Open Pilot Trial of a Resiliency Group Program for Caregivers of Children with Learning and Attentional Difficulties

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Study Protocol and Statistical Analysis Plan (English-language Version)

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Intervention/Interaction Detailed Protocol

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1. Background and Significance

Caregivers of children with LAD are a growing population, at risk for deleterious consequences of chronic stress. There is a growing population of children with LAD.[1,2] Specific learning disabilities are characterized by difficulties understanding or in using spoken or written language, or difficulties with reading, writing, listening, speaking, reasoning, or math.[3] Attentional disorders are characterized by difficulty with ongoing inattention and/or hyperactivity that interferes with functioning.[4] Having a child with a learning and attentional disorder (LAD) presents distinct challenges and stressors which can impact the mental and physical health of parents. As such caregivers of children with LAD are a population in need of mind-body interventions targeted to improve resiliency and wellbeing.

Caregivers of children with LAD experience more stress than those of neurotypical children, including heightened emotional distress that impacts the family.[5] Qualitative interviews conducted with parents of children with LAD and professionals from advocacy and teaching organizations found high levels of parental stress, with primary stressors including navigating the educational system, social isolation, familial concerns, and financial and professional sacrifices. Stress was linked to emotional and physical exhaustion, social isolation, and strained familial relationships.[6] Notably, high levels of parenting stress experienced by the parents of those with attentional disorders are associated with increased likelihood of parental psychopathology and maladaptive parenting practices, both of which directly impact the child's wellbeing.[5]

Modifiable resiliency skills leveraging growth enhancement may ameliorate the deleterious effects of chronic stress. Resilience is often characterized as a *response to adversity*; specifically, it refers to a set of protective factors and resources within an individual and their environment that facilitate one's ability to "bounce back." [7–14]Resilience is demonstrated when one is able to maintain adaptive functioning while faced with ongoing chronic stress, as experienced by parents of children with LAD.[10,15–18]

We have developed a mind-body program to enhance resiliency for individuals with chronic stress exposure. The SMART-3RP is an evidence-based group intervention, developed by our study team and colleagues at the Massachusetts General Hospital's Benson-Henry Institute for Mind Body Medicine, to promote resilience and adaptation to stress.[19] Program strategies integrate stress management principles from cognitive behavioral theory, positive psychology, and research on the relaxation response. Structured weekly sessions incorporate relaxation training, stress awareness, and adaptive strategies for

coping with stress and enhancing growth and wellbeing. Our study team and colleagues have tested the SMART-3RP model in diverse populations using in-person and telehealth modalities. This includes adults with specific medical conditions or life stressors as well as heterogeneous community cohorts. Results support that the intervention is feasible and acceptable, and may enhance resilience, coping and mood.[15,20–23]The SMART-3RP is an 8-session, approximately 90 minutes per week multimodal intervention that incorporates relaxation techniques, stress awareness discussion, and adaptive strategies for coping with stress.

Outreach to vulnerable parent populations is needed. As parenting stressors are highest among parents from ethnic and racial minority status[24,] we have partnered with the Federation for Children with Special Needs (Federation) to carry out the proposed study aims. The Federation is a non-profit organization that provides information, support, and assistance to over 45,000 parents of children with disabilities annually; 30% are parents of children with learning and attentional disabilities. The Federation oversees over 15 projects related to supporting families who have educational needs in the state of Massachusetts which are targeted to assure equitable access to diverse families' educational, medical, and community supports. Partnering with the Federation provides the opportunity to extend our work with underserved families and caregivers of color, low income, and rural parents of children with LAD via outreach through their website and affiliated social media (e.g., Facebook), listservs and webinars.

Based on qualitative feedback from our recent English- and Spanish-language qualitative study conducted together with theFederation (MGB IRB # 2023P001820), we are refining the SMART-3RP and active control group (Health Education Program; HEP) to better fit the needs of parents of children with LAD. The goal of the present protocol is to gather preliminary data regarding the feasibility and acceptability of this refined protocol, as well as to gather pilot data regarding preliminary effect sizes and outcome measures, which will inform a future randomized pilot trial.

