PROTOCOL TITLE: Targeting teacher stress and well-being to improve child outcomes: Impact of the Be Well Care Well program

PRINCIPAL INVESTIGATOR: Angela Moreland, Ph.D.

1.0 Objectives / Specific Aims

The capacity of adults to provide nurturing early care environments shapes the foundation of children's health and wellbeing.[1,2,3] Children enrolled in center-based care has increased in recent decades to more than 10 million[4], increasing impact of the two million early care and education (ECE) teachers on young children's lives. Given that a healthy social and emotional climate supports young children's cognitive, social, emotional, physical, and behavioral development[5,6], it is particularly important for ECE teachers to interact with children in a sensitive and responsive manner.[7,8] Research shows that ECE teacher's mental health, personal resources, and access to support outside the workplace influence capacity to provide responsive care to young children[9,10], and that high levels of stress in ECE teachers is associated with negative interactions with young children.[11] Physical activity in ECE teachers is significantly related to teacher-child outcomes, in that teachers involved in more physical activity display less negative job-related outcomes (e.g., absenteeism, turnover, teacher burnout)[12] and more positive interactions with children.[13] Given the strong links between ECE teacher wellbeing and quality of care given to young children, it is concerning that ECE teachers display heightened levels of stress[14,15,16] and that higher stress is associated with negative wellbeing and physical health problems in teachers.[17] Research is needed to examine well-being, stress, and emotional and physical health among ECE teachers[18] as well as to develop and test effective, feasible intervention models for this population.[19] As the social and emotional classroom climate provides immediate benefits to teachers and children, it is imperative to examine programs that target improving wellbeing and decreasing stress among ECE teachers working with young children.

The Be Well Care Well (BWCW) Program, developed by the study team (PI Moreland and Co-I Schnake), is a program aimed at building wellbeing in ECE teachers to reduce and buffer the effects of stress and hardship, and making them better able to meet the developing social-emotional needs of young children in their care. In 2018-2019, BWCW was implemented at 33 childcare centers in SC, in which 250 ECE teachers participated in the program aimed at building social support networks, developing stress reduction techniques, improving self-efficacy and executive functions, and facilitating access to support services. Results indicated that all teacher outcomes, including stress and physical activity, were significantly improved from pre- to post-program implementation. While this provides significant preliminary support for the efficacy of the BWCW program, a randomized clinical trial (RCT) is needed to examine the impact of BWCW compared to a control intervention.

This multi-disciplinary investigative team from the Medical University of South Carolina (MUSC) and the University of Delaware (UD) have built a strong collaborative relationship via participation in an ACCEL-sponsored research planning retreat, multiple collaborations that have grown from that meeting, including pilot data collection. Built from this foundation, we aim to evaluate the feasibility and preliminary impact of the BWCW program on ECE teacher outcomes, including teacher stress, physical activity, parent-child interactions, and nutrition. Our study will address the following specific aim and hypothesis:

Aim 1: **Assess the impact of the BWCW program on teacher stress and physical activity**, as measured by validated survey tools at pre-BWCW, post-BWCW, and 6-month follow-up, in 144 ECE teachers within 12 centers who receive the BWCW program compared to 144 ECE teachers within 12 centers who receive the wait-list control condition in a pilot RCT Hybrid Type 1 study. We aim to finalize the trial design for a large-scale, rigorous R01-level effectiveness-implementation Hybrid Type 1 study. Benchmarks are:

(a) Test feasibility and implementation of the pilot RCT of the BWCW program
(b) Obtain variability estimates of outcomes (less than 10% missing data) and initial indicators of treatment effects at post-BWCW and 6-month follow-up for the subsequent efficacy trial

Findings will build the evidence on effective strategies to improve stress and physical activity among ECE teachers, which could ultimately contribute to positive changes in both academic and health outcomes in young children. Study completion will well-position the investigators to successfully translate the intervention, if efficacious, to Delaware and pursue an R01-level Hybrid Type 1 study to examine the impact

of BWCW on Delaware ECE teachers and to study the impact of BWCW on children in South Carolina and Delaware.

Aim 2: Examine feasibility of collecting cortisol data from a subsample of 20 ECE teachers, to assess feasibility of collecting this data from teachers, including acceptability and preliminary variability estimates.

2.0 Background

Early childhood is a critical period for child development. Early childhood is a very critical developmental period that influences health throughout the life span, given significant neurological and social developments in early childhood.[22,23] Early child behavior problems are a critical source of concern for schools, families, and public health, as they are the most frequent reason for referral to child mental health clinics.[24] Significant behavior problems can begin in the preschool years, as early as age 3 to 4 years of age[25], and research shows that these "early starters" remain disruptive into childhood and beyond[26] – with approximately 66% of preschoolers with early disruptive behavior having a clinical diagnosis of disruptive behavior by age 9[27]. Thus, targeting children in the preschool years can have lasting impact on ongoing child development and well-being.

