COMPASSION CULTIVATION TRAINING FOR NURSES

The title should be easy to remember, recognizable by administrative support staff, and sufficiently different from other protocol titles to avoid confusion. Brevity with specificity and neutrality is the goal. If there is a "short title" (e.g., an abbreviation used to refer to the study title, include here and that can be used throughout this document in place of the full title).

Protocol Number: 20170290

National Clinical Trial (NCT) Identified Number: NCT03286192

Principal Investigator: William F Pirl

Sponsor means an individual or pharmaceutical or medical device company, governmental agency, academic institution, private organization, or other organization who takes responsibility for and initiates a clinical investigation.

Funded by: Sylvester Comprehensive Cancer

Center Version Number: 3

10 August 2017

All versions should have a version number and a date. Use the international date format (day month year) and write out the month (e.g., 23 June 2015).

Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale

1) Protocol Title*
Compassion Cultivation Training for Nurses

2) IRB Review History*
This is a new study protocol that has not been previously submitted to any IRB**.**

3) Objectives*
1. To determine the feasibility of a compassion training program for oncology nurses.
Hypothesis 1:
- 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.

2. To explore changes in burn out, perceived stress, and coping skills after the training program.
Hypothesis 2:
- Investigate the effect of an educational program on perceived stress in nurses.
- Explore the effect of an educational program on three target skill areas (coping, self-efficacy, mindfulness, and distress tolerance), burn out, and health related quality of life.

4) Background*
Counseling a patient through treatment has been identified as one of the most important and rewarding aspects of oncology nursing. However, oncology nurses work in a high-stress environment which is face-paced, detail oriented, and emotionally charged. Prior research has shown that oncology nurses frequently suffer from burn-out and compassion fatigue, more so than other types of nurses, with estimates as high as 70% (Ramirez, et al., 1995; Kash, et al., 2000; Potter, et al., 2010; Jones, et al., 2011; Emold, et al., 2011). This stress takes its toll physically on nurses (Kash, et al., 2000; Morikawa, et al., 2005), and has also been associated with higher risk for medical errors in prior research (Schulmeister, 1999; Elfering, et al., 2006; Halbesleben, et al., 2008; Brady, et al., 2009; Tanaka K, et al., 2010).

Previous interventions for oncology nurses, specifically communication training and stress management programs, have not demonstrated lasting benefit for stress and burn out (Rask, et al., 2009; van Wyk and Pillay-Van Wyk, 2010), and support groups have actually been found to increase negative feelings. Programs that provided extensive psychological training (105 hours) have shown the greatest impact on decreasing stress and burn out (Delvaux, et al., 2004), but few nurses have the time and resources to do such trainings. We propose to deliver and test a novel educational intervention that focuses on contemplation and compassion.

Previous Studies leading up to, and supporting, the proposed research: Practices based on meditation, such as mindfulness and compassion, can help cultivate attention, awareness, and emotion regulation (Ricard, Lutz, Davidson, 2014).

Mindfulness is defined as paying attention to the present moment, on purpose, without emotional reactivity and non-judgmentally (see Kabat-Zinn, 1990; Jha, et al. 2010). Available evidence has revealed that mindfulness training can increase focused attention, awareness, and attentional control (Lutz, Slagter, Dunne & Davidson, 2008), and can decrease task-irrelevant thinking (referred to as mind wandering; Mrazek et al., 2013) and levels of stress (Creswell et al., 2016). Mindfulness training may have beneficial effects for healthcare providers, who often experience high demands in their profession that can lead to elevated levels of stress, burnout and medical errors (Seppala et al., 2014). In fact, mindfulness training has been successfully applied as a stress reduction intervention in nurses (Cohen-Katz, et al., 2005; Mackenzie, et al., 2006).

While mindfulness has been shown to provide benefits to healthcare providers, little is known about the benefits of compassion in similar cohorts. Compassion is defined as a complex construct that involves noticing suffering, being emotionally influenced by it, and cultivating the desire and motivation to alleviate it (Jazaieri et al., 2012). Prior work demonstrates that compassion is positively associated with adaptive qualities such as life-satisfaction and wisdom and negatively associated with maladaptive qualities such as self-criticism, depression and rumination (Jazaieri et al., 2013).

As seen above, compassion may indeed be a powerful tool to help cultivate meaningful, high-quality healthcare service. Cultivating compassion requires high levels of mindful awareness and leads to compassion satisfaction (a sense of achievement or pleasure resulting from the caregiving experience; Figley, 2002). As such, both mindfulness and compassion, together, are skills that may be beneficial in high-demand healthcare environments, as these skills support caring behaviors (Jazaieri et al., 2015). Moreover, mindfulness and compassion may be of benefit in such environments because, when compassion is threatened (e.g. by stress, emotional difficulties, difficult patients, fatigue, time pressure, etc.), healthcare providers are at risk of empathic distress, compassion fatigue (a secondary traumatic stress reaction that arises from helping or desiring to help others; Figley, 2002), and decreased caring behavior (Seppala et al., 2014).

One way of training compassion is through the Compassion Cultivation Training program (Jinpa, 2013). CCT is an 8-week program that involves mindfulness and compassion training through pedagogical instruction, meditation, exercises and home practices (see #10 ‘Procedures Involved’ for details). CCT has been shown to reduce fears of compassion (i.e., fear of receiving compassion from others, fear of offering compassion to oneself and others; Jazaieri et al., 2012) and increase caring for oneself and to others (Jazaieri et al., 2015). More specifically, available research suggests that CCT can promote psychological health and wellbeing (Jazaieri, et al., 2014). For instance, CCT has been linked to decreased worry and emotional suppression as well as increased self-reported mindfulness and happiness (Jazaieri, et al., 2014).

