Official Title: Survivor Moms' Companion: A Perinatal Post-Traumatic Stress Disorder Program

Unique Protocol ID: STUDY00007685

Date: 8/28/2023

## BACKGROUND/RATIONALE

Posttraumatic stress disorder (PTSD) related to maltreatment is a strong predictor of intergenerational cycles of abuse and vulnerability. These cycles intersect during the childbearing years when unresolved trauma often adversely affects a woman's mental health. Women of color are especially at risk for developing PTSD as well experiencing disparities related to maternal and infant morbidity and mortality. Pregnancy is an opportune time to intervene to disrupt these cycles, however, screening and treating PTSD in the perinatal period is rarely undertaken. Therefore, readily available interventions for low-resourced and high-risk settings are warranted. Our agency, Buffalo Prenatal Perinatal Network (BPPN) provides home visiting and other supportive services to pregnant women and their families who bear considerable burden of poverty, adversity, and disparities. As such, we are well positioned to conduct research to address perinatal PTSD. Our previous research has established initial acceptability and feasibility for a novel front-line PTSD-specific perinatal intervention, the *Survivor Moms' Companion (SMC)*. In the proposed study, we will advance this trajectory of research and build our capacity for mental health service provision by conducting an initial randomized controlled pilot study.

### PTSD and the Childbearing Year

In the U.S. and globally, approximately 20% of women experience sexual violence and other forms of maltreatment, including childhood physical, sexual, emotional abuse and neglect.[1-3] Unresolved reactions to trauma can manifest as PTSD and its complex forms or comorbidities.[4] Rates of childhood trauma exposure may be even higher in pregnancy, with 35% of pregnant women reporting at least one type of childhood abuse or neglect.[5] As a result, PTSD incidence is higher during pregnancy (8%) than at any other time during the lifespan (5%),[4] and increases risk for adverse outcomes including lower birth weight and shorter gestation,[6-8] less breastfeeding,[9,10] postnatal PTSD and depression,[11] impaired bonding,[12,13] less sensitive parenting,[14] a dysregulated infant,[15,16] and more protective service involvement.[17] This affirms the need to address PTSD with trauma-exposed mothers in order to help prevent negative intergenerational effects.[18, 19]

### Disparities in Risk

African American families in particular are disproportionately affected by maternal and infant morbidity and mortality.[20] However, pregnancy PTSD remains an understudied area of health disparity. African American women bear a four-fold greater rate of PTSD in pregnancy compared to all other groups (13.4% vs. 3.5%).[4] This is likely due to disproportionate exposure to racism, discrimination, and violence. In prior research by our team, this disparity was evidenced in multivariate models that took race/ethnicity and maltreatment-related PTSD into account, finding PTSD was a significantly stronger predictor of shorter gestational age than African American race and was a nearly equal predictor of decrements in birthweight.[6] Therefore, addressing PTSD with pregnant African American women has the potential to reduce disparities in prematurity.

### Addressing Perinatal PTSD

Addressing trauma and PTSD has been identified as a public mental health priority.[21-23] However, currently in the U.S., maternity services focus on depression and do not address PTSD, despite there being a high rate of comorbidity between perinatal depression and PTSD (~50%)[4]. Although there are some existing programs for women with maltreatment histories,[24-36] these have not been designed to address the specific needs of those with PTSD in the perinatal period and are not integrated in maternity care. Further, treatment of PTSD during pregnancy is hindered by several potential barriers including the lack of screening, lack of readily available behavioral health resources, stigma around seeking help, lack of cultural consideration, unacceptability due to navigating simultaneous demands of pregnancy, transportation, child care, and the high cost of mental health counseling.[38-40] Our proposed research provides opportunity to evaluate the first intervention specifically designed to address PTSD in pregnant women, the *Survivor Moms' Companion*.

The *SMC* is designed for low-resourced settings and includes provision of information regarding the negative effects of PTSD during the perinatal period, incorporates skill building for managing traumatic reactions, and provides emotional support via client/interventionist discussion sessions. The *SMC* utilizes best practices for behavioral therapies development[41] including that it: (a) was designed with input from target clients and clinicians, (b) is manualized per NIH workgroup best practices for behavioral interventions, and (c) has strong support for acceptability in preliminary studies.[42-45] The *SMC* focuses on helping women manage PTSD symptoms in the presence of specific childbearing triggers, such as fear of labor pain, and promotes maternal development by anticipating parenting concerns, such as feelings elicited in response to infant crying. The

*SMC* is also designed to target theorized mechanisms that maintain PTSD,[46, 47] including intrusive re-experiencing, hyperarousal, avoidance, and emotion dysregulation and interpersonal sensitivity.