Early care and education (ECE) teachers have significant impact on the lives of young children. The capacity of adults to provide nurturing early care environments shapes the foundation of children's health and wellbeing.[1,2,3] In the lives of many young children, early care and education (ECE) environments and teachers are important extremely important. As maternal participation in the workforce has increased in recent decades, so has the percentage of children cared for outside the home, with growth in the use of center-based care.[4] Specifically, approximately 59% of children under age 5 who were not enrolled in kindergarten participated in center-based ECE programs in 2016.[28] Center-based early care occurs in non-residential settings, typically staffed by a director and numerous teachers. A particularly important role of the ECE teacher is interacting with children in a sensitive and responsive manner thereby promoting a healthy social and emotional classroom climate.[7,8,29,30] A healthy social and emotional climate supports cognitive, social, emotional, physical, and behavioral development.[5,6,31,32,33] Research indicates that demographic and workplace characteristics, and relationships with co-workers influence the quality of their interactions with young children.[8,31,34,35,36,37]

Impact of classroom environment on the teacher and child. A healthy social and emotional classroom environment provides immediate benefits to both the teacher and child. An ECE teacher who is engaged in supportive and responsive interactions is more effective in managing classroom behaviors in a proactive, rather than reactive, manner.[38] Teachers who report a positive social and emotional climate results in feelings of fulfillment and success, and reduced likelihood of burnout for ECE teachers.[18,35,39] Further, responsive care provides scaffolding of children's developing cognitive, linguistic, social, and emotional skills[8,40], which can have long-term benefits for developing children.[41,42,43]

ECE teachers experience high levels of stress, mental health, and physical health difficulties, which influences capacity to effectively work with children. ECE teachers report high levels of stress, with 96% of ECE teachers describing their jobs as "extremely stressful," and 36% considering giving up teaching due to this stress.[17] These numbers are alarming, given that high levels of stress are related to job dissatisfaction, burnout, and negative mental health in the general population, as well as within teachers.[44] A study of 179 ECE teachers showed that higher levels of stress are related to increased depression and burnout.[13] This is extremely critical, given that ECE teacher's mental health, personal resources, and access to support outside the workplace influence capacity to provide responsive care to young children[9,10], and that high levels of stress in ECE teachers has been associated with negative interactions with young children.[11] Further,

research demonstrates that teacher stress is significantly related to more disruptive behaviors in the ECE classroom.[45] Physical activity in ECE teachers is also significantly related to teacher and teacher-child outcomes, in that teachers involved in more physical activity display less negative job-related outcomes (e.g., absenteeism, turnover, teacher burnout)[12] and more positive interaction with children. ECE teachers are increasingly asked to serve as healthy role models for children, with best practice approaches to child nutrition specifying that teachers sit with the children at meals and consume the same food and snacks.[46] Teacher role modeling has been associated with child-level likelihood to try and consume fruits and vegetables, whole grains, and other healthier options.[47,48]

Increasing well-being among ECE teachers: The Be Well Care Well (BWCW) program. Due to research on the importance of the ECE environment on the health and well-being of children, various agencies (e.g., National Academy of Medicine, Children's Environmental Health Network, American Academy of Pediatrics, and National Resource Center for Health and Safety in Child Care and Education) have called for interventions aimed at improving well-being of teachers to impact the well-being and health of children. Research indicates that teacher well-being can be improved by targeting several factors including self-efficacy, life satisfaction, financial stability, emotional and physical health, and autonomy.[49,50,51] The BWCW program is a voluntary program, developed by the study team (PI Moreland and Co-I Schnake), that aims to build well-being in ECE teachers to reduce and buffer the effects of stress and hardship, and in so doing, allowing them to better meet the developing social-emotional needs of young children in their care. In 2018-2019, the BWCW program was implemented in 33 childcare centers in South Carolina, in which 250 ECE teachers participated in the program. Specifically, through both individual and group interactions with ECE participants, the program aims to build teachers' social support networks, develop stress reduction techniques, improve self-efficacy and executive functions, and facilitate access to support services. Results of this study found that all teacher outcomes, including stress and physical activity, were significantly improved from pre- to 1-year post-program implementation. Attrition of ECE programs was very high (81%) from pre- to post-assessment, and all ECE programs engaged in at least 2 activities and 72% completed all goals outlined at program start. Further, teachers reported high satisfaction with the BWCW program (Mean = 4.3 out of 5). **While this provides significant preliminary support for the efficacy of the BWCW program, a randomized clinical trial (RCT) is needed to examine the impact and effectiveness of the BWCW program**.

3.0 Intervention to be studied (if applicable)

The Be Well Care Well (BWCW) program. The BWCW program is a 6 to 12-month intervention model that encourages building social support networks, improving physical and emotional health, developing stress reduction techniques, improving caregivers' sense of self-efficacy and executive function, and facilitating access to financial resources and services. As part of BWCW, a coach is assigned to each center, who provides orientation and support for the development of a Well-Being Committee (WBC). Using the Well-Being Activities Guide (WBAG), the WBC develops a Well-Being Action Plan (WBAP) by setting goals and choosing activities (see description below). The coach works with the program throughout implementation to assist with selection of activities, problem solving around barriers, and coordinating requests. The coach is trained and supervised by Schnake, who developed BWCW and has significant expertise in improving well-being among ECE teachers.