Two CCT components, self-compassion and loving-kindness, are of particular relevance for healthcare providers. The first component, self-compassion, includes cultivating a caring behavior toward oneself, being present for one’s own suffering, and monitoring one’s own needs (Jazaieri, et al., 2014). Increased self-compassion has been linked to

caring behaviors for others (Jazaieri, et al., 2014). This finding suggests that CCT may not only directly benefit healthcare providers by protecting them from burnout, but it may also indirectly benefit patients through increased caring behavior from their healthcare providers. The second component, loving-kindness, is a practice used to increase feelings of caring and warmth towards oneself and others (Salzberg, 1995; Jazaieri et al., 2012). Loving-kindness has been shown to promote feelings of connection, warmth, and care towards others, which in return can induce feelings of happiness toward oneself (Seppala et al., 2014). For instance, a 10-minute session of loving-kindness has been shown to increase ratings of social connectedness and closeness to strangers and decreased self-focus (Seppala et al., 2014).

Altogether, the aforementioned findings highlight the need to investigate the benefits of mindfulness and compassion training, through CCT, in healthcare providers; particularly in nurses who are a high-demand cohort due to their responsibilities at work. Broadly speaking, providing nurses with CCT may promote caring behavior for oneself and others, improve connection with patients and co-workers, and give rise to altruistic behavior and generous actions. More specifically, CCT may help nurses build resilience and reduce burnout and stress by (i) strengthening their awareness of the suffering of others without being overwhelmed, and (ii) promoting the experience of suffering in the present moment without holding onto it and with an attitude of willingness and curiosity rather than denial and rejection. However, there is currently limited evidence regarding the outcomes of CCT in nurses. The present study aims to address this issue.

Rationale behind the proposed research and potential benefits to patients and/or society: Research evidence suggests high rates of stress and compassion fatigue among oncology nurses, with large numbers of nurses considering positions outside of cancer care. These findings are important, given that nurse providers with specialized training are already in short supply. However, the extent to which on-site resources and educational programs are available to support oncology nurses varies widely across cancer care institutions. The development of efficient, low-cost programs to increase provider coping skills and to reduce stress and compassion fatigue may be a key priority for retaining experienced oncology nurses. There is limited and mixed evidence as to whether brief interventions can enhance psychosocial outcomes among oncology nurses, although findings may depend on the specific intervention targets and outcomes being studied.

5) Inclusion and Exclusion Criteria*

To be included, participant must:

1. Be 18 years of age or older
2. Be willing and able to give informed consent
3. Be a Registered Nurse (RN)
4. Currently works at Sylvester Comprehensive Cancer Center
5. Currently works at least 20 hours/week
6. Be able to speak and read English

Exclusion Criteria:

1. Any participants who are deemed to present an acute safety risk to self or others.
2. Any infants, children, or teenagers under 18 years of age.
3. Prisoners

Potential participants will be recruited via flyers and staff meetings. Interested individuals will be invited to call the clinical research coordinator to discuss eligibility criteria. If they meet eligibility criteria, the research coordinator will discuss the informed consent form. For eligible and interested individuals, consent will be emailed via REDCap (Research Electronic Data Capture).

6) Number of Participants*

The overall study aims to enroll one cohort up to 25 participants in total.

7) Study-Wide Recruitment Methods*

This is not a multicenter study. All study-related recruitment will be at the Sylvester Comprehensive Cancer Center. Potential participants will be recruited via flyers and staff meetings. Interested individuals will be invited to contact the study team directly. A study team member will then screen for eligibility and initiate the process of informed consent. For interested and eligible individuals, consent will be obtained and the decision to join the study will be documented. A member of the study team will then perform consent procedures by presenting the individual with a detailed, consent form to be electronically signed following the explanations by the study team member.

8) Procedures Involved*

After eligibility is determined and electronically written consent is obtained, study procedures will continue as follows:

Upon enrollment of our target sample (up to 25 enrollees), all participants will receive an email link to complete an online baseline assessment in REDCap. This will ensure that all participants complete the assessment within the same approximate timeframe.

Light food and beverage will be provided at each educational session. The training sessions will take place in the University of Miami IRB-approved HIPPA-compliant location at the Sylvester Comprehensive Cancer Center. Training sessions with participants may be recorded or filmed for the purposes of missed-session make up (see #11 'Data Storage' bottom paragraph), training quality assurance, and practice materials. Participants will receive up to 16 nursing continuing education credits, one for each hour of the program that they attend. Additionally, as *compensation* for their time and effort, all participants will receive a $15 gift card after completing the post assessment.

Program

The Compassion Cultivation Training (CCT) protocol is a secular course that was developed by the Center for Compassion & Altruism Research and Education (CCARE) at Stanford University, School of Medicine (Jinpa, 2013). The course was developed by Thupten Jinpa, PhD, in collaboration with contemplative scholars, psychologists, and scientist at Stanford. The goal of CCT is to provide a structured and systematic way of

cultivating daily-life skills needed to strengthen qualities of compassion, empathy, and kindness for oneself and others. CCT typically includes (i) eight weekly 2-hour classes and (ii) daily practice. The in-class activities include pedagogical instruction and active group discussion, guided meditation, interactive practical exercises, and sharing of inspiring readings/stories to prime feelings of open-heartedness or connection to others. The daily practice includes both formal and informal practices. Participants are provided with formal guided meditations that are 15 to 30 minutes long in the form of MP3 or cds. Participants may receive practices and instructions via email with a link to the location of the MP3. They will be provided with practice logs to report their amount of practice as well as some basic observations to the research team.

In the present study, we will follow the official CCT manual. The training is composed of 8 sessions, which can be delivered in 7-10 weeks. The components of each session are described below. The content, order, and duration of each component may vary depending on the group dynamic and needs.