Based on feedback from our qualitative study, we are also modifying the focus of our open pilot to increase cultural appropriateness and inclusivity to focus on the needs of individuals who identify as **co-primary caregivers (i.e., inclusive of co-parents, guardians, or grandparents who hold significant caregiving responsibilities)** of children with LAD. Another modification that we are making to the protocol based on feedback received from parents in the qualitative study phase is reducing session length to 60 minutes.

2. Specific Aims and Objectives

The proposed research has the following objectives:

Aim 1 (Feasibility & Acceptability): Based on findings from our qualitative study (MGB IRB # 2023P001820; Refining a Resiliency Program for Parents of Children with Learning and Attentional Disorders), the primary objective of this protocol is to conduct an open pilot to elicit initial quantitative and qualitative feedback regarding feasibility and acceptability of the interventions (SMART-3RP and HEP) that we have refined. To do so, we will deliver our novel intervention to 4 groups of English- and Spanish-speaking parents of children with LAD (1 English-language SMART-3RP group, 1 English-language HEP group; 1 Spanish-language SMART-3RP group, 1 Spanish-language SMART-3RRP group; approximate *n* up to 10 per group, approximate total N ~ 40) and collect qualitative and quantitative data regarding participants' experiences in the trial. To inform plans for ongoing program refinement, we will also elicit specific feedback regarding study assessment tools, recruitment procedures, and group composition. **Please see Table 1 for a listing of all feasibility and acceptability measures that we intend to assess.**

Aim 2 (Exploratory Efficacy): Though this study is not intended to support a fully-powered test of intervention efficacy, we will explore clinical effect sizes for specific outcomes of interest to inform ongoing protocol refinement (i.e., intervention design and selection of relevant outcome measures). Our primary clinical outcome for these exploratory analyses is resiliency, assessed by the Current Experience Scale (CES). Secondary self-report outcomes are stress coping, depression/anxiety, worry mindfulness, social support, positive affect, empathy, fatigue, and healthy behaviors (healthy eating, physical activity, and sleep). **Please see Table 1 for a listing of all study outcomes.**

In future, larger-scale, work, we intend to conduct a larger randomized pilot trial to assess intervention acceptability, feasibility, as well as preliminary efficacy on essential indices of sexual well-being.

3. General Description of Study Design

This will be a fully randomized open pilot trial enrolling up to 40 English- and Spanish-speaking co-primary caregivers of children with LAD. To compare group remote delivery, participants will be assigned based on availability to either a mind-body resiliency group (SMART-LAD, intervention) or an evidence-based Health Education Program (HEP, control) which is a multiple behavior change program that addresses sleep, exercise, nutrition, substance use, and working with one's healthcare team. Both the SMART-3RP and HEP programs have been modified based on adaptions from our previous qualitative study (MGB IRB # 2023P001820). There will be 4 pilot groups total- 2 for English-speaking co-primary caregivers of children with LAD (SMART and HEP) and 2 for Spanish-speaking co-primary caregivers of children with LAD (SMART and HEP). We will include up to 10 parents in each group.

***The present submission only includes study documents for English-speaking parents, as we are awaiting final translations for Spanish-speaking parents from our certified translation service. We will submit these documents as an amendment as soon as they are available.*

4. Subject Selection

Inclusion criteria: We aim to recruit English- speaking and Spanish-speaking co-primary caregivers (18+ years) of a child (< age 18) with LAD.

Exclusion criteria: We will only exclude co-primary caregivers with significant psychiatric conditions (i.e., active suicidality or psychosis) or who are otherwise unable to participate, at the investigators' clinical discretion. Only one caregiver per family can participate. Based on feedback from our community partner (Federation), we will exclude caregivers whose children have a primary diagnosis/disability other than a learning or attentional disorder; this decision was made based on clinical and professional observation that caregivers of children with primary learning and attentional disabilities have unique concerns from parents whose children receive supports for other diagnoses/disabilities.

