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ClinicalTrials.gov ID: NCT03132220
Project Title: A Mindfulness Based Cognitive Therapy (MBCT) Resiliency Program for Critical
                   Care Nurses
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I.   **Hypotheses and Specific Aims**:

There are several study design issues that require delineation before the MBCT-ICU can be tested in a multi-center clinical trial to determine its effect on building resilience, reducing burnout syndrome (BOS) and ultimately diminishing the high ICU nursing turnover rates. In this proposal, we plan to use quantitative and qualitative (mixed) methods to answer specific study design questions that are very responsive to the NCCIM R34 mechanism and the NCCIM strategic plan.

II.   **Aim 1: With stakeholder engagement, we will optimize our MBCT resiliency program for ICU nurses.**

III.   **Aim 2: By conducting a randomized pilot clinical trial, we will:**
  a.   **Aim 2a: Refine the acceptability of the MBCT resiliency program and the control intervention.**
  b.   **Aim 2b: Identify the most feasible randomization level to minimize contamination between the control and intervention groups.**

 II. **Background and Significance**:

Burnout syndrome (BOS) is a growing concern for critical care professionals 1-3. Initially described in the 1970s, BOS is a work related mental health condition defined by three dimensions: emotional exhaustion, depersonalization, and reduced personal accomplishment. As mounting expectations and inherent stresses have increased in the workplace, BOS is reaching epidemic proportions in the healthcare profession 4, 5, 6, 7-10. Recently, there is increasing awareness about BOS. Commentaries on healthcare-related BOS have been published in the Lancet, Lancet Respiratory Medicine, and even Time Magazine 11-14. Regarding the critical care BOS crisis, Dr. Moss is the lead author on a BOS manuscript that will be simultaneously published in four prominent pulmonary and critical care journals.

Intensive Care Unit (ICU) nurses have especially stressful jobs. Each year in the US, more than 5 million patients are admitted to ICUs; with an estimated hospital mortality rate of greater than 14%. ICU nurses must cope with many daily stressors including: 1) the complexity and demands of ICU nursing, 2) unpredictable changes in work routines, 3) unrealistic expectations from patients and their families, and 4) common encounters with traumatic and ethical issues. Repeated exposure to traumatic events and an inability to adjust to their work environment can result in the development of BOS. Until recently, the magnitude of BOS in ICU nurses was unknown 15-17. Based our national survey, up to 80% of ICU nurses have BOS symptoms 18.

In ICU nurses, BOS is associated with decreased work performance, poor patient care, and increased nursing turnover rates. Nursing BOS is also associated with lower quality of

care, lower patient satisfaction, increased number of medical errors, increased rates of health-care associated infections, and higher 30-day mortality rates 19, 20. In addition, BOS contributes to our growing nursing shortage that is shortly expected to exceed 1,000,000 positions (29% vacancy rate) 21, 22. The national nursing shortage is even more of a problem in specialty areas such as the ICU 23. One reason for the shortage is that nurses are leaving their profession at an alarming rate. In a national survey, 41% of nurses were not satisfied with their job and 22% planned on leaving their profession. When asked why they were considering leaving the nursing profession, 56% desired a less stressful position 24. In the ICU, annual national nursing turnover rates exceed 17-20% 25, 26. Our recent survey confirmed these findings and also identified annual ICU nursing turnover rates as high as 40% (unpublished data). Independent of BOS, ICU nursing turnover is also associated with increased healthcare costs, decreased nursing productivity, reduced the quality of nursing care, and diminished staff morale 26, 27, 28. National surveys reveal that replacing one critical care nurse costs more than $65,000 29. Therefore, at a medium sized hospital with 40 ICU beds, the cost of ICU nursing turnover is over $1,000,000 per year. As a result, hospital administrators have prioritized implementing methods to reduce ICU nursing turnover rates 30.

