time through 2 months post-ICU discharge. In our study, the depressive symptoms increased in the VidaTalk™ group later during the follow-up period and remained high through 6-months post-ICU discharge, whereas the AC group showed decreased depressive symptoms over time. The biggest between-group difference in depressive symptom changes was found at T4 (6-mos) with medium effect size ($d = 0.54$) in which the VidaTalk™ group had increased depressive symptoms whereas the AC group had decreased symptoms. This time point is the last time point with the lowest sample size ($n = 14$) in which the most dropouts occurred. All five family caregivers in the VidaTalk™ group were still experiencing their patient's continuous critical illness (three were re-admitted to the ICU during the post-ICU period) or bereavement (two patients died). On the other hand, five out of nine patients in the AC group had returned home after the ICU discharge, and four family caregivers were experiencing their patient's chronic illness or bereavement (one patient died, three patients were re-admitted to the ICU). Previous research identified patient death, readmission, and residing in institution post-ICU as risk factors associated with increased depressive symptoms (Douglas & Daly, 2003; Douglas et al., 2010; Pochard et al., 2005; Van Pelt et al., 2010). In this context, higher depressive symptoms in family caregivers in the VidaTalk™ group were understandable. We can hypothesize that higher depressive symptoms and the continued high depressive symptoms over time may be associated with psychological distress or burden associated with the patient's continuous critical illness. In the future, external factors during the post-ICU period, such as caregiving burden or chronic critical illness, other stressors should be measured and controlled for in a larger study.

While conducting the follow-up measures, we learned that the post-ICU period is chaotic for family caregivers. Family caregivers revealed several factors as stressors during post-ICU

discharge follow-up data collection including the patient's re-hospitalization, patient's non-compliance with care, patient's deteriorated condition, caregiving burden related to patient's care/treatment, family caregiver's own health condition, and competing for caregiving (e.g., grandchildren, elderly parents) demands. In a small sample, a cluster of cases experiencing stressors like these can make a difference in outcome measures. Moreover, these cases showed that expectations about the long-term effect or dose-effect that improved patient-family communication during the ICU period may have been overly optimistic.

Two family caregivers expressed their wish to have the VidaTalk™ app on their own tablet computers and continue to use it to communicate with the patient after the ICU discharge. We provided those two family caregivers with free VidaTalk™ app for their own tablet computers. Among them, one kept using the VidaTalk™ app occasionally depending on the patient's continuous MV treatment and condition until 6-mos follow-up time point. Another was lost to follow-up at 1-mos, so the usage for this family caregiver was unknown. The inconsistent provision of the VidaTalk™ after the ICU discharge may have affected our study results.

We also provided six participants (5 in the AC group / 1 in the VidaTalk™ group) who showed high scores on HADS-D or IES-R above the threshold with mental health resources and encouraged them to contact their provider for an evaluation. Among those, one participant lost to follow-up at the next time point, and one had already been getting psychological support when we provided mental health resources. Four other participants thanked us for the resources provided but did not obtain any additional support. Although none sought additional psychological support after receiving the resources and encouragement from us, this additional supportive contact may have affected our study results. We felt ethically compelled to provide mental health resources when the study participant was suspected of having severe psychological

distress according to the measurement scores, although it is not a standard evident in prior ICU family caregiver research studies.

FSM and the Moderating effect of perceived communication difficulty

The FSM was applied to a patient-family communication interaction in the ICU to guide this study as a theoretical framework. We hypothesized mechanisms of action for a patient-family communication intervention based on the FSM (Davidson, 2010). First, the VidaTalk™ may help family caregivers meet their own needs for effective communication with the patient to understand and make sense of the patient's situation, feelings/thoughts, and what they are experiencing. Secondly, the VidaTalk™ tablet app may serve as a bedside activity (second sensemaking goal) or help family caregivers perform bedside activities while visiting their loved one in the ICU. In the same vein, we hypothesized that baseline perceived communication difficulty may act as a moderator on the effect of the VidaTalk™ on families' adverse psychological outcomes. If a significant moderating effect was identified in this analysis, we aimed to provide pilot data for further understanding of the mechanisms of the intervention effect. However, we were not able to test the moderating role of communication difficulty in this study due to the small sample size. Further research is needed to examine the mechanisms and test the moderating role of communication difficulty on the intervention effect with a larger sample.

Based on our study findings, we evaluated the FSM for its usefulness to guide a communication intervention for the nonvocal ICU patients and their family caregivers. There were two sensemaking goals for family caregivers in our theoretical framework (Figure 1): 1)

make sense of what is happening in the new situation, and 2) make sense of their new role as a caregiver of ICU patients. Our qualitative analysis found that the VidaTalk™ helped the families to meet the first goal by understanding the patient's experience and feelings/thoughts better. The families were satisfied with the VidaTalk™ as evidenced by their positive perceptions of it as useful and helpful to communicate with the patients. VidaTalk™ allowed patients and family caregivers to communicate various messages including their emotions and feelings, conversations about home/family, patient's discomfort and symptoms, expressed needs, and questions about finances. The second sensemaking goal incorporates the family's role as ICU caregiver serving the bedside activities and *brining normalcy into the room* (Davidson, 2010). VidaTalk™ helped the families understand the patient's expressed needs/requests as well as the patients express their wishes clearly. The clear communication, as a result of using the VidaTalk™, may promote family caregivers' bedside activities. For example, families described knowing, through VidaTalk™ communication, that the patient needed turned or pain medication and was able to provide that bedside care assistance. Also, the ability to communicate a variety of messages including conversations about everyday events outside of the hospital such as home/family and patient's feelings/emotions was helpful for the families to *bring normalcy into the room*. Happ et al. (2007) described communication processes between patients and families during weaning from mechanical ventilation that emphasized the importance of normalizing talk to distract patients. In their study, normalizing talk referred to talking about everyday, non-illness-related events (Happ et al., 2007). Consistent with these findings, the FSM also suggests 'bring normalcy into the room' as an important component of the sensemaking process in family caregivers (Davidson, 2010). Our participants described conversations not related to the illness or hospital such as home/family or feelings/emotions indicating that the VidaTalk™ helped the

families serve in the caregiver role distracting patients from the stressful ICU environment with normalizing talk.

Exploration of participant's experience with VidaTalk™

We investigated how family members perceived the VidaTalk™ while communicating with their nonvocal family patient during the ICU stay and their emotional reactions to patient-family communication. The families described communication difficulty and frustration regarding their limited communication with the patient before they received the VidaTalk™. These findings are consistent with previous study findings describing family caregivers' negative emotions with communication difficulty during MV treatment in the ICU (Alasad & Ahmad, 2005; Broyles et al., 2012; Dreyer & Nortvedt, 2008; Engstrom & Soderberg, 2004; Happ, 2000). Family's communication experience was different before and after using the communication app. VidaTalk™ opened up communication with their loved one by allowing multiple levels of communication.

One of the most frequently mentioned messages communicated with the patient using the VidaTalk™ app was the patient's "I love you" message to the family. This finding is consistent with a prior study exploring the use of electronic voice output communication devices with nonvocal ICU patients in which "I love you" was the most frequently observed message content (Happ, Roesch, & Garrett, 2004). Among seven family caregivers who participated in the qualitative interview, patients of five family members died either during the ICU stay or shortly after the ICU discharge. Although we did not plan to explore end-of-life communication in the qualitative interviews, the families' communication experience turned out to be end-of-life

communication with nonvocal ICU patients. “I love you” is one of the five essential messages in end-of-life communication by dying patients (Keeley, 2007). Considering that these patients were faced with the real possibility of impending death, the “I love you” message between the nonvocal patient and the family caregiver was incredibly poignant and meaningful, with the VidaTalk™ app playing a crucial role enabling the patient to express love in a vocal way to the family caregiver.

One family member in this study emphasized how meaningful it was to hear the voice output of ‘I love you’ message from the VidaTalk™: “..he pointed to the icon “I Love You” every day which means a lot when you can’t hear your spouse’s voice.”

Similarly, the meaningfulness of the voice output from a communication tool was also found in previous research (Happ, Roesch, & Garrett, 2004): “You have a son and his parents and they walk into the room and he was hunting for and pushed ‘I love you.’ . . .and look how it affected [his mother]. It was almost like his own voice telling her that.” (p. 97).

Happ first described how meaningful restoration of the patient’s voice is to the family caregiver (Happ, 2000): “Once, her blood pressure was low and I was frightened. I wanted to hear her talk. I thought I’d never be able to hear her voice again. The nurse deflated the trach (tracheostomy) cuff and let me hear her voice. I can’t tell you how much it meant to me to hear her voice. And the nurse knew. It only compares to watching the birth of my grandchild.” (p. 1250).

These consistent findings of the importance of the voice between patients and family caregivers over the last decades indicate that the speech-generating feature of a communication tool may provide a crucial role in patient-family communication.

Family caregivers used VidaTalk™ when they needed more complicated communication than a simple yes-no conversation. These findings suggest that VidaTalk™ allowed more complicated and emotion-laden conversations to be possible in patient-family communication during MV treatment. Previous studies also suggested that communication between family members and patients may be more stressful since the patient's conversation with the family member often took the form of emotional expressions or novel messages such as questions about home or finances (Broyles et al., 2012; Happ, Roesch, & Kagan, 2004; Happ, Tuite, et al., 2004). Our study findings confirm that the VidaTalk™ helped family caregivers have conversations about patient's feelings, emotions, home, finances, and "I love you" message, which are more complicated than yes-no conversation.

