Official Title of Study: Evaluation of a resiliency intervention for parents of children with Autism Spectrum Disorder (ASD)

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PARTNERS HUMAN RESEARCH COMMITTEE DETAILED PROTOCOL

Date: 1/14/21

I. BACKGROUND AND SIGNIFICANCE

According to the Center for Disease Control in 2012, 14.6 per 1,000 children aged 8 years old have a diagnosis of Autism Spectrum Disorder (ASD).[1] Having a child with ASD is associated with medical expenditures of 4.1-4.6 times more than having a child without autism, and associated with 8.4-9.5 times greater general expenditures.[2] Furthermore, children with ASD are more likely to use out-of-school behavioral health services than children without developmental or psychiatric diagnoses.[3] Parents of children with ASD consistently show high levels of perceived distress and anxiety related to child-parent relationships, intellectual functioning, adaptive behaviors,[4,5,6] in addition to poorer health than parents of children of typical development.[7] These parents also exhibit significant stress related to the emotional and financial challenges of putting together treatment and future-related plans for their children.[8] Recent studies have found a positive relationship between caregivers' stress levels while raising a child with ASD and child behavioral and conduct problems.[9,10,11,12,13]

There is growing literature on the increased levels of parental stress associated with caring for children with ASD. One study found that caregivers of children with ASD with behavioral, hyperactivity, and emotional problems displayed atypical cortisol patterns, a biological marker of increased stress.[9] A review article provides a comprehensive overview of the links between high levels of parental stress among parents of children with intellectual and developmental disabilities and child health and well-being.[14] In addition to social phobias associated with children with ASD,[15] one study even found that caring for a child with ASD showed higher stress levels for the parents correlated with the child's social impairment severeity.[11] Finally, recent studies have also found that many parents of children with ASD exhibit psychological and physical depressive symptoms.[16] Therefore, having a children with ASD is associated with an increased risk of problems with emotional and physical health and social well-being. Resiliency is a multidimensional construct that refers to the ability to maintain adaptation and effective functioning when faced with stressors.

Resiliency provides a framework for understanding the adjustment to stress as a dynamic process. Allostasis refers to the capacity to maintain stability of physiological systems in the face of adversity.[17] When exposed to chronic stressors, such as care for a child with ASD, individuals expend a great deal of energy attempting to maintain allostasis; this can lead to the metabolic wear and tear described as allostatic load. Evidence is accumulating that this wear and tear is mediated by changes in basal stress system activity and by effects of these changes on dependent systems.[18] Allostatic load and resilience can therefore be assessed by measuring basal stress system activity (HPA axis and salivary alpha-amylase).

Thus, research to reduce these parents' exposure to stress and, moreover, improve parental responses to stress, may improve the wellbeing of both parents and their children. Yet, a treatment focused on the psychosocial needs in relation to stress and allostatic load of parents of children with ASD has not been developed. Research is warranted to examine and intervene upon parental stress. This study aims to design and develop a resiliency intervention to provide support to parents of children with ASD.

This intervention will be a modified version of Dr. Park's evidence-based 8-week multimodal treatment which is designed to promote adaptation to stress and promotion of resiliency. The program is an 8 session, 1-1.5 hours a week multi modal intervention that incorporates relaxation techniques, stress awareness discussion, and adaptive strategies for coping with stress. This study will refine an 8-session group virtual-delivered resiliency treatment program consisting of 8 virtual group 1-1.5 hour sessions. The goal of this study would be to advance our ultimate objective to implement a national parental resiliency program.

II. SPECIFIC AIMS

The proposed research has the following objectives:

Specific Aim 1 (Phase II): Informed by Phase I findings, (approved in a previous IRB protocol #2016P001698), we aim to develop and determine the feasibility (by assessing the number of sessions attended and adherence to Relaxation Response practice) and acceptability (assessed using the Participant Feedback Survey) of an 8-session Relaxation Response Resiliency (SMART-3RP) program for parents of children with ASD.
Hypothesis: The SMART-3RP virtual delivery will be feasible to implement and acceptable to parents of children with ASD.