Parents who have participated in an earlier part of the study (i.e., qualitative protocol; MGB IRB # 2023P001820) will also be excluded from participation.

Screening for "Bots" and "Bad Actors." To reduce the likelihood of responses from "bots" or "bad actors" who may misrepresent their eligibility in order to receive remuneration, we will also require all participants to provide a US phone number (not google voice or another internet service) where they can be reached by the study team. We may ask participants to provide greater detail or clarification regarding their children's diagnosis to confirm veracity. Participants will be required to complete study procedures with "camera on" to confirm confidentiality and security for all group participants. We will follow best-practices for clinical research studies recruiting online, based on the recommendations of our MGH and DFCI colleagues.[25]

Diverse Recruitment. We emphasize outreach to underserved families and caregivers of color, low income, and rural families and fathers.

Source of subjects and recruitment methods

Initial proactive and reactive outreach. The Federation outreach specialists, along with the Federation Communications Coordinator, will reach out to caregivers using a variety of proactive and reactive recruitment techniques. This may include posting our study flyer (attached) on their website and affiliated social media (e.g., Facebook, Instagram, X), listservs, email lists (including SEPAC outreach), phone, email, and texting options. Study personnel from MGH and/or Federation may also attend in-person or live virtual informational events for caregivers of children with LAD, where they will provide information about the study and collect information from individuals interested in completing further screening for potential participation.

Both MGH RA and Federation Human Subjects-approved staff contact information will be provided in all recruitment documents so that participants can choose the initial contact person with whom they feel most comfortable indicating interest. Postings on their affiliated social media (e.g. Facebook) will use the attached text describing the study, accompanied by an image of our study flyer. As in the attached recruitment text, social media posts will include contact info for the study investigators at Federation and MGH, should potential participants wish to learn more about the research. Recruitment posts on social media will disable chat and comment features in order to protect privacy.

The Federation will also advertise the trial at Federation project workshops and support groups and via listservs and newsletters. The Federation has committed to working with local family advisors to support the sharing of information and to target outreach to diverse parent communities (e.g., underserved families and caregivers of color, low income, and rural communities). Please see example study flyers attached to this protocol, which may be used to share study information online and in person. As we are unfortunately not able to directly target recruitment of indigenous communities for this small pilot protocol, this research does not require any IRB review by Indian Health Service (IHS) and/or Tribal IRBs.

Electronic survey for participants recruited via Internet (e.g., Facebook, listserv). Participants who learn about the study over the internet or via a study flyer, rather than via direct Federation staff referral, will be invited to complete an initial pre-screening survey in REDCap, linked via a QR code (see attached flyer). Following best practices for internet research[25], we will include a combination of closed-and open-ended questions on this brief eligibility pre-screener in order to reduce incidence of "bots and bad actors." Participants referred directly by Federation staff, community partners, or another direct medium may alternatively complete screening items via phone with a member of our study team.

Engagement of our Community Partner (Federation) for Initial Eligibility Screening. As was the case for our Phase 1 qualitative study (MGB IRB # 2023P001820), we plan to include several *Federation* staff members as personnel on this protocol. As advised by MGB IRB staff, we plan to add *Federation* as a child site under this parent protocol following approval of the parent protocol. All *Federation* personnel included on the protocol will complete MGB-approved human-subjects training. Following approval, IRB-approved *Federation* staff will be available to answer initial study-related questions posed by interested parents and support initial pre-screening using our eligibility pre-screener in REDCap (see above).

5. Subject Enrollment

Confirming Study Eligibility. The MGH study RA or another qualified team member (MGH and/or Federation staff) will follow-up and confirm eligibility with all interested participants who appear likely to be eligible based on the initial screening survey and document ineligibility and refusal information (see attached screening template).

