Title: VIDATALK COMMUNICATION APPLICATION: USABILITY, ACCEPTABILITY AND EFFICACY STUDY

(Phase II STTR)

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Significance: Communication-vulnerable patients, such as those with limited English proficiency (LEP), or those who are hearing-impaired, aphasic, or intubated for mechanical ventilation (MV), can experience extreme frustration, panic, anxiety, sleeplessness, fear, frustration, isolation and insecurity when ineffectively attempting to communicate.[1-6] Despite multiple studies validating the *Vidatak EZ Board*™ (a disposable, prefabricated communication board) as the preferred intervention by patients and nurses and capable of reducing frustration with communication,[7,8] the EZ Board has many shortcomings, which likely negatively impacts its lack of standardization in practice. Without effective communication, MV patients' needs often go unrecognized and unfulfilled which may prolong mechanical ventilation as well as length of ICU and hospital stay, resulting in an increased incidence of ventilator associated pneumonia, days in delirium, and healthcare costs.

Vidatak is a small business entity (our collaborating business partners) developing *VidaTalk*™, a patient-centric, evidence-based touch pad software solution that will provide MV patients and those with LEP an evidence-based solution for effectively communicating their needs to care providers and family. A previous Phase I small business technology transfer research (STTR), funded through National Institute of Nursing Research and conducted at The Ohio State Wexner Medical Center (OSUWMC), was successful in defining basic user requirements and product specifications and developing a prototype of *VidaTalk*. The Phase I study confirmed the feasibility of a digital communication tool as a solution for selected MV patients to communicate their needs. The proposed, **Phase II STTR** program, also funded by NIH, will build on the knowledge gained in this study to test a commercial android version of *VidaTalk* with MV patients and determine its efficacy in improving patient outcomes.

SPECIFIC AIMS

Specific Aim 1. Develop a commercial prototype of VidaTalk that will include multilingual and customizable communication, picture symbols, and integration with mobile communication devices. *Criteria for acceptance*: Design output requirements meet input requirements determined by defined user specifications for multilingual and customizable communication, picture symbols, and integration with other communication systems.

Specific Aim 2. Demonstrate usability with iterative user assessment testing in a clinical setting. *Criteria for acceptance*: MV patients will provide feedback on acceptability, will perform test messages with minimal errors, and will rate VidaTalk an overall average score of 4.5 or higher (Likert-type scale; 1 to 7) on usability questions.

Specific Aim 3. Test the clinical efficacy of VidaTalk with MV patients by examining qualitative and quantitative endpoints in a clinical setting. We will employ a randomized clinical trial with attention control. *Criteria for acceptance*: MV patients using VidaTalk will demonstrate notable reductions in sedation exposure, delirium/coma-free days, time to successful liberation from MV, and patient-reported frustration, communication difficulty, and satisfaction with ICU care compared to patients receiving the standard of care at OSUWMC.

Specific Aim 4: Establish criterion validity of the electronic VAS-a for use among mechanically ventilated patients in the ICU who are participating in Aim 3 of this study. *Hypothesis:* The electronic version of the VAS-A tool will demonstrate a high correlation with the validated paper version.

Specific Aim 5.a. Test the 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.

Specific Aim 5.b. Examine the role of the family caregivers' perceived communication difficulty in moderating the effects of VidaTalk on the caregiver's psychological symptoms.

Specific Aim 5.c. Explore the family caregiver's perceptions of communication with, or without, VidaTalk and their emotional experience in communicating with a patient family member during critical illness and MV treatment.

BACKGROUND AND SIGNIFICANCE

For more than twenty years, communication boards have been used to assist patients with communicating their needs when they cannot speak or write. Previous experimental research demonstrated that post-operative cardiac surgical patients who received communication boards reported significantly higher satisfaction than those who received usual care.[9] As an extension of this work, Patak et al. developed the first evidence-based communication board, the *Vidatak EZ Board*[TM], designed with the assistance of patients who had recently (<24hr) been mechanically ventilated (MV).[10] Despite these advances, as well as multiple studies validating the EZ Board as the preferred intervention by patients and nurses, the EZ Board still has many shortcomings, which likely negatively impacts its standardization in practice.[7,8,10] **Limitations include: 1) it is prefabricated and cannot be personalized, and 2) the EZ board is visually complex and some patients require more focused, single page options**.

Communication disability is a significant factor contributing to adverse patient outcomes such as physical restraint, misinterpretation of pain/symptoms, and medication and treatment errors during acute care hospitalization.[11-13] More than 2.7 million intensive care unit (ICU) patients in the USA each year are unable to speak, in large part, because of the presence of artificial airways and mechanical ventilation.[14,15] Treatment-induced communication impairment is one of the most common and distressful symptoms to MV patients in ICU[1,2,5,6,16-19] and is associated with anxiety, panic, anger, frustration, sleeplessness, and distress.[1-5,16-18,20-30] Few solutions have been offered or systematically tested with intubated ICU patients.[9,31,32] Furthermore, **the technologies and resources that are currently available for critically ill patients to communicate have many shortcomings which impact effectiveness in communications and outcomes for these patients and contribute to the lack of standardization for the provision of communication resources to patients who cannot communicate in clinical practice**. The Joint Commission has identified the significance of this problem with new accreditation standards and new Elements of Performance, requiring assessment of communication needs for all hospitalized patients and provision of appropriate augmentative and alternative communication (AAC) tools and services.[33] Despite this, there remains no Standard of Care for the required provision of patient communication assistance in ICU.