CATEGORY	ACTIVITIES
Getting Started	(1) Establish well-being committee; (2) Staff well-being priorities written in program materials; (3) Develop specific goals and objectives
Team Building	(1) Recognition of staff achievements; (2) Create and encourage staff to participate in walking or running

	group; (3) Participate as an employee team; (4) Implement weight management program or challenge
Physical Activity and Nutriton	(1) Teachers participate in physical activity with young children for 5-10 minutes at least 2x a day; (2) Provide information to staff and families about fitness opportunities in the community; (3) Provide on-site exercise equipment; (4) Provide on-site classes; (5) Bring in guest speakers on staff professional development days that can present on healthy eating and active living; (6) Secure discounts to local fitness facilities; (7) Coordinate cooking demonstrations or cooking classes for staff; (8) Coordinate a Cooking Matters Shopping Tour; (9) Offer healthy snack options during meeting times with staff and families; (10) Incorporate "Brain Breaks" or 3 minutes of physical activity breaks at meeting times.
Culture of Well-Being	(1) Coordinate annual health screening for staff; (2) Provide list of community supports for mental health services and other social support services; (3) Year-round staff incentive program that positively reinforces healthy choices; (4) Coordinate a mobile market or community supported agriculture opportunity to provide staff with access to fresh produce; (5) Provide a private space for nursing mothers; (6) Create/promote a resource library for staff on healthy living; (7) Bring in guest speakers on staff professional development days that can present on financial planning and resources
Administrative Goals	(1) Conduct employee well-being needs or interest survey yearly with staff; (2) Develop written policy that address recommended food choices in break areas, staff parties, and/or vending machines; (3) Develop and communicate, and implement a written policy that provides 5-10 minutes for employees to participate in well-being activities during work days in addition to break times; (4) Program offers discounted child care rates for staff; (5) Develop a written policy that allows nursing mothers to nurse or pump during working hours; (6) Program directors maintain a list, and make use of, resources to support teachers who are challenged by children's behaviors or special needs; (7) Provide space for staff to store/prepare food; (8) Offer Employee Assistance Program; (9) Allocate funds annually for well-being initiative; (10) Support exercise breaks during the work day for activities such as stretching or walking
Relaxation and Reflection	(1) Integrate stress relief activities into programs during meetings; (2) Coordinate discounts for relaxation experiences; (3) Create a quiet, meditative space where staff can go relax during break times; (4) Bring in guest speakers on staff professional development days that can present on topics related to relaxation and reflection; (5) Offer life skills training
Sustainability	(1) Create a community partnership with a business that will sponsor healthy events; (2) Create fundraising opportunities to support health and well-being

Due to research on the importance of the ECE environment on the health and well-being of children, various agencies (e.g., National Academy of Medicine, Children's Environmental Health Network, American Academy of Pediatrics, and National Resource Center for Health and Safety in Child Care and Education) have called for interventions aimed at improving well-being of teachers to impact the well-being and health of children. Research indicates that teacher well-being can be improved by targeting several factors including self-efficacy, life satisfaction, financial stability, emotional and physical health, and autonomy.[49,50,51] The BWCW program is a voluntary program, developed by the study team (PI Moreland and Co-I Schnake), that aims to build well-being in ECE teachers to reduce and buffer the effects of stress and hardship, and in so doing, allowing them to better meet the developing social-emotional needs of young children in their care. In 2018-2019, the BWCW program was implemented in 33 childcare centers in South Carolina, in which 250 ECE teachers participated in the program. Specifically, through both individual and group interactions with ECE participants, the program aims to build teachers' social support networks, develop stress reduction techniques, improve self-efficacy and executive functions, and facilitate access to support services. Results of this study found that all teacher outcomes, including stress and physical activity, were significantly improved from pre- to 1-year post-program implementation. Attrition of ECE programs was very high (81%) from pre- to post-assessment, and all ECE programs engaged in at least 2 activities and 72% completed all goals outlined at program start. Further, teachers reported high satisfaction with the BWCW program (Mean = 4.3 out of 5).

4.0 Study Endpoints (if applicable)

Involvement in the Be Well Care Well program is not in itself a study procedure. Study procedures include the surveys and interviews. Following enrollment and completion of informed consent procedures, the Project Coordinator will conduct the baseline assessment with ECE teachers, who will each be reimbursed $25. A post-BWCW and 6-month follow-up assessment will be conducted with each participant, who will each be reimbursed $25 for the post-survey and $25 for the 6-month follow-up survey. See Table 1 for description. Cortisol samples will be collected with 20 participants, who will each be reimbursed $60 for completing the four cortisol tests in one day. To promote study retention, strategies will include phone, text, and email reminders; continued communication with center directors; allowing participants to update contact information online; and increasing monetary remuneration.