Several studies have tried to identify methods to reduce BOS in a variety of high stress occupations. These studies have examined many interventions including: relaxation therapy, laughter therapy, counseling and psychosynthesis. However, the majority of these studies were hampered by several important limitations.
1. Most studies were performed in a non-randomized manner and did not include a control group.
2. Usually, those studies with a control arm used a passive control arm. Passive control arms cannot account for the important impact of simply delivering additional support and attention to the treatment group.
3. In those studies of healthcare professionals, the most common outcome was simply the change in BOS symptoms. Clinically relevant outcomes such as quality of care or turnover rates have not been examined.
4. Most studies did not develop targeted interventions for specific cohorts, and none of the previous trials have examined ICU nurses. Our previous pilot study was the first intervention designed specifically for ICU nurses.
5. None of these studies used a MBCT approach, and none focused on building resiliency.

Resiliency enables one to thrive in the face of adversity 31. Humans respond to stress and trauma in a variety of ways. Some people are resilient; defined as the ability to succeed, to live, and to develop in a positive way despite the stress or adversity that would normally involve the real possibility of a negative outcome. In practice, resilient individuals believe that what they do can have a positive impact on a situation, that some components of the 'system' can be controlled or influenced by one's own actions, that persistent effort is worthwhile, and that setbacks or potentially threatening events are inevitable and surmountable. A variety of qualities are associated with resiliency including the ability to engage the support of others, the belief that stress can be strengthening, and overall optimism 32, 33, 34. *Though some individuals are inherently resilient; resiliency can be learned.* Developing resiliency may be one strategy to prevent and treat symptoms of BOS. We have demonstrated that resilient ICU nurses were less likely to have symptoms of anxiety, depression, PTSD, and BOS 35. We also identified methods used by ICU nurses to promote resiliency and emotional wellness. Our ICU nursing pilot program also increased resiliency and decreased symptoms of BOS 36.

III. **Preliminary Studies/Progress Report:**

1. We are an established and productive multidisciplinary team. We are already committed to relieving psychological distress in ICU nurses. Our investigators span the disciplines required to conduct the proposed research including nursing, critical care, psychiatry, mindfulness training, CBT, and MBCT. Dr. Moss has lectured internationally on BOS and will be the lead author on a published commentary entitled "Burnout Syndrome in Critical Care Healthcare Professionals: A Call for Action". This article will be simultaneously published in four major pulmonary and critical care journals. Dr. Mealer has also lectured internationally on BOS. The cohesiveness of our research team is demonstrated by our continuous working relationship over the last decade, and our ability to enroll almost 2,000 nurses in qualitative interviews, surveys, and clinical trials.

2. Collectively we have extensive experience conducting multi-center clinical trials. Dr. Moss is currently the NHLBI protocol committee co-chair for a multi-center trial of 1408 critically ill patients at 49 hospitals across the country. Drs. Rothbaum and Dimidjian have also conducted numerous multi-center behavioral clinical trials.

3. There is a high prevalence of psychological distress in nurses 18. In a survey of 810 nurses, we identified a high prevalence of BOS and PTSD 3. When these nurses were grouped into three categories: those with PTSD and BOS, those with only BOS, and those with neither BOS nor PTSD, there were significant differences between groups in perception of collaborative nursing care ($p = 0.006$), confidence in physicians ($p = 0.01$), and perception that their work impacted patient outcomes ($p = 0.01$). In addition, nurses with BOS and PTSD were more likely to have difficulties in their life outside of work when compared to those with BOS alone.

4. BOS is associated with shorter duration of employment 18. When nurses were categorized into: those with PTSD and BOS (n=59), those with only BOS (n=217), and those with neither BOS nor PTSD (n=46), their years of employment as a nurse were different (8.0±7.9 years; 11.7±9.3 years, &19.6±12.5 years respectively; $p < 0.0001$).