Primary Aim 2 (Phase III): To test the effectiveness of a pilot waitlist controlled trial on improving resiliency, as measured using the General Self-Efficacy Questionnaire, Current Experiences Scale, and the Visual Analogue 0-10 scales (including stress, distress, coping, and physical discomfort), and on improving stress reactivity (as measured by the Measure of Current Status-A), growth enhancement (as measured by the Cognitive and Affective Mindfulness Scale-Revised), and parental stress (as measured by the Parental Stress Scale).

Primary Hypothesis: Patients randomized to the Immediate group will report significantly greater scores on the primary outcomes (measures of resilience) and on the secondary outcomes (measures of stress reactivity, growth enhancement, and parental stress) at 3 mo. post enrollment.

Secondary Aims: Among participants randomized to both conditions, to investigate the extent of pre-post changes in primary and secondary outcomes (Immediate: assessments from baseline-3 mo.; Waitlist: from 3-6 mo.).
Secondary Hypothesis: Scores on primary and secondary outcome measures will improve from pre-post intervention.

Secondary Aim 2: Among immediate condition group only**,** to assess whether end-of-treatment (3 mo. post enrollment) improvements will be sustained at 6-mo. post enrollment.
Hypothesis: These end-of-treatment effects will show sustained improvement on primary and secondary outcome measures from 3 to 6-mo. Post enrollment.

Secondary Aim 3: To pilot test the end-of-treatment effects of the SMART-3RP on parents' stress levels using hair cortisol. A mixed effects models approach will be used to examine group

differences in hair cortisol concentrations (HCC) at baseline and 3 mo. post enrollment. Pearson correlation or Spearman's rank correlation will be used to examine the association of HCC with each of our psychological outcomes.

Hypothesis: Parents randomized to the Immediate group will show improvements in biomarkers of stress system function, in particular the hypothalamus pituitary adrenal (HPA) axis and sympathetic nervous system (SNS) relative to baseline. It is expected that stress-related alterations will be found in parents before the intervention and will improve in those individuals that respond favorably to the treatment. Biomarkers will thus allow an additional level of testing for chronic stress, and efficiency of the intervention; measuring basal HPA axis and SNS activity further allows us to draw conclusions about the adverse long-term health effects of chronic stress and to evaluate the efficiency of the intervention in ameliorating such biological changes.

III. SUBJECT SELECTION

We will recruit through our contacts in the community including other MGH clinicians, as well as through local and national support groups and list serves using IRB approved recruitment materials. MGH child psychologists may also refer potentially eligible participants. Interested participants may call or email the study staff to learn more about the study.

The current study will employ a pretest-posttest, pilot waitlist controlled design to test the 3RP for parents of children with ASD. Participants will be recruited from local, national, and international organizations, school systems, and hospital clinics.

Inclusion/Exclusion Criteria

Inclusion criteria are:

1) Being the parent of at least one child with an autism spectrum disorder
2) Age 18 or older
3) Can read and speak English

One or more of the following exclusion criteria will render an individual ineligible:

1) Unable or unwilling to sign the informed consent documents
2) Regular use of corticosteroids at the discretion of the Principal Investigator
3) Unable or unwilling to participate in an intervention delivered via videoconferencing.

Recruitment

A total of approximately 70 participants will be recruited for this study. Both males and females from diverse racial and ethnic backgrounds will be recruited using IRB approved procedures. Potential participants will be recruited from our contacts in the community including other MGH clinicians, as well as through local and national support groups and list serves using IRB approved recruitment materials. MGH child psychologists may also refer potentially eligible participants. In each case, interested participants will be directed to our pre-screen REDCap survey and will be given the option to contact the study staff to learn more about the study.

IV. SUBJECT ENROLLMENT

Methods of enrollment

Participants will contact the PI or study staff by telephone, email, or by completing our IRB approved pre-screen REDCap survey in response to advertisements. Subject will be contacted by phone, informed about the study and given an pre-screen REDCap to determine whether they meet inclusion/exclusion criteria (see the attached pre-screening questionnaire). Subjects may also be referred to the study. Subjects must respond "yes" to all inclusion criteria and "no" to all exclusion criteria to be eligible for the study. Eligible participants will be consented and will complete the baseline survey online into REDCap, a secure, web-based application designed to support data capture for research studies.