Table 1. Data Collection and Assessment Measures Table

Construct	Measures	Citation/Author	Time	
			T1	T2
Social networks	Devereux Adult Resilience Survey (DARS; Relationships)	Mackrain (2013)[73]	X	X
Internalized beliefs	Devereux Adult Resilience Survey (DARS; Internal beliefs)	Mackrain (2013)[73]	X	X
Emotional health	Lifestyle Questionnaire (Motivation and state of mind)	IRCM (2008)[74]	X	X
Executive functioning	Behavior Rating Inventory of Executive Function – Adult (BRIEF-A)	Roth et al. (2012)[75]	X	X
Provider stress	Child Worker Job Stress Inventory (CCW-JSI) Classroom Appraisal of Resources and Demands (CARD) Perceived Stress Scale (PSS – 4)	Curbow et al. (2000)[76], Lambert et al. (2009)[77], Cohen et al. (1983)[78]	X	X
Budget and financial management skills	Money Management Questionnaire Survey	Developed for study	X	X
Professional skills and knowledge	Devereux Adult Resilience Survey (DARS)	Mackrain (2013)[73]	X	X
Physical activity and health	Lifestyle Questionnaire (Physical activity, medication, and smoking) International Physical Activity Questionnaire (IPAQ)	IRCM (2008)[74] Craig (2003)[80]	X	X
Job satisfaction	Early Childhood Job Satisfaction Survey	Bloom (1989)[81]	X	X
Exposure to traumatic events	SC Adverse Childhood Experiences Questionnaire (ACES)	Finkelhor et al. (2015)[82]	X	
Study satisfaction	Study satisfaction questionnaire	Developed for study		X
Study relevance	Study relevance questionnaire	Developed for study		X

Qualitative Interviews. Qualitative interviews will be conducted with n=30 participants (n=15 BWCW, n=15 WLC); each will take 30-45 minutes and will include probes assessing feasibility and implementation. All qualitative interviews will be conducted by the research assistant, who is blind of condition. Participants will be reimbursed $25 each upon completion of the interview. Data will inform the planned, larger scale R01-level Hybrid Type 1 RCT study to examine effectiveness of BWCW in various settings.

5.0 Inclusion and Exclusion Criteria/ Study Population

ECE centers will be selected based upon the following criteria: (1) at least 4 classrooms of 0 to 6-year-old children in the center; (2) ABC accreditation from Department of Social Services. Participants will include ECE teachers that meet the following criteria: (1) currently employed as a teacher or assistant teacher at a participating ECE center; (2) ages 18 or older; (3) men or women; (4) able to speak, read, and write English. Participants will be provided information on the study and instructed to tell the Be Well Care Well coach if they are interested in participating in the study.

Inclusion Criteria
Teachers that meet the following criteria will be included:
(1) currently employed as a teacher or assistant teacher at a participating ECE center;
(2) ages 18 or older;
(3) men or women;
(4) able to speak, read, and write English.

Exclusion Criteria
None

6.0 Number of Subjects

Given the average of 12 ECE teachers per center, an estimated 288 teachers will participate in the study; with n=144 from the BWCW group and n=144 from the WLC. Cortisol samples will be collected in 20 participants (n=10 from the BWCW group and n=10 from the WLC).

7.0 Setting

Recruitment of centers will include contacting center directors throughout the South Carolina upstate area and arranging a meeting to discuss the BWCW program. During this meeting, the BWCW program will be discussed and questions will be answered by the research team member. The South Carolina Program for Infant/Toddler Care (SCPITC) already serves ECE centers across the state to support and promote high-quality, responsive, relationship-based care for infants and toddlers by working intensively with ECE centers and teachers across the state on a variety of initiatives. Through connections with ECE centers throughout the state, the team has already identified and been in contact with multiple ECE centers who are interested in the BWCW program.

8.0 Recruitment Methods

Recruitment of centers will include contacting center directors throughout the South Carolina upstate area and arranging a meeting to discuss the BWCW program. During this meeting, the BWCW program will be discussed and questions will be answered by the research team member. The South Carolina Program for Infant/Toddler Care (SCPITC) already serves ECE centers across the state to support and promote high-quality, responsive, relationship-based care for infants and toddlers by working intensively with ECE centers and teachers across the state on a variety of initiatives. Through connections with ECE centers throughout the state, the team has already identified and been in contact with multiple ECE centers who are interested in the BWCW program.

Once a center enrolls in the program, the Director informs all staff at the center about the BWCW project. A BWCW research team member visits the center during a designated meeting and describes the study to the staff. All interested staff are enrolled in the study after given the opportunity to ask questions. Staff who do not wish to participate in the research study will still receive the BWCW program, but will not complete the surveys or interview.

9.0 Consent Process

We are requesting waivers of signed consent for the surveys and interview group, as including the consent document would increase the risk of confidentiality breach since it would be the only linking document of

responses between data and participant name. Participants will be given information about the survey and interview before the study procedures and will be given the opportunity to ask questions.

At the end of the survey, participants will be asked if they are interested in participating in the cortisol component of the study. Those who answer yes will be sent to another confidential webpage, where they will provide their name and contact information. Being sent to another webpage will ensure that participant survey data is not linked to name and contact information. Potential participants will be contacted by the study team, where the participant will be provided with all information about the study and given the opportunity to ask questions. If the participant is interested in enrolling, e-consent will be conducted with the participant via video conference platform.