5. When compared to non-ICU inpatient nurses, ICU nurses have a higher prevalence of PTSD. To determine whether symptoms of PTSD were more common in ICU nurses, we surveyed 351 inpatient nurses. ICU and general medical/surgical nurses reported equivalent amounts of stress in their life outside of the hospital, $p = 0.7$. However, 24% of ICU nurses were positive for symptoms of PTSD compared to only 14% of the general medical/surgical nurses, $p = 0.03$. Adjusting for multiple differences in primary hospital of employment, gender, marital status, primary shift (day vs. night), or being responsible for the primary household income, being an ICU nurse was the only variable that remained significantly associated with positive symptoms of PTSD (OR, 1.45; 95% CI, 1.24–1.72; $p = 0.02$).To determine the generalizability of these results, we surveyed an additional 195 ICU nurses at hospitals across the Southeast United States. The percentage of ICU nurses with PTSD symptoms were similarly increased (29%), demonstrating the generalizability of our previous single institution results.

6. The presence of resiliency is associated with less psychological symptoms in ICU nurses 35. Next, we conducted a national survey of 744 ICU nurses to determine whether highly resilient ICU nurses were less likely to have symptoms of PTSD. Overall, 22% of the ICU nurses were highly resilient, defined as a CD-RISC score of ≥ 92. Resiliency was associated with lower prevalence of all psychological disorders. In individual logistic regression models, resiliency was independently associated with the absence of PTSD, the absence of BOS and the absence of anxiety and depression symptoms. Highly resilient nurses were less likely to report problems outside of the work environment.

7. We developed a multimodal resiliency training program. Our semi-structured telephone survey qualitative study identified coping mechanisms used by resilient ICU nurses. Purposive sampling was used to identify ICU nurses who were highly resilient and ICU nurses with BOS/PTSD. Highly resilient nurses identified a supportive social network, a sense of humor, and optimism as the important characteristics used to cope with stress experienced in their work environment. ICU nurses with BOS/PTSD possessed unhealthy psychological characteristics including: a poor social network, intrusive thoughts, regret, and lost optimism.

8. We conducted a single center pilot study of a multimodal resiliency training program. A total of 27 ICU nurses participated and completed the 12-week trial (Intervention arm n=13, Control arm n=14). The resiliency program included four main components: 1) MBSR, 2) CBT, 3) writing therapy, and 4) exercise. Participants in the intervention arm also attended an introductory weekend session. During the informed consent process, control subjects were informed about psychological distress in ICU nurses. During the trial, control subjects also recorded the time spent performing aerobic exercise. All subjects completed pre/post psychological surveys. The intervention was successfully implemented in the treatment arm with 100% attendance at the introductory workshop, 100% completion of weekly writing sessions, 88% completion of the required exercise sessions (42% of the control group exercised at a rate similar to intervention subjects) and 100% attendance at CBT sessions. Using the client satisfaction measure, there was a high level of satisfaction with the program as evidenced by mean scores: 25.2 (SD4.6) for the introduction session, 22.6 (SD 8.1) for written therapy, 28.2 (SD 4.3) for exercise and 24.5 (SD 5.4) for CBT. These scores demonstrate acceptability for our program

9. Nurses randomized to the treatment group had increased resiliency scores and diminished PTSD and BOS symptoms. Following completion of the 12 week trial, a repeated measure analysis demonstrated that the intervention was associated with increased resiliency, and decreased PTSD and BOS-emotional exhaustion scale (BOS data not shown in Figure 4). There were also modest improvements in the control subjects that may be related to interactions between subjects in the intervention and control groups, or problems with assessment reactivity. In our proposed pilot study, we will determine the proper level of randomization at either the individual or unit level. This work was published in the *American Journal of Critical Care* (AJCC) with a November 2014 press release. Dr. Mealer was interviewed for the May 2015 Nursing Show.

