1. Study Summary

Study Title	Supporting the mental health of healthcare workers during COVID-19.
Study Design	Randomized Controlled Trial
Primary Objective	To support resilience in healthcare workers during a time of increased stress.
Secondary Objective	To enhance inter-professional teamwork and patient care by providing a universal approach to self care and respect for others.
Research Intervention	Brief training in trauma informed care and somatic awareness.
Study Population	Healthcare Workers
Sample Size	300
Study Duration	3 months
Study Specific Abbreviation	CRM: Community Resiliency Model TRI: Trauma Resource Institute IPE: Interprofessional education
Funding Source	WHSC IPEC Synergy Grant

2. Objectives:
Purpose: To examine whether CRM training resulted in improved resilience for nurses attending training.

Specific Aims:
1. Increase participants' sense of wellbeing both 1 week and 3 months after the training intervention, compared to participants who did not receive the training intervention.

2. Increase participants' reported work engagement, both 1 week and 3 months after the training intervention, compared to participants who did not receive the training intervention.
3. Test the reliability and validity of an instrument designed to measure the effect of using the Community Resiliency Model as an intervention to improve well-being.

3. Background

The implications of the current pandemic include the "second wave" of mental health concerns to come. In the meantime our healthcare workers have a compounded threat to their wellbeing as front line care providers and as citizens who have been forced to undergo change to their natural support structure such as extended family, childcare, or previous self-care routines. Working with emotionally-distraught clients or in stressful work situations puts healthcare workers at higher risk for secondary traumatic stress, burnout and mental health problems, such as depression, anxiety, suicidality, or post-traumatic stress disorder (PTSD). Yet, healthcare workers are often unavailable to participate or unwilling to seek out needed mental health support due to increased work demands, the associated stigma of mental health, concern over confidentiality, and the historical culture of self-reliance or stoicism in their work settings. As a result, front line personnel often receive little or no mental healthcare (Jones, 2016).   This can result in negative consequences for patients and employers because of the decreased quality of care that can follow compromised well-being (Letvak, Ruhm, & McCoy, 2012). The intervention for this study will be Community Resilience Model (CRM) training. This model was found to be protective of burnout for nurses who received a 3 hour CRM training (Grabbe, 2018). Emotion regulation skills that are gained from CRM can improve coping in the face of stress and trauma and therefore can increase resilience. Increased resilience can protect from burnout and thereby maintain or increase engagement in work and the interprofessional team.

The Mental Health of Front-Line Service Providers

Healthcare and public safety professionals can suffer from a range of mental health symptoms. Three principle conceptualizations of care providers' stress have been described: compassion fatigue, secondary traumatic stress, and vicarious trauma (McGibbon, Peter, & Gallop, 2010).   Burnout, another cumulative response to stress, is characterized by emotional exhaustion, depersonalization, and loss of a sense of personal accomplishment (Panteleoni et al., 2014). To cope with these syndromes, people may engage in unhealthy or high-risk behaviors, such as substance abuse, which makes the need for preventative intervention even more compelling.

Nurses

Research on nurses has shown high rates of anxiety, depression, burnout, and PTSD (Day, 2015; Stathopoulou et al, 2011; Letvak, Ruhm, & McCoy, 2012; Mealer et al., 2009; Shu-Ti, et al., 2013; Gao et al., 2012).   A survey of over 1,000 North Carolina hospital nurses showed an 18% rate of depression, which is double the national average (Letvak, Ruhm, & McCoy, 2012). A survey of over 300 Colorado hospital-employed nurses demonstrated anxiety (16%), depression (13%), post-traumatic stress disorder (PTSD) (18%), and burnout (86%); overall, of the nurses in this study, 89% had mental health symptoms (Mealer et al., 2009). The impact of mental health problems among nurses is serious, impacting quality of work, the rate of medical errors, and the intention to terminate employment (Garrouste-Orgeas, 2015; Chang & Chang, 2012). Among nurses, the health-related loss of productivity due to work-related poor mental health has been estimated at $2 billion dollars per year (http://www.inqri.org/grantee/dr-susan-

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letvak). Many nurses simply leave nursing for other professionals when they become "burned-out."

Coronavirus Pandemic

There is genuine concern about the post-pandemic mental well-being of front-line healthcare workers (Greenberg et al., 2020; Lai et al., 2020), as well as general members of the public at this time of stay-at-home recommendations.   A preventative mental wellness intervention may reduce the aftermath of depression, anxiety, and PTSD for many.