10.0 Study Design / Methods

The pilot RCT follows a 2 (treatment type) x 3 (time points) study design, in which 24 ECE centers will be randomly assigned to: (1) BWCW or (2) wait-list control (WLC), resulting in a cluster randomized trial. Using centers as the unit of assignment will reduce risk of intervention contamination among teachers. Centers will be recruited in four "waves" of six and randomly assigned to condition (3 BWCW and 3 WLC in each wave). Similar designs have been used to demonstrate efficacy of programs through RCT designs.[70,71]

Pre-BWCW, post-BWCW, and 6-month follow-up surveys will be given to each participant. Surveys are completed online by participants via survey link sent to the participant.

Cortisol samples will be collected from 20 participants at baseline and 6-month follow-up time points. The samples will be collected by the participant and placed in a small cooler that a study team member will pick up from the center.

Qualitative interviews will be conducted with 30 participants enrolled in the study. Random selection for ECE teacher qualitative interviews occur through a parallel subgroup sampling procedure[72] using random sampling conducted by wave. All participants within each wave will be assigned a number. Using a random number generator, 7-8 participants per wave will be randomly selected to participate in a qualitative interview. Participants will be recruited using this procedure until the target sample is reached (n=15 BWCW, n=15 WLC). The qualitative interviews will be audio recorded and stored on the study Box drive. Recordings will be transcribed using VerbalLink and audio tapes will be destroyed. The transcribed interviews will be labeled with the participant ID and will be stored on the Box drive.

11.0 Specimen Collection and Banking (if applicable)

N/A

12.0 Data Management

With regard to data safety issues, PI Dr. Moreland and the research team will work together to support electronic data security. Questionnaire data will be collected via REDCap survey software, which is maintained by the South Carolina Clinical and Translational Research (SCTR) Institute, an NIH Clinical and Translational Science Award (CTSA) program. SCTR has extensive experience safeguarding the security and integrity of sensitive materials, including protected health information and sensitive financial information. The secure servers that will house the data files collected from the web applications on the smartphones and web usability assessments are located at MUSC in SSL (Secure Sockets Layer) 128-bit encrypted servers behind firewalls. After each stage of the study, SCTR will provide the PI data sets for the self-report questionnaires. Respondent confidentiality will be masked in all data files by the use of project

identification numbers rather than personal information. The personal information will be linked to the project identification numbers in one file. Electronic records, including digital recordings of sessions and the file with the linked information will be maintained in password-protected locations on the secure server. All paper records will be coded with the project identification number and maintained in a locked file cabinet on a secure floor. The only document linking participants with identification numbers will be retained in an encrypted file on the secure server with access limited to the PI and research team (Drs. Back, Danielson, and Baker). Data presented at professional meetings or published in journals or books will not allow identification of individual participants. These procedures are expected to minimize any potential adverse effects from participating in this study.

All project staff will be required to sign a statement of confidentiality when hired. They will also be trained to obtain informed consent and provide information regarding confidentiality in the same manner, and to address confidentiality issues as they may arise in the course of interviews, assessment, or intervention. Project staff will have access to research data only for the purposes detailed in the proposal and to the extent that they need such access to fulfill their responsibilities. No information about a participant will be released to third parties (i.e., outside agencies) without written consent from participants.

All raw data will be stored in rooms that have restricted access during the day and are locked during non-working hours. All computer data will be password-protected and identified by code numbers rather than family or staff names. All data and participant records will be entered, edited, and maintained in a locked file cabinet in locked offices at the National Crime Victims Research and Treatment Center (NCVC) at the Medical University of South Carolina (MUSC). These rooms have restricted access during the day and are locked during non-working hours. These rooms are equipped with computers that have all necessary data management software. To ensure completeness and high quality of all data files, data entry personnel will always work in pairs to verify each other's work, and their work will be regularly checked by PI Dr. Moreland. Descriptive analyses will always include the computation of summary means, standard deviations, and ranges that will be checked to ensure that the results are in keeping with the properties of the measures and to flag and correct invalid entries when found. Once entered and verified for accuracy, data will be backed-up on encrypted hard drives and all data shredded and recycled. This will be done by placing data booklets in specially-designated, locked containers designed for the management of all University confidential data.

Research records of individual participants will be identified by code rather than by participant name or other identifying information (e.g., address, phone number, date of birth, social security number). PI Dr. Moreland will keep a master file containing the names and addresses of participants who are willing to be contacted for the purpose of the follow-up assessments. This master file will be kept in a different room from the data entry rooms. It will be stored in a locked filing cabinet in a room that will itself be locked whenever it is not being used by PI Dr. Moreland. The master file will be destroyed at the end of the study (two years following the end of the last assessment), at which point there will be no way to link names to participants' data code numbers. Data presented at professional meetings or published in journals or books will not allow identification of individual participants.

Interviews will be recorded and saved under the project identification number. All audio recordings from interviews and sessions will be stored in a secure file on the PI's computer. Audio recordings will be transcribed by a professional transcription service and will be coded by the PI and Project Coordinator. Coders and the PI will have access to this data only when coding the information; audio recordings will be destroyed once the coding process is complete.