The families felt relieved, happy, and thankful to communicate with their loved one using the VidaTalk™. The VidaTalk™ helped reduce the families' frustration and additional stress with an inability to communicate as well as patient's frustration and distress. On the other hand, the patient's ability to express their negative feelings such as their worries or anxiety about their treatment/care using the VidaTalk™ sometimes made families feel sad or distressed. One study of the impact of chronic critical illness on family caregivers found that the patient's negative emotions such as anxiety, worries, sadness, or distress and pain/discomfort caused family caregiver's the most perceived distress (Choi, Donahoe, Zullo, & Hoffman, 2011). These findings suggest that a communication strategy is helpful for patient-family communication, but can also cause another psychological distress by allowing the patient to express negative feelings and worries to the family member. Future studies need to further explore patient-family communication about negative feelings and its impact on their psychological symptoms.

Further exploration of the families' feelings/emotions and the influence of conversations with the patient on families' psychological distress is needed in future studies. A previous study suggests that family members' verbal encouragement and coaching could reduce the patient's fear (Happ et al., 2007). In other studies, families expressed their wish to help the patients and feelings to protect them by calming and encouraging (Agard & Harder, 2007; Hupcey & Penrod, 2000). We also found that some families provided verbal encouragement and emotional support when the patient expressed their fear or worries about their treatment/care. These findings indicate a need for coaching family caregivers on how to calm, encourage, and support the patient and that additional support may be most important when patient communication is facilitated with the VidaTalk™ app or other communication tools.

We found several barriers to use of the VidaTalk™ by patients and family caregivers during the ICU stay. Some families did not use the VidaTalk™ as much as they wanted due to the patient's deteriorated condition, sedated status, or lack of strength. Other families preferred different communication tools such as an LCD writing tablet (Boogie Board) because it was found to be easier for them to use or did not need to use the VidaTalk™ since natural communication methods such as mouthing words/lip reading worked well for them. These findings support a need for a toolbox or options and skilled /trained clinicians in a programmatic way so that when patients are unable to use one method, others are available (Happ et al., 2010; Happ, Garrett, et al., 2014).

When we further compared the qualitative themes by tablet usage, the family caregivers in the low use group had reasons (barriers) for low use such as patient's deteriorated condition, sedation, patient's lack of strength, or no perceived need to use VidaTalk™ since other communication methods worked. Despite those barriers and relatively little or brief use of the

VidaTalk™, they recognized benefits from using the VidaTalk™, including reduced stress/frustration, better understanding communication, and helpful for communication. Also, we found that family caregivers in both high and low use groups experienced positive emotions related to communication with the VidaTalk™, however, the high use group experienced more variable feelings. The high use group experienced negative feelings of sadness or distress as well as positive feelings while communicating with the patient, whereas the low use group reported only positive feelings. This is an interesting finding, which suggests that future research need to focus on family caregiver's both positive and negative emotional experiences while communicating with the nonvocal MV patients in the ICU.

Study Strengths and Limitations

The VidaTalk™ for ICU family caregiver pilot study has several strengths and limitations to consider. To our knowledge, this is the first study to provide and test a communication tool with ICU family caregivers. Our hypotheses on the impact of the VidaTalk™ communication app to help families reduce psychological symptoms were theory-driven. This novel adaptation of a communication tool shifts the lens on patient-family communication and the impact of communication on family caregiver's psychological distress.

Although it was challenging to compare between-group differences in family outcomes due to the small sample size and differential dropouts, we involved an intervention group and an attention control group to compare. Also, we followed family participants until long after the ICU discharge to provide data to evaluate change and sustainability of change over time. Despite low retention rates over time, we were able to explore the family's post-ICU experience as well

as the process of the intervention during the ICU stay. By having conversations with family caregivers during the follow-up, we were able describe the chaotic situations in the post-ICU period which would have not been apprehended with more simple study design and helped explain our results in the context of their post-ICU life.

This pilot study used multiple data sources including quantitative data using standardized measurement tools, recorded observations by research staff in field notes, participant's narrative comments in the multiple forms, as well as qualitative interviews. The use of comprehensive data amplified study findings and enabled us to conduct multiple data exploration.

The major limitation of this study is the small sample size. Due to the small sample size, the study results should be interpreted with caution. Since this dissertation study used a nested design within the parent RCT study, the sample size was limited. Recruitment was limited to family caregivers of patients who had already been enrolled in the parent study. Moreover, family withdrawals were influenced by patient withdrawals. If the patient participant became unable to use the tablet due to delirium, unresponsiveness, or being in the end-of-life care, the family participant sometimes requested withdrawals for the patient as well as for themselves. Due to higher dropout rates over time, the sample size was smaller at the end of the study. Additional participant retention strategies such as effective text reminders, increased amount of incentives, building relationship and identity, emphasizing study benefits, and contact/scheduling strategies (Chhatre et al., 2018; Dilworth-Anderson & Williams, 2004) should be considered in the future studies.

Another major limitation is the differential dropout between the VidaTalk™ and the AC groups. We had more dropouts in the VidaTalk™ group than the AC group. More family

caregivers in the VidaTalk™ group experienced patient's death (7 in VidaTalk™ group / 2 in AC group) and most family caregivers whose family member died dropped out (5 in VidaTalk™ group / 1 in AC group). Several bereaved participants expressed discomfort with questions about their feelings and emotions (questions from HADS or IES-R) shortly after the patient's death and elected to discontinue participation or were lost to follow-up after the patient's death. Those were unexpected and uncontrollable events that had a real impact on our ability to retain participants. These barriers could be minimized with a larger sample size in future studies.

We found that life after ICU discharge was chaotic for several family caregivers fraught with financial and caregiving burdens and difficult situations. Although we proposed to test the effect of the VidaTalk™ communication app on family caregivers' short- and long-term psychological symptoms, we learned that there are many confounding factors during the post-ICU period. There are several strategies introduced, developed, and being implemented to help ICU patients and families recover from the traumatic situation and seek support for themselves, such as an ICU rehabilitation program in the form of post-ICU clinics (Jones et al., 2003). As we found that family's distress and burdens are still ongoing after the ICU discharge, more strategies are needed to help them to overcome challenges during the post-ICU period. We suggest that a communication intervention might be combined with other family support interventions (such as ICU diary) or post-ICU support programs such as ICU rehabilitation group or centers (Stollings & Caylor, 2015).

Another limitation of this study is the lack of a direct intervention which requires the family caregiver's active involvement in the study. Because this study was a companion study with the parent study, no direct intervention such as family training/instruction to the VidaTalk™

or active encouragement to use the VidaTalk™ was provided to prevent interference with the parent study intervention. More active involvement of family caregivers in the use of VidaTalk™ in the form of a training or coaching intervention could have greatly impacted the use of the tablet by patients participating in the parent study, which would have changed the parent study procedures for some but not all patients and, therefore, confounded the results. Although the VidaTalk™ application for family caregivers was a theoretically-driven intervention based on the FSM, in which an iterative and active intervention was suggested, we could not provide it. Instead, this study followed the natural course when the families were present and relied on their decisions to use the communication tool or not. When the family showed greater interest in the use of the tool than others, their family patients may have received a booster dose as a result of family participation in the study, but others may have not. We may need to conduct further analysis combining data from the parent study and this family caregiver study to examine the impact of family involvement and tablet usage by family caregivers on patient's outcomes. In the future, theoretically sound interventions such as family training for the use of the tool or AAC strategies or coaching should be designed and implemented.

The qualitative phase of this study explored family caregivers' communication experience with the VidaTalk™ with the nonvocal ICU family patients during the MV treatment. However, we did not explore the communication experience in family caregivers in the AC group who received standard care in terms of communication in the ICU which could have provided qualitative comparison of between-group differences in the communication experience.

Implications

Pilot testing the VidaTalk™ app was an excellent opportunity to explore a theory-based intervention for patient-family communication and psychological symptoms in ICU family caregivers. Although there are several communication interventions developed and tested in the ICU settings in previous research, those focused only on communication between the patient and care providers or between family caregivers and care providers. Research on communication interventions between the patient and family caregivers is limited. Moreover, the impact of perceived communication difficulty by family caregivers on their adverse psychological outcomes has been ignored. The results of this study combined with previously accumulated evidence could potentially address this gap. Findings of this study may guide future larger, more rigorous randomized controlled trials.

Conclusion

The VidaTalk™ communication app demonstrated potential as a communication intervention for ICU family caregivers of nonvocal MV patients. This study provides beginning knowledge of the impact of a communication strategy on psychological symptoms in family caregivers and guides future studies about patient-family communication in the ICU. The study results indicate that the VidaTalk™ is mostly feasible to provide, acceptable by ICU family caregivers. We also found that providing the VidaTalk™ may reduce the level of anxiety and PTSD-related symptoms in ICU family caregivers post-ICU discharge.

More studies are needed to improve patient-family communication in the ICU and to examine the relationship between families' communication difficulty and families' outcomes.

Future study should focus on developing a sound communication intervention which may enhance family involvement, an important key to family-centered care (Davidson et al., 2018). Future studies are also needed to explore the impact of family involvement in communication strategies, patient-family communication, and family's encouragement on the patient's outcomes.

References

Abshire, M., Dinglas, V. D., Cajita, M. I. A., Eakin, M. N., Needham, D. M., & Himmelfarb, C.

