PARTNERS HUMAN RESEARCH COMMITTEE DETAILED PROTOCOL

Principal Investigator:	Ana-Maria Vranceanu, PhD
Protocol Title:	Recovering Together: Building resiliency in dyads in patients admitted to the Neuroscience Intensive Care Unit (NICU) and their caregivers
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I. BACKGROUND AND SIGNIFICANCE

Acute neurological illnesses (ANIs) are common, costly and often lead to long-term disability. ANIs are biologically distinct injuries that disrupt the normal function of the brain. The most common ANIs in Neuroscience Intensive Care Units (NICU) include cerebrovascular (stroke/hemorrhage and brain aneurysm), structural (tumors and lesions/brain masses), and traumatic (TBI) brain injuries. NICU admissions for ANIs are prevalent (e.g., 795,000 acute stroke/year; 275,000 acute TBI/year) and costly[1,2]; post NICU prolonged rehabilitation is common[3].

ANIs are associated with chronic emotional distress in both patients (pts) and caregivers (cgs). Although biologically heterogeneous, ANIs are unified by sudden onset, and substantial emotional distress in both pts (e.g., 12-43% anxiety[4-7]; 10-58% depression[4,7,8]; 20-29% post-traumatic stress PTS[5,9]) and family cgs (27-60% depression, anxiety or PTS [4,10,11]). These symptoms often become chronic and treatment resistant[26,27].

Pt and cg factors interact and influence physical and emotional outcomes in both pts and cgs. Post ANI emotional distress is associated with pts' poor medical adherence[28], slower recovery[28-30], higher mortality[29-31], and need of more caregiving assistance[32], which further increase cgs' distress[30,33,34] and own risk for morbidity[35,36] and mortality[37]; in turn cgs' emotional distress interferes with ability to provide high-quality care to pts[38,39] and negatively impacts pts' outcomes.

Current management of ANIs does not meet the psychological needs of pts and cgs for 3 reasons[40-51]. First, although recognition of the emotional burden associated with NICU admission has increased, and some NICUs have social workers available to assist pts and cgs, there are no formal screening methods for emotional distress routinely integrated in practice during hospitalization, when the primary focus is on medical care and survival; further, there are no formal evidence-based treatments integrated within the medical care. When social workers are included to help pts and cgs, the care is brief and occurs only during hospitalization. When referrals to mental health services are provided to families at discharge, few will access additional treatment due to burden associated with traveling outside of home. Second, psychosocial interventions available for ANI pts or cgs are limited in that they are delivered when symptoms are already chronic, address only one emotional illness (e.g., depression or anxiety or PTS), and/or are focused on a *single member* of the pt-cg dyad. Even interventions labeled as "dyadic," which include pts and cgs, typically address only the pts' needs and do not

focus on cg outcomes or on the dyad's interpersonal communication and bond/relationship[12,52]. These interventions are not consistent with the *dyadic framework*[22] which specifies that dyadic interventions should account for the interdependence between pt and cg psychosocial factors including their interpersonal bond by ensuring that both pts and cgs attend each session together, and by targeting improvement in outcomes for both pts and cgs. Third, most interventions are delivered using uniform protocols. However, the needs of ANI dyads are heterogeneous due to varying levels of post ANI impairment, identity of the cg, context and stage of life. A recent systematic review[52] urged for the development of dyadic interventions that address the needs of *both* pts and cgs and are tailored to the specific needs of each ANI dyad.

We developed the first dyadic skills-based intervention – Recovering Together - to prevent chronic heightened emotional distress in at risk ANI pt-cg dyads. The "Recovering Together" program is informed by the theoretical response-shift framework of adaptation to acute illness[53] (successful adaptation implies recalibration of values and life goals), the family strength vulnerability model[24] (within dyads relational systems have strengths and weaknesses in how they cope with life events), the dyadic longitudinal model[22] (distress travel from one member of the dyad to the other across time), the APIM model[54], and the resiliency framework[17]**.** The program is in line with recent recommendations for skill-based interventions for critical care patients, and uses preliminary data collected by our team for the past 3 years[4, 13-15]. The intervention teaches pts and cgs resiliency factors that are associated with well-being after trauma for both pts and cgs: *mindfulness* – the ability to stay present and defer judgment in the face of adversity[18]; *coping*– the arsenal and application of one's behavioral, cognitive, and emotional strategies to manage stress[19]; *social support* –empathetic interpersonal interactions that meet one's emotional and functional needs[20]; *self-efficacy* – perceived ability to adapt under adversity[21] and *positive dyadic interpersonal communication to increase interpersonal bond[12]*. Informed by the aforementioned theoretical models, our conceptual model hypothesizes that by teaching both members of the dyad resiliency and interpersonal communication skills (e.g., Recovering Together) we will be able to sustainably decrease emotional distress in both members of the dyad