Barriers to widespread use of AAC tools and electronic communication devices in the ICU include patients' physical and cognitive fluctuation or deterioration, poor positioning, use of physical restraints, discontinuity in communication partner(s), and staff lack of knowledge or access to AAC tools.[34-42] Patients vary substantially in their cognitive ability and physical dexterity during critical illness, a circumstance which likely influences their ability to successfully use available AAC strategies.[43-45] **In summary, technology has yet to provide MV patients with an effective means to communicate which is due in part to the complexity of critically ill patients' user requirements that have yet to be identified.**

Dr. Patak et al.[18] first identified just over one hundred words and phrases patients wanted to communicate when intubated in the ICU and then organized them on a disposable dry-erase patient communication board. The EZ Board has been shown to improve communication between nurses and impaired patients.[10,18] However, many patients with LEP are still underserved because hospitals limit the number of non-English versions of the EZ Board they keep on-hand. A digital communication device could provide an unlimited number of translations in one product as well as expand on the communication tools made available to patients.

Dr. Happ's (PI) study of electronic communication devices in the ICU showed that MV patients initiated communication more often when using electronic devices and patient ease of communication ratings improved; however, observed patient use of the devices was sparse and inconsistent.[37] This study established the team's expertise in testing and observation of electronic AAC device use and confirmed feasibility in ICU. Dr. Happ led the Study of Patient-nurse Effectiveness with Assisted Communication Strategies (SPEACS) to test the impact

of two levels of training and AAC support interventions on communication between nurses and nonvocal ICU patients. Intervention groups demonstrated a greater percentage of successful communication exchanges about pain (F=3.99, p=0.03) than the control group. Patients who received electronic devices and speech language consultation used significantly more AAC methods (F=6.14, p=0.002) and reported high communication difficulty less often (F=8.95, p<0.001). Patient delirium negatively impacted communication outcomes.[46, 62] Communication boards (including the Vidatak EZ Board) and electronic devices were among the AAC tools most frequently (18/53) used in patient-family member communication.[47] Case exemplars showed that communication boards and electronic devices enhanced patient autonomy and accurate information transfer, particularly in regard to medical needs.[48] The SPEACS study and the translational follow-up SPEACS-2 study[49] provided a variety of communication boards in single formats (alphabet/pictures) and in combination format (e.g., EZ Board); however, nurses had to select one or juggle several tools at the bedside. **VidaTalk offers the capacity for several communication board options in a single tool.**

Initial, Phase I development and testing of VidaTalk conducted at OSUWMC demonstrated high ease of use and satisfaction ratings among newly extubated and intubated mechanically ventilated patients who were awake, alert, and cognitively intact (non-delirious) and had good upper motor and fair fine motor control. Participants requested picture symbols for common messages and customizability of communication pages. Additionally, we identified a need for android compatibility particularly in the OSUWMC where android tablet computers are made available at patient bedsides for use of the Epic MyChartBedside™ application.

Little is known about patient-family communication during mechanical ventilation in the ICU. Family caregivers of critically ill patients report difficulty and frustration with patient communication and are eager to use augmentative and alternative communication tools to communicate with their ill family members.[47] Family caregivers of critically ill patients demonstrate high rates of depression, anxiety and post-traumatic stress symptoms during and after the patient's hospitalization.[50,51] Completion of Aim 5 will provide basic knowledge of 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 during and following the ICU admission. In addition, this study will contribute important knowledge 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.

METHODS AND APPROACH

Phase II Approach

This iterative research process presents a deliberative, systematic and comprehensive approach to device design and usability testing and will provide the necessary product validity in order to determine the impact VidaTalk has on MV patient outcomes. Table 1 presents research aims, inclusion/exclusion criteria, and tools/measures for data collection.

Table 1. Summary of Phase II research activities, and inclusions and exclusion criteria

Aim/Activities	Inclusion criteria	Exclusion criteria	Measures
Aim 1. Two group iterative design. Conduct staged testing with 7 ICU surviving patients, who have experienced intubation, in each group (n=14)	1) ≥18 yr, 2) able to communicate in English, 3) awake alert, responding appropriately to commands, 4) normal (aided or unaided) hearing and vision, 5) able to control head, arm and hand movements 6) physiologically stable and in no acute distress (per nurse report)	1) pre-existing communication impairments 2) diagnosis of severe dementia or severe brain injury 3) Confusion Assessment Method (CAM-ICU)[73] positive for delirium 4) unresponsiveness or inattention	• Demographics • APACHE III • Intubation history • ASQ • Qualitative feedback • Observation • Task time • Task success • Error number and type
Nurse focus group interviews. (n= 5 nurses).	1) Nurse employed in the study site unit 2) Critical care nursing experience > 1 year.	Pre-existing speech or hearing impairment that limits functional communication	• Demographics • Focus Group Interview