The mental well being of front-line providers was identified as a critical concern, but preventative mental health care for these groups is just beginning. Many resilience interventions are multimodal or otherwise cumbersome. They are lengthy, complex, and often costly; such as cognitive reframing, yoga, exercise, meditation, Reiki, journaling, massage, guided imagery, and Healing Touch (Mealer et al., 2014; Chesak et al., 2015; Potter et al., 2013). "Critical incident stress debriefing," commonly used for first responders, refers to processing of trauma after it has occurred, so is not a prevention intervention. Cognitive behavior therapy, a highly accepted, evidence-based, individual or group therapy, may be inadequate for front-line providers because of the postulated biological nature of trauma experiences. A new direction in trauma therapy and mental wellness self-care focuses on biologic approaches (van der Kolk, 2014), and this is the approach proposed here. The above research studies implicitly and explicitly underscore the need for preventative interventions to increase resistance to stress, improve mental well being, and increase resiliency among front-line service providers.

Evidence for the Community Resiliency Model
CRM is **derived from well-established somatic and sensory-motor psychotherapies (**Heller & LaPierre, 2012; **Levine, 2010; Ogden, 2015). CRM has a "bottom-up" approach, as opposed to the standard "top-down" or cognitive approach. CRM targets autonomic nervous system regulation through an awareness of sensation in the body. This awareness of internal sensation, also called "interoception," is well developed in highly-resilient elite athletes and military commandos (Haase et al, 2016) and may be developed or cultivated.   In CRM training, participants learn to understand the biology of their reactions to stress and trauma; they also learn specific skills** to track sensations connected to their wellbeing or resilience. The skills may increase the person's ability to return from a dysregulated emotional state to a balanced state when the nervous system becomes overwhelmed, and these same emotion regulation skills may be of value in one's ongoing ability to handle stress.

CRM is innovative, and it is an acceptable means to improve emotion regulation with a growing body of research to support its effectiveness. The **Department of Defense designated CRM a "promising practice" (Miller-Karas, 2015)**, and one study of CRM trainees demonstrated a significant improvement in symptoms of depression, anxiety, hostility, and bodily pain **(**Citron & Miller-Karas, 2013).   Front-**line service providers in disasters also demonstrated the positive benefits of CRM techniques.** Following Hurricanes Katrina and Rita, the CRM intervention (then called TRM) was used with 91 social service workers who demonstrated statistically lower PTSD symptoms and increased resilience compared with a control group (Leitch, Vanslyke, & Allen, 2009). Finally, in the aftermath of the Sichuan Province earthquake in China in 2008, Leitch and Miller-Karas (2009) trained more than 350 doctors, nurses, teachers, and counselors in six cities during the 18-month period following the earthquake. Their

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evaluation demonstrated that 88% used the skills in their work and over 60% used the skills for their own self-care (Leitch and Miller-Karas 2009). CRM's evidence continues to accumulate. The first randomized controlled trial of CRM in 77 hospital nurses found reduced secondary traumatic stress and physical health problems in the participants, as well as improved emotional well-being and resiliency after a single 3-hour "dose" of CRM (Grabbe et al., 2019).

CRM has only had minimal testing in healthcare workers during this pandemic. Further research can help us understand its effectiveness in emotional regulation and whether this may improve productivity and satisfaction in current jobs during this time of added stress. This current project can contribute to the growing body of evidence while providing an innovative, resiliency- enhancing intervention for workers at increased risk for compromised mental health and well-being, potentially compromising the effectiveness of the entire interprofessional team.

4. Study Endpoints

Measures of wellbeing, work engagement, and sensory experience integration will be collected as evidence that this is a useful model to address wellbeing and protect from the second wave of health consequences from COVID 19 on our healthcare workforce and the patients they care for. These measures will be collected at baseline, one week after intervention and three months or more after intervention.

5. Study Intervention/ Design

The Community Resiliency Model (CRM), proposed here as a preventative mental wellness promotion intervention, is a low-cost, low-intensity training. This intervention is consistent with a call by the Institute of Medicine (IOM) in its 2015 Report on Psychosocial Interventions for Mental and Substance Use Disorders to use mental health programs incorporating interpersonal strategies targeting biological, behavioral, cognitive, interpersonal, social, or environmental factors to meet the goal of improving health functioning and wellbeing.(IOM, 2015). CRM was developed originally as a psychological first aid tool in disaster situations, where cognitive models were inadequate and too lengthy. It has evolved into a model of mental wellness skills, which can be easily learned and practiced (Miller-Karas, 2015). The practice of these skills contribute to resiliency and the ability to withstand stress, without losing flexibility or adaptability.