In addition, our team has an established record of collaboration on published or ongoing investigations. **Emotional distress is prevalent in dyads, interdependent between pt and cg, and negatively associated with resiliency factors[4].** Our team conducted a cross-sectional study of pt-cg dyads in the NICU (40% stroke, 30% tumor). 75% pts and 84% cgs approached agreed to participate. 74% pts had been intubated at one time during NICU admission, and 2/3 were discharged home. Rates of clinically significant symptoms of depression, anxiety and PTS did not differ between pts (24%, 43%, 21%) and cgs (24%, 46%, 17%), or by any demographic or medical characteristic. Dyadic modeling showed that for both pts and cgs, mindfulness and coping impacted both self and partner's emotional distress symptoms. We showed: 1) feasibility of recruitment; 2) high emotional distress in dyads; and that 3) modifiable resiliency factors (mindfulness and coping) are intervention targets interdependently associated with distress in pts and cgs, regardless of the identity of cg (e.g., spouse, friend, etc).

Resiliency factors are associated with lower emotional distress in NICU dyads[13]. Our team found that resiliency factors of mindfulness, coping, self-efficacy and patient-caregiver interactions were associated with decreased emotional distress in dyads of ANI. This study confirms mindfulness, coping as intervention targets and provides novel evidence on self-efficacy and patient-caregiver interaction as additional important intervention targets.

ANI pts have greater anxiety than cancer patients at early diagnoses[14]. We led the first cross-comparison study of emotional distress among dyads with ANI and cancer. This study supports the priority of addressing emotional distress in ANI dyads as has been emphasized for cancer dyads.

Clinically significant emotional distress in one member of the dyad at hospitalization predicts chronic emotional distress in at least 1 of the dyad members 3 and 6 months later[55]. Our team has an ongoing prospective study of dyads with ANI. Retention rates for dyads due for assessments at 3 and 6 months thus far are 84% and 91% for pts and 87.7% and 95.7% for cgs, confirming our ability to retain post-ANI participants. Within each dyad, if one member screens in for clinically significant symptoms for any diagnosis (i.e., depression, anxiety or PTSD) at hospitalization there is good sensitivity and specificity that one member of the dyad will endorse clinically significant symptoms 3 months later. This study shows a reliable method for identifying dyads of patients at risk for chronic heightened emotional distress by identifying dyads in which either the pt or cg screens in for heightened emotional distress (symptoms of depression, anxiety or PTSD).

Caregiver gender moderates the prospective association of resiliency factors to emotional distress[87]. This study found that at the time of admission resiliency factors have main effects on emotional distress, with no differences by cg gender. However, significant interaction effects emerged prospectively such that male cgs with high mindfulness at baseline demonstrated lower levels of emotional distress at 3 and 6 months later than did males with low mindfulness ($p = 0.026$ and $p < 0.013$). Similarly, women cgs with high intimate bond at baseline reported the lowest levels of depression symptoms 3 and 6 months later ($p < 0.020$). This study confirmed the need to assess and address resiliency factors early in the recovery process, and identified important gender differences to be accounted for in intervention development.

Recovering Together; Developing a novel dyadic resiliency skills program for ANI pt-cg dyads at risk for chronic emotional distress[15]. With funding from American Heart Association, we conducted 20 qualitative interviews with pt-cg stroke dyads at risk for chronic emotional distress during NICU hospitalization. We also conducted additional clinical interviews with 10 pt-cg dyads representative of other ANI diagnoses. 83% dyads approached agreed to participate. Pts (23) and cgs (25) were mostly women. Dyads were mostly spouses and mothers-daughter. Data was analyzed with Nvivo10. Main themes did not differ by medical diagnoses: 1) most challenging and distressing experiences: uncertainty about future, anxiety, depression, sleep difficulties, worries about the future, guilt, managing job with caretaking, making treatment decisions, lack of predictability; 2) concerns about interpersonal relationships (self-image, role changes, role fulfillment); 3) fear of recurrence; 4) adjusting to sequelae. Dyads noted interest in a resiliency program (30/30) and preferred a combination of in person and live video sessions (30/30). Dyads learned about resiliency skills (e.g., name, description and goal) and agreed they would be helpful to them. They also noted interest in learning about: survivorship plans, adaptation to deficits (present or anticipated), and return to normal living. We found no thematic differences between stroke dyads and other ANI dyads. Challenges associated with embracing the caregiver role emerged as a theme while differences by the identity of caregiver (e.g., spouse vs. friend, vs parent) did not. Themes associated with the gender of the cg emerged and have been incorporated in the intervention.