Aim 2. One group non-iterative design. Conduct in situ testing for usability and feasibility with intubated MV patients. (n=10)	Same as Aim 1 Patient group except intubated via oral endotracheal or tracheal tube without speaking valve, receiving mechanical ventilation.	1) same as Aim 1 Patient groups	• Demographics • APACHE III • Intubation history • ASQ • Qualitative feedback • Observation • Task time • Task success • Error number and type • Difficulty • Frustration
Aim3. Test the clinical efficacy of VidaTalk using two group RCT, experimental/ (n=35) and attention control (n=35)	Same as Aim 2 above except Intubated via oral endotracheal or tracheal tube without speaking valve as primary communication tool; receiving MV within 48 hrs of enrollment.*	Same as Aim 2.	See Table 3.
Aim 4: Criterion Validity of electronic VAS-A tool	Same as Aim 3	Same as Aim 3	• Anxiety score (mm) • Patient preference: paper or electronic version
Aim 5.a. Test the efficacy of VidaTalk on family caregivers Aim 5.b. Test the mediating effect of communication difficulty perceived by family caregivers Aim 5.c. Semi-structured interviews with subsets of family caregivers	1) Family caregivers of the enrolled patient participants in the parent study as identified by the patient or self 2) >/=18 years old 3) Able to read and speak English 4) Non-professional, unpaid caregiver 5) Plans to visit at least 3 days/ week during ICU stay 6) Reliable telephone access (for follow-up assessment)	1) Age under 18 years 2) Unable to read and speak English 3) Severe uncorrected hearing loss 4) Self-reported diagnosis of dementia or Alzheimer's 5) Self-reported psychiatric disorder (bipolar disorder, schizophrenia) or substance abuse requiring inpatient treatment within the last 12 months 6) Unreliable telephone access	<u>Family Characteristics</u> • Demographics • ICU experience • Psychological support <u>Family Outcomes</u> • Anxiety (HADS) • Depression (HADS) • PTSD-related Symptoms • Communication Difficulty
Nurse focus group interviews. (n= 10 nurses).	1) Nurse employed in the study site unit 2) Critical care nursing experience > 1 year. 3) Communicates in English	Same as Aim 1.	• Demographics • Focus Group or individual Interview

Legend: ASQ= After Scenario Questionnaire;[52] SUS=System Usability Scale;[53] APACHEIII= Acute physiology age and chronic health evaluation.[54]

*allows for enrollment of long-term tracheostomy patient after weaning from MV.

Specific Aim 1. Develop a commercial prototype of VidaTalk that will include multilingual and customizable communication, picture symbols, and integration with mobile communication devices. *Criteria for acceptance*: Design output requirements meet input requirements determined by defined user specifications for multilingual and customizable communication, picture symbols, and integration with other communication systems.

Rationale: For *VidaTalk* to be effective for patient communication, the user requirements for customizable communication, picture symbols, and integration with mobile communication devices of MV critically ill patients need to be identified and defined by the end users, programmed and then tested for acceptability in an iterative fashion.

Experimental design/methods: A mixed methods iterative design is planned for **Aim 1**. Two groups (Group 1 and Group 2) of five previously MV patients will be recruited from the Intensive Care Units at the OSUWMC,

including The OSU Ross Heart Hospital and the James Cancer Hospital ICUs and including patients transferred or discharged from those ICUs. Our sample size is based on prior research suggesting that testing technologies with at least 5-8 users will expose the majority of usability problems, using >50% of users reporting a problem as a threshold for modification.[55,56] To account for potential attrition, we will recruit up to 21 subjects. Potential participants will be identified by the critical care clinical research coordinators in collaboration with the unit charge nurse or clinical nurse specialist. The clinical research coordinator will then review the medical record to ensure that all eligibility criteria are met. Following this confirmation, the research coordinator will ask the bedside RN to introduce the coordinator to the potential subject. Participation will be voluntary and confidential. After informed consent and confirmation of eligibility, each participant will be assigned a unique study ID.

Group 1 will be approached using an initial prototype of VidaTalk android version to be assessed for functionality (ergonomics, ease of use, ease of learning, simplicity, effectiveness and user interface) and usability on customizable communication, picture symbols, and integration with mobile communication devices. After completing the demographic questionnaire, the patient will be reclining in bed with head of the bed elevated or seated in bedside chair. Data collection will be conducted by two trained data collectors according to **Table 2** and is expected to take 40-60 minutes.

One of the data collectors will conduct the test while the other records structured field notes. Both data collectors will review the data before finalizing. Each session will be audio-recorded via screen capture software to obtain usage record, user comments, compute task completion time and for fidelity monitoring. Patients will be asked to think aloud as they complete the task[57,58] to optimize user recall of their experience and to obtain a more direct understanding of what features are most acceptable or cause the most problems.[59] Observations made during the sessions will be reviewed and Usability Testing Reports generated[60] to document problems. Prior to engaging Group 2 for Aim 1, the company will perform iterative design assessments and engineer an improved alpha prototype, which will be transferred to OSU for assessments with the second group of seven patients.

Table 2. Group 1 and 2 Sequence of Data Collection

(1) Ask the patient to hold the device and touch the screen to activate a series of messages on pain, symptoms and other topics using the Picture version VidaTalk application: (a) Tell me you are tired.   (b) Tell me you are having pain.   (c) Rate this pain.   (d) Tell me there is pain in your back.   (e) Tell me your pain is sharp.   (f) Ask to see the doctor.   (g)Write your favorite color by drawing with your finger.   (h) Type "How are you?"
(2) Observation of task completion: Time completion of each task, count errors, note type of errors, time from error to completion.
(3) Patients complete a 1-item difficulty rating after each task and a 3-item After-Scenario Questionnaire (ASQ)[74] at the end of testing.
(4) Ask patients to (a) comment on the customization of the app and make suggestions for improvements; (b) rate the extent to which they would use the device if they were an ICU patient and unable to speak (acceptability);
(5) Having become familiar with how the app works and the content that is already available, would you want to be able to modify the app, change the words, add some or remove some? Y   N
(6) Qualitative open-ended question: If yes, describe some of the way you would like to customize the app.   If no, why would you not want to customize the app?