Spanish-speaking participants will be screened and consented by qualified Spanish-speaking study personnel in consultation with Drs. Giselle Perez and Dr. Esteban Barreto, both of whom are Native Spanish Speakers and Doctoral-level Clinical Scientists with experience doing clinical research in Spanish. The personnel will be study staff (e.g., MGH and/or Federation staff) with professional level Spanish, as assessed by members of the study team with native-level fluency. We do not anticipate needing Spanish-language medical interpreters for this study.

Procedures for obtaining informed consent: When eligibility is confirmed, the RA or another qualified team member will email and administer an electronic informed consent document using REDCap. Participants will provide an electronic signature on this document and will receive a final signed copy via postal mail or email, depending on their preference. This procedure will be conducted in either English or Spanish by qualified study staff (as above).

At this point of initial informed consent, participants may also be asked if they would like to be contacted for: 1) future participation in studies conducted by this team and 2) participation on an advisory board whose goal is to provide feedback to our research team regarding program development for parents of children with LAD. The potential participant will be allowed to ask questions at this time. Participation will not be recorded in medical or employment records. Participants will be informed at the point of initial consent that we will audio-record all intervention sessions for fidelity; they will also be reminded of this at the start of the first intervention group, should they enroll.

Parents will be informed that videoconferencing services and remote intervention will be provided by secure HIPAA-compliant videoconferencing software. In accordance with the HIPAA Privacy and Security Regulations, and to provide maximum security, research staff will send emails containing confidential information using encrypted email (Send Secure). Certain emails within low-risk category may be sent using non-encrypted methods, with participant permission. Non-encrypted emails will be sent upon participant request, with participant preference documented in our study records.

At any point, eligible participants may opt out of enrollment. Reasons for refusal and ineligibility, among those who make contact, will be documented.

6. STUDY PROCEDURES

6.1: Group Assignment

This is a single site pilot clinical trial of SMART-3RP versus HEP to intervene with caregivers of children with LAD. Participants who have completed the baseline survey will be assigned to treatment arm or group time according to availability.

6.2: Intervention Structure and Content

Interventionist expertise training. Both SMART-3RP and HEP groups will be led by qualified study staff with relevant clinical expertise. Dependent on staff availability, we may also include IRB-approved Federation staff members as group co-leaders together with MGB and Stony Brook personnel. Any Federation group co-leaders will attend a full-day training via videoconference, led by MGB and Stony

Brook faculty, to review the intervention manuals for SMART-3RP and HEP. Key elements of training include role-playing of various scenarios to practice skills delivery and facilitate learning. Weekly clinician meetings for personnel leading SMART-3RP and HEP groups will also include reviews of protocol fidelity, using audio recordings of intervention sessions. Brief descriptions of the SMART-3RP and HEP content, which is being refined based on our qualitative findings (MGB IRB # 2023P001820) are provided below:

SMART-3RP: The intervention groups will be co-led by an MGB clinician with a possible (IRB-approved) Federation co- leader with 8 weekly 1.5-hour session groups (approximate n = up to 10 parents per group). The intervention was created at the 8th grade reading level and 8 sessions focused on 3 treatment components: 1) Eliciting the relaxation response (RR) involves sustained mental focus with an attitude of open receptive awareness. Techniques are aimed at reducing muscle tension and breathing rate. 2). Cognitive-Behavioral Therapy (CBT) to improve stress awareness and management involves increasing awareness and identification of the components of one's stress response (negative thoughts, emotions, physical reactions, behaviors, and relationships) and learning skills to alter these components (e.g., cognitive restructuring). 3) Positive psychology strategies to achieve growth enhancement focus on utilizing different techniques and skills to promote positive growth. Skills and exercises focus on increasing social support, acceptance, healthy behaviors (recuperative sleep, mindful eating, physical activity), positivity, humor, and appreciation.