D. (2017). Participant retention practices in longitudinal clinical research studies with high retention rates. *BMC medical research methodology*, 17(1), 30-30.

doi:10.1186/s12874-017-0310-z

Agard, A. S., & Harder, I. (2007). Relatives' experiences in intensive care--finding a place in a world of uncertainty. *Intensive & Critical Care Nursing*, 23(3), 170-177.

doi:10.1016/j.iccn.2006.11.008

Aitken, L. M., Rattray, J., Hull, A., Kenardy, J. A., Le Brocque, R., & Ullman, A. J. (2013). The use of diaries in psychological recovery from intensive care. *Critical Care*, 17(6), 253.

doi:10.1186/cc13164

Alasad, J., & Ahmad, M. (2005). Communication with critically ill patients. *Journal of Advanced Nursing*, 50(4), 356-362. doi:10.1111/j.1365-2648.2005.03400.x

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders : DSM-5*. Washington, D.C.: American Psychiatric Association.

American Speech Language Hearing Association (ASHA). (2018). Augmentative and Alternative Communication Retrieved from

<https://www.asha.org/public/speech/disorders/AAC/>

Anderson, W. G., Arnold, R. M., Angus, D. C., & Bryce, C. L. (2008). Posttraumatic stress and complicated grief in family members of patients in the intensive care unit. *J Gen Intern Med*, 23(11), 1871-1876. doi:10.1007/s11606-008-0770-2

- Anderson, W. G., Arnold, R. M., Angus, D. C., & Bryce, C. L. (2009). Passive decision-making preference is associated with anxiety and depression in relatives of patients in the intensive care unit. *J Crit Care*, 24(2), 249-254.
- Aylard, P., Gooding, J., McKenna, P., & Snaith, R. (1987). A validation study of three anxiety and depression self-assessment scales. *Journal of psychosomatic research*, 31(2), 261-268.
- Azoulay, E., Pochard, F., Kentish-Barnes, N., Chevret, S., Aboab, J., Adrie, C., . . . Schlemmer, B. (2005). Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *Am J Respir Crit Care Med*, 171(9), 987-994. doi:10.1164/rccm.200409-1295OC
- Azoulay, E., & Sprung, C. L. (2004). Family-physician interactions in the intensive care unit. *Crit Care Med*, 32(11), 2323-2328.
- Barnato, A. E., Schenker, Y., Tiver, G., Dew, M. A., Arnold, R. M., Nunez, E. R., & Reynolds III, C. F. (2017). Storytelling in the early bereavement period to reduce emotional distress among surrogates involved in a decision to limit life support in the ICU: A pilot feasibility trial. *Crit Care Med*, 45(1), 35.
- Beck, J. G., Grant, D. M., Read, J. P., Clapp, J. D., Coffey, S. F., Miller, L. M., & Palyo, S. A. (2008). The Impact of Event Scale-Revised: Psychometric properties in a sample of motor vehicle accident survivors. *Journal of anxiety disorders*, 22(2), 187-198.
- Bergbom, I., & Askwall, A. (2000). The nearest and dearest: a lifeline for ICU patients. *Intensive & Critical Care Nursing*, 16(6), 384-395. doi:10.1054/iccn.2000.1520

- Bjelland, I., Dahl, A. A., Haug, T. T., & Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale: an updated literature review. *Journal of psychosomatic research*, 52(2), 69-77.
- Boeije, H. (2002). A purposeful approach to the constant comparative method in the analysis of qualitative interviews. *Quality and quantity*, 36(4), 391-409.
- Bramley, P. N., Easton, A. M. E., Morley, S., & Snaith, R. P. (1988). The differentiation of anxiety and depression by rating scales. *Acta psychiatrica scandinavica*, 77(2), 133-138.
- Broyles, L. M., Tate, J. A., & Happ, M. B. (2012). Use of augmentative and alternative communication strategies by family members in the intensive care unit. *American Journal of Critical Care*, 21(2), e21-e32.
- Cameron, J. I., Chu, L. M., Matte, A., Tomlinson, G., Chan, L., Thomas, C., . . . Canadian Critical Care Trials, G. (2016). One-Year Outcomes in Caregivers of Critically Ill Patients. *N Engl J Med*, 374(19), 1831-1841. doi:10.1056/NEJMoal511160
- Carroll, S. M. (2004). Nonvocal ventilated patients perceptions of being understood. *West J Nurs Res*, 26(1), 85-103; discussion 104-112. doi:10.1177/0193945903259462
- Chhatre, S., Jefferson, A., Cook, R., Meeker, C. R., Kim, J. H., Hartz, K. M., . . . Jayadevappa, R. (2018). Patient-centered recruitment and retention for a randomized controlled study. *Trials*, 19(1), 205. doi:10.1186/s13063-018-2578-7
- Choi, J., Donahoe, M. P., Zullo, T. G., & Hoffman, L. A. (2011). Caregivers of the chronically critically ill after discharge from the intensive care unit: six months' experience. *Am J Crit Care*, 20(1), 12-22; quiz 23. doi:10.4037/ajcc2011243

- Choi, J., Hoffman, L. A., Schulz, R., Ren, D., Donahoe, M. P., Given, B., & Sherwood, P. R. (2013). Health risk behaviors in family caregivers during patients' stay in intensive care units: a pilot analysis. *Am J Crit Care*, 22(1), 41-45. doi:10.4037/ajcc2013830
- Choi, J., Sherwood, P. R., Schulz, R., Ren, D., Donahoe, M. P., Given, B., & Hoffman, L. A. (2012). Patterns of depressive symptoms in caregivers of mechanically ventilated critically ill adults from intensive care unit admission to 2 months postintensive care unit discharge: a pilot study. *Crit Care Med*, 40(5), 1546-1553. doi:10.1097/CCM.0b013e3182451c58
- Cox, C. E., Hough, C. L., Carson, S. S., White, D. B., Kahn, J. M., Olsen, M. K., . . . Porter, L. S. (2018). Effects of a telephone-and web-based coping skills training program compared with an education program for survivors of critical illness and their family members. a randomized clinical trial. *Am J Respir Crit Care Med*, 197(1), 66-78.
- Creamer, M., Bell, R., & Failla, S. (2003). Psychometric properties of the Impact of Event Scale—Revised. *Behaviour Research and Therapy*, 41(12), 1489-1496. doi:<http://dx.doi.org/10.1016/j.brat.2003.07.010>
- Creswell, J. W. (2012). *Qualitative inquiry and research design: Choosing among five approaches*: Sage publications.
- Creswell, J. W., Plano Clark, V. L., Gutmann, M. L., & Hanson, W. E. (2003). Advanced mixed methods research designs. *Handbook of mixed methods in social and behavioral research*, 209-240.
- Curtis, J. R., Treece, P. D., Nielsen, E. L., Gold, J., Ciechanowski, P. S., Shannon, S. E., . . . Engelberg, R. A. (2016). Randomized Trial of Communication Facilitators to Reduce

- Family Distress and Intensity of End-of-Life Care. *Am J Respir Crit Care Med*, 193(2), 154-162. doi:10.1164/rccm.201505-0900OC
- Davidson, J. E. (2010). Facilitated sensemaking: a strategy and new middle-range theory to support families of intensive care unit patients. *Crit Care Nurse*, 30(6), 28-39.
- Davidson, J. E., Aslakson, R. A., Long, A. C., Puntillo, K. A., Kross, E. K., Hart, J., . . . Curtis, J. R. (2017). Guidelines for Family-Centered Care in the Neonatal, Pediatric, and Adult ICU. *Crit Care Med*, 45(1), 103-128. doi:10.1097/ccm.0000000000002169
- Davidson, J. E., Daly, B. J., Agan, D., Brady, N. R., & Higgins, P. A. (2010). Facilitated sensemaking: a feasibility study for the provision of a family support program in the intensive care unit. *Crit Care Nurs Q*, 33(2), 177-189.
- Davidson, J. E., Hopkins, R. O., Louis, D., & Iwashyna, T. J. (2013). Post-intensive Care Syndrome. Retrieved from <https://www.sccm.org/MyICUCare/THRIVE/Post-intensive-Care-Syndrome>
- Davidson, J. E., Jones, C., & Bienvenu, O. J. (2012). Family response to critical illness: postintensive care syndrome-family. *Crit Care Med*, 40(2), 618-624. doi:10.1097/CCM.0b013e318236ebf9
- Davidson, J. E., McDuffie, M., & Kay, M. (2018). *Chapter 10. Family-Centered Care* Sandra Goldsworthy P, Ruth Kleinpell, & G. Williams. (Eds.), Retrieved from <http://wfccn.org/ebook/>
- Davidson, J. E., Powers, K., Hedayat, K. M., Tieszen, M., Kon, A. A., Shepard, E., . . . Barr, J. (2007). Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of Critical Care Medicine Task Force 2004–2005. *Crit Care Med*, 35(2), 605-622.