10. Nurses who participated in the pilot study provided valuable feedback to improve the intervention. During exit interviews, participants recommended several ideas to improve the study conduct. They suggested: 1) simplify the intervention and focus on the MBSR and CBT, 2) increase the duration and intensity of the MBSR, 3) increase the frequency of CBT sessions, and 4) remove the expressive writing therapy component.

11. In a national survey of ICU nurses, MBSR and CBT were highly endorsed interventions to combat BOS. To determine the interest of ICU nurses in a variety of interventions that can build resiliency and reduce BOS symptoms, an e-newsletter survey was sent to American Association of Critical-Care Nurses (AACN) members. The e-newsletter is distributed to approximately 200,000 addresses with a 14% open rate. A total of 381 individuals completed the survey. The majority of participants were female (89%, 338/381) who had been practicing ICU nursing for 14 years (SD 11.1, range 5-23). Respectively, 85%, 49%, and 4% of nurses exercise, perform some mindfulness techniques, and seek individual counseling on at least a weekly basis. Participants were then asked to rank their preference for participation in eight interventions (a score of 1 being the most preferable and a score of 8 being the least

preferable). MBSR (mean score 2.95; SD 1.84; range 1-4) and CBT counseling (mean score 4.04; SD 2.13; range 2-6) were two of the highest preferred interventions.

12. Exit interviews. In the last month, University Human Resources identified 13 ICU nurses who were either leaving the institution or transferring to a non-ICU unit. Four nurses participated in exit interviews. All 4 nurses completed the HADS, PDS, MBI and CD-RISC surveys. Stress/burnout was listed as the predominant reason of greater than 50% (n=3/4, 75%) for nurses leaving the ICU. The results from the first month of exit interviews demonstrate our feasibility to complete Aim #3 of this proposal. By determining the attributable contribution of BOS to ICU nursing turnover rates, we will more effectively power our subsequent clinical trial.

IV. Research Methods

Recruitment and Informed Consent Process: When a nurse hears about the study and they are interested in participating, they will contact the study team by phone or email. They may also be contacted while study staff are recruiting in-person.

- Next, the nurse will complete the pre-consent, screening survey: the Connor-Davidson Resilience Scale (CD-RISC), Maslach Burnout Inventory (MBI) and demographic questions. This will happen one of two ways: 1) in-person hard copy form, OR 2) survey link sent through email.
- If the participant scores:
    - *< 82 on the Connor-Davidson Resilience Scale (CD-RISC) indicating decreased resiliency; **AND**, positive scores in at least one BOS dimension using the Maslach Burnout Inventory (MBI): emotional exhaustion score of >17, depersonalization score of >7, or a personal accomplishment score of < 31; **AND**,*
    - *They work at least 20 hours per week in an ICU; **AND**,*
    - *They do not have a known diagnosis of bipolar disorder, psychotic disorder, or an active substance dependence,*
    - they have passed the first eligibility screen for the study and will either receive a REDCap prompt to complete the electronic informed consent OR will complete the informed consent after having all their questions addressed by study staff. If they do not receive these scores, they will be automatically notified by RECap that they do not qualify for the study OR the study staff will score the hard-copy tools and will notify them in-person.
- **Electronic Consent:** If a nurse completes the REDCap pre-consent survey link and they are eligible to participate, they will be prompted to read and sign an electronic consent. There will be a statement notifying them to contact a member of the study team if they have questions, or need more information before signing the consent. Nurses will confirm that they have read the consent language, understand the risks and benefits of the study, understand their involvement in the study and are prepared to consent to the study. They will then give their informed consent electronically. Study staff will have in-person, email or phone contact with the nurse before the consent is signed, so the study staff can affirm that the nurse is prepared to provide informed consent.