Session One: Settling and Focusing the Mind (2 hours)

- Introduction to the course content, instructor and basic guidelines (approximately 20 minutes).
- Exercise: The well exercise, a guided visualization, and debrief (approximately 10 minutes).
- Group introduction (approximately 20 minutes).
- Pedagogy and science: Definition of basic concepts (e.g., meditation, mindfulness, and compassion). Introduction to breath awareness practice as the basic skill needed for any contemplative or reflective practice (approximately 40 minutes).
- In-class practice: Settling and focusing the mind (approximately 20 minutes).
- Closing: Assigning a home practice and sharing an inspirational story (approximately 10 minutes).
  - Formal practice: Settling and focusing the mind.
  - Informal practices:
- Use the breath as a way to connect to present moment and find peace/focus.
- Choose an activity to practice and enjoy mindfully.

Session Two: Loving-Kindness and Compassion for a Loved One (2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Introduction to loving-kindness and compassion for a loved one. This step is designed primarily to help participants recognize and become aware of the natural human capacity to connect and care (approximately 25 minutes).
- Exercise: Embodying loving-kindness or compassion and debrief (approximately 25 minutes).
- In-class practice: Loving-kindness and compassion for a loved one and debrief (approximately 40 minutes).
- Closing: Assigning a home practice and sharing an inspirational story (approximately 10 minutes).

- Formal Practice: Loving-kindness and compassion for a loved one.
- Informal Practices:
- Notice spontaneous feelings of loving-kindness, compassion, or their opposites. Notice what they feel like, when they tend to arise. Notice thoughts and turn attention to the body.

- Adopt a loving-kindness or compassion perspective at least once per day.

Session Three: Compassion for Oneself (2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Introduction to compassion for oneself in order to cultivate greater self-acceptance and being kinder to oneself (approximately 25 minutes).
- Exercise: Self-acceptance and self-forgiveness and debrief (approximately 25 minutes).
- In-class practice: Compassion for oneself (approximately 30 minutes).
- Closing: Assigning a home practice and sharing an inspirational story (approximately 10 minutes).
- Formal Practice: Compassion for oneself.
- Informal Practices:
- Notice when you are engaging in negative, self-critical thoughts and self-judgments. Recognize that these are just thoughts/interpretations, and practice a self-compassionate perspective.
- Notice and acknowledge your own stress, pain, and suffering.
- Adopt a common humanity perspective when you are in a difficult situation (e.g., your stress/pain/suffering connects you with other human beings rather than isolating you from them).

Session Four: Loving-Kindness for Oneself (2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Introduction to loving-kindness toward oneself in order to cultivate a friendly attitude and embrace one's natural aspiration for happiness. Introduction to gratitude practice (approximately 25 minutes).
- Exercise: Self-appreciation and debrief (approximately 25 minutes).
- In-class Practice: Loving-kindness for oneself and debrief (approximately 30 minutes).
- Closing: Assigning a home practice and sharing an inspirational story (approximately 10 minutes).
- Formal Practice: Loving-kindness for oneself.
- Informal Practices:
- Ask yourself, "In my heart of hearts, what do I really want in my life?"
- Notice any yearning for meaning, wholeness, and connection in your life and acknowledge that they are an essential part of your being. Notice any forceful emotion, such as anger, sadness, or frustration, and identify any underlying need that you are seeking to fulfill.
- Learn to recognize and appreciate the simple everyday joys that come your way during the day. Give yourself permission/encouragement to enjoy them.
- List up to three things you feel grateful for every day.

- Do something nice for yourself – however tiny – each day.

Session Five: Embracing Shared Common Humanity and Developing Appreciation for Others (2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Introduction to common humanity, which involves two key elements: (i) recognizing a worldview of shared and common humanity, and (ii) developing an appreciation for others (approximately 30 minutes).
- Exercise: Empathic attunement and debrief (approximately 30 minutes).
- In-class practice: Embracing shared common humanity, developing appreciation for others, and debrief (approximately 30 minutes).
- Closing: Assigning a home practice and sharing an inspirational story (approximately 10 minutes).
  - Formal Practice: Embracing shared common humanity and developing appreciation for others.
  - Informal Practices:
- Notice interdependence: practice seeing, appreciating, and thanking someone whose role you might have otherwise overlooked. Notice if this gives rise to a natural sense of connection or care.
- Practice reinterpreting your reaction to a situation/interaction when you are feeling something other than empathy (e.g. disgust, irritation, pity, envy, schadenfreude). This can be done by remembering, "Just like me, this person wishes to be happy, loved, and appreciated; just like me this, person wishes to be healthy, safe, and free of suffering." Notice if this gives rise to greater compassion.
- Notice something you have in common with someone who might be difficult for you.

Session Six: Cultivating Compassion for Others (2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Introduction to compassion toward all beings (approximately 30 minutes).
- Exercise: Eyes-on dyad exercise and debrief (approximately 15 minutes).
- In-class practice: Cultivating compassion for others and debrief (approximately 30 minutes).
- Closing: Assigning a home practice, sharing an inspirational story, and dedication practice (approximately 15 minutes).
  - Formal Practice: Cultivating compassion for others.
  - Informal Practices:
- Notice challenges to compassion in everyday life – where you feel your own resistance or limits.
- Practicing recognizing the common humanity, stress, pain, or suffering in others, especially strangers and/or "difficult" people. Mentally extend your own compassion to them. When possible, look for the opportunity to express compassion or act with compassion.
- Notice the benefits to yourself when broadening your compassion.