Nurses perception of the needs for and feasibility of "Recovering Together for ANI families[25]. We conducted 2 focus groups (N =15) with NICU nurses who provided feedback on the qualitative findings from our 30 ANI dyads and shared own experiences and opinions on

implementation and scalability of the intervention including nurse involvement. Nurses concurred with pts experiences, and suggested strategies to recruit and retain dyads for the study, which are now included in the methodology section of the current grant proposal. Studies 3.6 and 3.7 represent the building blocks for the development of our Recovering Together program and manual. Nurses provided edits and contributed to the iterative development of the manual. These studies also confirm feasibility of conducting the pilot RCT proposed through this R21.

II. SPECIFIC AIMS

The current study has the following objectives:

Aim 1: **To determine the feasibility of recruitment, feasibility of program delivery, program credibility, and program satisfaction using evidence-based benchmarks.**

Hypothesis 1: We hypothesize that > 75% of the dyads approached will agree to participate.
Hypothesis 2: We hypothesize that > 75% of dyads who start the intervention will complete at least 4 sessions.
Hypothesis 3: We hypothesize that > 75% of participants will report average credibility (Credibility and Expectancy Questionnaire) scores greater than the scale's midpoint.
Hypothesis 4: We hypothesize that > 75% participants will report average satisfaction (Client Satisfaction Scale) scores greater than the scale's midpoint.

Aim 2: **To demonstrate a proof of concept that the Recovering Together program can sustainably improve emotional distress [Hospital Anxiety and Depression Scale; HADS], Post Traumatic Symptoms (PTS) [PCL-S], resiliency variables (mindfulness, coping, social support and self-efficacy) and interpersonal factors (interpersonal bond).**

Hypothesis 1: We hypothesize that participation in the Recovering Together Program will be associated with a more potent decrease in emotional distress and PTS compared to participation in the educational program (control), and that these improvements will maintain at 3 month follow up.
Hypothesis 2: We hypothesize that Recovering Together Program will be associated with a more potent increase in resiliency variables (mindfulness, coping, social support, self-efficacy) and interpersonal factors (interpersonal bond) compared to participation in the educational program, and that these improvements will maintain at 3 month follow up.

For this feasibility pilot RCT, our primary outcomes (feasibility, credibility and satisfaction) will be assessed in Aim 1. Our secondary outcomes in this trial are: emotional distress, PTS, mindfulness, coping, social support, self-efficacy, and interpersonal bond, and will be assessed in Aim 2.

III. SUBJECT SELECTION

All participants will be recruited from the Massachusetts General Hospital Neuroscience ICU, using IRB approved recruitment materials.

Inclusion/Exclusion Criteria

Eligible dyads (Pts and Cgs) must meet the following inclusion criteria:

1) Age 18 or older
2) English fluency and literacy
3) Access to high speed internet for video sessions
4) Pt with an informal cg (family or friend who provides unpaid care) available and willing to participate
5) Hospitalized with an ANI within 1-2 weeks (pt) OR primary cg of a pt currently admitted with an ANI
6) Either pt or cg have clinically significant symptoms of depression, anxiety, and/or PTS

One or more of the following exclusion criteria will render a pt ineligible:

1) Permanent and severe cognitive impairment severe enough to impede participation – This will be determined by trained study staff through an assessment conducted as part of usual care and that includes the MMSE (score of <23) and GCS (score of <10). Nurses and study staff are trained and use these measures as part of NICU care.
2) Dyads where the pt is anticipated to die or to never be able to participate due to medical sequelae. This will be determined by nurses.

All adult patients and family caregivers, satisfying all inclusion criteria, are eligible for enrollment in this study regardless of sex, race, or ethnicity. Vulnerable populations will not be recruited.