Health Education Program (HEP): The intervention groups will be co-led by an expert MGB or Stony Brook-based clinician with a possible (IRB-approved) Federation co- leader. The HEP was developed based on Multiple Health Behavior Change (MHBC) literature[26] for individuals with co-occurring mental and physical health problems but can be adapted for a variety of different populations and applications. The components (1) education on the co-occurrence of mental and physical problems and healthy lifestyles; (2) goal setting for health behavior change; and (3) self-monitoring. Didactic, psychoeducational content was informed by national guidelines.[27–31] Goal setting is based on the health behavior change framework (i.e., Specific, Measurable, Attainable, Relevant and Time-based).[32] Self-monitoring involves tracking health behaviors, and mood, anxiety, and stress symptoms.[33] Topics in the educational component include physical activity, nutrition and healthy eating, sleep hygiene, alcohol and substance abuse, and managing healthcare.

6.3: Data Collection

Survey Data collection. We will administer surveys at 2 timepoints: approximately pre-intervention and approximately post-intervention. Surveys will be available in both English and Spanish, depending on participant preference, and they will take approximately 30 minutes each to complete. Participants can pause and go back to the survey later, with approximately 4 weeks allowed for completing each survey. Electronic links to complete study surveys may be sent via email and text on a secure REDCap link. *If a parent prefers, surveys may be completed over the phone/Zoom with the MGH staff member*. We may follow-up with participants who have not completed study surveys in entirety to request that they do so within approximately 4 weeks. We have selected appropriate participant-reported measures based on our prior studies and the resiliency intervention theoretical framework documenting resiliency, coping, and psychological distress. [34]. We have prioritized brevity in selecting study surveys to reduce participant burden. All participant-reported study measures have strong psychometric properties with high internal and external validity and responsiveness to change.

6.4: Participant Remuneration

Participants will receive $20 per session attended (up to $160 for 8 sessions) and $20 for completing a post-group survey. Participants can receive up to a total of $180. A single-time payment will be made

according to parts of the study procedure that were completed (i.e. attendance at each study session and post-treatment survey). They will receive payment in the form of gift cards.

6.5: Participant Communication with Study Team

Participants will provide contact information to study staff and specify preferred contact modalities. Study staff may use phone and email to schedule group meetings and send study reminders. Study staff will explain the encrypted, "Send Secure" default feature of emails sent from within the Mass General Brigham network. Study staff will verify that no sensitive information will be disclosed in emails but ensure that the patient understands that by opting out of the send secure feature, information will not be as secure.

7. Risks and Discomforts

Participants may feel uncomfortable completing various questionnaires. As in any research study, there is a small risk that confidentiality may be breached; all efforts to minimize this risk will be taken. In addition, participants may find it time consuming to practice techniques learned in the intervention or tracking behavior such as elicitation the relaxation response.

No participant will be required to participate, and personal information about decisions to participate will not be shared outside of the study team. Participation is voluntary for all subjects. In addition, all volunteer participants are allowed to withdraw at any point without any consequences. Participants will be informed that they may refuse to answer questions that make them feel uncomfortable.

Participant information will remain confidential unless there is a reasonable concern for risk of harm to self or others. When a group facilitator identifies acute emotional distress in a participant, the facilitator may offer the participant to take a break from the meeting or continue the meeting and may remind the participant that they can opt out of study procedures at any time. The group facilitator will inform the study team (PI or designee) and discuss how to proceed further. If study staff identify concerns about a participant during study procedures outside of group intervention sessions (e.g., during reminder calls or other phone contact), the study team will contact the group facilitators to discuss how to proceed further. We may recommend that a participant stop their study participation. Depending on the nature of the situation, the group facilitators may provide the participant with a clinical referral and/or contact appropriate authorities to ensure safety.