- de Miranda, S., Pochard, F., Chaize, M., Megarbane, B., Cuvelier, A., Bele, N., . . . Azoulay, E. (2011). Postintensive care unit psychological burden in patients with chronic obstructive pulmonary disease and informal caregivers: A multicenter study. *Crit Care Med*, 39(1), 112-118. doi:10.1097/CCM.0b013e3181feb824
- Dilworth-Anderson, P., & Williams, S. W. (2004). Recruitment and retention strategies for longitudinal African American caregiving research: the Family Caregiving Project. *J Aging Health*, 16(5 Suppl), 137s-156s. doi:10.1177/0898264304269725
- Dithole, K., Thupayagale-Tshweneagae, G., & Mgutshini, T. (2013). Posttraumatic stress disorder among spouses of patients discharged from the intensive care unit after six months. *Issues Ment Health Nurs*, 34(1), 30-35. doi:10.3109/01612840.2012.715235
- Douglas, S. L., & Daly, B. J. (2003). Caregivers of long-term ventilator patients: physical and psychological outcomes. *Chest*, 123(4), 1073-1081.
- Douglas, S. L., Daly, B. J., Kelley, C. G., O'Toole, E., & Montenegro, H. (2005). Impact of a disease management program upon caregivers of chronically critically ill patients. *Chest*, 128(6), 3925-3936. doi:10.1378/chest.128.6.3925
- Douglas, S. L., Daly, B. J., O'Toole, E., & Hickman, R. L., Jr. (2010). Depression among white and nonwhite caregivers of the chronically critically ill. *J Crit Care*, 25(2), 364.e311-369. doi:10.1016/j.jcrc.2009.09.004
- Dreyer, A., & Nortvedt, P. (2008). Sedation of ventilated patients in intensive care units: relatives' experiences. *Journal of Advanced Nursing*, 61(5), 549-556.
- Egerod, I., Schwartz- Nielsen, K. H., Hansen, G. M., & Lærkner, E. (2007). The extent and application of patient diaries in Danish ICUs in 2006. *Nursing in Critical Care*, 12(3), 159-167.

- Ellis, P. D. (2010). *The essential guide to effect sizes: Statistical power, meta-analysis, and the interpretation of research results.*: Cambridge University Press.
- Engstrom, A., Nystrom, N., Sundelin, G., & Rattray, J. (2013). People's experiences of being mechanically ventilated in an ICU: a qualitative study. *Intensive & Critical Care Nursing*, 29(2), 88-95. doi:10.1016/j.iccn.2012.07.003
- Engstrom, A., & Soderberg, S. (2004). The experiences of partners of critically ill persons in an intensive care unit. *Intensive & Critical Care Nursing*, 20(5), 299-308; quiz 309-210.
- Engstrom, A., & Soderberg, S. (2007). Receiving power through confirmation: the meaning of close relatives for people who have been critically ill. *Journal of Advanced Nursing*, 59(6), 569-576. doi:10.1111/j.1365-2648.2007.04336.x
- Flint, A. J., & Rifat, S. L. (2002). Factor structure of the hospital anxiety and depression scale in older patients with major depression. *International journal of geriatric psychiatry*, 17(2), 117-123.
- Garrouste-Orgeas, M., Coquet, I., Périer, A., Timsit, J.-F., Pochard, F., Lancrin, F., . . . Blel, Y. (2012). Impact of an intensive care unit diary on psychological distress in patients and relatives. *Crit Care Med*, 40(7), 2033-2040.
- Garrouste-Orgeas, M., Coquet, I., Perier, A., Timsit, J. F., Pochard, F., Lancrin, F., . . . Misset, B. (2012). Impact of an intensive care unit diary on psychological distress in patients and relatives*. *Crit Care Med*, 40(7), 2033-2040. doi:10.1097/CCM.0b013e31824e1b43
- Garrouste-Orgeas, M., Max, A., Lerin, T., Gregoire, C., Ruckly, S., Kloeckner, M., . . . Misset, B. (2016). Impact of Proactive Nurse Participation in ICU Family Conferences: A Mixed-Method Study. *Crit Care Med*, 44(6), 1116-1128. doi:10.1097/CCM.0000000000001632
- Gibbs, G. (2007). Analysing qualitative data.

- Haines, K. J., Denehy, L., Skinner, E. H., Warrillow, S., & Berney, S. (2015). Psychosocial outcomes in informal caregivers of the critically ill: a systematic review. *Crit Care Med*, 43(5), 1112-1120. doi:10.1097/ccm.0000000000000865
- Hamilton, R. J., & Bowers, B. J. (2006). Internet recruitment and e-mail interviews in qualitative studies. *Qual Health Res*, 16(6), 821-835. doi:10.1177/1049732306287599
- Happ, M. B. (2000). Interpretation of nonvocal behavior and the meaning of voicelessness in critical care. *Soc Sci Med*, 50(9), 1247-1255.
- Happ, M. B. (2009). Mixed methods in gerontological research: Do the qualitative and quantitative data “touch”? *Research in gerontological nursing*, 2(2), 122-127.
- Happ, M. B. (2016-2018). Improving outcomes for mechanically ventilated patients with the digital EZ board. NIH/ National Institute of Nursing Research. Grant # 5R42 NR014087.
- Happ, M. B., Baumann, B. M., Sawicki, J., Tate, J. A., George, E. L., & Barnato, A. E. (2010). SPEACS-2: intensive care unit "communication rounds" with speech language pathology. *Geriatr Nurs*, 31(3), 170-177. doi:10.1016/j.gerinurse.2010.03.004
- Happ, M. B., Dabbs, A. D., Tate, J., Hricik, A., & Erlen, J. (2006). Exemplars of mixed methods data combination and analysis. *Nursing research*, 55(2), S43-S49.
- Happ, M. B., Garrett, K., Thomas, D. D., Tate, J., George, E., Houze, M., . . . Sereika, S. (2011). Nurse-patient communication interactions in the intensive care unit. *American Journal of Critical Care*, 20(2), e28-e40.
- Happ, M. B., Garrett, K. L., Tate, J. A., DiVirgilio, D., Houze, M. P., Demirci, J. R., . . . Sereika, S. M. (2014). Effect of a multi-level intervention on nurse-patient communication in the intensive care unit: results of the SPEACS trial. *Heart Lung*, 43(2), 89-98. doi:10.1016/j.hrtlng.2013.11.010

- Happ, M. B., Roesch, T., & Kagan, S. H. (2004). Communication needs, methods, and perceived voice quality following head and neck surgery: a literature review. *Cancer Nurs*, 27(1), 1-9.
- Happ, M. B., Roesch, T. K., & Garrett, K. (2004). Electronic voice-output communication aids for temporarily nonspeaking patients in a medical intensive care unit: a feasibility study. *Heart Lung*, 33(2), 92-101. doi:10.1016/j.hrtlng.2003.12.005
- Happ, M. B., Sereika, S. M., Houze, M. P., Seaman, J. B., Tate, J. A., Nilsen, M. L., . . . Barnato, A. E. (2015). Quality of care and resource use among mechanically ventilated patients before and after an intervention to assist nurse-nonvocal patient communication. *Heart Lung*, 44(5), 408-415.e402. doi:10.1016/j.hrtlng.2015.07.001
- Happ, M. B., Swigart, V. A., Tate, J. A., Arnold, R. M., Sereika, S. M., & Hoffman, L. A. (2007). Family presence and surveillance during weaning from prolonged mechanical ventilation. *Heart Lung*, 36(1), 47-57. doi:10.1016/j.hrtlng.2006.07.002
- Happ, M. B., Tuite, P., Dobbin, K., DiVirgilio-Thomas, D., & Kitutu, J. (2004). Communication ability, method, and content among nonspeaking nonsurviving patients treated with mechanical ventilation in the intensive care unit. *Am J Crit Care*, 13(3), 210-218; quiz 219-220.
- Happ, M. B., Walaszek, L., Von Visger, T., Weber, M., Vermillion, B., Chipps, E., . . . Patak, L. (2014). 603: USABILITY AND ACCEPTABILITY TESTING OF AN IPAD COMMUNICATION APPLICATION IN THE INTENSIVE CARE UNIT. *Crit Care Med*, 42(12), A1505.
- Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)—a metadata-driven methodology and workflow

- process for providing translational research informatics support. *Journal of biomedical informatics*, 42(2), 377-381.
- Helvik, A.-S., Engedal, K., Skancke, R. H., & Selbæk, G. (2011). A psychometric evaluation of the Hospital Anxiety and Depression Scale for the medically hospitalized elderly. *Nordic journal of psychiatry*, 65(5), 338-344.
- Horowitz, M., Wilner, N., & Alvarez, W. (1979). Impact of Event Scale: a measure of subjective stress. *Psychosomatic medicine*, 41(3), 209-218.
- Hupcey, J. E., & Penrod, J. (2000). Going it alone: the experiences of spouses of critically ill patients. *Dimens Crit Care Nurs*, 19(3), 44-49.
- Johnson, C. C., Suchyta, M. R., Darowski, E. S., Collar, E. M., Kiehl, A. L., Van, J., . . . Hopkins, R. O. (2019). Psychological Sequelae in Family Caregivers of Critically-Ill Intensive Care Unit Patients: A Systematic Review. *Ann Am Thorac Soc*(ja).
- Jones, C., Backman, C., Capuzzo, M., Egerod, I., Flaatten, H., Granja, C., . . . group, R. (2010). Intensive care diaries reduce new onset post traumatic stress disorder following critical illness: a randomised, controlled trial. *Crit Care*, 14(5), R168. doi:10.1186/cc9260
- Jones, C., Backman, C., & Griffiths, R. D. (2012). Intensive care diaries and relatives' symptoms of posttraumatic stress disorder after critical illness: a pilot study. *Am J Crit Care*, 21(3), 172-176. doi:10.4037/ajcc2012569
- Jones, C., Skirrow, P., Griffiths, R. D., Humphris, G., Ingleby, S., Eddleston, J., . . . Gager, M. (2004). Post-traumatic stress disorder-related symptoms in relatives of patients following intensive care. *Intensive Care Med*, 30(3), 456-460. doi:10.1007/s00134-003-2149-5