Data Analytic Plan

This study is an RCT pilot study to examine feasibility and estimate efficacy of the BWCW program for teacher stress reduction. We will randomize 12 ECEs with 12 participants/site to the BWCW and WLC arms (24 ECE sites and 288 participants). **Aim 1** will (**1a**) evaluate the feasibility and implementation of the BWCW program and (**1b**) estimate treatment response and variability at 6 months. Feasibility in **Aim 1a** will be evaluated in the 144 participants randomized to ECEs where the BWCW program is implemented. A sample size of 144 for **1a** allows us to estimate a two-sided 95% confidence interval for all feasibility outcomes with a width no larger than 0.17 and 0.24 respectively. If the lower end of the confidence interval for any feasibility outcome is smaller than 0.5 we will deem the study infeasible. For **Aim 1b**, participant reported stress in both groups will be evaluated at baseline and 6 months using a validated survey instrument and treatment effect will be estimated as the difference between the BWCW and controls in change in stress from baseline to post-BWCW and 6-month follow-up. The model in **1b** will include a fixed effect for treatment group and a random site effect to account for clustering within ECE site. We anticipate approximately 10% loss to follow-up in both study arms and aims at post-BWCW and 6-month follow-up yielding an expected sample size of approximately 129 participants in each arm at 6-month follow-up for Aim 1b. It is also expected that treatment response among participants at the same site will be correlated. Assuming a conservative interclass correlation between participants at the same site of $\rho = 0.2$, the effective sample size for each treatment arm is 40 for **1a**. For **1b** this sample size allows us to estimate a two-sided 95% confidence interval with a distance from the difference in means to within 0.45 standard deviations. The estimated confidence interval widths are conservative as the within site correlation will likely be smaller than 0.2. Most importantly, the results from this pilot study will provide valuable information for planning a future definitive cluster randomized trial of BWCW.

15.0 Risks to Subjects

The two potential risks to participants that may be associated with involvement in the study include: (1) potential threats to confidentiality, particularly with regard to reporting substance use, as well as loss of confidentiality in terms of collected data and subject identity; and (2) potential embarrassment or distress from responding to questions targeting sensitive topics including substance use and past traumatic events. These risks are discussed in greater detail as follows.

First, regarding threats to confidentiality, there may be emotional and/or legal consequences if personal information obtained during the assessment is released to outside parties. That is, mandatory reporting laws necessitate that new disclosures (i.e., previously unreported) of child abuse be reported to the Department of Social Services/DSS. Reports may result in DSS involvement with the family, removal of family members or the child from the home, or criminal charges/arrests. Participants will be informed of these risks of mandatory reporting laws prior to completing the assessments. PI Dr. Moreland, a licensed psychologist, will be immediately informed in such instances. Similarly, if a participant is threatening to hurt herself or someone else, confidentiality may have to be broken to make a report to necessary authorities.

The second potential risk of the proposed study is the possibility that some participants might experience distress when asked questions pertaining to substance use or past traumatic events. Many people assume that asking such questions produces substantial distress, particularly in research settings. However, our prior clinical research experience, as well as the empirical literature, suggest that the risk is minimal, and that individuals actual report obtaining positive benefits from their participation in studies using assessment instruments similar to the ones proposed. Procedures to protest against this risk are described in more detail below. Nonetheless, protocols are in place in the unlikely event that participants become significantly distressed during the assessment or program process.

16.0 Potential Benefits to Subjects or Others

Benefits of this study include potential benefit of information to the field. Although there is a small reimbursement for participants, we do not believe that this small reimbursement constitutes a substantial benefit for participation.

17.0 Sharing of Results with Subjects

Results will not be shared with subjects.

References

1. Biglan, A., Flay, B. R., Embry, D. D., & Sandler, I. N. (2012). The critical role of nurturing environments for promoting human well-being. *American Psychologist, 67*(4), 257.
2. Britto, P. R., Lye, S. J., Proulx, K., Yousafzai, A. K., Matthews, S. G., Vaivada, T., . . . Fernald, L. C. (2017). Nurturing care: promoting early childhood development. *The Lancet, 389*(10064), 91-102.
3. Shonkoff, J. P., Radner, J. M., & Foote, N. (2017). Expanding the evidence base to drive more productive early childhood investment. *The Lancet, 389*(10064), 14-16.
4. Burgess, K., Chien, N., Morrissey, T., & Swenson, K. (2014). Trends in the use of early care and education, 1995-2011. *US Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation*.
5. Chazan-Cohen, R., Zaslow, M., Raikes, H. H., Elicker, J., Paulsell, D., Dean, A., & Kriener-Althen, K. (2017). *Working toward a definition of infant/toddler curricula: Intentionally furthering the development of individual children within responsive relationships*. Retrieved from
6. Ritblatt, S. N., Hokoda, A., & Van Liew, C. (2017). Investing in the early childhood mental health workforce development: enhancing professionals' competencies to support emotion and behavior regulation in young children. *Brain sciences, 7*(9), 120.
7. Cassidy, B. S., Sprout, G. T., Freeman, J. B., & Krendl, A. C. (2017). Looking the part (to me): effects of racial prototypicality on race perception vary by prejudice. *Social Cognitive and Affective Neuroscience, 12*(4), 685-694.
8. Mortensen, J. A., & Barnett, M. A. (2016). The role of child care in supporting the emotion regulatory needs of maltreated infants and toddlers. *Children and youth services review, 64*, 73-81.
9. Hamre, B. K., & Pianta, R. C. (2004). Self-reported depression in nonfamilial caregivers: Prevalence and associations with caregiver behavior in child-care settings. *Early Childhood Research Quarterly, 19*(2), 297-318.
10. Manlove, E. E., Vazquez, A., & Vernon-Feagans, L. (2008). The quality of caregiving in child care: Relations to teacher complexity of thinking and perceived supportiveness of the work environment. *Infant and Child Development: An International Journal of Research and Practice, 17*(3), 203-222.
11. Shin, H., & Rhee, U. (2005). Effects of teachers' job stress and belief of efficacy on the quality of teachers' interaction behaviors in child care. *Korean Journal of Child Studies, 26*(5), 105-121.
12. Carson, R. L., Baumgartner, J. J., Matthews, R. A., & Tsouloupas, C. N. (2010). Emotional exhaustion, absenteeism, and turnover intentions in childcare teachers: Examining the impact of physical activity behaviors. *Journal of Health Psychology, 15*(6), 905-914.
13. Hong, K.-H., & Jung, H. (2013). Effect of preschool teacher's job stress and depression on burnout: Focusing on the moderating effect of depression. *Korean Journal of Childcare and Education, 9*(1), 263-280.
14. Stormont, M., & Young-Walker, L. (2017). Supporting professional development needs for early childhood teachers: an exploratory analysis of teacher perceptions of stress and challenging behavior. *International Journal on Disability and Human Development, 16*(1), 99-104.