Session Seven: Active Compassion Practice (up to 2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Introduction to an "active compassion" practice where one imagines taking away others' pain and sorrow and offering to them one's own joy and happiness (approximately 30 minutes).
- Exercise: "Breath in, breath out" and debrief (approximately 15 minutes).
- In-class practice: Active compassion and debrief (approximately 30 minutes).
- Closing: Assigning a home practice, sharing an inspirational story, and dedication practice (approximately 15 minutes).
  - Formal Practice: Active compassion.
  - Informal Practices:
- Practice active compassion when aware of someone's suffering (including your own).
- Practice being present when someone else is in a difficult situation. Practice to "breathe it in" without having to immediately fix it, but rather recognizing that your willingness to "be with (breathe with)" the person and his/her suffering is an act of compassion.

Session Eight: Integrated Daily Compassion Cultivation Practice (2 hours)

- Opening practice: Settling the mind and intention-setting (approximately 10 minutes).
- Check-in about last week's home practice (approximately 10 minutes).
- Pedagogy and science: Brief summary of the topics covered in each of the previous classes. Discussion on how to integrate the different steps of the meditation practices and set up a daily practice (approximately 25 minutes).
- In-class practice: Integrated daily compassion cultivation practice and debrief (approximately 30 minutes).
- Group sharing: Participants are encouraged to reflect on their personal experience with the course and provide feedback (approximately 30 minutes).
- Closing: Home practice, reading/quote, and dedication practice (approximately 15 minutes).
  - Meditation Practice: Integrated daily compassion cultivation practice.
  - Informal Practices:
- Reflect how you would like to continue practicing compassion in everyday life. Select your favorite informal practices and review your own intentions for choosing compassion.

Assessments

To protect the confidentiality of participants, all data will be collected using study ID numbers and assessments will be completed on-line with an e-mail link to the questionnaires in RedCap. Only the study PI and research coordinator will have access to the key that links code names to real names.

At baseline, all nurses will be asked to complete a demographic questionnaire with questions on age, sex, race/ethnicity, practice site, years of nursing experience, and type of nursing experience.

All nurses will complete the following assessments at baseline and post program (7-10 weeks).

Perceived Stress Scale (Cohen, et al., 1983; Cohen and Williamson, 1988): This 14-item instrument is the most widely used scale to measure the perception of stress. The items ask the frequency of different feelings of stress over the past 30 days.

Maslach Burn Out Inventory, Human Services version (Maslach, et al., 2009): This 22-item self-report instrument measures three areas of burn out: emotional exhaustion, depersonalization, and personal achievement. It is considered the standard for assessing burn out.

Medical Outcomes Study Questionnaire Short Form 36 (Ware and Sherbourne, 1992): The SF-36 is a 36-item self-report instrument for measuring health related quality of life. It contains 8 subscales: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. It is perhaps the most widely used quality of life instrument in individuals without a specific medical disorder.

Self-Efficacy Scale (Marksherer, et al., 1982): The Self Efficacy Scale is a 30-item self-report instrument that asks participants to rate their agreement with statements about their attitudes and feelings.

Philadelphia Mindfulness Scale (Cardaciotto, et al., 2008): This 20-item self-report instrument was developed to measure present-moment awareness and acceptance. The items ask participants to rate how often they have encountered certain experiences over the past week.

Distress Tolerance Scale (Simons and Gaher, 2005): The Distress Tolerance Scale is a 15-item self-report instrument that asks participants to rate their agreement with statements about their beliefs about feeling distressed. It, along with the Philadelphia Mindfulness Scale, is being used to assess the core skills of DBT.

Cognitive Failures Questionnaire (Broadbent, Cooper, FitzGerald & Parkes, 1982): This is a 25-item instrument that assesses the frequency of minor cognitive mistakes.

Mind Wandering Questionnaire (Mrazek, et al., 2013): This is a 5-item questionnaire assessing attention and mind wandering during daily life.

Resistance to Sunk Cost (Bruine de Bruin, Parker, & Fischhoff, 2007): This is 10-item scale that measures the tendency to continue a task once time, money, or effort has already been invested. This is a subscale of the Adult Decision-Making Competence scale.

At post (7-10 weeks) and 24 weeks, participants will be asked to complete:

Questionnaire on using skills in practice (if completed at least 75% of the educational program).

9) Study Timelines*

The following table depicts the assessments, measures and time points for the proposed data collection.

	Baseline	**7-10 weeks**	**24 weeks**
Demographics	X		
Perceived Stress Scale	X	X	
Maslach Burn Out Inventory	X	X	
Medical Outcomes Study Questionnaire Short Form 36	X	X	
Self-Efficacy Scale	X	X	
Philadelphia Mindfulness Scale	X	X	
Distress Tolerance Scale	X	X	
Cognitive Failures Questionnaire	X	X	
Mind Wandering Questionnaire	X	X	
Resistance to Sunk Cost	X	X	
Questionnaire on using skills in practice		X	X

The participants are anticipated to complete the study between 6-7 months.

10) Study Endpoints*

The primary outcome will be feasibility defined by at least 75% of the participants completing at least 75% of the program. The secondary outcome will be changes in Perceived Stress Scale from baseline to post-intervention. Other secondary outcomes will be tested on a preliminary basis: changes in target skill areas (e.g., coping self-efficacy, mindfulness, and distress tolerance), burn out, and health-related quality of life from baseline to post-intervention.

11) Data Storage*

We are collecting data on participant demographics (e.g., age, sex, race/ethnicity, work location, nursing experience) and the following instruments/questionnaires: Perceived Stress Scale, Maslach Burn Out Inventory, SF-36, Self-Efficacy Scale, Philadelphia Mindfulness Scale, Distress Tolerance Scale, Cognitive Failures Questionnaire, Mind Wandering Questionnaire, Resistance to Sunk Cost and Questionnaire on using skills in practice.