Our team conducted an initial pre- to post-test pilot of the *SMC* at BPPN from June 2018 to December 2019.[45] Ahead of implementation we engaged in community-based participatory research to optimize the *SMC* for our specific context. We recruited 56 women to the pilot; our sample included majority African American (57%), European American (18%), Latinx American (21%), Asian American (2%) women, and those identifying more than one race/ethnicity (9%).[45] The entire sample struggled with poverty, and the vast majority reported having experienced 4 or more childhood adversities,[45] which has been identified as placing individuals at high-risk for a variety of poor physical and mental health outcomes.[48] All participants had clinically significant PTSD.[45]

**Table 1:** Pre-posttest results of the *Survivor Moms' Companion* initial pilot study at BPPN in Buffalo, NY

| Measure | n | M | SE | P |
|---|---|---|---|---|
| PTSD symptom severity (PCL-5), range 0-80[a] | 56 | | | |
| Pretest | | 38.98 | 2.54 | <.001 |
| Posttest | | 23.69 | 1.91 | |
| Depression (EPDS), range 0-30[b] | 56 | | | |
| Pretest | | 14.20 | 0.83 | <.001 |
| Posttest | | 9.15 | 0.64 | |
| Anger (STAXI-AX), range 0-24[c] | 56 | | | |
| Pretest | | 18.02 | 0.93 | .02 |
| Posttest | | 16.12 | 0.65 | |
| Interpersonal Sensitivity (SCL-90), range 0-36[d] | 56 | | | |
| Pretest | | 17.73 | 1.40 | <.001 |
| Posttest | | 10.11 | 0.90 | |

[a] PTSD Checklist for DSM-5[74]
[b] Edinburgh Postnatal Depression Scale[75]
[c] State Trait Anger Expression Inventory[73]
[d] Symptoms Checklist-90 Revised/Interpersonal Sensitivity Subscale[76]

Intent-to-treat analyses (**Table 1**) showed improvements in PTSD symptom severity, interpersonal reactivity, and two indicators of affect dysregulation: anger expression and depression.[45] The findings were also *clinically* important; for the per protocol sample at pretest, 25 individuals had symptom severity scores indicating they were in the clinical range for meeting PTSD diagnosis; at posttest, only 9 of those individuals remained in clinical range.[45] Qualitative analysis found the *SMC* was highly acceptable, with the majority of clients indicating they would do it again if given a chance and would recommend it to others. They expressed appreciation in a variety of ways, including that "the *SMC* made me realize that not all has to be looked at in a negative way," and that "without the support I got from BPPN and the *SMC*, I don't know how I would have gotten through with this pregnancy."

Given the burden of PTSD among our clients, and these promising results,[42-45] we propose a pilot randomized trial as the next logical step toward evaluating the *SMC*. We also wish to expand and improve our capacity to continue to conduct clinical research and to deliver and sustain the *SMC* through dedicating staff exclusively to the delivery and maintenance of the program.

**Relevance**

This proposed study is relevant for the following reasons: 1) it is designed to meet the needs of the 1 in 5 pregnant women with a childhood maltreatment history; 2) it has the potential to reduce perinatal racial disparities related to PTSD symptomatology and poor outcomes; 3) it advances PTSD-specific care in the perinatal period; 4) it has strong theoretical underpinnings; 5) and it has the potential to play a significant role in preventing potential childhood adversity. Finally, this study will provide for the sustainability of the *SMC* at BPPN and help address the needs of our at-risk clients. Positive findings from this preliminary efficacy trial would advance the evidence base for the *SMC* and holds promise as a first step toward addressing intergenerational negative outcomes that result from maternal PTSD.

**Proposal Aims**

Our specific research aims are:

**Aim 1:** Examine feasibility of the *SMC* by tracking participant engagement, accrual, and retention rates.

**Aim 2:** Evaluate the preliminary efficacy of the *SMC* for reducing PTSD symptomatology as compared to the waitlist control group. **Hypothesis:** At posttest, intent to treat analyses will show that participants in the *SMC* intervention condition will have significantly lower levels of PTSD symptomatology as compared with participants in the waitlist control group.

**Aim 3:** Assess acceptability of the *SMC* through post-intervention assessment feedback and evaluation of lost-to-follow-up rates.