(7) If yes, tell me more about customizing the app. What would you want added to this tab and how would you like to be able to customize it? Repeat for each tab.
(8) Do you like the idea of adding your own pictures to represent the words? Y   N   Explain. _____
(9) Would you prefer your family member or your nurse make these customized changes for you or would you prefer to do it? _____

Phase II - Data analysis & interpretation: *Qualitative data* will be analyzed using a basic qualitative descriptive approach. Qualitative data (audio recorded patient interview questions, nurse focus group interview, and observational field notes) will be transcribed verbatim, checked for accuracy, imported into Atlas. TI for data management, and analyzed using qualitative manifest content analysis.[61] In this approach portions of text are labeled or coded with terms that are low inference and descriptive of the user opinions and testing observations. The participants' unique study identifiers will be attached to each transcript and all documents will be kept in a locked file cabinet and a password-protected electronic file copy. Codes will be identified and defined in an iterative process by investigators (Happ, research assistant) independently coding the data and arriving at agreement in discussion/review. Codes are sorted and categorized into themes, which will be discussed in research meetings. Drs. Happ, Patak, and Traughber will examine qualitative findings and testing reports to determine the severity and the frequency of problems reported. A threshold of 50% of patients reporting the same problems will necessitate a revision of that feature, however each finding or problem report will be evaluated for potential feature revision.

      Quantitative data, collected via questionnaires or field observation, will be descriptively analyzed using SAS (version 9.1.3, SAS Institute, Inc., Cary NC). Data will be screened for data anomalies prior to the main data analyses to address research aims. Consistent with the intent of this multi-phase, pilot feasibility study, no formal testing of hypotheses will be conducted. Given the small sizes for each sample (ranging from 5 to 10), descriptive analysis of quantitative data (e.g., task completion time, success rate, ASQ) will include frequency distributions and measures of central tendency and dispersion as is appropriate. For descriptive summary statistics (e.g., mean, median), both the point and interval estimates (95% confidence interval) will be computed. For multi-item scales (e.g., ASQ), descriptive statistics will be computed for both the scale/subscale scores and for individual items. Additionally, for longitudinally assessed responses for functionality and usability (e.g., ASQ, time to task completion, task success), individual response profile plots will be produced to explore within-subject changes. As this is a developmental project, interim analyses may be conducted before a sample is fully enrolled to inform the refinement of a VidaTalk application feature. Reasons for non-eligibility, non-participation, and attrition will also be documented and summarized.

Potential pitfalls/alternative approaches: If a patient participant becomes fatigued (secondary to his/her medical condition) during data collection, breaks or rest will be provided and the research team will ask for permission to return later in the day to complete the assessment.

Expected outcomes: The outcome of this research will provide both the use content and the product specifications to complete development for the VidaTalk application that will successfully meet the end user needs of MV patients and deliver a beta prototype of the final product.

Phase II - Specific Aim 2. Demonstrate usability with iterative user assessment testing in a clinical setting. *Criteria for acceptance*: MV patients will provide feedback on acceptability, will perform test messages with minimal errors, and will rate VidaTalk an overall average score of 4.5 or higher (Likert-type scale; 1 to 7) on usability questions.

Rationale: Based on findings on human factor requirements and end user needs from Aim 1, the beta design of VidaTalk will be developed for testing *in situ* with intubated, MV patients in ICU.

Procedures: Prior to implementing procedures for Aim 2, the company will have performed further iterative design assessments and engineered an android prototype which will be used with a final group of ten (10) intubated patients receiving MV support to field-test the prototype for functionality (human-device interaction factors, feasibility, and usability) and acceptability. Purposive sampling will be used to recruit a diverse sample (age, gender, race/ethnicity, naïve and experienced touchpad users). Potentially eligible participants (awake, alert/responsive, and intubated ICU patients) will be identified by the critical care clinical research coordinators in collaboration with the critical care nurses, attending physicians, fellows, or clinical nurse specialist. The clinical research coordinator will review the medical record and place records of all awake, alert/responsive, intubated patients into the IHIS In-Basket for trained research staff to review and to ensure that all eligibility

criteria are met. Following this confirmation of eligibility, the research staff will ask the bedside RN for introduction to the potential subject. Privacy protections will be observed as in Aim 1. Data will be collected by a trained data collector as in Aim 1 (See **Table 2**) steps 3-6 with the addition of Ease of Communication and Frustration ratings before and after the testing sequence. To reduce burden, patients in this group will complete the 3-item ASQ[52] one time after all tasks are completed. They will also complete a 13-item System Usability Scale (SUS).[53]

Five critical care nurses will be recruited from the study units for variation in age, experience, gender and race/ethnicity to participate in a focus group. The focus group will be conducted in a hospital conference room led by Dr. Happ, an experienced qualitative researcher, using a semi-structured guide based on the guide used in Phase 1. Nurses will review the VidaTalk tablet device applications providing feedback on functionality and acceptability, with particular emphasis on the new features and their willingness to facilitate and engage in patient communication with this device. We will also assess the logistical aspects of providing the tablet device technology in the clinical setting.

Data analysis & interpretation: Both qualitative and quantitative data will be analyzed as stated above.

Potential pitfalls/alternative approaches: If a patient participant becomes fatigued (secondary to his/her medical condition) during data collection, breaks or rest will be provided and the research team will ask for permission to return later in the day to complete the assessment.

Expected outcomes: The outcome of this research will provide functionality, usability, and acceptability data necessary to refine the product to a commercial version of VidaTalk for efficacy and comparison testing to other communication modalities and the standard of care (**Aim 3**).

Phase II - Specific Aim 3. Test the clinical efficacy of VidaTalk with MV patients by examining qualitative and quantitative endpoints in a clinical setting. We will employ a randomized clinical trial with attention control. *Criteria for acceptance*: MV patients using VidaTalk will demonstrate notable reductions in sedation exposure, delirium/coma-free days, time to successful liberation from MV, and patient-reported frustration, communication difficulty, and satisfaction with ICU care compared to patients receiving the standard of care at The Ohio State University Hospital.