All participant information will remain confidential and stored on the study PI's and research coordinators computers and in REDCap. Identifiers such as name will only be used during the initial data retrieval process and can be destroyed once all data records have been obtained and data analysis completed. REDCap is a free, secure, HIPAA-compliant web-based application hosted by the University of Miami's Research Information Technology. The REDCap system offers easy data management with audit

trails, reports for monitoring and querying participant records, and an automated export mechanism to statistical packages (SPSS, SAS, Stata, R/S-Plus). The program will include 8 sessions and each session will be recorded. The recordings will be done with a digital video camera. Files will be immediately downloaded after each session and will be uploaded privately to Dr. Amishi Jha's Youtube Account. The videos will be accessible only to the participants with whom we share a link with and are not searchable online. The files will be also backed up to a secured server to which only lab members have access. These files will also be backed up on to an external hard drive and stored in a locked cabinet. After the files are backed up, they will be permanently deleted from the camera memory cards.

12) Data Management*

To protect the confidentiality of participants, all data will be collected using study ID numbers and assessments will be completed on-line with an e-mail link to the questionnaires in RedCap. All participants will be assigned unique alphanumeric numbers as they enroll in the study. No personally identifying information will appear on any questionnaires or other material. All participant information will be de-identified at the Sylvester location or the University of Miami Coral Psychology Department in Coral Gables, Florida. Likewise, information matching the participant number to a name or other identifying information will be kept in a locked cabinet at the Sylvester location or UM Psychology Department. Only the study PI and research coordinator will have access to the key that links code names to real names.

Standard operating procedures specifying the rules, methods, and procedures to follow will be used and checked by the study staff.

The research coordinator will be in weekly contact with Dr. Pirl to review any issues with the data (i.e., missing data) and ensure data integrity. A study team member will also review all consent forms to ensure that they are complete.

Velos database system will be used to help input participant demographics and study related information.

13) Data Analysis Plan*

Descriptive statistics will be compiled on the characteristics of the sample using data from the demographics questionnaire.

1. <u>To determine the feasibility of a compassion training program for oncology nurses.</u>
   Hypothesis 1:
- 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.

2. <u>To explore changes in burn out, perceived stress, and coping skills after the training program.</u>
   Hypothesis 2:

- Investigate the effect of an educational program on perceived stress in nurses.
- Explore the effect of an educational program on three target skill areas (coping self-efficacy, mindfulness, and distress tolerance), burn out, and health related quality of life.

We will compare changes from baseline to 7-10 weeks in the Perceived Stress Scale between the participants who completed the educational program and participants on the waitlist with a paired t-test. If the two-sided p-value is $\leq .05$, our hypothesis that the program results in reduction of perceived stress will be supported.

Similarly, we will compare differences from baseline to 7-10 weeks in scores on the Self-Efficacy Scale; Maslach Burnout Inventory; the two components of the Philadelphia Mindfulness Scale (Present-Moment Awareness and Acceptance); the Distress Tolerance Scale; and the SF-36.

Power Analysis
Effect sizes for changes in psychological factors following a compassion-based educational intervention in oncology nurses have not been tested. The goal of this trial is to estimate effect sizes for a larger adequately-powered trial. The sample size is similar to other small feasibility studies of educational interventions in healthcare workers. We will conduct hypothesis testing to examine differences in our endpoints from pre- to post-intervention, to aid in planning a future trial.

14) Provisions to Monitor the Data to Ensure the Safety of Participants*

There will be no independent monitoring of the data outside of the study staff and the UM IRB.

To ensure the usability of self-report data, the research coordinator will review all assessment measures to ensure their completeness.

All participant data will be kept in a computer file that is password protected and changed whenever staff changes. Only study staff will have access to these data. A link between ID number and participant's name will be kept in a separate file, also password protected (with a different password), accessible only to the study PI and research coordinator.

We do not plan to employ a Data Safety Monitoring Board because potential risks to participants are minimal.

OUTCOMES MONITORING

Quality Assurance of Collected Data
Data collection will be conducted in the form of assessments completed on-line via e-mail and in some cases via mail. The research coordinator will also review all measures to ensure their completeness, and tracking forms will be developed to ensure that the assessments have occurred.

All participant data will be kept in electronic files that are password protected and changed whenever staff changes. Only study staff will have access to the data. A link between ID number and participant's name will be kept in a separate file, also password protected (with a different password), accessible only to the study PI and research coordinator. The PI will work with the research coordinator to ensure that the data were accurately entered into the data storage system. For every new consent form, the PI (or designee) will review the form within one week of completion, and make an action plan to address any concerns that may arise. The research coordinator will present a quality control report to the PI on a bi-weekly basis.

Quality Plan for Monitoring Recruitment and Retention
The research coordinator will produce a weekly recruitment and retention report during the recruitment phase to be reviewed with the PI or designee. This report will yield important data in the event that changes to recruitment or retention procedures are required.

Protocol Integrity
Each individual educational session will be presented to the PI on a weekly basis, with a primary emphasis on what occurred during study sessions. The research coordinator will track the assessments to ensure that they are occurring at the appropriate times.

15) Withdrawal of Participants*

Participants will be informed that they have the right to discontinue participation at any time.

Participants may be withdrawn from the training at any time at the principal investigator's discretion due to:

- Non-compliance
- Clinical judgment of the investigator
- Worsening of clinical condition as reflected by 1) cognitive inability to complete assessments on 2 consecutive occasions 2) clear decline in psychosocial or behavioral functioning 3) safety concerns (aggression towards self or others) that, per clinician judgment, requires in-patient psychiatric care; 4) onset of new, severe psychiatric illness such as mania, psychosis, or severe depression.

If a participant decides to withdraw from the research, they will be thanked for their time and efforts. They will also be informed that their decision to withdraw from the study will in no way affect the medical treatment they receive at the University of Miami. Any data collected prior to withdrawal will be destroyed in compliance with IRB procedures.