Methods/Randomization: At study entry all participants will complete the Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-item screening scale developed to indicate the possible presence of anxiety and depression [128, 129]. HADS consists of a 7-item anxiety subscale and a 7-item depression subscale. A score of > 8 identifies a positive history of anxiety or

depression symptoms [129]. The validity of the HADS has been extensively studied in a variety of populations including the general population, general practice and psychiatric patients. In our previous analyses of ICU nurses, the HADS Cronbach's alpha was 0.86 [3, 8]. In order to complete Aim 2.2 and due to our staffing capacity, we will conduct one treatment and one control group in each 16 hour intervention period. We will recruit ~24 nurses at a time, who will be randomized on a 1:1 basis to either treatment (n=12) or control (n=12). Therefore at least 10 months will be required to complete the pilot study (5 treatment and 5 control cohorts x 2 month interventions = 10 months).

A. Outcome Measure(s):

Outcomes Variables:
1. **The primary outcome** will be post-pre changes in the CD-RISC scores in intervention and control subjects.
2. **Acceptability** will be measured with the eight-item self-report Client Satisfaction Questionnaire (CSQ-8) [103, 138]. The CSQ-8 is designed to yield a homogeneous estimate of general satisfaction. Scores range from 8 to 32 (higher scores indicating greater satisfaction). The CSQ-8 will be administered after the final treatment and control session.
3. **Adherence** will be measured for each component of the intervention and a total overall adherence will be calculated. Our research personnel will record study participant's attendance at each of the sessions and completion of assigned daily practices. Study participants will complete REDCap diary cards and record their weekly participation in out of class activities. Adherence will be calculated from these two sources of information. The total adherence will be calculated by adding each individual intervention component adherence divided by the total number of components.
4. **Additional outcomes:** Participants will also complete post-intervention MBI, PDS, and HADS surveys.
5. **Qualitative Interviews** will also be administered to provide an assessment of participant satisfaction with the intervention and control program. Interviews will be digitally audio recorded and transcribed for coding. Three questions specifically inquired about the helpfulness of the intervention and control programs: "Has the program been helpful to you?" "Has the program changed how you cope with work related stress?" and "Has the program changed how you cope with times when you feel you may start to become stressed at work?" Additional open-ended questions will be used to elicit participant descriptions of their program experience. These interviews will be audio recorded and transcribed as described in Aim 1.

B. Description of Population to be Enrolled:

We will enroll ICU nurses from four Colorado hospitals. From the beginning of our proposal preparation, all of the Chief Nursing Officers (CNOs) and ICU Nurse Managers have been involved in the study development. Uniformly, these CNOs are excited to have nurses from their hospital participate in the trial. Enrollment at diverse hospitals will help substantiate the generalizability of our findings. There are no studies at these hospitals that compete with this study enrollment.

Inclusion Criteria:

1. Male or female, ages 18+
2. Employed as a critical care nurse and work at least 20 hours per week as an ICU.
3. Baseline score of < 82 on the Connor-Davidson Resilience Scale (CD-RISC)

4.   Positive symptoms of at least one BOS dimension using the Maslach Burnout Inventory (MBI): emotional exhaustion score of >17, depersonalization score of >7, or a personal accomplishment score of < 31

Exclusion Criteria:

1.   A self-reported diagnosis of bipolar or psychotic disorder, active substance dependence, or immediate risk of self-harm or need for hospitalization
2.   Unwillingness to participate in the entire study protocol
3.   Employment on a time limited contract (i.e. a traveling nurse)

C. Study Design and Research Methods

The MBCT resiliency program (MBCT-ICU):
The MBCT-ICU will teach participants to remain aware of the present and not allow thoughts to become overpowering, especially in times of emotional upheaval. Participants will receive training in sitting, movement, speaking, listening, and compassion for others and self. They will learn how to apply these techniques to ICU nursing and everyday life. The MBCT-ICU intervention will be 16 in-person hours conducted in group sessions or 16 hours of mixed in-person and online intervention, using the MMB (insert program here, developed by Zindel an Dimidjian) and Skype/Zoom. New material is introduced through experiential exercises followed by group input and discussion. Participants in the program will also be asked to engage in a daily meditation practice and complete homework exercises to integrate the application of awareness skills into daily life. The first sessions are devoted to facilitating non-judgement awareness of the present experience. This is accomplished, in large part, via the formal meditation practices, that help participants to learn a number of important skills including concentration, awareness of thoughts, feelings, and bodily sensations as well as being in the present moment. Together, these skills facilitate the participants' ability to deconstruct their experience into the component elements of physical sensations and the accompanying thoughts and emotions. The second half of the program develops more flexible and deliberate responses at time of stress at work. Acceptance as a skillful step in dealing with one's work environment is explicitly explored. All participants will receive an audio file for home practice. The MBCT-ICU program will be taught by two instructors.