Rationale: In order to become a standard of care, evidence-based communication devices must demonstrate improve qualitative and quantitative outcomes in mechanically ventilated patients.

Procedures: Prior to implementing Aim 3, the company will have completed product development of the commercial release candidate of VidaTalk. The commercial release candidate will be tested with a sample of 70 intubated patients receiving MV to field-test VidaTalk for efficacy in improving patient outcomes. Patient inclusion/exclusion criteria are the same as for Aim 2 (See Table 2). However, we have clarified that patients with tracheostomies and speaking valves will be included as long as the valves are not the primary method of communication and patients weaning from mechanical ventilation (within 48 hours) who are still intubated and unable to vocalize will be eligible for inclusion. Thirty-five (35) patients will be randomized to the intervention arm and will be provided an android tablet with the VidaTalk application as their primary communication resource. The other 35 patients will be considered the attention-control arm and will receive an android tablet configured according to the standard OSUMC MyChartBedside display and the standard of care for communication, which includes primarily writing tools (paper and pen) and, occasionally, picture or alphabet communication charts. EZ Boards (communication boards) will be available on all units. Android tablets are available in each participating ICU. No AAC application is planned yet for these devices.

Potentially eligible participants (awake, alert/responsive, intubated ICU patients) will be identified by the critical care clinical research coordinators in collaboration with the critical care nurses, attending physicians, fellows, or clinical nurse specialist. The clinical research coordinator will then review the medical record and place records for all awake, alert/responsive, and intubated patients into the IHIS In-Basket for trained research staff to review and to insure that all eligibility criteria are met. Following this confirmation of eligibility, the research staff will ask the bedside RN for introduction to the potential subject. Privacy protections will be observed as in Aims 1 & 2. Family members identified by the enrolled patient who are at least 18 years of age and read and understand English will be recruited for measures of psycho-emotional symptoms (Aim 5) and satisfaction survey (Aim 3) at discharge from the ICU.

Patients and family visitors in the intervention group will receive a protocolized instruction in the use of the VidaTalk application and mounting of the device including patient return demonstration of key features, and review/ testing to competence conducted by a trained AAC interventionist. When available, a family member will be included in the instruction and asked about preferred messages if patient agrees. The interventionist will visit patients briefly (5-10 minutes) each day to check user needs and concerns and will review or retrain on message options if needed. The interventionist will record all interactions in the interventionist log using the format established by Dr. Happ in the SPEACS trial.[62] The VidaTalk app will be available until the patient is extubated or discharged from ICU whichever comes first. Patients randomized to the control group will receive a protocolized introduction to the bedside Android device without the VidaTalk app focused instead on a popular, simple game application which is standard on OSUMC bedside devices. Daily visits will be conducted with control group patients to query on use of the standard tablet apps.

Data collection: Data will be collected for all participants by a trained research assistant (See Table 3). Demographic data (age, sex, race/ethnicity, ICU, number of days intubated prior to study enrollment, diagnosis, severity of illness (APACHE III) and comorbidity (Charlson Index), physical restraint) will be collected on enrollment. The data collector will conduct daily measures of physical restraint (covariate), communication difficulty (single item), frustration, anxiety, agitation, sedation exposure, and delirium for a maximum of 28 ICU days. In addition to the daily measures, patients in the experimental group will complete a 13-item System Usability Scale (SUS)[53] on study Day 2. Patients will be asked a single item satisfaction with care survey and to complete the 10-item Ease of Communication Scale[17] (5 minutes) at ICU discharge. Family members identified by the patient will be invited to complete a 24-item Family Satisfaction in the Intensive Care Unit (FS-ICU)[63] (10-15 minutes) at ICU discharge.

Sample Size Justification: A sample of 70 patients (35 in each arm) would provide the necessary variability in all measures to provide confidence in the judgment of "notable differences" in clinical outcomes and is reasonable to recruit from the ICUs in 8 months (5 per month for each group). Two groups of 35 provide greater than 80% power to detect medium size effects (d_z = .5) within group using dependent t-tests at alpha = .05 and 80% power to detect medium size effects (d = .5) between groups using one-tailed independent t-tests at alpha = .10. This sample would provide greater than 80% power to detect a medium size effect (f^2 = .15) in a multiple regression model with 3 predictors (i.e., intervention group, age, and acuity) at alpha = .05. We anticipate 35% attrition and so will recruit 95 participants.

Table 3. Phase II, Aims 3 & 4 - Main Variables, Measures, Data Collection Time Points

Variables	Measures	Data Source	Cronbach's Alpha	T0	T1	T2	T3
Covariates							
Demographic information	Demographic questionnaire (age, sex, race, days intubated prior to study, diagnosis)	EHR	NA	X			
Severity of Illness	APACHE III[54]	EHR	NA	X			
	Charlson Comorbidity Scale[64]	EHR	NA	X			
Physical Restraint Use	Physical Restraint – any part of day in physical restraint	EHR	NA	X	X		
Fidelity - Usability							
Intervention Exposure/Dose	Intervention component checklist, time with patient (minutes/day),	Log	NA	X	X		
	Reported patient use (qualitative category)	Patient	NA		X		
Usability	System Usability Scale (SUS)[53]	Patient	0.92			X	