Adverse events:
As a result of participant self-report, study staff discovery, or study assessment, the study staff may become aware of an adverse event. The PI will be responsible for the reporting of any adverse events to the IRB or federal agencies as necessary. Study-related adverse events will be reported to the IRB as soon as they are discovered by any study staff member and discussed with the PI or designee as soon as possible and no later than 10

working days/14 calendar days and 20 working days/30 calendar days after the PI is notified for serious and non-serious unexpected adverse events, respectively. Adverse events that are not study related are reported at continuing review. If any untreated condition (e.g. onset of substance abuse or physical condition) is discovered via self-report assessment or spontaneous disclosure during training, the PI (or designee) will evaluate and triage accordingly, including referral to private, confidential services as needed, and will follow mandated reporting guidelines as applicable.

16) Risks to Participants*

It is unlikely that participants will be at any risk for physical harm as a result of study participation. Participants may find some of the questions asked as part of the assessments to be emotionally upsetting. Please refer to the below section regarding minimization of psychosocial risks of this study.

PSYCHOSOCIAL RISKS

The educational program represents a minimal risk procedure. Participants may choose to discontinue their participation in the study at any time if they feel uncomfortable.

Participants will be informed that they may refuse to answer questions in the assessments that emotionally upset them. In the event that a participant is suspected to be in acute emotional distress, the research coordinator will page the study PI (or designee), and the PI (or designee) will evaluate participant safety. If the participant is determined to be actively suicidal and at risk for self-harm, the PI (or designee) will triage accordingly.

All data will be kept confidential, under lock-and-key, accessible only to the study PI and research coordinator. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock and key.

17) Potential Benefits to Participants*

While few studies have evaluated psychosocial interventions for oncology nursing providers, it is hoped that participants will learn new skills that may reduce work-related stress and compassion fatigue.

POTENTIAL BENEFITS TO SOCIETY

The purpose of this study is to test an intervention to enhance skills among oncology nurses and support staff to cope with work-related stress. Rates of stress and emotional exhaustion are high among nurses with specialized training, and the extent to which quality on-site support and education programs are available to providers varies widely. Given the existing nursing shortage and the potential for work-related burnout, the development of an efficient, low-cost psychosocial training program for oncology nurses has the potential to reduce both patient and provider frustrations, to increase provider retention, and to enhance care provision.

18) Vulnerable Populations*

This study does not enroll any vulnerable populations. This study does not include any pregnant women, neonates, prisoners, children, or cognitively impaired adults.

19) Setting*

The training will take place at the University of Miami Sylvester Comprehensive Center.

20) Resources Available*

Principal Investigator, Dr. William Pirl is an Associate Professor of Psychiatry at the University of Miami Miller School of Medicine and Associate Director of Cancer Support Services at the Sylvester Comprehensive Cancer Center. Dr. Pirl has been conducting research on oncology providers with the goal of improving patient care. He conducted a NIH-funded national survey on how oncologists manage psychosocial distress and is currently studying the relationships between oncologists' dispositional affect and the care that they deliver, also funded by NIH. Dr. Pirl developed and tested psychological skills training interventions for oncology nurses that have decreased work-related stress and medical errors. Dr. Pirl will oversee the research coordinator in the recruitment of participants and management of data.

Dr. Amishi Jha, Associate Professor of Psychology and Director of Contemplative Neuroscience, Mindfulness Research & Practice Initiative, University of Miami. Her research focuses on the brain bases of attention, working memory, and mindfulness-based training. She has experience in the development of mindfulness treatment manuals for psychological distress. Dr. Jha will oversee the study personnel involved in the educational training and administration.

Dr. Debbie Anglade serves as Assistant Professor of Clinical at the University of Miami School of Nursing and Health Studies. Dr. Anglade received her BSN from City College of the City University of New York (CCNY) and her MSN in nursing education and PhD from the University of Miami School of Nursing and Health Studies. Dr. Anglade is a member of Sigma Theta Tau, Beta Tau Chapter. She was named the 2014 Student Nurse/Graduate March of Dimes Nurse of the Year. Dr. Anglade's significant areas of interest include patient safety, healthcare quality, performance improvement, and regulatory alignment. Her dissertation topic was: Patient safety culture, compassion fatigue, compassion satisfaction: Impact on nurse-sensitive patient outcomes. Dr. Anglade teaches adult health clinical classes and has a shared role with Sylvester Comprehensive Cancer Center as a nurse researcher collaborating with the hospital Research and Evidence Based Practice Council to build a program of nurse led research at Sylvester.

William Hurwitz is a Clinical Research Coordinator for Cancer Support Services at the University of Miami's Sylvester Comprehensive Cancer Center and Miller School of Medicine. He works under the supervision of Dr. Pirl. He has a Masters in Psychology with a concentration in Mental Health and Substance Abuse Counseling and has been trained to carry out and manage clinical research studies. He will be responsible for the management of this project, including participant recruitment, screening, consenting, data collection, and data management. He will manage communications with the IRB. He will

be the direct contact for interested participants and will be in charge of collecting the data.

Maria Paula Jimenez Palacio is a certified teacher for the Compassion Cultivation Training Program from Stanford University's Center for Compassion and Altruism Research and Education. Prior to arriving at the University of Miami, she offered mindfulness and compassion trainings in Colombia, Chile, Mexico, & Spain and she had a private practice which integrated psychotherapy with a contemplative approach. She received her Bachelor's degree in Psychology from Los Andes University with a minor in Business Administration. In addition, she studied Corporate Social Responsibility at Sergio Arboleda University and Integrative Therapies at the School of Medicine at El Rosario University. She will be the main individual responsible for administering the educational training to oncology nurse participants.

21) Confidentiality*

All participants will be assigned a unique study ID number. Identifying information will be stored separately from other study data in a password-protected, encrypted Excel file. All data will be stored on secure servers at the University of Miami. REDCap software will be utilized during the study to maximize data security. Only authorized study personnel will have access to identifying information throughout the course of the study.