Recruitment

Patients will be recruited from the NICU at MGH from the medical team (nurses). Recruitment will be facilitated by the nursing team who will introduce the study to eligible dyads and who will also assess whether pts are able to consent, consistent with medical presentation, and cognitive status. Trained study staff will be administering the MMSE and nurses will administer the GSC, to all patients and will refer only dyads where the patients scores are higher than the established cut off scores on these measures. Consistent with NICU practice, nurses will administer the GSC. They will refer participants to the study only if they are cleared medically and cognitively. The team will page the RA using the secure Voalte system used by our team and nursing staff, when both the pt and cg are present and able to hear more about the study. The RA will only approach pts identified and cleared by the medical team. The RA will ensure eligibility of both pts and cgs based on the additional inclusionary and exclusionary criteria depicted above. The RA will finalize the screening and conduct informed consent**.** All participants will receive a physical copy of the informed consent form which has the contact information for the PI. If cg~~s~~ cannot be reached in person in the hospital, they will be contacted via phone for screening and completion of informed consent. Cgs will be given a copy of the consent form to review while discussing the study over the telephone. We will fax or securely e-mail the consent form prior to obtaining consent. Cg will return a signed copy of the consent form. If a patient who is interested in enrolling in the study is unable to provide a full written signature due symptoms from their

ANI (unable to move or use their arm to write), then we will ask them to make their mark on the signature line in the consent form. People who cannot make their mark on the consent form can indicate consent by other means, e.g., orally, nodding their head, etc. The means by which consent was given by the subject will be documented in the consent form and research record. Patients and caregivers will be considered enrolled when they sign the consent form with the study staff. Please see details on the informed consent process in the next section, Subject Enrollment (Section IV). These procedures will be completed in a private medical space.

Participants will be explicitly informed that this intervention is a research study that does not constitute individualized, personal care. The intervention is a broad-based method of training that is not tailored to any particular individual. Should any participant seek formal mental healthcare, study staff will refer them to either MGH Psychiatry, as appropriate.

We will recruit pts with any type of ANI and their cgs, ensuring representation of all NICU diagnoses. All cgs will be recruited within the first week of the pts' hospitalization. Pt's medical team will also alert the research assistant whether they anticipate that the patient might be able to participate in the study at a future point during the hospital stay. In situations where patients are unable to consent due to the severity of the ANI, we will enroll the informal cg and return to enroll the pt as soon as their mental capacity improves. The research assistant will not approach patients who are not mentally or physically capable to participate. This study does not include participants with impaired decision making.

We will not include patients who do not have a caregiver. Informal caregivers will be designated by the health care proxy and verbally confirmed by the patient. Nurses will assist the study team with identifying the patient's health care proxy.

Eligible cases may also be identified by daily screening of Epic admission reports.

The study team will keep track of all pts and cgs approached who refuse to participate (along with reasons for refusal), as well as those who were not approached and reasons why.

When the RA approaches a patient, patients and caregivers will be given the choice of watching a short recruitment video that contains testimonials from previous patients.

The recruitment process was developed and refined through prior research for the past 2 years.

IV. SUBJECT ENROLLMENT

Participants will be referred to the study by the nursing team who will ensure that patients are medically and cognitively able to participate. Eligible dyads will next be screened, consented, and enrolled by the research assistant.

After determining eligibility, study staff will meet with potential dyads to review the informed consent document. Patients who cannot make their mark on the consent form because of lingering symptoms from the ANI can indicate consent by other means, e.g., orally, nodding

their head, etc. The means by which consent was given by the subject will be documented in the consent form and research record. If cgs cannot be reached in person in the hospital, they will be contacted via phone to complete informed consent. Cgs will be given a copy of the consent form to review while discussing the study over the telephone. We will fax or securely e-mail the consent form prior to obtaining consent. Cgs will return a signed copy of the consent form. After the document has been reviewed, study staff will answer any and all questions the pt or cg may have. Once all questions have been addressed, each member of the dyad will sign the consent form, which will include a description of all study procedures, the option to receive text message reminders, information about potential risks and benefits of participation, and study contact information (including that of the IRB) in case questions arise at a later time. The consent form will also explicitly state that study participation is voluntary, and that participants may refuse to answer any questions that make them uncomfortable, and may discontinue participation at any time. In addition, participants will be assured that withdrawal from the study will not compromise their medical care in any way.