- Jones, C., Skirrow, P., Griffiths, R. D., Humphris, G. H., Ingleby, S., Eddleston, J., . . . Gager, M. (2003). Rehabilitation after critical illness: a randomized, controlled trial. *Crit Care Med*, 31(10), 2456-2461.
- Karlsson, V., Forsberg, A., & Bergbom, I. (2010). Relatives' experiences of visiting a conscious, mechanically ventilated patient--a hermeneutic study. *Intensive & Critical Care Nursing*, 26(2), 91-100. doi:10.1016/j.iccn.2009.12.001
- Keeley, M. P. (2007). Turning toward death together': The functions of messages during final conversations in close relationships. *Journal of Social and Personal Relationships*, 24(2), 225-253.
- Khalaila, R., Zbidat, W., Anwar, K., Bayya, A., Linton, D. M., & Sviri, S. (2011). Communication difficulties and psychoemotional distress in patients receiving mechanical ventilation. *Am J Crit Care*, 20(6), 470-479. doi:10.4037/ajcc2011989
- Kloos, J. A., & Daly, B. J. (2008). Effect of a Family-Maintained Progress Journal on anxiety of families of critically ill patients. *Crit Care Nurs Q*, 31(2), 96-107; quiz 108-109. doi:10.1097/01.CNQ.0000314469.41507.cb
- Koszalinski, R. S., Tappen, R. M., Hickman, C., & Melhuish, T. (2016). Communication needs of critical care patients who are voiceless. *CIN: Computers, Informatics, Nursing*, 34(8), 339-344.
- Koszalinski, R. S., Tappen, R. M., & Viggiano, D. (2015). Evaluation of Speak for Myself with Patients Who Are Voiceless. *Rehabil Nurs*, 40(4), 235-242. doi:10.1002/rnj.186
- Kynoch, K., Chang, A., Coyer, F., & McArdle, A. (2016). The effectiveness of interventions to meet family needs of critically ill patients in an adult intensive care unit: a systematic

- review update. *JBIS Database System Rev Implement Rep*, 14(3), 181-234.
- doi:10.11124/jbisrir-2016-2477
- Lautrette, A., Darmon, M., Megarbane, B., Joly, L. M., Chevret, S., Adrie, C., . . . Azoulay, E. (2007). A communication strategy and brochure for relatives of patients dying in the ICU. *N Engl J Med*, 356(5), 469-478. doi:10.1056/NEJMoa063446
- Lemiale, V., Kentish-Barnes, N., Chaize, M., Aboab, J., Adrie, C., Annane, D., . . . Pochard, F. (2010). Health-related quality of life in family members of intensive care unit patients. *J Palliat Med*, 13(9), 1131-1137. doi:10.1089/jpm.2010.0109
- Leventhal, H., & Johnson, J. (1983). Laboratory and field experimentation: Development of a theory of self-regulation. *Behavioral science and nursing theory*, 189-262.
- Levine, T. R., & Hullett, C. R. (2002). Eta squared, partial eta squared, and misreporting of effect size in communication research. *Human Communication Research*, 28(4), 612-625.
- Lisspers, J., Nygren, A., & Söderman, E. (1997). Hospital Anxiety and Depression Scale (HAD): some psychometric data for a Swedish sample. *Acta psychiatrica scandinavica*, 96(4), 281-286.
- Long, A. C., Kross, E. K., & Curtis, J. R. (2016). Family-centered outcomes during and after critical illness: current outcomes and opportunities for future investigation. *Curr Opin Crit Care*, 22(6), 613-620. doi:10.1097/mcc.0000000000000360
- MacAulay, F., Judson, A., Etchells, M., Ashraf, S., Ricketts, I. W., Waller, A., . . . Gordon, B. (2002). *ICU-Talk, a communication aid for intubated intensive care patients*. Paper presented at the Proceedings of the fifth international ACM conference on Assistive technologies, Edinburgh, Scotland.
- <http://delivery.acm.org/10.1145/640000/638290/p226->

macaulay.pdf?ip=164.107.5.27&id=638290&acc=ACTIVE%20SERVICE&key=1D8E1CA5B8D7D8DD%2ED6B9658582656CB8%2E4D4702B0C3E38B35%2E4D4702B0C3E38B35&_acm_ =1522145190_85d15b9f2e899e6c1cc88d5e76c3a61b

- Magnus, V. S., & Turkington, L. (2006). Communication interaction in ICU--Patient and staff experiences and perceptions. *Intensive & Critical Care Nursing*, 22(3), 167-180.
doi:10.1016/j.iccn.2005.09.009
- McAdam, J. L., Dracup, K. A., White, D. B., Fontaine, D. K., & Puntillo, K. A. (2010). Symptom experiences of family members of intensive care unit patients at high risk for dying. *Crit Care Med*, 38(4), 1078-1085. doi:10.1097/CCM.0b013e3181cf6d94
- McAdam, J. L., Fontaine, D. K., White, D. B., Dracup, K. A., & Puntillo, K. A. (2012). Psychological symptoms of family members of high-risk intensive care unit patients. *Am J Crit Care*, 21(6), 386-393; quiz 394. doi:10.4037/ajcc2012582
- McDowell, I. (2006). *Measuring health : a guide to rating scales and questionnaires* (Vol. 3rd ed). Oxford ; New York :: Oxford University Press.
- Meho, L. I. (2006). E- mail interviewing in qualitative research: A methodological discussion. *Journal of the Association for Information Science and Technology*, 57(10), 1284-1295.
- Menzel, L. K. (1998). Factors related to the emotional responses of intubated patients to being unable to speak. *Heart Lung*, 27(4), 245-252.
- Miglietta, M. A., Bochicchio, G., & Scalea, T. M. (2004). Computer-assisted communication for critically ill patients: a pilot study. *J Trauma*, 57(3), 488-493.
- Moreau, D., Goldgran-Toledano, D., Alberti, C., Jourdain, M., Adrie, C., Annane, D., . . . Azoulay, E. (2004). Junior versus senior physicians for informing families of intensive

- care unit patients. *Am J Respir Crit Care Med*, 169(4), 512-517.
doi:10.1164/rccm.200305-645OC
- Motlagh, H. (2010). Impact of Event Scale-Revised. *Journal of Physiotherapy*, 56(3), 203.
doi:[http://dx.doi.org/10.1016/S1836-9553\(10\)70029-1](http://dx.doi.org/10.1016/S1836-9553(10)70029-1)
- Myhren, H., Ekeberg, O., & Stokland, O. (2011). Satisfaction with communication in ICU patients and relatives: comparisons with medical staffs' expectations and the relationship with psychological distress. *Patient Educ Couns*, 85(2), 237-244.
doi:10.1016/j.pec.2010.11.005
- Naga, B. S. B., & Al-Atiyyat, N. M. (2009). Roy AdAptAion Model. *MIDDLE EAST JOURNAL*, 59.
- Nelson, J. E., Meier, D. E., Litke, A., Natale, D. A., Siegel, R. E., & Morrison, R. S. (2004). The symptom burden of chronic critical illness. *Crit Care Med*, 32(7), 1527-1534.
- Nilsen, M. L., Morrison, A., Lingler, J. H., Myers, B., Johnson, J. T., Happ, M. B., . . . DeVito Dabbs, A. (2018). Evaluating the Usability and Acceptability of Communication Tools Among Older Adults. *J Gerontol Nurs*, 44(9), 30-39. doi:10.3928/00989134-20180808-07
- Paparrigopoulos, T., Melissaki, A., Efthymiou, A., Tsekou, H., Vadala, C., Kribeni, G., . . . Soldatos, C. (2006). Short-term psychological impact on family members of intensive care unit patients. *J Psychosom Res*, 61(5), 719-722.
doi:10.1016/j.jpsychores.2006.05.013
- Patak, L., Gawlinski, A., Fung, N. I., Doering, L., & Berg, J. (2004). Patients' reports of health care practitioner interventions that are related to communication during mechanical ventilation. *Heart Lung*, 33(5), 308-320.

Patak, L., Gawlinski, A., Fung, N. I., Doering, L., Berg, J., & Henneman, E. A. (2006).

Communication boards in critical care: patients' views. *Appl Nurs Res*, 19(4), 182-190.

doi:10.1016/j.apnr.2005.09.006

Petrinec, A. B., & Daly, B. J. (2016). Post-Traumatic Stress Symptoms in Post-ICU Family

Members: Review and Methodological Challenges. *West J Nurs Res*, 38(1), 57-78.

doi:10.1177/0193945914544176

Pochard, F., Darmon, M., Fassier, T., Bollaert, P. E., Cheval, C., Coloigner, M., . . . Azoulay, E.

(2005). Symptoms of anxiety and depression in family members of intensive care unit

patients before discharge or death. A prospective multicenter study. *J Crit Care*, 20(1),

90-96.

Polit, D. F. (2010). *Statistics and data analysis for nursing research* (2nd edition ed.). Saratoga

Springs, NY.

: Pearson

Polit, D. F., & Beck, C. T. (2012). *Nursing research : generating and assessing evidence for*

nursing practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins.