22) Local Number of Participants*

The maximum number of participants to be recruited locally is 25.

23) Consent Process*

Oncology nurses who work at the University of Miami Sylvester Comprehensive Cancer Center may receive a flyer that will instruct them to reach out to the research coordinator to discuss eligibility. If they meet eligibility criteria and are interested in participating, informed consent will be presented in the first page of the online survey process, participants will electronically sign and enters their name, and clicks submit to agree to participate in the study. The consent page on the online survey will be available in English.

24) Process to Document Consent in Writing*

All participants recruited will have to enter their full name to electronically sign the consent before starting the online surveys. The password-protected database to which the data is transferred will be at the University of Miami Miller School of Medicine's secure server, REDCap.

References:

Brady AM, Malone AM, Fleming S. (2009) A literature review of the individual and sy*stems factors that contribute to medication errors in nursing practice.* J Nurs Manag 17: 679-697.

Bruine de Bruin, W., Parker, A.M., & Fischhoff, B. (2007). Individual differences in Adult Decision-Making Competence. *Journal of Personality and Social Psychology, 92*, 938-956.

Cardaciotto L, Herbert JD, Forman EM, Moitra E, and Farrow V. (2008) The assessment of present-moment awareness and acceptance: the Philadelphia Mindfulness Scale. *Assessment 15*: 204-223.

Chochinov HM, Hack T, Hassard T, Kristjanson LJ, McClement S, Harlos M. (2005) Dignity therapy: a novel psychotherapeutic intervention for patients near the end of life. *J Clin Oncol 23*: 5520-5525.

Chochinov H. (2007) Dignity and the essence of medicine: the A, B, C, and D of dignity conserving care. *BMJ 334*: 184-187.

Cohen MZ, Ferrell BR, Vrabel M, Visovsky C, Schaefer B. (2010) What does it mean to be an oncology nurse? Reexamining the life cycle concepts. *Oncol Nurs Forum 37*: 561-570.

Cohen S, Kamarck T, and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior 24:* 386-396.

Cohen S and Williamson G. (1988) Perceived Stress in a Probability Sample of the United States. Spacapan, S. and Oskamp, S. (Eds.) *The Social Psychology of Health.* Newbury Park, CA: Sage.

Cohen-Katz J, Wiley SD, Capuano T, baker DM, Kimmel S, Shapiro S. (2005) The effects of mindfulness-based stress reduction on nurse stress and burnout, Part II: a quantitive and qualitative study. *Holist Nurs Pract 19*: 26-35.

Creswell, J.D., Pacilio, L.E., Lindsay, E.K. & Brown, K.W. (2014). Brief mindfulness meditation training alters psychological and neuroendocrine responses to social evaluative stress. *Psychoneuroendocrinology, 44,* 1-12

Delvaux N, Razavi D, Marchal S, Bredart A, Farvacques C, Slachmuylder JL. (2004) Effects of a 105 hours psychological training program on attitudes, communication skills and occupational stress in oncology: a randomized study. *Br J Cancer 90*: 106-114.

Elfering A, Semmer NK, Grebner S. (2006) work stress and patient safety: observer-rated work stressors as predictors of characteristics of safety-related events reported by young nurses. *Ergonomics 49*: 457-469.

Emold C, Schneider N, Meler I, Yagli Y. (2011) Communication skills, working environment and burnout among oncology nurses. *E J Oncol Nurs 15*: 358-363.

Figley, C. (2002). *Treating compassion fatigue* (Brunner-Routledge psychosocial stress series ; 23).

Guest RS, Baser R, Li Y, Scardino PT, Brown AE, Kissane DW. (2001) Cancer surgeons' distress and well-being, II: modifiable factors and the potential for organizational interventions. *Ann Surg Oncol 18*: 1236-1242.

Halbesleben JR, Wakefield BJ, Wakefield DS, Cooper LB. (2008) Nurse burnout and patient safety outcomes: nurse safety perception versus reporting behavior. *West J Nurs Res 30*: 560-577.

Hadlington, L. (2015). Cognitive failures in daily life: Exploring the link with Internet addiction and problematic mobile phone use. *Computers in Human Behavior, 51*, 75-81.

Jazaieri, H., Jinpa, G., McGonigal, T., Rosenberg, K., Finkelstein, E., Simon-Thomas, L., . . . Goldin, J. (2013). Enhancing Compassion: A Randomized Controlled Trial of a Compassion Cultivation Training Program. *Journal of Happiness Studies*, 14(4), 1113-1126.

Jazaieri, H., McGonigal, K., Jinpa, T., Doty, J., Gross, R., & Goldin, J. (2014). A randomized controlled trial of compassion cultivation training: Effects on mindfulness, affect, and emotion regulation. *Motivation and Emotion*, 38(1), 23-35.

Jazaieri, H., Lee I. A., McGonigal, K., Jinpa, T., Doty, J., Gross, R., & Goldin, J. (2015). A Wandering mind is a less caring mind: Daily experience sampling during compassion meditation training. *Journal of Positive Psychology*, Vol. 11, Iss. 1, 2016

Jha, A., Stanley, E., Kiyonaga, A., Wong, L., Gelfand, L., Anderson, Adam K., & Segal, Zindel V. (2010). Examining the Protective Effects of Mindfulness Training on Working Memory Capacity and Affective Experience. *Emotion*, 10(1), 54-64.

Jones MC, Wells M, Gao C, Cassidy B, Davie J. (2011) Work stress and well-being in oncology settings: a multidisciplinary study of health care professionals. *Psychooncology*, Sep 28, 2011 (Epub ahead of print).

Jinpa, T. (2010). Compassion cultivation training (CCT): Instructor's manual. Unpublished, Stanford, CA.