As informed consent is a continuous process, participants will be given a copy of the signed informed consent document, and will be invited to ask questions about their participation at any point over the course of the study.

Following a study enrollment and baseline assessment, dyads will be randomly assigned to either the newly developed psychosocial intervention or to the educational program (control) using a random number sequence generator to ensure comparability between groups. We will document time between assessment and intervention initiation, and analyze as a predictor of study outcomes as needed. Randomization will be developed by the statistician, without any input from the rest of the team.

V. STUDY PROCEDURES

After enrollment, participants will complete study assessments. All subjects will be given baseline psychological and behavioral assessments that will assess depression, anxiety, PTS symptoms, and other psychological constructs. Assessments will be administered online, using the REDCap system. Subjects may choose to fill out these questionnaires on-site, or to fill them out at home on a personal computer or other Internet-equipped device. This assessment includes demographic information and a battery of psychological questionnaires. We will also collect information about important clinical variables including duration of acute hospitalization. All questionnaires are itemized below:

Administered at Baseline Only:
Demographics
Prior Mental Health History questions
Credibility Questionnaire

Administered at Baseline, Post-Intervention, and Follow-up:
Medical history information from LMR (i.e., prior ANI status, current psychotropic meds, comorbid medical conditions, etc.)
Post-Traumatic Stress Disorder Checklist (PCL-S)[29]

Hospital Depression and Anxiety Scale (HADS)[30]
Measure of Current Status Part A (MOCS-A)[31]
The Cognitive and Affective Mindfulness Scale (CAMS)[32]
World Health Organization Quality of Life (WHOQOL-BREF)[33]
Dyadic Relationship Scale (DRS)
Experience in Close Relationships – Relationship Structure (ECR-RS)

Administered Post-Intervention and Follow-up Only:
Client Satisfaction Questionnaire (CSQ-3)[34]

The study staff will complete the following questionnaires to assess symptom severity for each patient at all 3 timepoints (baseline, post intervention and follow up):
Modified Rankin Scale (mRS)[35] [Pts only]
Barthel Index[36] [Pts only]

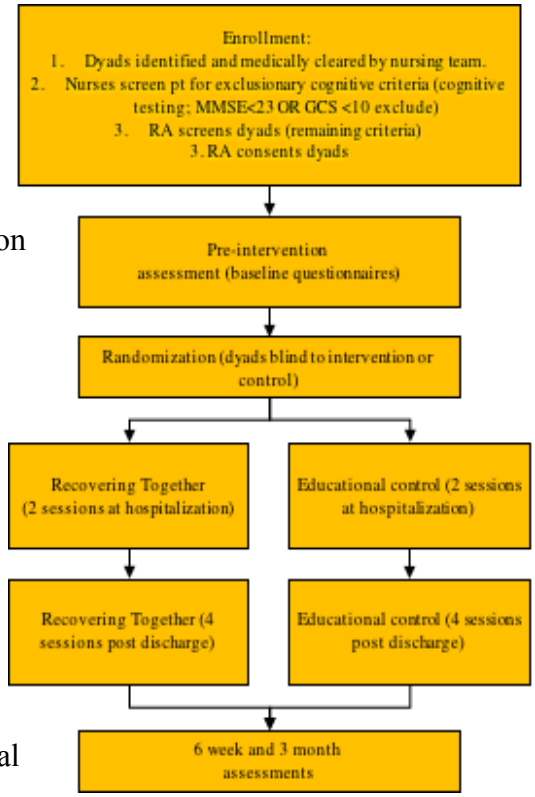
After completing the baseline assessments, dyads will be randomized to either the newly developed psychosocial intervention or to treatment as usual.

The psychosocial intervention entails 6 sessions, each 30 minutes. Both the pt and cg participate in each session. The intervention is manualized, and teaches dyads resiliency (mindfulness, social support, self-efficacy, coping skills) and interpersonal communications (interpersonal bond) skills. The first 2 sessions will occur in person, during hospitalization. The next 4 sessions are chosen from 5 available, depending on each dyad's preference, and are delivered after discharge via secure live video. For the video sessions, dyads can participate from the same or different locations. During the in hospital sessions, dyads learn diaphragmatic breathing, mindfulness, self-care, and dialectics. During the video sessions, dyads learn how to identify negative thinking patterns and replace them with adaptive thoughts, how to communicate effectively and openly, how to engage in self-care, and how to accept things that can't be changed. Participants in the intervention group will also receive treatment as usual. This may include meeting with nurses, physical therapist**s**, medical doctors, and other members of the pt's medical team. Treatment as usual may also involve administration of SSRI to those patients with motor problems.