Patient Outcomes							
Anxiety	Visual Analogue Scale – Anxiety (VAS-a)[65]	Patient	0.78				
	• Electronic			X			
	• Paper			X	X		
Sedation-Agitation	Richmond Agitation-Sedation Scale (RASS)[66]	Observer	NA	X	X		
Sedation *Exposure* (24hr)	Midazolam and Opiate Equivalents[67]	EHR	NA	X	X		
Delirium/Coma-Free Days	Confusion Assessment Method- ICU (CAM-ICU)[68]	Patient	NA	X	X		
Communication Difficulty	Ease of Communication Scale (ECS)[69]	Patient	0.93-.96				X
& Frustration	Communication Difficulty – single item scale[62]	Patient	NA	X	X		
	Frustration scale – single item scale[18]	Patient	NA	X	X		
Satisfaction with ICU Care	Family Satisfaction in the Intensive Care Unit (FS-ICU)[63]	Family	0.88-.94				X
	Patient Satisfaction with Care – single item scale	Patient	NA				X

*T0= baseline/enrollment, T1 = daily in ICU x 28 days maximum; T2 = study day 2; T3 = ICU discharge/extubation; NA= not available/ not applicable; EHR = electronic health record

Product Development: Vidatak will conduct a series of workshops that will use High Tech Anthropology® methods for creating and testing user designs that will be incorporated into prototypes, tested with participants from the community whom are critical care nurses or people whom had recently (<6 months) been a patient in an ICU. The iterative design process will likely involve over 20 design test kits testing with input from 20 community participants. These procedures will stagger 2-3 formal product design workshops intended to solidify progressive staged prototypes for each user test groups at the OSU. Consultants Patak, Traughber and Costello will be provided summaries of each design assessment and provide insight and advisement throughout the process. Programming activities will follow recommendations that arise from each phase of user testing.

At the conclusion of participant enrollment and data collection for Aim 3, ten critical care nurses who experienced use of the VidaTalk during communication with study patients will be recruited from the study units for variation in age, experience, gender and race/ethnicity to participate in a final focus group or individual interviews. The focus group or individual interviews will be conducted either in person in a hospital conference room, via Skype or Phone, led by Dr. Happ, using a semi-structured guide, and audio recorded. The individual interview options are designed to accommodate nurses who are unable to attend focus group sessions before or after a 12-hour shift but are willing to be interviewed remotely, Nurses will review the final versions of VidaTalk android and iPad applications providing feedback on the overall performance of VidaTalk and its ability to impact patient care, with particular emphasis on their willingness to facilitate and engage in patient communication with this device. Logistical aspects of providing both the android and iPad technology in the clinical setting will also be assessed along with clinical implications and acceptability of VidaTalk communicating with provider devices.

Data analysis & interpretation: **Qualitative data** (patient feedback, nurse focus group transcripts) will be analyzed as stated above. The **quantitative data** will be cleaned and descriptive statistics will be estimated to ensure the quality of the data (check distributions, examine outliers) and to describe the sample (e.g., age, education, race/ethnicity). Data will be graphed to visually identify any patterns of change over time. Missing data are not expected to pose a problem; nevertheless, we will examine the nature of missingness in the data. If necessary, we will conduct analyses using Multiple Imputation (SAS 9.2). We will conduct appropriate bivariate tests for all clinical outcomes (i.e., sedation exposure, patient-reported frustration) using dependent t-tests within groups and independent tests between groups for continuous outcomes and contingency table analyses for categorical outcomes. We will also construct change scores when there are notable differences and fit exploratory regression models predicting change scores by intervention group and two control variables.

Potential pitfalls/alternative approaches: If a patient participant becomes fatigued (secondary to his/her medical condition) during data collection, breaks or rest will be provided and the research team will ask for permission to return later in the day to complete the assessment.

Expected outcomes: The outcome of this research will provide functionality, usability, and acceptability data necessary to refine the product to a commercial version of VidaTalk for efficacy and comparison testing to other communication modalities and the standard of care (**Aim 3**).

Phase II - Specific Aim 4. Develop an electronic version of the visual analog scale for anxiety (VAS-A) on an android tablet. Evaluate the criterion validity of the electronic VAS-A for use among mechanically ventilated patients in the ICU who are participating in Aim 3.

Rationale: Electronic measures of medical self-assessments and psychological inventories are becoming increasingly available and frequently used. They offer various advantages over paper measures including more efficient data collection, data handling and analysis, and most importantly, increased patient compliance and recording accuracy. For example, with the dissemination of computerized, psychological assessments growing, (e.g. in smartphone applications), the VAS-A can be embedded in internet-based protocols of therapy interventions.[70] Completion of this Aim will establish the validity of an electronic mechanism for quickly and reliably capturing the state anxiety of a patient for more effective patient communication in the ICU.

Procedures: All patients eligible to participate in Phase II, Aim 3 will participate in Aim 4. Patients will be randomized to the presentation order of the two anxiety assessment tools. At baseline, anxiety will be assessed using both the electronic and paper versions of the VAS-A by the data collector. On all subsequent days, the data collector will utilize the paper version of the VAS-A to assess patient anxiety.

Data collection: Patient assessment of anxiety will be collected by the data collector at baseline using both the electronic and paper versions of the tool as noted above. Anxiety will be measured in millimeters on both the electronic and paper versions of the VAS-A tools.
In addition to the millimeter measure of anxiety on both the electronic and paper versions of the VAS-A tools, we will capture the patient's concerns or difficulties with touch sensitivity or screen brightness.

Sample Size Justification: A sample of 30 patients (assuming 35% attrition) would be sufficient to provide confidence in the criterion validity of the electronic VAS-A with 80% power, alpha=0.05 with a Cronbach correlation coefficient of r = 0.6. However, all patients enrolled in both arms of Aim 3 will participate in Aim 4 for a total of 70 participants for similar exposure.