8. Benefits

Participants will be benefited by the exchange of information with colleagues and community members, which in turn has the potential to lead to an improvement and awareness in patient care. They may benefit from receiving information about strategies to enhance resiliency, stress management, and health. In addition, experts and parents may directly benefit from contributing to this project, because of their participation, care for parents and their children with learning and attentional disorders may be improved.

9. Statistical Analysis

Quantitative. Statistical significance will be considered as two-tailed $p < .05$. To explore feasibility of the adapted intervention, we will use descriptive statistics (i.e., frequency and percentages) to evaluate the proportion of enrolled participants who completed 6/8 intervention sessions (75%) in each study arm as well as additional feasibility indices listed in **Table 1**. To establish acceptability, we will examine participant scores on the Group Cohesiveness Scale (GCS-7).[36] We will also include brief items addressing treatment satisfaction, for which our criteria for acceptability will require a Mean (or Median,

depending on data distribution) score ≥ 4 on a 1-5 Likert scale from 1 (not at all) to 5 (extremely); see **Table 1**. These data will be interpreted holistically to identify areas for revision.

Effect Sizes (Exploratory). Although the intent of this open pilot trial is *not* to perform a fully-powered hypothesis test,[37] we will conduct exploratory analyses of strength of change (i.e., effect sizes) in our primary outcome of interest (resiliency) as well as secondary outcomes (see **Table 1**). We will consider clinical improvements using within-person analysis of change from pre- (T0) to post-intervention (T1). Mixed effect multivariable models will be tested using the "lme4" package[38] for R, which allows for use of all available data in the context of missingness.

Table 1. Measures for Open Pilot Data Collection

Construct	**Measurement**	**Data Source**
Feasibility		
Access	# of potentially interested participants identified through different recruitment sources	REDCap, Recruitment tracking log
Reach	% of interested caregivers that are eligible, % of eligible caregivers that enroll and associated characteristics	REDCap, Recruitment tracking log
Treatment Delivery	# of 1:1 remote sessions completed (6/8; 75% as criterion for completers)	REDCap, tracking log
Acceptability (Post-Intervention Only)		
Group Format	Group Cohesiveness Scale-7[36]	Self-report in REDCap
Assessment	Overall satisfaction with program delivery, session # and length, program content, needs met, and helpfulness	Self-report in REDCap (1 item each for total of 6 items)
Sociodemographic Characteristics (Pre-Intervention only)		
Sociodemographic background	1. Age; 2. Sex; 3. Gender identity; 4. Race; 5. Ethnicity; 6. Relationship Status; 8. Employment; 9. Education; 10. Language; 13. Religiousness; 14; Spirituality; 15. Housing status; 16. Food insecurity; 17. Access to transportation; 18. Access to basic needs; 19. Ability to use technology	Self-report in REDCap (19 items)
Characteristics of Child with LAD	1. Child age; 2. Diagnoses	Self-report in REDCap (2 items)
Primary Outcome (Pre- and Post-Intervention)		

Resiliency	Current Experience Scale (CES)[34]	Self-report in REDCap (23 items)
Secondary Outcomes (Pre- and Post-Intervention)		
Stress Coping	Measure of Current Experience, Part A; ability to relax, recognize stress, elicit support, and restructure maladaptive thoughts[39]	Self-report in REDCap (13 items)
Depression & Anxiety	Patient Health Questionnaire- 4 items (PHQ-4); Anxiety and depression symptoms [40]	Self-report in REDCap (4 items)
Mindfulness	Cognitive and Affective Mindfulness Scale- Revised (CAMS-R); Mindfulness (e.g., present focus, emotional regulation)[42]	Self-report in REDCap (10 items)
Fatigue	Fatigue; 0-10 Analog scale of fatigue[44]	Self-report in REDCap (1 items)
Positive Affect	Positive and Negative Affect Schedule (PANAS-Pos); Measure of Positive Affect[45]	Self-report in REDCap (10 items)
Global Well-Being	WHO-5 Well-Being Index[46,47]	Self-report in REDCap (5 items)
Social Connection	PROMIS-Emotional Support 4a and PROMIS-Isolation 4a[48]	Self-report in REDCap (1 item from each, 2 items total)
Healthy Behaviors	Mindful Eating Behaviors Scale (Hunger Cues and Eating with Awareness Subscales)[49]; Physical Activity Vital Sign, meeting weekly physical activity recs (150 mins of moderate-rigorous)[50]; PROMIS Sleep Disturbance Short Form, assessment of sleep duration and quality[51]	Self-report in REDCap (2 items- PROMIS Sleep Disturbance SF); Self-report in REDCap (2 items- MEBS); Self-report in REDCap (2 items- PAVS)