**Aim 4:** This exploratory aim will examine how changes in the theorized targeted mechanisms (i.e., emotion regulation, and interpersonal sensitivity) mediate the relationship between the intervention and PTSD symptomatology. **Hypothesis:** At posttest, intent to treat analyses will show that participants in the *SMC*

intervention condition will have lowered levels of emotion dysregulation and interpersonal sensitivity as compared with participants in the waitlist control group.

## RESEARCH ACTIVITIES

### Study Overview

To achieve these aims, we will conduct a pilot randomized controlled trial. For Aim 1, we will assess feasibility of the *SMC* intervention through tracking and close monitoring of participant engagement, accrual, and retention rates. For Aim 2, we will conduct baseline assessments for all participants for trauma, PTSD diagnosis and symptoms, affect regulation including depression, anger expression, dissociation, and emotion regulation, as well as interpersonal sensitivity. We will then randomize participants to either the *SMC* intervention group or to the waitlist control group. Those in the *SMC* intervention (n = 30) will receive a minimum of 4 *SMC* modules and corresponding weekly sessions with an interventionist prior to completing the post-intervention assessment. Those in the waitlist control (n = 30) will complete a post-intervention assessment at 6 weeks following their baseline assessment and will then be offered the *SMC* intervention. We will use intent-to-treat analyses to evaluate the preliminary efficacy of the *SMC* for reducing PTSD. For Aim 3, we will examine post-intervention indices of client satisfaction and evaluation of drop-out rates. For Aim 4, we will examine how changes in the theorized targeted mechanisms mediate the relationship between the *SMC* intervention and PTSD. We will utilize knowledge gained to prepare applications for continued evaluation of the impact and implementation of *SMC*. Prior to beginning any study activities, we will apply for approval with the Institutional Review Board (IRB) at the University at Buffalo and will require human subjects training for all study team members through the Collaborative Institutional Training Initiative (CITI Program).[49]

### Participants

***Recruitment Site and Sample Size.*** We will recruit pregnant participants at BPPN, which provides services to over 800 families per year; services begin in pregnancy and include screening for risk factors and stressors and supportive home-based services. Consistent with the NIH-wide initiative to increase diversity in research, recruiting at BPPN ensures representation of women of color. Based on the previous *SMC* pilot studies,[43, 45] we expect that 30% who initially consent to the study will not complete the full 4 intervention sessions. We plan to enroll and randomize 78 participants to retain 60 (30 *SMC*, 30 waitlist control).

***Eligibility Criteria.*** Inclusion criteria are: (1) English-speaking, (2) currently pregnant and after 12 weeks but before 30 weeks gestation to allow for study completion prior to expected delivery, (3) aged 18 and older, (4) a history of trauma and PTSD, (5) able to comprehend the study protocol, consent form and provide written consent, and (6) able to commit to a minimum of 4 weekly intervention sessions. Exclusion criteria are: (1) non-English-speaking, (2) less than 18 years of age, (3) those with psychotic conditions or developmental disabilities requiring guardianship, (4) those with high-risk pregnancies necessitating extended bedrest or inpatient care, and (5) those unable to commit to completing the intervention sessions.

### Study Procedures

*For Aim 1*, we will maintain a master tracking file that indicates mode of invitation (handouts or flyers, word of mouth), screening and determination of eligibility, random assignment to *SMC* or waitlist control, receipt of informed consent, mode of delivery (in-person or by telehealth), and completion of assessments and intervention sessions. We will also track *SMC* uptake for waitlist controls, who will be invited to begin the *SMC* 6 weeks following baseline and immediately following the post-intervention assessment. We will enroll 3-4 participants per week (divided between intervention and control groups) during the active recruitment period.

*For Aim 2,* our procedures include baseline assessment for all participants, randomization to *SMC* or the waitlist control group, provision of a minimum of 4 *SMC* sessions for those in the *SMC* intervention arm, and post-intervention assessments (for both *SMC* and waitlist control groups).

*For Aim 3,* we will assess the acceptability of the *SMC* through post-intervention assessment feedback and through evaluation of lost-to-follow-up rates.

*For Aim 4,* we will examine how changes in the theorized targeted mechanisms mediate the relationship between the intervention and PTSD symptomatology, using the same assessment data utilized for Aim 2.