15. Todd, C. M., & Deery-Schmitt, D. M. (1996). Factors affecting turnover among family child care providers: A longitudinal study. *Early Childhood Research Quarterly, 11*(3), 351-376.
16. Porter, G. W., King, J. A., Goodkin, N. F., & Chan, C. K. (2012). Experiential Learning in a Common Core Curriculum: Student Expectations, Evaluations, and the Way Forward. *International Education Studies, 5*(3), 24-38.
17. Clipa, O., & Boghean, A. (2015). Stress factors and solutions for the phenomenon of burnout of preschool teachers. *Procedia-Social and Behavioral Sciences, 180*, 907-915.
18. Hall-Kenyon, K. M., Bullough, R. V., MacKay, K. L., & Marshall, E. E. (2014). Preschool teacher well-being: A review of the literature. *Early Childhood Education Journal, 42*(3), 153-162.
19. Lessard, L. M., Wilkins, K., Rose-Malm, J., & Mazzocchi, M. C. (2020). The health status of the early care and education workforce in the USA: a scoping review of the evidence and current practice. *Public Health Reviews, 41*(1), 1-17.
20. Badanes, L. S., Dmitrieva, J., & Watamura, S. E. (2012). Understanding cortisol reactivity across the day at child care: The potential buffering role of secure attachments to caregivers. *Early Childhood Research Quarterly, 27*(1), 156-165.
21. Lisonbee, J. A., Mize, J., Payne, A. L., & Granger, D. A. (2008). Children's cortisol and the quality of teacher–child relationships in child care. *Child Development, 79*(6), 1818-1832.
22. Council, N. R. (2000). *From neurons to neighborhoods: The science of early childhood development*: National Academies Press.
23. Fox, S. E., Levitt, P., & Nelson III, C. A. (2010). How the timing and quality of early experiences influence the development of brain architecture. *Child Development, 81*(1), 28-40.
24. Keenan, K., & Wakschlag, L. S. (2000). More than the terrible twos: The nature and severity of behavior problems in clinic-referred preschool children. *Journal of Abnormal Child Psychology, 28*(1), 33-46.
25. Keenan, K., Shaw, D., Delliquadri, E., Giovannelli, J., & Walsh, B. (1998). Evidence for the continuity of early problem behaviors: Application of a developmental model. *Journal of Abnormal Child Psychology, 26*(6), 441-452.
26. Zahn-Waxler, C., Iannotti, R. J., Cummings, E. M., & Denham, S. (1990). Antecedents of problem behaviors in children of depressed mothers. *Development and Psychopathology, 2*(3), 271-291.
27. Campbell, S. B., & Ewing, L. J. (1990). Follow-up of hard-to-manage preschoolers: Adjustment at age 9 and predictors of continuing symptoms. *Journal of child psychology and psychiatry, 31*(6), 871-889.
28. National Center for Education Statistics. (2018). *Enrollment of 3-, 4-, and 5-year olds in preprimary programs*. Retrieved from https://nces.ed.gov/programs/digest/d17/tables/dt17_202.10.asp
29. Howes, C. (2000). Social-emotional classroom climate in child care, child-teacher relationships and children's second grade peer relations. *Social development, 9*(2), 191-204.
30. Reyes, M. R., Brackett, M. A., Rivers, S. E., White, M., & Salovey, P. (2012). Classroom emotional climate, student engagement, and academic achievement. *Journal of Educational Psychology, 104*(3), 700.
31. Gerber, E. B., Whitebook, M., & Weinstein, R. S. (2007). At the heart of child care: Predictors of teacher sensitivity in center-based child care. *Early Childhood Research Quarterly, 22*(3), 327-346.
32. Skinner, E. (2018). Children's Developmental Needs During the Transition to Kindergarten: What Can Research on Social-Emotional, Motivational, Cognitive, and Self-Regulatory Development Tell Us? In *Kindergarten Transition and Readiness* (pp. 31-57): Springer.
33. Whitaker, R. C., Dearth-Wesley, T., Gooze, R. A., Becker, B. D., Gallagher, K. C., & McEwen, B. S. (2014). Adverse childhood experiences, dispositional mindfulness, and adult health. *Preventive Medicine, 67*, 147-153.