Randomization

After enrollment, participants will be randomized to the Immediate intervention group (IG) or Waitlist control group (WG). Randomization will be conducted using a random plan generator, with 1:1 randomization. The WG will begin their program approximately 3 months after the SMART-3RP group. For both groups, the intervention will last approximately 8 weeks, weekly with groups meeting once per week for approximately 1-1.5 hours.

Informed consent process

Eligible and interested participants will be sent a consent form and scheduled for a phone consent. Informed consent and authorization will be obtained and documented through use of a written consent form approved by the Partners Human Research Committee (PHRC) and signed by the participant. The PI or qualified study staff will complete informed consent procedures.

Participants will be asked to read the consent form fully on their own before discussing the consent form with a study staff member (either on the phone or using videoconferencing). The participant will have the opportunity to ask any and all questions about the study. Once all questions have been addressed, they will sign the consent form and send it to the study staff member (either via email, scan, fax, or mail). The study staff member will then sign the participant's signed copy and send a copy back to the participant for their records. As informed consent is a continuous process, participants will be invited to ask questions about their participation at any point over the course of the study.

The consent form will include a description of all study procedures, information about potential risks and benefits of participation, and study contact information (including that of the IRB) in case questions arise at a later time. The consent form will also explicitly state that study participation is voluntary, and that participants may refuse to answer any questions that make them uncomfortable, and may discontinue participation at any time. The consent will also explicitly state that this intervention is psycho-educational and is not clinical care.

In addition, special attention will be given during the consent process to the implications of receiving an intervention online via a videoconferencing platform. Subjects will be explicitly informed that the video conferencing services provide secure HIPAA-compliant videoconferencing software. We will explain to participants that although we will do our best to ensure confidentiality on our end, we cannot guarantee 100% that other group members will not

share the content of the group. Participants will also be advised to wear headphones and sit in a quiet place to protect their own, and other group members' privacy.

V. STUDY PROCEDURES

Program development
The Phase I (described previously in protocol #2016P001698) findings will be used to guide the development of a resiliency program targeted to the needs of parents of children with ASD.

Study staff will administer the consent form with participants either on phone or using the videoconferencing system. To facilitate proficiency with the software, participants will test the software with a study staff member either during consent or on a brief test call prior to the start of the intervention.

Assessments
Study assessments include a battery of questionnaires via REDCap and two hair cortisol sample collections. At baseline, participants will be administered baseline questionnaires and asked to provide a hair cortisol sample. At 3 months post enrollment, participants are administered a second set of questionnaires and asked to complete a second hair cortisol sample. At 6 months post enrollment, participants are administered their final set of questionnaires.

Hair Cortisol
At enrollment (baseline) and at 3 months post enrollment, all participants will be asked to provide a hair sample to measure potential changes in cortisol levels, a method used successfully in stress studies. Participants will be asked to cut a small amount of hair (approximately 150 strands, which is about the diameter of a small paperclip) as close to the scalp as possible (about 3 cm), and from the back of their head. They will be asked to band or tie the strands near the scalp end, place on the sample in aluminum foil, and return in an envelope to MGH. Participants will be sent detailed sampling instructions and stamped, addressed envelopes to facilitate mailing. We are asking participants about their use of corticosteroids because they may interfere with hair cortisol samples.

The assessments are itemized below. In addition, participants will be asked to complete practice notes throughout their intervention.

Administered at Baseline:
3RP Battery of questionnaires
Hair Cortisol Samples

Administered 3 months post enrollment:
3RP Battery of questionnaires
Hair Cortisol Samples
Participant Feedback Questionnaire

Administered during Intervention (either starting after baseline or 3 months post enrollment)

Progress Note

Administered 6 months post enrollment
3RP Battery of questionnaires
Participant Feedback Questionnaire

Intervention

In the SMART-3RP intervention, sessions focus on developing an understanding of stress physiology and the physiology of the relaxation response (RR), on developing a regular practice of eliciting the RR, and on learning cognitive behavioral and positive psychology/resilience skills. In addition to the weekly group sessions, participants will receive audio recorded guided meditations for independent relaxation practice. Participants are expected to practice eliciting the RR for approximately 20 minutes a day throughout the course of the study, using the audio recording provided and/or any other meditative or mind body techniques. Participants will complete a daily log reporting how often and by which methods they are practicing the RR. (Please see attached practice log).