***Recruitment Strategy.*** We will disseminate study information to all BPPN clients through informational handouts and fliers. Those interested will be invited to contact the licensed master social worker (LMSW) for screening. Women who meet all inclusion criteria and no exclusion criteria will be provided with a detailed explanation of the study, and will be encouraged to ask questions prior to providing written consent. They will then be invited to complete the baseline assessment with the LMSW. Once baseline assessment is completed, participants will be: 1) randomized to the *SMC* or waitlist control arm in a 1:1 fashion using a block randomization scheme, 2) will be mailed the *SMC* materials and 3) be assigned to the community health

worker (CHW) who will contact the participant and arrange the first session, either in-person or remotely according to the participant's preference. Consent forms will outline remuneration for each aspect of the study ($30 for the baseline and $40 for the post-intervention assessments).

**Structure of *SMC.*** Weekly client modules with embedded worksheets will facilitate and guide practice of skills specific to addressing PTSD in the perinatal period. Weekly intervention sessions will center on reinforcement of information introduced in each *SMC* module, emotional support, and referrals to additional services or specialists as needed. A key activity of each session is to practice applying knowledge and skills using the module's vignettes. Process guides prompt inquiry about *in vivo* management of PTSD reactions, and emotional and interpersonal reactions to events since the last session. Based on previous work, we anticipate each module will require 45 minutes of self-study prior to each session and 45 minutes of in-session time spent with the interventionist. This weekly commitment was highly acceptable in prior pilot efforts.

**Intervention Team.** We will hire and train a half-time LMSW to facilitate consent processes, complete baseline and post-intervention assessments, bill for services and provide regular clinical supervision, and will hire a full-time CHW to deliver the *SMC*. Both the LMSW and CHW will have experience working in perinatal health and will undergo 40 hours of training with PI Sperlich on the *SMC*. Supervised training will include review of the module content, role-playing of sessions, and fidelity to the *SMC* manual.

**Intervention Integrity and Safety.** A detailed treatment manual for the *SMC* will guide the content and flow of the sessions, and we will regularly assess for fidelity. At the end of each session, we will employ brief 'mirror image' fidelity checklists which will be completed separately by the CHW and participant. In preliminary studies these forms reached an inter-rater agreement of >94%. Co-PI Sperlich will review these weekly for inter-rater agreement and intervene if necessary. The sessions include monitoring of suicidality, substance use, and domestic violence. In instances where a participant expresses these concerns, the CHW and/or licensed social worker will notify the Co-PIs, who will initiate referral protocols to psychiatric, substance abuse, or domestic violence urgent care, as appropriate. The team will review each case in light of adverse event definitions and report any adverse events to the UB IRB.

**Table 2: Study Measures**

| Measure | Eligibility | Baseline | During Intervention (5 weeks) | Post-Intervention |
|---|---|---|---|---|
| Eligibility | | | | |
| Demographics/Background Questionnaire | X | | | |
| Childhood Trauma Questionnaire (CTQ)[50] | X | | | |
| Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)[51] | X | | | |
| Adversity/PTSD Outcomes | | | | |
| Adverse Childhood Experiences Questionnaire (ACE)[48] | | X | | |
| PTSD Checklist for DSM-5 (PCL-5)[52] | | X | | X |
| Dissociative Subtype of PTSD Scale (DSPS)[53] | | X | | X |
| Theorized Mechanisms of Change | | | | |
| Patient Health Questionnaire-9 (PHQ-9)[54] | | X | | X |
| State Trait Anger Expression Inventory (STAXI-AX)[55] | | X | | X |
| Symptoms Checklist-90 Revised/Interpersonal Sensitivity Subscale (SCL-90/IPS)[56] | | X | | X |
| Difficulties in Emotion Regulation Scale Short Form (DERS)[57] | | X | | X |
| Treatment Attendance, Satisfaction, Distress | | | | |
| Number of Completed Modules/Sessions | | | X | |
| Client Satisfaction Questionnaire (CSQ-8)[58] | | | | X |
| Fidelity Checklist | | | X | |
| Subjective Units of Distress (SUD)[59] | | | X | |

**Measures**

We plan to use reliable and valid measures, these and their schedule of use are listed in **Table 2**. **For eligibility screening** we will use the 5 sentinel items from the Childhood Trauma Questionnaire (CTQ),[50] and the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5).[51] **For the baseline assessment** we will assess trauma exposures, PTSD and its dissociative subtype, and measurements related to the theorized mechanisms of change, including for affect regulation and interpersonal sensitivity. All of these will be repeated at the **post-intervention assessment.** Also, at post-intervention, participants in the *SMC* arm will complete the

Client Satisfaction Questionnaire (CSQ-8), [58] and invite feedback regarding perception and experience of in-person vs telehealth sessions based on their choice of modality. For those in the *SMC* arm we will utilize two measures during each weekly intervention session: *SMC* fidelity checklists, as well as Subjective Units of Distress (SUD).[59] The SUD will be assessed on a 0-10 scale by asking the participant to rate any distress experienced ahead of session, at mid-session, and at the close of the session. Those with SUD rating of 5 or above at the session's end will be encouraged to participate in a brief relaxation exercise until their rating is reduced to 4 or lower. All who complete baselines and are randomized will be scheduled for the post-assessment; those who fail to complete will be scheduled based on their anticipated completion date.