Rash, C. J., Coffey, S. F., Baschnagel, J. S., Drobles, D. J., & Saladin, M. E. (2008).

Psychometric properties of the IES-R in traumatized substance dependent individuals

with and without PTSD. *Addictive behaviors*, 33(8), 1039-1047.

Rodriguez, C. S., Rowe, M., Koeppel, B., Thomas, L., Troche, M. S., & Paguio, G. (2012).

Development of a communication intervention to assist hospitalized suddenly speechless

patients. *Technol Health Care*, 20(6), 489-500. doi:10.3233/THC-2012-0695

- Rodriguez, C. S., Rowe, M., Thomas, L., Shuster, J., Koeppel, B., & Cairns, P. (2016). Enhancing the Communication of Suddenly Speechless Critical Care Patients. *Am J Crit Care*, 25(3), e40-47. doi:10.4037/ajcc2016217
- Rotondi, A. J., Chelluri, L., Sirio, C., Mendelsohn, A., Schulz, R., Belle, S., . . . Pinsky, M. R. (2002). Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. *Crit Care Med*, 30(4), 746-752.
- Scheunemann, L. P., McDevitt, M., Carson, S. S., & Hanson, L. C. (2011). Randomized, controlled trials of interventions to improve communication in intensive care: a systematic review. *Chest*, 139(3), 543-554. doi:10.1378/chest.10-0595
- Shin, J., Tate, J., Happ, M. B. (Under review). The Facilitated Sensemaking Model as a Framework to Study a Communication Intervention for Family Caregivers of Mechanically Ventilated Patients in the Intensive Care Unit. Submitted on May 1st 2019.
- Skoog, M., Milner, K. A., Gatti-Petito, J., & Dintyala, K. (2016). The Impact of Family Engagement on Anxiety Levels in a Cardiothoracic Intensive Care Unit. *Crit Care Nurse*, 36(2), 84-89.
- Snaith, R. P. (2003). The hospital anxiety and depression scale. *Health and Quality of Life Outcomes*, 1(1), 29.
- Snaith, R. P., & Taylor, C. M. (1985). Rating scales for depression and anxiety: a current perspective. *British Journal of Clinical Pharmacology*, 19(S1), 17S-20S.
- Stollings, J. L., & Caylor, M. M. (2015). Postintensive care syndrome and the role of a follow-up clinic. *American Journal of Health-System Pharmacy*, 72(15), 1315-1323.

- Ten Hoorn, S., Elbers, P. W., Girbes, A. R., & Tuinman, P. R. (2016). Communicating with conscious and mechanically ventilated critically ill patients: a systematic review. *Crit Care*, 20(1), 333. doi:10.1186/s13054-016-1483-2
- Tolotti, A., Bagnasco, A., Catania, G., Aleo, G., Pagnucci, N., Cadorin, L., . . . Carnevale, F. A. (2018). The communication experience of tracheostomy patients with nurses in the intensive care unit: A phenomenological study. *Intensive and Critical Care Nursing*, 46, 24-31.
- Trotta, R. L., Hermann, R. M., Polomano, R. C., & Happ, M. B. (2019). Improving Nonvocal Critical Care Patients' Ease of Communication Using a Modified SPEACS-2 Program. *Journal for healthcare quality: official publication of the National Association for Healthcare Quality*.
- van Beusekom, I., Bakhshi-Raiez, F., de Keizer, N. F., Dongelmans, D. A., & van der Schaaf, M. (2016). Reported burden on informal caregivers of ICU survivors: a literature review. *Crit Care*, 20, 16. doi:10.1186/s13054-016-1185-9
- Van Pelt, D. C., Milbrandt, E. B., Qin, L., Weissfeld, L. A., Rotondi, A. J., Schulz, R., . . . Pinsky, M. R. (2007). Informal caregiver burden among survivors of prolonged mechanical ventilation. *Am J Respir Crit Care Med*, 175(2), 167-173. doi:10.1164/rccm.200604-493OC
- Van Pelt, D. C., Schulz, R., Chelluri, L., & Pinsky, M. R. (2010). Patient-specific, time-varying predictors of post-ICU informal caregiver burden: the caregiver outcomes after ICU discharge project. *Chest*, 137(1), 88-94. doi:10.1378/chest.09-0795
- Weick, K. E. (1995). *Sensemaking in organizations* (Vol. 3): Sage.

- Weiss, D. S. (2007). The Impact of Event Scale: Revised. In J. P. Wilson & C. S.-k. Tang (Eds.), *Cross-Cultural Assessment of Psychological Trauma and PTSD* (pp. 219-238). Boston, MA: Springer US.
- Weiss, D. S., & Marmar, C. R. (1995). The Impact of Event Scale-Revised *Assessing psychological trauma and PTSD: A Practitioner's Handbook*. (pp. 399-411). New York Guilford.
- Wendler, D., & Rid, A. (2011). Systematic review: the effect on surrogates of making treatment decisions for others. *Ann Intern Med*, 154(5), 336-346. doi:10.7326/0003-4819-154-5-201103010-00008
- White, D., Leach, C., Sims, R., Atkinson, M., & Cottrell, D. (1999). Validation of the Hospital Anxiety and Depression Scale for use with adolescents. *The British Journal of Psychiatry*, 175(5), 452-454.
- Young, E., Eddleston, J., Ingleby, S., Streets, J., McJanet, L., Wang, M., & Glover, L. (2005). Returning home after intensive care: a comparison of symptoms of anxiety and depression in ICU and elective cardiac surgery patients and their relatives. *Intensive Care Med*, 31(1), 86-91. doi:10.1007/s00134-004-2495-y
- Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety And Depression Scale. *Acta Psychiatr Scand*, 67. doi:10.1111/j.1600-0447.1983.tb09716.x
- Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatr Scand*, 67(6), 361-370.

Appendix A. Study Brochure

Electronic Tablet Applications for ICU Patients

We look forward to having you join us.

Please contact:

Ann McDaniel,
Project Coordinator
(614-946-1602)

Principal Investigator for the study at the Ohio State University:

Mary Beth Happ, Ph.D.,
RN., College of Nursing
(614-292-8336)

Supported by the National Institutes of Health (#R42 NR014087-02)

Approved by the Institutional Review Boards (#2016H0006)

Help us understand your experience

We are conducting a study to compare two electronic tablet applications (apps) among patients who are unable to speak while receiving care in the ICU. Apps are assigned randomly (like flipping a coin).

We want to learn about your feelings and experience, including how you communicate while using the app during your stay in the Intensive Care Unit (ICU).

By participating in our research study, you can provide valuable information that will help us improve the use of electronic tablet apps and communication between non-speaking patients, caregivers, and their family members and better understand the practical and emotional experiences of both patients and their family members.

Joining the study is easy

Once you agree to participate, we will ask you several questions about yourself and your feelings. You will then receive an android tablet and instructions on how to use the app throughout your stay in the ICU. Next, you will have brief daily visits to ask you questions about your experiences and how you are feeling. We will also make sure the electronic tablet is working and address any questions you might have. At the time you are leaving the ICU or once you are able to speak, we will ask you a final set of questions regarding your patient and communication experiences.

Family visitors can participate too

If you are a family member of the enrolled patient, and plan to visit the patient three or more times per week, we want to better understand your feelings and experiences both during and after the patient's ICU visit.

Participating in the study is easy

There are no medical tests or treatments associated with participating in this research study. This study only consists of asking you and your family member (optional) questions about feelings, emotions, and communication experiences. Your participation is completely voluntary and you may choose to stop at any time. Your medical care is not affected in any way whether or not you choose to participate, and will continue as planned by you and your doctor.

Participation may help others

The information you provide will help us optimize electronic tablet apps for future patients and their family members facing similar challenges.

If you are interested in participating, please ask your nurse or family member to contact Dr. Mary Beth Happ at 614-292-8336.

The Ohio State University Consent to Participate in Research

Study Title: VIDATALK™ COMMUNICATION APPLICATION:
USABILITY, ACCEPTABILITY AND EFFICACY STUDY
(Family caregiver)

Principal Investigator: Mary Beth Happ PhD, RN, FAAN

Sponsor:

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this research is to compare family caregiver responses to two different electronic tablet applications provided to patients who are unable to speak while in the intensive care unit (ICU). We are interested in your experience in communicating and interacting with the patient and your emotions or feelings during and after the patient's ICU stay.

2. How many people will take part in this study?

Family caregivers of 70 patients who are participating in the electronic tablet application study will be invited to participate.

3. What will happen if I take part in this study?

A member of the research team will find a good time to meet with you in the hospital room or family waiting area located in the ICU. The researcher will ask you some questions about your feelings and emotions and experience communicating and interacting with your family during the ICU visit. We will ask you about additional information such as your age, sex, race/ethnicity, previous ICU experience, and psychological support.

The researcher will meet you and ask the same questions about your feelings, emotions, and communication experience when the breathing tube is removed or your family patient is discharged from the ICU. You will receive a contact from a researcher using one of the methods including phone calls, emails with electronic surveys, or mailing surveys depending on your preference. You will be contacted at 1-month, 3- months, and 6-months after your family is discharged from the ICU and, the researcher will ask you questions about your feelings and emotions and additional information about your ICU experience and psychological support.

You may also be contacted to participate in a follow-up e-mail interview shortly after discharge to receive your feedback and opinions about the application and your experience while visiting your family in the ICU. You may refuse to participate in this interview while still participating in the other study activities.