The in-person sessions will be video recorded for intervention fidelity purposes. The videos will be stored on a HIPAA compliant file that will only be shared with select study staff. The videos will be destroyed after the study concludes.

Control Book Club Group:
There will be one to two instructors,, both trained in leading group discussions. 2-3 books will be chosen in advance, by the study team, to read during the intervention period.

Homework Assignments:
Your homework assignment will include reading daily for at least 25-30 minutes.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Protection against risks of confidentiality: Because we are collecting potentially sensitive/stigmatizing information, we will keep the data stored in an electronic format

(REDCap), and we will keep this information on a password protected and encrypted laptop and under lock and key. The office where the information will stay is a study staff only office.

There is the potential risk of breach of confidentiality related to subjects' responses to survey questions. This risk is minimized by using a unique subject ID instead of name when filling out surveys. RedCap will also be used for the survey responses, which further protects confidentiality by using a secure and encrypted environment. Since some subjects are nurses within the University system and the study team is faculty of the University system, an anonymous and confidential environment will help ensure disclosure by the participants.

Protection against risks of mental health issues: There is also a potential risk for identifying underlying mental health issues through the MBCT sessions, and the survey responses. For issues such as passive suicidal ideation or symptoms of depression, anxiety, or PTSD, an informational sheet will be provided with resources available for additional mental health services. Additionally, at the beginning of the program, all subjects will be informed that the training program may uncover unresolved and distressing thoughts or feelings; and a list of resources will also be provided at that time.

Suicidality Response Plan: We have developed a specific protocol if any study participant expresses suicidal thought at any point during the study. All study participants will be informed of this suicidality response plan prior to signing the informed consent for their participation in the study. We will require all of our personnel to complete the online Columbia Suicide Severity Rating Scale (C-SSRS) training. Training can be administered through a 30-minute interactive slide presentation followed by a question-answer session or using a DVD of the presentation. Those completing the training are certified to administer the C-SSRS, and will receive a training certificate. The training certificate is valid for two years. This scale can be used to delineate high, moderate, and low-risk levels. If the participant is deemed to be at high risk, then the PI or one of the co-investigators will be notified immediately. Using the C-SSRS, the PI will then help to assess the participant to determine if they endorse active suicidal ideations. The PI will also determine of the participant is currently being treated by a mental health professional.

If the patient is deemed to not be actively suicidal, then they will be given a list of local mental health resources. If the participant is considered to be actively suicidal then one of the following plans will be followed depending on the location of the participant 1. If the participant is with one of the study personal: a. The study personnel will notify Dr. Moss or one of the co-investigators immediately. b. Then the study personnel will either physically walk the subject to the emergency department, or call the Psychiatric Emergency services (303-602-7221). Resources are available 24 hours a day, 7 days a week. 2. If the participant is on the telephone: a. The study personnel will notify Dr. Moss or one of the co-investigators immediately. b. The study personnel will stay on the telephone with the subject participant. c. The study personnel will immediately contact 911 to initiate an on-site rescue if such action is clinically indicated. d. The study personnel will stay on the telephone with the subject until EMS services have contacted the participant. 3. If there are any active suicidal concerns in any of the surveys or questionnaires: a. The study personnel will notify Dr. Moss or one of the co-investigators immediately. b. Next, the study personnel will contact the participant by telephone. c. The study personnel will stay on the telephone with the subject participant. d. The study personnel will use a different telephone line to immediately contact 911 to initiate an on-site rescue if action is clinically indicated. e. The study personnel will stay on the telephone with the subject until EMS services have contacted the participant. If the participant if determined to be actively suicidal and require immediate medical therapy, they will be withdrawn from the study.