34. Castle, S., Williamson, A. C., Young, E., Stubblefield, J., Laurin, D., & Pearce, N. (2016). Teacher–child interactions in early head start classrooms: Associations with teacher characteristics. *Early Education and Development, 27*(2), 259-274.
35. Hossain, Z., Noll, E., & Barboza, M. (2012). Caregiving involvement, job condition, and job satisfaction of infant-toddler child-care teachers in the United States. *Education Research International, 2012*.
36. Kinman, G., Wray, S., & Strange, C. (2011). Emotional labour, burnout and job satisfaction in UK teachers: The role of workplace social support. *Educational Psychology, 31*(7), 843-856.
37. Klassen, R. M., & Chiu, M. M. (2010). Effects on teachers' self-efficacy and job satisfaction: Teacher gender, years of experience, and job stress. *Journal of Educational Psychology, 102*(3), 741.
38. Jennings, P. A., & Greenberg, M. T. (2009). The prosocial classroom: Teacher social and emotional competence in relation to student and classroom outcomes. *Review of educational research, 79*(1), 491-525.
39. Spilt, J. L., Koomen, H. M., & Thijs, J. T. (2011). Teacher wellbeing: The importance of teacher–student relationships. *Educational Psychology Review, 23*(4), 457-477.
40. Trawick-Smith, J., & Dziurgot, T. (2011). 'Good-fit'teacher–child play interactions and the subsequent autonomous play of preschool children. *Early Childhood Research Quarterly, 26*(1), 110-123.
41. Burchinal, M., Howes, C., Pianta, R., Bryant, D., Early, D., Clifford, R., & Barbarin, O. (2008). Predicting child outcomes at the end of kindergarten from the quality of pre-kindergarten teacher–child interactions and instruction. *Applied Development Science, 12*(3), 140-153.
42. Downer, J., Sabol, T. J., & Hamre, B. (2010). Teacher–child interactions in the classroom: Toward a theory of within-and cross-domain links to children's developmental outcomes. *Early Education and Development, 21*(5), 699-723.
43. Mashburn, A. J., Pianta, R. C., Hamre, B. K., Downer, J. T., Barbarin, O. A., Bryant, D., . . . Howes, C. (2008). Measures of classroom quality in prekindergarten and children's development of academic, language, and social skills. *Child Development, 79*(3), 732-749.
44. Tang, C. S. K., Au, W. T., Schwarzer, R., & Schmitz, G. (2001). Mental health outcomes of job stress among Chinese teachers: Role of stress resource factors and burnout. *Journal of Organizational Behavior: The International Journal of Industrial, Occupational and Organizational Psychology and Behavior, 22*(8), 887-901.
45. Lambert, R., O'Donnell, M., Kusherman, J., & McCarthy, C. J. (2006). Teacher stress and classroom structural characteristics in preschool settings. *Understanding teacher stress in an age of accountability, 111*, 105-120.
46. Buscemi, J., Kanwischer, K., Becker, A. B., Ward, D. S., Fitzgibbon, M. L., & Committee, S. o. B. M. H. P. (2015). Society of Behavioral Medicine position statement: early care and education (ECE) policies can impact obesity prevention among preschool-aged children. *Translational Behavioral Medicine, 5*(1), 122-125.
47. Esquivel, M. K., Nigg, C. R., Fialkowski, M. K., Braun, K. L., Li, F., & Novotny, R. (2016). Influence of teachers' personal health behaviors on operationalizing obesity prevention policy in head start preschools: a project of the Children's Healthy Living Program (CHL). *Journal of Nutrition Education and Behavior, 48*(5), 318-325. e311.
48. Hendy, H., & Raudenbush, B. (2000). Effectiveness of teacher modeling to encourage food acceptance in preschool children. *Appetite, 34*(1), 61-76.
49. Abenavoli, R. M., Jennings, P. A., Greenberg, M. T., Harris, A. R., & Katz, D. A. (2013). The protective effects of mindfulness against burnout among educators. *Psychology of Education Review, 37*(2), 57-69.
50. Roeser, R. W., Schonert-Reichl, K. A., Jha, A., Cullen, M., Wallace, L., Wilensky, R., . . . Harrison, J. (2013). Mindfulness training and reductions in teacher stress and burnout: Results

from two randomized, waitlist-control field trials. *Journal of Educational Psychology, 105*(3), 787.

51. Schussler, D. L., Jennings, P. A., Sharp, J. E., & Frank, J. L. (2016). Improving teacher awareness and well-being through CARE: A qualitative analysis of the underlying mechanisms. *Mindfulness, 7*(1), 130-142.