Data Analysis: We will use qualitative analysis to describe the average level of patient concerns or difficulties, such as touch sensitivity or screen brightness preferred by patients. Criterion validity between the electronic and paper versions of the VAS-A will be determined by calculating a Cronbach's alpha in a correlation analysis. Finally, we will determine if there is a significant difference between the preferred versions of the VAS-A utilizing a bivariate, dependent t-test and contingency table analyses for categorical outcomes (Chi-squared).

Potential pitfalls/alternative approaches: Per the procedure in Aim 3, if a patient participant becomes fatigued (secondary to his/her medical condition) during data collection, breaks or rest will be provided and the research team will ask for permission to return later in the day to complete the anxiety assessment.

Expected outcomes: This study will establish the criterion validity of a newly developed, electronic VAS-A on an android tablet which can be used to improve the effectiveness of patient communication and contribute to the standardization of care for critically ill patients.

Phase II - Specific Aim 5.a) Test the 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. b) Examine the role of the family caregivers' perceived communication difficulty in moderating the effects of VidaTalk on the caregiver's psychological symptoms. c)

Explore the family caregiver's perceptions of communication with, or without, VidaTalk and their emotional experience in communicating with a patient family member during critical illness and MV treatment.

Rationale: Comparison of family caregivers with and without exposure to the VidaTalk communication tool will provide basic knowledge of 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 mechanical ventilation of a family patient. Qualitative interviews with family caregivers will help us better understand their communication experience, how the VidaTalk influences their communication with a family member/patient in ICUs, and how they feel while communicating with the family patient before and after using the VidaTalk.

Design/methods: A nested, mixed methods design with repeated measures is planned for **Aim 5.** The qualitative phase of the study will be devoted to exploring family caregivers' experience of communication with or without VidaTalk while they were visiting the family in ICUs and their emotional reactions to communication with a family member- patient during critical illness and MV (Aim 5.c.).

Sampling procedures: Family caregivers of patient participants enrolled in the clinical efficacy trial (Aim 3) will be recruited. A family caregiver is defined as "the person who is primarily 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 does not have to be a blood relative."[71,72] A patient may have more than one family caregivers who are responsible for the patient's care, and each family member can have a different role in communication with the patient. One or more family caregivers for each patient can be recruited as identified by the patient and/or by the family caregiver. Potential family participants identified by the patient, clinicians, or by family members themselves who meet the eligibility criteria will be provided information about the study purpose and procedures and verbal consent will be obtained for study participation. If an eligible family caregiver is not present at patient enrollment, informed consent will be obtained over the phone. All participants will be informed about the possibility of an optional qualitative interview after the discharge. A purposeful sampling procedure will be used for the qualitative phase Family caregiver participants in the intervention group ; a total of 10-15 participants will be recruited to participate in the qualitative interview after discharge.

Procedures: The enrolled family participants whose family patient is assigned to the intervention group will be informed that their family patient may communicate with or without the VidaTalk while family visit. Over the clinical efficacy test phase (Aim 3), the bedside Android device with the VidaTalk application and a user instruction card will be available for the patient participants in the intervention group until they are extubated or discharged from ICU. Each visit, the family caregivers will be asked to complete a visitor log. The visitor log will ask about visiting start/end time, who is visiting, the use of VidaTalk (yes or no), and a question about communication topics during the visit. The family participants whose family patient is assigned to the attention control group will receive the standard of care regarding communication. When they are visiting the patient, writing tools (paper and pen), and occasionally, picture or alphabet communication charts will be provided for communication at the discretion of the bedside nurse. Each visit, the family caregivers in the attention control group will be asked to complete a visitor log. The visitor log will ask about visiting start/end time (start and end), who is visiting, the use of the MyChart Bedside and/or game app (yes or no), and the topic of communication during the visit.

Data Collection: Baseline assessment will be performed after consent. Baseline assessment includes demographic information, communication difficulty (Family Communication Survey),[74] anxiety (HADS-A),[73] and depression symptoms (HADS-D)[73] in family participants. Family participants' demographics include age, gender, race, highest education level, occupation, and relationship to the patient. Previous ICU experience as a patient or a family caregiver prior to this hospitalization will be also assessed at baseline. Patient's demographic characteristics including age, gender, and race and clinical characteristics such as severity of illness, primary diagnosis, physical restraint use, ICU/hospital length of stay, the length of time on MV will be

obtained from the electronic medical record (EMR). The Hospital Anxiety and Depression Scale (HADS)[73] will be performed at baseline (enrollment) and at patient's extubation or ICU discharge to measure anxiety and depression symptoms for family participants. Total scores out of 42 (21 per subscale) will be derived by summing responses for each of the two subscales (HADS-A and HADS-D) performed at baseline and at extubation/ICU discharge. Family caregivers' communication difficulty and satisfaction with communication will be measured using the Family Communication Survey (FCS) at patient' ICU discharge or extubation whichever comes first. At one month after the ICU discharge, anxiety (HADS-A), depression (HADS-D), and PTSD-related symptoms (The Impact of Event Scale-revised (IES-R)) will be measured by one of the methods including electronic surveys via email, mailing surveys, or telephone interview depending on the participant's preference.[75,76] Participants who do not respond to electronic/mailing surveys will receive at least two telephone contact attempts for survey completion. Psychological outcomes including anxiety, depression, and PTSD-related symptoms will be followed until six months after the ICU discharge. The same procedure will be repeated at three and six months after the ICU discharge. At each follow-up assessment, the additional experience of being a caregiver of ICU patient or being admitted to an ICU as a patient during the study will be assessed. Whether or not family caregivers get any help from psychiatrists, psychologists, counselors, any institutional services for their psychological problems, and use of psychoactive medications during the study will be identified by self-report at each time point. Additionally, whether or not the patient returns home or goes to long-term care facilities will be assessed at ICU discharge and one month follow-up time point.