Your name will be kept separately from the rest of the information to protect your privacy and confidentiality.

4. How long will I be in the study?

Each in-person or telephone interview will take about 15 - 20 minutes. If at any time you get tired or feel upset in any way, you may ask to stop and you can take a break and return to the study at a time that is convenient for you. You will be in the study up to 6 months after your family's discharge from the ICU.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you or your family in the ICU, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or care for your family member.

6. What risks, side effects or discomforts can I expect from being in the study?

There will be minimal potential risks. Fatigue or emotional distress are possible when answering questions about your feelings or emotions. We will provide rests or breaks if needed. If you become unable to continue, we will end the data collection session and reschedule.

The only risk associated with this study is an unintentional breach of confidentiality. However, several protections are in place to prevent this from happening: you will receive a unique study identification number; your name will not be associated with the survey; and all study information are contained in locked office and double password protected computer files.

7. What benefits can I expect from being in the study?

Participation in this study may provide no direct benefit to you. However, the knowledge gained in this study may benefit future family caregivers of patients who are unable to speak while on the breathing tube.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and

Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

No one will have access to any information except for the research team on this and related projects.

The NIH issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents. The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if the National Institute for Nursing Research that is funding this study requests the information, or if the FDA tells us to release this information.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

- ☐ I give permission to have this information made available to other researchers in an unidentifiable manner for research related to family caregiver experience in the intensive care unit. (optional)

10. What are the costs of taking part in this study?

There will be no costs to you for participating in this study

11. Will I be paid for taking part in this study?

You will receive gift cards for your participation. You will receive a \$5 gift card at the first meeting with a researcher, a \$10 gift card at 1-month telephone interview, and a \$5 gift card at each 3- and 6-month telephone interview after the discharge. After hospital discharge, you will receive gift cards by mail. You will receive this even if you are unable to complete the study. If you participate in a follow-up e-mail interview, you will receive an additional \$10 gift card. You will receive this even if you are unable to complete the study.

- ☐ I give permission to be contacted by a researcher for a follow-up e-mail interview shortly after discharge. (optional)

By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

There is minimal to no risk of injury from participating in this study. However, if you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects' research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Mary Beth Happ at 614-292-8336 or Ji Won Shin at 614-254-0983.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Mary Beth Happ @ 614-292-8336.**

Contact Information

If you agree to be contacted by the researcher for follow-up interviews, please leave your contact information here.

- 1) Main phone number:** _____
- 2) Alternate phone number:** _____

Email address: _____

Mailing address

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Printed name of subject	_____ Signature of subject
	_____ Date and time
	AM/PM
_____ Printed name of person authorized to consent for subject (when applicable)	_____ Signature of person authorized to consent for subject (when applicable)
_____ Relationship to the subject	_____ Date and time
	AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____ Printed name of person obtaining consent	_____ Signature of person obtaining consent
	_____ Date and time
	AM/PM

Witness(es) - *May be left blank if not required by the IRB*

_____ Printed name of witness	_____ Signature of witness
	_____ Date and time
	AM/PM
_____ Printed name of witness	_____ Signature of witness
	_____ Date and time
	AM/PM

Appendix C. Verbal Script

Verbal Script for Obtaining Informed Consent – Aim 5 (Recruitment of Family Caregivers)

Dear _____,

“Hello, my name is [name]. I am working with a research team from the College of Nursing at The Ohio State University on a study of electronic tablet applications for patients while they are unable to speak in the intensive care unit (ICU).

The purpose of this research is to compare family caregiver responses to electronic tablet applications provided to patients in the ICU. We are interested in your experience in communicating and interacting with the patient and your emotions or feelings during and after your family’s ICU stay.

Here is what is involved:

We will ask you to complete some survey questions about your feelings and emotions and experience communicating and interacting with your family during the ICU visit. This takes approximately 10 minutes.

We will also ask your age, sex, race/ethnicity, previous ICU experience, and emotional support.

You will fill out a family visitation log which basically involves signing in & out on visits to the ICU so we can count the length of visits in the ICU.

The researcher will meet you and ask you to complete the same surveys about your feelings, emotions, and communication experience when the breathing tube is removed or your family patient is discharged from the ICU and again by phone at 1-month, 3-months, and 6-months after your family is discharged from the ICU.

You may also be contacted to participate in an optional e-mail interview shortly after discharge to receive your feedback and opinions about the tablet application and your experience while visiting your family in the ICU. You may decide not to participate in this interview while still participating in the other study activities.

Benefits and Risks:

The information you share with us may benefit future family caregivers of patients who are unable to speak while on the breathing tube.

Each in-person or telephone survey will take about 10-15 minutes. If at any time you get tired or feel upset in any way, you may ask to stop and you can take a break and resume at a time that is convenient for you.

With any research, there is a small risk of a breach of confidentiality, but all efforts will be made to keep the information that you share with us protected, private, and secure. All information is locked and electronic files are password protected in research-secure servers. We use study identification numbers and your name will not be linked to the information that you provide, in any research reports or publications.

Voluntary Participation:

Participation is voluntary. If you decide not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled. You can, of course, decline to answer any questions as well as to stop participating at any time, without any penalty or loss of benefits to which you are otherwise entitled.

As a thank you for participating, you will receive a \$5 gift card at the first meeting with a researcher, a \$10 gift card at 1-month telephone survey, and a \$5 gift card at each 3- and 6-month telephone survey after the discharge. By law, payments to subjects are considered taxable income.

If you participate in a follow-up e-mail interview, you will receive an additional \$10 gift card. You will receive this even if you are unable to complete the full interview.

If you have any additional questions concerning this research or your participation in it, please feel free to contact Mary Beth Happ at 614-292-8336 or Ji Won Shin at 614-254-0983.”

(The respondent will be given an information card containing name, institutional affiliation, and contact information.)

“Do you have any questions about this research? Do you agree to participate?

If so, let’s begin....”

Appendix D. Instruction Cards

a. Tablet and Vidatalk App Instructions for the intervention group

To Power On - hold the Power Button.

- To wake up the tablet - press the Power Button or the Home Button.
- To adjust volume - use the Volume Buttons.
- To return to the Home Screen - press the Home Button.
- To charge - plug the Charging Cable into an electrical outlet and then connect the Charging Cable to the Charging port on the side of the tablet.
- To open VidaTalk - select the VidaTalk Icon from the Tablet Home Screen.
- VidaTalk menu bar - to the left of the main screen is a blue menu bar:
 - **"Home"** - the most used phrases.
 - **"Questions"** - common questions that you may want to ask.
 - **"I Am"** - describe how you are feeling (symptoms, emotions).
 - **"I Want"** - things you may want (Ex: suction, lights on/off; blanket; mouth care).
 - **"Washing"** - washing and grooming needs.
 - **"People"** - asking to see your family, doctor, chaplain, etc.
 - **"Pain"** - There are three different sections for communicating about pain.
 - **"Describe the pain"** - Describe your pain (Ex: sharp, dull, aching, etc).
 - **"How bad is the pain?"** - Choose a number describing the pain you feel on a 0 - 10 scale.
 - **"Where is the pain?"** - Locate the area of your body that hurts.
 - **"Draw"** - a draw pad that allows you to write with your finger.
 - **"Keyboard"** - type out a message, then press **"Speak"**, and the device will read what you typed.
- For additional questions call the VidaTalk Study Team office during regular business hours at 614-688-2530.

b. Tablet Instructions for AC group

- To Power On - hold the Power Button.
- To wake up the tablet - press the Power Button or the Home Button.
- To adjust volume - use the Volume Buttons.
- To return to the Home Screen - press the Home Button.
- To charge - plug the Charging Cable into an electrical outlet and then connect the Charging Cable to the Charging port on the side of the tablet.
- To play Bubble Poke
 - Tap the Bubble Poke Icon from the Tablet Home Screen.
 - Tap the “Classic” button to start your game.
 - The goal is find bubbles in groups of 2 or more that are the same color that are touching each other and “poke” them.
 - As you clear the bubbles, you earn points.
 - The “UNDO” button in the upper right corner of the screen can be used if you make a mistake or want to undo a move.
 - Your game is over when there are no more groups of bubbles that can be cleared off the screen. At this point, your High Score will be displayed and you will have the option to play a new game.
- For additional questions call the Vidatalk Study Team office during regular business hours at 614-688-2530.

Appendix E. Family Visitation Log

Study ID#: _____

Family Visitation Log

[illegible]

Appendix F. Demographic Assessment Form

Family Caregiver Demographic Information (Baseline Assessment)

Please answer the following questions.

Choose only ONE answer for each question.

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*Have you visited your family patient since he/she has the tablet?

- ☐ Yes ☐ No

*Have you used the tablet?