The SMART-3RP will be delivered virtually, via the Partner's secure videoconferencing platform. The intervention will not be delivered clinically, and will be a psycho-educational intervention. Participants will be asked to wear headphones and sit in a quiet room by themselves for each of the sessions.

What does it involve?

The SMART-3RP involves participating in eight, 1-1.5 hour sessions, once a week via videconferencing. The SMART-3RP is a manualized psychoeducational program and each participant will be sent a manual to use during each session and to practice exercises each week. In each session, participants will learn a new type of relaxation response method, such as meditation or seated yoga. Participants will also learn more about stress and its effects on the body and mind. The program will discuss strategies and techniques to help participants manage daily stressors, through the use of breathing techniques, and cognitive reappraisal. We will also discuss adaptive strategies, such as incorporating more positive activities into participant's lives to add enjoyment and time for self care.

Groups consist of no more than 8 participants, and can be smaller as well. The group consists of participants, parents of children with ASD, as well as a group leader and a study staff member. The study staff member is fully trained in observing SMART-3RP groups, and will be setting up the videoconferencing group each week, and helping participants connect to the group.

At the start of the program, the leader clearly discusses the importance of confidentiality and asks that participants sit in a room alone, not record the sessions, and not share any other group members' personal information with others outside of the group. The program also discusses goal setting to help partcipants identify some personal goals and strategize ways to begin tackling them. These goals are addressed through weekly practice.

Homework and exercises

Homework each week involves practicing the skills discussed in the previous session. Participants are encouraged to listen to the audio recordings of meditation exercises that come with the program manual. In each session, participants are encouraged to discuss their thoughts about their practice, what they liked, and what they did not like. No one is required to do any practice that they do not find helpful. We collect copies of the practice logs.

The practice logs include:

a) Types of RR exercises practiced and duration of practice
b) Appreciations: participants are asked to list three things they appreciated each day of the week—this exercise helps bring awareness to the positive aspects of our lives, and allows us to re-live enjoyable moments through remembering them
c) SMART goals—participants are encouraged to write down specific small goals for the week such as, "take a walk outside at least twice"—to help them moved towards their larger goals

Other exercises that we practice in the SMART-3RP include exercises that help participants identify specific stressors, how they feel when they experience stress, what types of thoughts they have, and what it is about the particular incident that makes them feel stressed. We do a practice exercise as a group and encourage participants to practice for homework by thinking about their thoughts and feelings when they get stressed. They are also encouraged to complete a coping log if they are interested. They do not turn this into us as it is just for their own benefit.

An adaptive exerciuse we practice involves using humor as a coping mechanism. We read examples of using humor to cope with a stressful situation. We also encourage participants to complete an exercise (they do NOT have to share) in which they use humor to describe a personal incident that was stressful in the moment. We discuss the differences between sarcasm and humor and how humor is adaptive, but sarcasm is not.

SMART-3RP outline of each session:

Session 1

Overview

The goal of this session is to start to examine your personal stressors, and what resources you have to cope with stress. We start the session with an overview of the science of the stress response and the relaxation response, and the concept of resiliency. We examine the overall process involved in building resiliency and its three essential elements.

Session Content

The Science of Mind-Body Medicine

- **The stress response**
- **The relaxation response**

Components of the SMART program

- **Practicing RR techniques**
- **Stress awareness**
- **Adaptive strategies**

Breath Awareness

The weekly Practice Note

Tips for Developing a Consistent Practice

In-Session Exercises

Body awareness

RR Practice: Single-pointed focus meditation

RR Practice: Simple Breath awareness

Energy battery

Between-Session Practice

Complete the Practice Note

- **RR practice: simple breath awareness**
- **Daily appreciations**
- **Lifestyle behavior and social connectedness goals**
- **Symptoms check-in**

Session 2

Overview

In this session we explore different ways to bring about the RR and develop the concept of "mini" RR exercises. We deepen our understanding of the RR by practicing body awareness, and troubleshoot common problems in practicing the RR. We further explore the tendency to focus on negative emotions and physical sensations. We discuss how diminished sleep can be made worse by or promote stress and, conversely, how recuperative sleep can promote resiliency.