E. Potential Scientific Problems:

After the completion of each intervention and control cohorts, the research team will be convened to examine general trends and patterns in feedback from intervention and control participants and in the instructor's ratings across sessions. When necessary, this information will be used to revise the MBCT-ICU protocol. We did not include refresher sessions that are often offered every three months during the following year after the conclusion of other eight week MBCT courses 145. This decision was due to the time restrictions of an R34 mechanism

F. Data Analysis Plan:

Quantitative Statistical Analysis and Power Analysis: For Aim #2.1, our primary outcome variable will be the post-pre change in CD-RISC scores in intervention and control subjects. Previous studies suggest that clinically significant changes in CD-RISC scores range from 12-19 points with an approximate standard deviation of 20 points.118 With a total enrollment of 160 subjects, we will be able to detect a difference of 12 points in CD-RISC score between the control and intervention groups with 90% power (assuming a 2-sided significance level (alpha) of 0.05 and an equal variance t test; software: PASS 13); we will be able to detect a difference of 19 points in CD-RISC score between the control and intervention groups with 100% power. We will also examine the change in MBI, PDS, and HADS scores in both the treatment and control groups. We will corroborate our comparisons of changes in all scores using robust bootstrap and permutation methods. When measuring constructs involving psychological mood, there is always concern that the answers reflect transient, less stable responses. The participant responses may simply change over time making certain paired analyses difficult to interpret. Therefore, we will calculate a coefficient alpha to estimate measurement reliability.

If we fail to find a bigger increase in CD-RISC score in the intervention group, as we expect, that may be due to interactions (contamination) between members of the intervention and control groups. We will assess the extent of contamination in Aim #2.2, for which our primary outcome variable will be the change in mean baseline CD-RISC score over time within each ICU. If there is, on average, greater than 30% contamination (that is, if baseline pre-enrollment CD-RISC scores increase), we will consider using a randomized cluster design for the subsequent multi-center clinical trial. If baseline CD-RISC scores increase 4 points over each intervention period, we will be able to detect that progressive increase with roughly 92% power (10,000 simulations using the Jonckheere-Terpstra ordered alternatives procedure; software: R). Our assessment of changes in baseline CD-RISC scores over time will consider the point and interval estimates of the changes in addition to formal statistical significance which may be of less use in this setting. All analyses will use SAS 9.3 and $p < 0.05$ will be considered significant.

Qualitative Statistical Analysis: Analysis of qualitative data is planned as a continuous process beginning with initial interviews and continuing throughout and beyond the data generation period. Analysis of the transcripts will begin with repeated readings to achieve immersion, followed by coding using an emergent rather than a priori approach, in order to emphasize focus group perspectives and de-emphasize specific speculations142, 143. The synthesis stage of data analysis involves triangulating the findings from focus groups, as well as individual demographics. The trustworthiness of study results will be enhanced through attention to data credibility, transferability, dependability, and confirmability. The software package ATLAS.ti v 7.0 will be used to manage and analyze the qualitative data. Consistent with the NIH guidance on mixed methods research, we will integrate the findings from the quantitative surveys with the qualitative findings.144

G. Summarize Knowledge to be Gained:

By creating sustainable change in an ICU nurse's ability to adapt to their work environment, we anticipate that our MBCT-ICU program will enhance nursing performance in an extremely stressful job; decrease BOS symptoms; and allow nurses to more effectively care for patients in the challenging ICU environment. The results of this study will be used as preliminary data to support a larger clinical trial to determine the effectiveness of the intervention.

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