- ☐ Yes ☐ No

1. Age: What is your Age? _____

2. Sex:

- ☐ 1) Male
☐ 2) Female

3. Race/Ethnicity origin: Please specify your race/ethnicity. Choose all that apply.

- ☐ 1) African American
☐ 2) Alaska Native
☐ 3) American Indian
☐ 4) Asian Native
☐ 5) Caucasian
☐ 6) Latino/Hispanic
☐ 7) Hawaiian or Other Pacific Islander
☐ 8) Other; please specify: _____

4. Education:

- ☐ No schooling completed
- ☐ Some high school, no diploma
- ☐ High school graduate, diploma or the equivalent (for example: GED)
- ☐ Some college credit, no degree
- ☐ College graduate
- ☐ Advanced degree (Master's, Professional, or Doctorate degree)

5. Occupation:

- ☐ Employed for wages
- ☐ Self-employed
- ☐ Unemployed
- ☐ Military
- ☐ Other; please specify: _____

6. Relationship to the patient: Please complete this statement: "I am the _____."

- ☐ 1) Spouse/Partner
- ☐ 2) Father/Mother
- ☐ 3) Son/Daughter
- ☐ 4) Brother/Sister
- ☐ 5) Grandfather/Grandmother
- ☐ 6) Uncle/Aunt
- ☐ 7) Cousin
- ☐ 8) Other; please specify: _____

7. Previous ICU experience:

- Have you been a caregiver of an ICU patient before this hospitalization?
☐ Yes ☐ No
- Have you been admitted to the ICU as a patient before this hospitalization?

☐ Yes ☐ No

8. Psychological support:

- Have you taken any medications for your mood or nerves or sleep problems (e.g., anti-anxiety, anti-depression medications, or sleeping pills) since your family was admitted to the ICU?

☐ Yes ☐ No

If yes,

Was the medicine prescribed or over-the counter?

Were you taking the medicine before this hospitalization? ☐ Yes ☐ No

What is the name of the medication? _____

- Have you been under the care of a psychiatrist or psychologist/counselor?

☐ Yes ☐ No

If yes,

Was it started before this hospitalization? ☐ Yes ☐ No

What kind of the care was? (Choose all that apply)

- ☐ 1) Counseling with a psychologist
- ☐ 2) Counseling with a psychiatrist
- ☐ 3) Cognitive Behavioral Therapy (CBT)
- ☐ 4) Hospitalization
- ☐ 5) Other: _____

Follow-up Assessment (telephone interview)

: 1 mos, 3 mos, and 6 mos after discharge

1. Patient's location (discharge disposition): Where has your family member (patient) been living after the hospital discharge?

- ☐ Home
- ☐ Rehabilitation facility
- ☐ Nursing facility
- ☐ Ventilator facility
- ☐ Hospital
- ☐ Other: _____

2. Additional ICU experience:

- Have you been a caregiver for an ICU patient since our last conversation?
☐ Yes ☐ No
- Have you been admitted to the ICU as a patient since our last conversation?
☐ Yes ☐ No

3. Psychological support:

- Have you taken any medications for your mood or nerves or sleep problems (e.g., anti-anxiety, anti-depression medications, or sleeping pills) since our last conversation?
☐ Yes ☐ No

If yes,

Was the medicine prescribed or over-the counter?

What is the name of medication? _____

- Have you been under the care of a psychiatrist or psychologist/counselor since our last conversation? ☐ Yes ☐ No

What kind of the care is? (Choose all that apply)

- ☐ 1) Counseling with a psychologist
- ☐ 2) Counseling with a psychiatrist
- ☐ 3) Cognitive Behavioral Therapy (CBT)
- ☐ 4) Hospitalization
- ☐ 5) Other: _____

Hospital Anxiety and Depression Scale (HADS)

Place an “X” on the answer that is closest to how you have been feeling in the past week. Don’t take too long over you replies: your immediate is best.

- 1) I feel tense or ‘wound up’:
3 () Most of the time
2 () A lot of times
1 () From time to time
0 () Not at all

- 2) I still enjoy the things I used to enjoy:
0 () Definitely as much
1 () Not quite so much
2 () Only a little
3 () Hardly at all

- 3) I get a sort of frightened feeling as if something awful is about to happen:
3 () Very definitely and quite badly
2 () Yes, but not too badly
1 () A little, but it doesn't worry me
0 () Not at all

- 4) I can laugh and see the funny side of things:
0 () As much as I always could
1 () Not quite so much now
2 () Definitely not so much now
3 () Not at all

- 5) Worrying thoughts go through my mind:
3 () A great deal of the time
2 () A lot of the time

- 1 () From time to time, but not too often
- 0 () Only occasionally

6) I feel cheerful:

- 3 () Not at all
- 2 () Not often
- 1 () Sometimes
- 0 () Most of the time

7) I can sit at ease and feel relaxed:

- 0 () Definitely
- 1 () Usually
- 2 () Not Often
- 3 () Not at all

8) I feel as if I am slowed down:

- 3 () Nearly all the time
- 2 () Very often
- 1 () Sometimes
- 0 () Not at all

9) I get a sort of frightened feeling like 'butterflies' in the stomach:

- 0 () Not at all
- 1 () Occasionally
- 2 () Quite Often
- 3 () Very Often

10) I have lost interest in my appearance:

- 3 () Definitely
- 2 () I don't take as much care as I should
- 1 () I may not take quite as much care
- 0 () I take just as much care as ever

11) I feel restless as I have to be on the move:

- 3 () Very much indeed

- 2 () Quite a lot
- 1 () Not very much
- 0 () Not at all

12) I look forward with enjoyment to things:

- 0 () As much as I ever did
- 1 () Rather less than I used to
- 2 () Definitely less than I used to
- 3 () Hardly at all

13) I get sudden feelings of panic:

- 3 () Very often indeed
- 2 () Quite often
- 1 () Not very often
- 0 () Not at all

14) I can enjoy a good book or radio or TV program:

- 0 () Often
- 1 () Sometimes
- 2 () Not often
- 3 () Very seldom

Please check you have answered all the questions.

Appendix H. Impact of Events Scale-Revised (IES-R)

IMPACT OF EVENTS SCALE-Revised (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to _____ (event) that occurred on _____ (date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it	0	1	2	3	4
2. I had trouble staying asleep	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6. I thought about it when I didn't mean to	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Appendix I. Family Communication Survey (FCS)

Instrument Number:

Shade circles like this:

Not like this:

Please use **BLACK** Pen Only!

Study ID:

FAMILY COMMUNICATION SURVEY

ID Number: <div style="border: 1px solid black; width: 150px; height: 20px; display: flex; justify-content: space-around;"><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>					Administration Date: <div style="border: 1px solid black; width: 30px; height: 20px; display: flex; justify-content: center;"> </div> / <div style="border: 1px solid black; width: 30px; height: 20px; display: flex; justify-content: center;"> </div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: flex; justify-content: space-around;"><div></div><div></div><div></div><div></div></div> <div style="display: flex; justify-content: space-around; font-size: 0.8em;">(month) (day) (year)</div>				
Unit: <div style="display: flex; justify-content: space-around; font-size: 0.8em;"> 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ </div>			Administration: <div style="display: flex; justify-content: space-around; font-size: 0.8em;"> ☐ ☐ ☐ </div>		Team Member: <div style="display: flex; align-items: center; font-size: 0.8em;"> <div style="border: 1px solid black; width: 30px; height: 20px; display: flex; justify-content: center;"> </div> </div>				
(FOR STAFF USE ONLY)									

Please choose only ONE answer per question . . .

	<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Not Sure</i>	<i>Agree</i>	<i>Strongly Agree</i>
	1	2	3	4	5
1. My family member/friend can make most visitors and caregivers understand him/her without speaking.	☐	☐	☐	☐	☐
2. I can understand my family member/friend even though he/she is unable to speak.	☐	☐	☐	☐	☐
3. The nurses can understand my family member/friend even though he/she is unable to speak.	☐	☐	☐	☐	☐
4. The doctors can understand my family member/ friend even though he/she is unable to speak.	☐	☐	☐	☐	☐
5. My family member/friend's way of communicating meets his/her current needs.	☐	☐	☐	☐	☐
6. My family member/friend can say everything that he/she needs to say.	☐	☐	☐	☐	☐
7. I am satisfied with my family member/friend's communication even though he/she is unable to speak.	☐	☐	☐	☐	☐
8. My family member/friend never has a problem getting his/her point across.	☐	☐	☐	☐	☐
9. I am uncomfortable with communicating with my family member/friend in this condition.	☐	☐	☐	☐	☐

ID Number: _____
(for internal use only)

Date: ____ / ____ / ____
(for internal use only)

Study ID:

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10. Communication during my most recent visit with my family member/friend in the ICU made me feel:

(Please choose all that apply . . .)

- ⁽¹⁾
- ☐ a. Angry
 - ☐ b. Frustrated
 - ☐ c. Happy
 - ☐ d. Helpless
 - ☐ e. Sad
 - ☐ f. Relieved/relaxed
 - ☐ g. Anxious/nervous
 - ☐ h. Other; please specify: _____

(for office use only)		

11. Topics of our communication were *(Please choose all that apply):*

- ☐ a. Home ☐ b. News ☐ c. Family ☐ d. Feelings ☐ e. Things they needed
- ☐ f. Their condition ☐ g. Their pain/symptoms
- ☐ h. Other; Please specify: _____

12. We used the following methods to communicate:

(Please choose all that apply . . .)

- ⁽¹⁾
- ☐ a. Lip reading
 - ☐ b. Patient gesturing
 - ☐ c. Writing
 - ☐ d. Communication board
 - ☐ e. Touch Pad Computer
 - ☐ f. Phone/text
 - ☐ g. Other; please specify: _____

(for office use only)

ID Number: _____
(for internal use only)

Date: ____ / ____ / ____
(for internal use only)

Study ID:

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- 13. We are interested in any additional comments or information that you may have about communicating with ICU patients:**

(for office use only)