Those in the educational program (control) will receive general health information that mimics the Recovering Together Program, but without teaching any of the resiliency or interpersonal communication skills that are hypothesized to be responsible for improvement in emotional distress. The educational program will also have 6 sessions, 2 in-person dyadic visits in the NICU and 4 dyadic virtual visits following discharge. It controls for dose and support from clinician. Both members of the dyads participate in all sessions. The topics of each session include: education about the stress of the ANI on patient and caregiver; education on the importance of self-care; education on stress associated with discharge and home adjustment; education on the importance of following up with medical recommendations; education on interpersonal stress as part of adjustment to ANI; education on self-care. The educational program condition will ensure that patients will remain blind to intervention or control and increase confidence that improvement in outcomes are due to the active ingredients of the intervention and not confounds. Participants in the educational program will continue with their

current care. This may include meeting with nurses, physical therapists, medical doctors, and other members of the pt's medical team. Treatment as usual may also involve administration of SSRI to those patients with motor problems.

Participants in both groups will be given post-treatment psychological and behavioral assessments identical to those administered at baseline, in addition to the CSQ-3. As a baseline, participants will be given the option to complete post-treatment questionnaires on site or at home. Participants will be asked to complete questionnaires immediately after completion of the group intervention (T2), and 3 months (T3) after completion of the group intervention, in order to measure long term outcomes. Study staff will email these questionnaires to the participants via the REDCap system or give participants the option to complete them over the phone with a study staff member.



VI. BIOSTATISTIC ANALYSIS

We plan to conduct a RCT with patients from the Neuro-ICU. The main intervention goal is to provide dyads with resiliency and interpersonal communication skills necessary to optimize recovery. Dyads will be medically cleared by a member of the nursing staff. Nurses will then screen dyads for exclusionary cognitive criteria. Dyads will complete additional screening and baseline questionnaires with a trained research assistant. Dyads will be randomized to one of two groups 1) Psychosocial skills based intervention (Recovering Together), or 2) Educational Control.

We chose our study measures based on our theoretical frameworks, strong psychometric properties in studies of patients with ANI, and feasibility in our prior work with ANI dyads. Measures will be collected at baseline, post-intervention, and at 3 month follow up. Data collection and management will be conducted with Research Electronic Data Capture. Dyads will be given the option to complete measures electronically, by paper and pencil, or telephone.

1) Is the psychosocial skills-based intervention feasible, credible usable, and accepted by pts and cgs in the ICU?

Our primary aim focuses on trial feasibility, acceptability, credibility and preliminary effect. In pilot studies, ≥30 participants are recommended per group to establish feasibility and detect larger effect sizes for ≥1 outcome. We plan to recruit 80 dyads (160 participants), 40 dyads (80 participants) per arm to establish feasibility, acceptability, credibility and estimate effect size for emotional distress variables (primary quantitative outcomes). Assuming attrition of over 25% (in excess of what we experienced in our preliminary studies), we will have the necessary 30 dyads (60 participants) per arm. This

size is considered to yield stable estimates of M/SDs based on prior behavioral trial recommendations. Effect sizes from this study may overestimate power in future sample calculations. We chose study measures based on our theoretical frameworks, strong psychometric properties in studies of patients with ANI, and feasibility work in our prior work with ANI dyads. Feasibility will be reported as the percentage of patients enrolled in the study who complete at least 75% of the intervention sessions. Demonstration of feasibility will be assessed by the number of individuals who drop out of the study prior to completing the post- intervention assessment and the rate of missed sessions. If drop-out rate or missed-session rate exceeds 25%, revisions to the intervention may be needed. We will also report number of patients approached, enrolled, randomized and who completed time 2 and time 3 to determine feasibility.

2) Is the psychosocial skills-based intervention effective for pts and cgs in the ICU?