6. Procedures Involved

This study will use qualitative and quantitative methods to determine the impact of 1.) CRM skills on emotional state 2.) Sense of well-being, and 3.) Work engagement 4.) CRM-Sensory experience. These quantitative measures will be collected 1 week post-training, and 3 months post-training. Data analysis will include whether participants took advantage of the options of additional electronic information to reinforce their learning. All nurses in the state of Georgia will be invited to participate in the sessions. Nurses will register for a one or three hour online training being provided for free by the Georgia Nurses Association or other organizations such as the Georgia Association of School Nurses and Grady Hospital. The CRM training will include instruction, demonstration, and participation in skill-building activities through an interactive, virtual but synchronous video platform. Only healthcare workers from the local healthsystem will be invited to participate in the study.

The CRM teaching content will be taken directly from existing CRM skills training materials. The PI, Ingrid Duva, and other certified CRM trainers will deliver the content. Content of the session includes the CRM skills: tracking, resourcing, grounding, gesturing, help now, and shift and stay. The neurophysiology of stress and trauma responses will be taught and is foundational to the teaching of the skills. Handouts and PowerPoint slides will be used. Demonstration and practice during the training allows for immediate use and refinement of the skills. Use of the free 15-minute CRM app (ichill), which describes the CRM skills, will be encouraged; for those without a smart phone, the app is available at www.ichillapp.com. This app is an overview of the skills and rationale for the model. Regardless of the length of the session, training will provide a brief overview of the model and introduce skills and tools that can be immediately accessed during times of emotional dysregulation as well as to prevent dysregulation.

Virtual training about the model will be offered at numerous times during November through January. The second part of the intervention, viewing the film "Resilience" will occur in December. The film reinforces the model, raising awareness of the effects of trauma on the body. Two trainers participate during the session interventions. This allows for a dynamic presentation, supervised practice of the skills, and for support to participants in the unlikely event that any individual be emotionally dysregulated while learning the skills.

At the end of the training all participants will be provided a link to access the study instruments. This is voluntary and will require not only the decision to proceed with the provided measures but also an informed consent. Approximately 4 surveys, consisting of approximately 40 responses, will be completed by the participant on their device of choice and submitted upon completion. All tools and informed consent will be transferred back to the researchers via the RedCap tool. Post-test surveys of the measures will be requested at 1 week and 3 months after initial training

Brief written evaluations at the end of the training sessions and in the post-tests will ask about the usefulness and acceptability of the CRM training. Resilience, and the effectiveness of the CRM Skills will be measured by self-report tools (WHO well-being, Uchtrect's work engagement, a somatic experience scale), Job satisfaction, intent to leave current position will be asked in a single question format. At the 1 week and 3 month survey request, questions will be included to probe the extent and use of trained skills and how participants have used them in work or personal situations.

Research Instruments

Well-established, valid, and reliable instruments have been selected for the pre/post-tests:

1. A demographic survey (age, gender, years worked in healthcare, years in current position, type of work)
2.   Utrecht Work Engagement Scale (17 items); The Utrecht results, if improved, imply a more engaged, enthusiastic workforce.   A highly engaged workforce has been shown to provide higher quality care.
3.   WHO Well-being Scale (5 items) - self-reports current well-being. This score should go up or stay the same for the experimental group.
4. CRM-SES, A Sensory Experience Scale, measures the effectiveness of the CRM training and integration of the foundational tracking scale. (approx 10 questions)

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7. Data Specimen and Banking – N/A

8. Sharing of Results with Participants

Findings will be shared with participants via email or virtually after study analyses are concluded. A formal written summary will be provided to the WHSC in April 2021. These findings may also be disseminated through peer-reviewed journals, which will potentially benefit a larger population of service providers who work in emotionally-taxing environments.

9. Study Timeline

The study will begin in September 2020 with recruitment. The two-part training intervention will occur in October through December. For the intervention participants, the study is completed by March 2021, after the three-month survey completion. Analyses will begin immediately. Initial results will be written up and reported back to the Woodruff Health Science Center by April 2021. For the controls, there will be an opportunity provided to receive the intervention after their three-month data is collected. Tis opportunity will include an additional consent to continue with data collection. For those control participants, should they choose to attend a training, the study will end 3 months later once they have had the opportunity to complete post training surveys. Final results will be compiled in August 2021.