Kash KM, Holland JC, Breitbart W, Berenson S, Dougherty J, Ouellette-Kobasa S, Lesko L. (2000) Stress and burnout in oncology. *Oncology 14:* 1621-1633.

Kabat-Zinn, J. (2008). Full catastrophe living: [using the wisdom of your body and mind to face stress, pain, and illness] (Fifteenth anniversary edition / with a new introd. by the author. ed., Random House audio & listening library).

Ksiazek I, Stefaniak TJ, Stadnyk M, Ksiazek J. Burnout syndrome in surgical oncology and general surgery nurses: a cross-sectional study. *Eur J Oncol Nurs 15*: 347-350.

Lutz, Slagter, Dunne, & Davidson. (2008). Attention regulation and monitoring in meditation. *Trends in Cognitive Sciences*, 12(4), 163-169.

Mackenzie CS, Poulin PA, Seidman-Carlson R. (2006) A brief mindfulness-based stress reduction intervention for nurses and nurse aides. *Appl Nurs Res 19*: 105-109.

Maslach, C., Leiter, M. P., & Schaufeli, W. B. (2009). Measuring burnout. In C. L. Cooper & S. Cartwright (Eds.), The *Oxford handbook of organizational well-being* (86-108). Oxford UK: Oxford University Press.

Mrazek, M., Franklin, M., Phillips, D., Baird, B., & Schooler, J. (2013). Mindfulness Training Improves Working Memory Capacity and GRE Performance While Reducing Mind Wandering. *Psychological Science*, 24(5), 776-781.

Meyer F ans Block S. (2011) Personality disorders in the oncology setting. *J Support Oncol 9*: 44-51.

Morikawa Y, Kitaoka-Higashiguchi K, Tanimoto C, Hayashi M, Oketani R, Miura K, Nishijo M, Nakagawa H. A cross-sectional study on relationship of job stress with natural killer cell activity and natural killer cell subsets among healthy nurses. *J Occup Health 47*: 378-383.

Nhat Hanh T. (1999) The miracle of mindfulness: an introduction to the practice of meditation. *Beacon Press*, Boston.

Nhat Hanh T. (2011) True love: a practice for awakening the heart. Reprint edition. *Shambala Press*, Boston.

Perry B, Toffner G, Merrick T, Dalton J. (2011) An exploration of the experience of compassion fatigue in clinical oncology nurses. *Can Oncol Nurs J 21*: 91-105.

Piers RD, Van den Eynde M, Steeman E, Vlerick P, Benoit DD, Van Den Noortgate NJ. (2001) End-of-life care of the geriatric patient and nurses' moral distress. *J Am Med Dir Assoc,* Feb 10, 2011 (Epub ahead of print).

Potter P, Deshields T, Divanbeigi J, Berger J, Cipriano D, Norris L, Olsen S. (2010) Compassion fatigue and burnout: prevalence among oncology nurses. *Clinical Journal of Oncology Nursing 14*: E56-E62.

Ramirez AJ, Graham J, Richards MA, Cull A, Gregory WM, Leaning MS, Snashall DC, Timothy AR. (1995) Burnout and psychiatric disorder among cancer clinicians. *B J Cancer 71*: 1263-1269.

Rask MT, Jensen ML, Andersen J, Zachariae R. (2009) Effects of an intervention aimed at improving nurse-patient communication in an oncology outpatient clinic. *Cancer Nurs 32*: E1-E11.

Rheingans JI. (2008) Relationship between pediatric oncology nurses' mamagement of patients' symptoms and job satisfaction. *J Pediatr Oncol Nurs 25*: 312-322.

Matthieu Ricard, Antoine Lutz, & Richard J. Davidson. (2014). Mind of the Meditator. *Scientific American*, 311(5), 38.

Mrazek, M. D., Phillips, D. T., Franklin, M. S., Broadway, J. M., & Schooler, J. W. (2013). Young and restless: Validation of the Mind-Wandering Questionnaire (MWQ) reveals disruptive impact of mind-wandering among youth. *Frontiers in Perception Science, 4*, 560.

Salzberg S. (1995). Loving Kindness: The revolutionary art of happiness. Boston, MA: *Shambala Publications*, Inc.

Schulmeister L. (1999) chemotherapy medication errors: descriptions, severity, and contributing factors. *Oncol Nurs Forum 26*: 1033-1042.

Seppala, E., Hutcherson, C., Nguyen, D., Doty, J., & Gross, J. (2014). Loving-kindness meditation: A tool to improve healthcare provider compassion, resilience, and patient care. Journal of Compassionate Health Care, 1(1), *Journal of Compassionate Health Care*, 12/2014, Vol.1(1).

Sherer M, Maddux JE, Mercandante B, Prentice-Dunn S, Jacobs B, Rogers RW. (1982) The Self-Efficacy Scale: construction and validation. *Psychological Reports* 51: 663-671.

Simons JS and Gahere RM. (2005) The Distress Tolerance Scale: development and validation of a self-report measure. *Motivation and Emotion 29*: 83-102.

Sinclair, Shane, et al. "Compassion: a scoping review of the healthcare literature." *BMC Palliative Care*, vol. 15, no. 6, 2016.

Stewart AL & Ware JE (1992), eds., *Measuring Functioning and Well-Being: The Medical Outcomes Study Approach*, Durham, N.C.: Duke University Press.

Tanaka K, Otsubo T, Tanaka M, Kaku A, Nishinoue N, Takanao T, Kamata N, Miyaoka H. (1010) Similarity in predictors between near miss and adverse event among Japanese nurses working at teaching hospitals. *Ind Health 48*: 775-782.

Van Wyk BE & Pilay-Van Wyk V. (2010) Preventive staff-support interventions for health workers. *Cochrane Database Syst Rev* Mar 17 (3): CD003541