Dr. Vranceanu developed the proposed study design in collaboration with the NICU study team (nurses, physicians, clinical interns) and an MGH psychologist who specializes in using mindfulness and emotion regulation in both chronic illness and medically healthy populations. With funding from the American Heart Association, we conducted 20 qualitative interviews with pt-cg stroke dyads at risk for chronic emotional distress during NICU hospitalization. We also conducted additional clinical interviews with 10 pt-cg dyads representative of other ANI diagnoses. 83% of dyads approached agreed to participate. Pts (23) and cgs (25) were mostly women. Dyads were mostly spouses and mothers-daughter. Dyads noted interest in a resiliency program (30/30) and preferred a combination of in person and live video sessions (30/30). Dyads learned about resiliency skills (name, description, and goal) and agreed they would be helpful to them. They also noted interest in learning about: survivorship plans, adaptation to deficits (present or anticipated), and return to normal living. This led to the development and subsequent refinement (through feedback from the nursing team) of the Recovering Together Program active intervention.

3) Is the effect of the skills-based intervention for pts and cgs in the ICU durable?

We will assess feasibility, usability, and acceptability by the enrollment numbers, participants completion in at least 4 out of 6 sessions, and the questionnaires, The Credibility and Expectancy and Client Satisfaction Scale. These will be primary outcomes. The PCL-S, HADS, and resiliency measures will serve as the secondary outcomes.

We will use student's t-test to assess within-group differences in long-term outcomes. We will compare measures at the 3 month follow-up assessment to measures at the post-intervention assessment for both study arms.

We will also use t tests and chi squared tests to assess differences at the 3 month follow up.

VII. RISKS AND DISCOMFORTS

There is a risk that some participants may feel uncomfortable completing various psychological questionnaires or parts of the skills-based on intervention. Participants are free to withdraw from the study at any time, as the study is completely voluntary.

As in any research study, there is a small risk that confidentiality may be breached; all efforts to minimize this risk will be taken. In the unlikely event that participants will become suicidal during the duration of the study, the research assistant will contact the PI and the appropriate clinical intervention will be executed.

VIII. POTENTIAL BENEFITS

Participants in this study may observe a reduction in depression, anxiety, and/or psychological and physiological markers of stress, as well as an improvement in perceived qualify of life. It is hoped that the intervention will result in improvements across these domains. Participants may learn new techniques for managing distress and lifestyle factors that may enhance wellbeing, both in disease-specific domains as well as in their general lives. In addition, all participants will receive $20 for the completion of each of the 3 assessment points.

IX. MONITORING AND QUALITY ASSURANCE

Electronic information will be stored in REDCap (Research Electronic Data Capture), a free, secure, and HIPAA-compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group (based at the PHS Needham corporate datacenter). Data will be stored on password protected computers that will be stored in secure locations at all times. Paper data files (with coded subject identification) will be stored in a locked filing cabinet. Only research staff will have access to these data locations.

A unique anonymous identifier will be assigned to each subject; subsequently, all data collected will be associated exclusively with this identifier. This includes all questionnaires administered over the course of the study, as well as home practice logs.

Data from this study will be stored for three years after the publication of all study results, at which time all paper data files will be shredded, and computer files will be deleted.

Data Management and Quality Control Procedures

To maximize accuracy and security, all survey data will be collected and stored on REDCap. Research staff will ensure that proper consent has been obtained before sending the REDCap survey to each participant.

REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group. Vanderbilt University, with collaboration from a

consortium of academic and non-profit institutional partners, has developed this software toolset and workflow methodology for electronic collection and management of research and clinical study data. Data collection projects rely on a study-specific data dictionary defined by members of the research team with planning assistance from Harvard Catalyst, The Harvard Clinical and Translational Science Center EDC Support Staff. This iterative development and testing process results in a well-planned data collection strategy for individual studies. Using REDCap, the research team can also design web-based surveys and engage potential respondents using a variety of notification methods. REDCap provides flexible features that can be used for a variety of research projects and provides an intuitive interface to enter data with real time validation (automated data type and range checks). The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Since consistency of application of the study protocol is critical to acquiring high quality data, all research personnel have undergone or will undergo a competency-based training program prior to enrolling subjects.

Data and Safety Monitoring Plan

Adverse Event Monitoring: Throughout the study subjects will be monitored for the occurrence of events defined as any undesirable experience or unanticipated risk. Lack of effect of treatment is not considered an event. All adverse events will be reported on an adverse event form. The Principle Investigator has the responsibility of reporting serious adverse events (death, life threatening illness or injury, serious injury, or permanent disability) to PHRC within 24-72 hours of notification.

X. REFERENCES

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