Qualitative Interview: The selected family participants for the interview will answer open-ended questions asking about their perception of communication with and without 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 will ensure that the key issues are addressed and the interview flow is maintained during the interview. Qualitative interviews will be performed using e-mail interview method. There are several advantages of e-mail interview method. It will reduce time and cost of travel for the interview and intrusion of technology such as audiotaping or microphone. Moreover, the email interview is the raw data itself and there is no need for transcription, which eliminates transcription reliability issue.[77] The participants will be contacted via secure e-mail at a time point after the ICU discharge before 1-mos follow-up to be proximal to the family caregiver's experience without losing their ability to recall. The e-mail interview will involve a maximum of three cycles. The initial cycle will contain several questions of a general experience of communication with their family member while they were visiting in the ICU (question 1-3). That will be followed by the second cycle with questions of conversation 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 will be constructed based on the interview guide, and analysis of participant's answers in each previous cycle will allow the interviewer to ask for more details while developing the next set of questions.[77]

Box 1. Interview Guide for Qualitative Analysis

	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. Can you tell me about that experience? 2. How often did your family member use the VidaTalk to communicate? What other methods of communication did you use? 3. How did you feel when you were communicating with [patient's name] after starting to use the VidaTalk?

Cycle 2	4. What messages were communicated using the VidaTalk?
	5. Tell me about what conversation had the most impact on you? Which conversation was the most meaningful? Which conversation bothered you at 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 to communicate?

Data analysis & interpretation: The **quantitative data** will be cleaned and descriptive statistics (mean and standard deviation (SD) for continuous variables and frequency and percentage for categorical variables) will be used to describe relevant demographics and characteristics of the sample. Data screening and preliminary analysis will first be performed for data anomalies such as outliers or normality. The results from this analysis will: 1) describe data distributions; 2) evaluate the amount and patterns of missing data; 3) identify the associations between variables such as possible imbalances between groups and associations between the independent variables and suspected covariates; and 4) check for violation of underlying statistical assumptions for the primary analyses planned. If assumptions are violated, data transformations or more statistically robust procedures (e.g., nonparametric approaches) will be considered as alternative options.

Analysis plan for Aim 5.a.) To test the effect of VidaTalk on psychological outcomes in family participants, I will compare those psychological outcomes between two groups at each time point and across time. I will conduct mixed effect modeling to estimate the intervention effect on outcome measures (anxiety, depression, and PTSD-related symptoms). Mixed effect modeling for repeated measures will estimate the intervention effect at each time point by including the time of assessment and group as predictor variables. Mixed effect modeling also will model the change across time using a time by group interaction to determine if the two groups have different patterns of change in outcomes over time. I also will adjust for covariates that may impact those psychological outcomes as indicated by the results of our exploratory analyses.

that may impact those psychological outcomes.

Analysis plan for Aim 5.b.) Family caregivers' perceived communication difficulty measured by a structured instrument (FCS) will be tested as a potential moderator. Using mixed effect modeling, the potential moderator will be crossed with intervention and included as a fixed interaction term in the model. If a significant moderating effect is identified in this analysis, it will provide pilot data for the further understanding of the mechanisms of intervention effect.

Analysis plan for Aim 5.c.) The **qualitative data** (e-mail interviews) will be transferred into ATLAS_ti (Version 7.5.18) for data management. Basic qualitative description and constant comparative techniques will be used to code and analyze the text. This strategy involves 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.[78] Each interview will be read several times and then coded to identify initial themes. The line-by-line examination will be done to label meaning units, and additional codes may be added, or existing codes may be modified as the analysis continues. Recurring themes across transcripts will be identified using constant comparison and matrix construction .[79] With the dynamic and cyclic process, recurring patterns, new issues, and the connections linking themes will be identified.

Qualitative and quantitative data will be combined to amplify findings and identify within case and between case differences. The qualitative coding will be transformed to dichotomous variables that will be combined with quantitative data from the same caregivers. Mixed data matrices will be constructed to detect patterns/differences among psychological outcome phenotype groups by between-group comparisons. Moreover, the matrices will display the potential relationship between interview responses and demographic characteristics such as caregiver age, gender, relationship to patient, and VidaTalk usage from the visiting log to identify patterns and interpretations of the effect of the VidaTalk on family caregivers' psychological symptoms not initially recognized from single method analysis alone.

Potential pitfalls/alternative approaches

a) Emotional distress during data collection: Interviews will be stopped if a subject becomes emotionally distressed, and telephone numbers for mental health support will be provided. In addition, if a subject is found to be at risk for severe anxiety/depressive symptoms or sounds/appears suicidal, telephone numbers for mental health support will be provided and the interviewer will arrange for transportation to an emergency room, a mental health care provider, or the subject's primary care provider as desired by the subject.

b) Suicidal or emotionally distressed participants: If a participant is found to be at risk for high risk for major depression (HADS-D score of 15 or greater) or PTSD (IES-R score of 37 or greater), mental health resources will be provided, and he/she will be encouraged to contact their provider to schedule an appointment for evaluation. If the participant reports that they are actively suicidal, 911 will be called or the person taken directly to an emergency department.

c) For the family participants whose family patient has died, we will send a sympathy card to express our condolences to them and appreciation for their participation.

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