**Proposed Analysis**

***Data Quality Management.*** Biostatistician Wilding and PI Sperlich will oversee data collection, management, and storage using UB's established IT infrastructure. A created Data Management Plan will track any critical milestones and data review activities. A full study build will be implemented with use of REDCap[60] and all necessary electronic case report forms (eCRFs) will be created in direct contact with relevant study personnel. Rigorous quality control procedures will be implemented so as to ensure data integrity.

***Effect Size and Power Calculations.*** Because data will be generated as part of a pilot case-control study, our hypotheses should be viewed as exploratory. Analyses will be conducted to not only test the predictions, but also to examine effect sizes. If effects are clinically meaningful, effect sizes will be used to inform power calculations for a larger, planned Stage II clinical trial.

***Data Analyses.*** The amount and nature of missing data for study variables will be characterized and no method of imputation will be used for missing data for primary analyses. The robustness of primary results will be assessed using several statistical techniques including multiple imputation. Outcome variables will be summarized overall and by relevant demographic and baseline variables. Descriptive statistics will be computed for all categorical variables. Numeric variables will be summarized using mean, standard deviation and range. Statistical tests will be carried out using SAS version 9.4 (or higher) statistical software (Cary, NC).

***Aim 1 Analyses.*** Feasibility will be assessed via timely recruitment of participants, and through high study retention (70%). This will be carefully tracked and monitored closely by the Co-PIs.

***Aim 2 Analyses.*** To describe the observed variability in the data and test for differences between groups, a linear mixed model will be fit to each considered outcome at each post-baseline measurement. Each outcome will be modeled as a function of randomized group assignment and the baseline value of the outcome variable, both treated as fixed effects. Once the model is fit, a linear contrast based on the estimated model parameters will be constructed and used to test for the overall effect of random assignment using an approximate F-test as implemented by SAS PROC MIXED. A point estimate and corresponding confidence interval to quantify group differences will be provided. Subject-level covariates predictive of outcome and their interactions with randomized assignment, such as modality (in-person vs telehealth) will be added to the models as a series of supportive analyses. To evaluate the robustness of initial analysis results, these models will be moreover used to evaluate the group effect within subgroups. Analyses will be conducted using intent-to-treat. All tests will be two-sided and tested at a 0.05 nominal significance level. Standard diagnostic plots will assess model fit and transformations of variables may be considered to meet statistical assumptions.

***Aim 3 Analyses.*** We will examine acceptability of the *SMC* by evaluating the percentage of completion and drop-out rates as compared to similar PTSD treatments[46] and through analysis of the CSQ scores[58]

**Aim 4 Analyses.** We hypothesized that the effect of the intervention on PTSD symptomatology is mediated by emotion regulation and interpersonal sensitivity, that is, that there is a direct and indirect effect of the *SMC* on PTSD symptomatology. A generalized linear model-based approach will be utilized. After establishing the total effect of the *SMC* on PTSD symptomatology in the context of the unmediated model of Aim 2, the effects of the intervention on the theorized targeted mechanisms will be estimated. This will be followed by the conduct of a multiple regression analysis with each of the factors (considered one at a time) and the *SMC* as independent variables in the prediction of PTSD symptomatology. This approach allows for estimation of the direct and indirect effects. The 95% confidence intervals for mediated effects will be based on bias-corrected bootstrap methods, which uses the cumulative distribution functions of the bootstrap parameter estimates to determine the upper and lower endpoints of the confidence intervals. The percentages mediated of total effect of the *SMC* on PTSD symptomatology will be calculated. Additional analyses with interaction terms between the *SMC* with emotion regulation and interpersonal sensitivity will be conducted and compared.