10. Monitoring and Quality Assurance

As explicitly stated in study consent form, subjects may withdraw from participation at any time by notifying a member of the study team. Participants will not be required to provide a reason for withdrawal. Participants will also be reminded that they can withdraw from the group intervention programs at any point during their participation and may be offered the opportunity to continue completing study assessments (surveys) if appropriate.

Electronic demographic information will be stored in REDCap, a secure and HIPAA-compliant web-based application hosted by the Mass General Brigham Research Computing Enterprise Research Infrastructure & Services group. The system offers data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages. REDCap data will be monitored weekly by study staff.

Adverse Event Monitoring: Throughout the study participants will be monitored for occurrence of events defined as any undesirable experience or unanticipated risk. All adverse events will be reported on an adverse event form.

The study PI is ultimately responsible for data and safety monitoring. If study staff becomes aware of any adverse events, the event will be reported immediately to the study PI. All adverse events and/or unanticipated problems will be reported by the PI to the Mass General Brigham IRB within 5 working days (7 calendar days) of the date the investigator first becomes aware of the unapproved deviation. Unapproved minor deviations will be recorded in a protocol-specific Minor Deviation Log.

11. Data and Research Material Sharing

11.1 Sending Data/Materials to Research Collaborators outside Mass General Brigham

Coded study data, including self-report data from REDCap surveys and aggregated program feedback provided by study participants, may be shared with IRB-approved research collaborators at Stony Brook and the Federation to inform collaborative efforts to refine the study interventions. We will remove identifiers from the dataset shared with non-MGB collaborators. Data will be coded according to participants' study ID number with a key linking participants' identifying information to study ID number kept in a password-protected file accessible only to MGB personnel with access to RISO-approved drives/cloud environments. We will share data with outside collaborators using encrypted email and/or MGB's secure file transfer service. Stony Brook and the Federation personnel will only use de-identified study data for purposes described in this protocol. Should participants withdraw their data, we will notify the study team and ensure that data are appropriately removed from all study records based on coded ID number.

We do not plan to share files containing recordings of study intervention groups with outside collaborators, though these may be reviewed remotely during study team meetings. Audio recording files will be stored to MGB's RISO-approved drives/cloud environments for the purposes of protocol fidelity review.

11.2 Receiving Data/Materials from Research Collaborators outside Mass General Brigham

We may receive contact information for potential study participants from our collaborators at the Federation. As outlined above, this information (e.g., name, phone, email address) will be sent securely via our MGB-hosted REDCap eligibility survey.

We do not expect to receive identifying study data from Stony Brook personnel.

12. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☒ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☒ Additional privacy and/or confidentiality protections

Study sessions will be conducted using Zoom, a secure, HIPAA compliant web-based videoconferencing platform. Recording is necessary for protocol fidelity. All group sessions will be password protected, and the password will only be shared with trained study staff, study participants, and group facilitators. We will also audio-tape group sessions. To further protect participant privacy, audio files will be labeled with group number and date as well as an identification code. All audio files will be transferred off of recorders onto a password protected MGB-hosted server (RISO-approved drive) immediately following each group. All audio files will be securely destroyed at the completion of the project.

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