10. Subject population

Inclusion Criteria: All healthcare workers at participating health centers who have not participated in CRM training in the past. Volunteers who comprise the sample will be recruited through their workplace. The distribution of information related to the study will follow the recommendation of the Healthcare systems.

Exclusion Criteria: None

11. Vulnerable Populations – N/A

12. Local Number of Participants

This study targets a local population. We will aim for 300 participants. 100 volunteers are needed for the intervention arm of the study and 100 for the control (volunteers who will not receive training).

13. Recruitment Methods All interprofessional team members in the organizations affiliated with the local Healthsystems can participate and this invitation will be distributed via email. Volunteer participants will register themselves for the training. Once the training begins information about the study will be provided via a link. There will be no remuneration for participation. Study participants will need to be motivated to provide data that may ultimately help other healthcare workers. The flyer will mention free apps or wellness resources for persons who do not want to participate but are feeling stressed.

14. Withdrawal of Participants - There are no anticipated circumstances that would lead to the withdrawal of participants without their consent. If participants choose not to continue providing data once the first round of surveys are completed, their data will be handled in the analysis as a baseline or comparison and will not be able to fulfill the study purposes for the extended analysis of survey responses.

15. Risks to Participants

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Some of the CRM skills exercises might be challenging, for example, describing sensations in the body, but in general, none of the skill practice should aggravate emotional distress. Participants are always given the option of not trying out the skills. If accessing body sensations causes discomfort or emotional triggering in anyone, a trainer will be available to help the participant.

16. Benefits of Participation

It is expected that the CRM skills training will have direct benefits for participants. The benefits of CRM may include a state of reduced reactivity to stress and increased ability to focus; these skills may enhance the resilience of the participants, i.e., the ability to bounce back from stress or trauma and increase their emotion regulation ability. If participants are not comfortable using certain CRM skills, they need not practice them. The findings of the study will be disseminated through peer-reviewed journals, which will potentially benefit a larger population of service providers who work in emotionally-taxing environments. Findings will also be shared with participants via the host organization's webpage.

17. Data Analysis, Management and Confidentiality

All REDCap data will be entered into SPSS software and analysis of the data will take place in the principal investigator's office. Data will be cleaned; descriptive statistics will be run to understand the sample. Experimental and control group means will be compared using t-tests. Logistic regression will be used to determine if the assessment scores for CRM-SES are associated with the well-being and work engagement scores. Demographic surveys and the data from the quantitative and qualitative evaluation surveys from participants will be shared in a summary format.

18. Provisions to Monitor the Data to Ensure the Safety of Participants

Participants who show signs or identify signs of emotional dysregulation during the intervention (training) will be contacted by trained study team members for regulation or referral. These participants will be asked to immediately terminate intervention training. A list of trauma-focused therapists will be made available to all participants.

Data collection will consist of pre and post-intervention surveys. The quantitative data will be entered into the SPSS system at the School of Nursing, identified by the participant code number only. The monitoring plan consists of the PI reviewing all data and following up on any concerns or trends seen in the data that may implicate there are safety concerns for any participants. Any adverse events noted will be reported to the IRB.

19. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data.

The data file will be password protected, and stored on a secure drive. All completed data collection instruments will be kept in a locked file in Dr. Duva's locked office in the School of Nursing. No names will be collected on any of the instruments. Only personnel associated with the study will have access to the surveys or the files on the secure drive. All research personnel will complete CITI training in Human Subjects (or its equivalent) research.

20. Economic Burden to Participants

No economic burden is anticipated for participants in this study. It is a free training and only minimal time is required to complete the post training surveys.

21. Consent Process

Written consent to participate in the CRM study will be obtained electronically before beginning the pre training survey. Participants will be advised that the decision not to participate, or to cease participation at any time will not affect their work situation. Participants will be providing their consent remotely, from their own chosen training location. Based on the education of the population, healthcare workers, it is expected that providing a written explanation in English will be adequate to assure understanding. After consultation with IRB staff in similar studies, it was determined that the general nature of the survey will not require HIPAA patient protection clauses in the consent.

22. Setting

The setting for this study is at the local Healthcare system and the surrounding community and metro-area. Potential participants will be recruited from the healthsystem. Recruitment flyers will be distributed electronically explaining the study and inviting volunteers. The intervention participation and the follow up research questionnaires will be completed at the participants own convenience in the setting of their choice. Unit and hospital leadership will be consulted in the recruitment phase and be aware of the study but the training and the film viewing will be offered virtually, not necessarily on the hospital campus or other healthcare setting.

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