## OUTCOMES/IMPACT

The SMC holds promise for addressing the needs of pregnant women with PTSD and bridges the gap between maternity health and mental health care. Our study aims to assess the feasibility, acceptability and initial

efficacy of the intervention for reducing PTSD symptomatology among pregnant women. If successful, these findings could be used to inform testing of the intervention in a Stage II randomized clinical trial to determine efficacy. Our long-term goal is to develop a brief, evidence-based intervention that addresses perinatal PTSD, thus improving health outcomes for pregnant women with PTSD and their children. This has the potential to significantly advance treatment for perinatal PTSD and disrupt cycles of abuse and psychiatric vulnerability.

Provision of the *SMC* at BPPN is closely aligned with our overall mission to improve maternal and infant health for women and families in our catchment area and is fully aligned with the IMPROVE program's mission to reduce maternal health disparities. This project will help us expand and improve our capacity to continue to conduct clinical research at BPPN and to deliver and sustain the *SMC* with our at-risk clients, providing potential benefits to pregnant women and also to their infants.

## RISKS/BLOCKERS AND MITIGATION STRATEGIES

A potential risk to the success of this research would be a lag in sample recruitment. However, as BPPN serves 800 families annually, we anticipate success in meeting our targeted goal of enrolling 78 to retain 60 participants. However, it will be critical to maintain regular contact with all study participants to encourage their participation in all phases of the project (i.e., baseline assessment, intervention, and post-intervention assessments). If necessary, we can pivot our recruitment efforts to reach more broadly into the community using established partner networks through BPPN to identify additional study sites.

Another potential risk/blocker would be any threats to intervention integrity. To mitigate this risk, Co-PI Sperlich will monitor the fidelity checklists for inter-rater agreement between client and interventionist versions; those with less than substantial agreement (Kappa < .80) will necessitate remedial interventionist training. PI Sperlich will focus on intervention adherence, competent delivery of the interventions in the weekly team meetings and will provide corrective feedback as needed. To promote intervention integrity, treatment sessions may be monitored through audiotaping (with written participant permission) allowing Sperlich to separately rate the session. There will be a shift to 100% monitoring of sessions and coaching if significant departures are noted.

## EXPERTISE AND RESOURCES

PI LuAnne Brown, Chief Executive Officer at BPPN, oversees the two flagship programs at BPPN, including the national evidence-based Healthy Families Home Visiting Program, and the Maternal Infant Community Health Collaborative. Brown has extensive previous relevant experience, including serving as Vice President and Chief Nursing Officer at Women and Children's Hospital of Buffalo, and as Director of their Maternal Neonatal services. BPPN's overall mission is to promote equity and honor the dignity of all women, fathers, and families and to provide education, support, advocacy, and connection to community services in Western New York. It currently employs 53 staff to serve a predominately Black and Hispanic population residing in 21 zip codes identified as high-risk due to poor infant mortality and morbidity rates and inadequacy of prenatal care. BPPN's facilities include meeting rooms equipped with audio-visual equipment and phones for the duration of the study, as well as computers with internet access and Microsoft Office suite.

Co-PI Sperlich, Assistant Professor at the UB School of Social Work, has been conducting research on trauma and its effects on childbearing processes for over 20 years. In addition to being a co-creator of the *SMC*, she has been involved with other cutting-edge research characterizing the prevalence and effects of perinatal PTSD. She has experience in the conduct of clinical research, data analysis, and ethical response to research with vulnerable human subjects. Together, Brown and Sperlich have successfully previously piloted the *SMC* at BPPN and have collaborated on other projects in the community, including a project with United Way of Erie County to provide training on trauma informed care to local obstetric providers.

Co-I Wilding is a statistician with extensive expertise in the design of pilot randomized clinical trials, clinical trials, permutation tests, resampling techniques, goodness-of-fit tests, and distributional characterizations. He directs the Biostatistics, Epidemiology, and Research Design Core of the UB Clinical and Translational Science Institute where he oversees the statistical efforts as it pertains to associated interdisciplinary clinical and non-clinical research projects. Co-PI Sperlich and Biostatistician Wilding will utilize resources at UB, including the Buffalo Center for Social Research (BCSR) and the UB Department of Biostatistics. The BCSR has 4,000 sq. ft. of office and interview space for project utilization, and provides infrastructure to assist investigators in their research studies, promotes and supports interdisciplinary collaboration, and disseminates research findings into the community and clinical practice. In addition, the BCSR coordinates effort with the UB Department of

Biostatistics to facilitate secure capture and storage of sensitive data, utilizing such resources as REDCap, which is a secure web application for building and managing online surveys and databases.[60]