Session Content

Recuperative sleep

- **Sleep tips**
- **The sleep diary**

The Mini

In-Session Exercises

RR Practice: Body scan

Assessing your sleep

Identifying emotions and positive physical sensations

RR: Minis

New Between-Session Practice Items

Biodot awareness exercise

Sleep diary

Session 3

Overview

In this session, we continue to explore different ways to decrease stress reactivity, and we introduce the concept of mindfulness. We also develop awareness of stress-linked thoughts, emotions, behaviors, and physical experience, and introduce the concept of social support. We discuss the different types of social support, and we examine which types of social support you have, give, and utilize.

Session Content

Mindful Awareness

Social Support

In-Session Exercises

RR Practice: Mindful Awareness Meditations

Mindful Eating

Stress Warning Signals

The Social Support Diagram

Mini of the Week: Mindful Body Awareness

New Between-Session Practice Items

New and Good

Mindful Awareness in Daily Living

Mini of the Week: Mindful Body Awareness

Session 4

Overview

In this session we examine how stress affects both the mind and the body. We begin this session by introducing a body-based RR technique: yoga. Then, we introduce the concepts of negative automatic thoughts and thought distortions and focus on adaptive strategies to cope with stress.

Session Content

Awareness of Movement

- **Awareness of Movement in Daily Living**

Negative Automatic Thoughts

Thought Distortions

In-Session Exercises

RR Practice: Yoga

Mini of the Week: Walking Meditation

New Between-Session Practice Items

Coping Log, Part 1

List of Pleasant Behaviors

Session 5

Overview

In this session we introduce guided imagery, which utilizes the imagination to evoke a sense of well-being and encourage insight. We continue to raise awareness of negative thoughts and introduce how to change negative perspectives to adaptive ones. We encourage ongoing reflection in order to create meaning from daily events that would otherwise have gone unnoticed. We discuss the value of purposeful engagement in pleasant behaviors and provide tips to remember to eat mindfully.

Session Content

Creating an Adaptive Perspective

Healthy Eating

In-Session Exercises

RR Practice: Insight imagery

Coping Log, Part 2

Achieving Acceptance

Mini of the Week: Joyful Place Imagery

New Between-Session Practice Items

Stop, Breathe, Reflect, Choose

Food Pyramid

Session 6

Overview

We begin with a meditation that emphasizes the cultivation of positive, adaptive qualities such as kindness and love. Next, we expand our discussion of adaptive perspectives by exploring how expressing ourselves optimistically and pessimistically can influence resiliency and stress. We then look at the underlying fears that lead to pessimistic thinking. We address the importance of physical activity to stress reduction and health. Finally, we reflect on the experience of being in the RR to date, and how it contrasts with the experience of being in the stress response.

Session Content

Promoting Physical Activity

In-Session Exercises

RR Practice: Contemplation

Comparing Optimism and Pessimism

Relaxation Signals

Good, Bad, Routine

Mini of the Week: Contemplation

New Between-Session Practice Items

From Pessimism to Optimism

Session 7

Overview

In this session we explore the practice of problem solving and acceptance as adaptive responses to stressful situations. We will examine the fears that may underlie our negative thinking. We will discuss the importance of creativity and will use poetry to demonstrate how creative expression and insight support adaptive responses.

Session Content

Coping Strategy: Problem-Solving vs. Acceptance

Creative Expression

Empathy

In-Session Exercises

RR Practice: Loving Kindness

Root Fear

Poetry

Empathy/Mindful Awareness of Another

Mini of the Week: I am… at peace

New Between-Session Practice Items

Practice Creativity
Letter to Self

Session 8

Overview

In this session, we learn how to use humor and imagination to enhance adaptive coping. We review the program content and reflect upon what participants have learned, what has been particularly helpful for them, and how they can achieve their "idealized selves," reminding them that imagery of idealized self is helpful. We end with an important skill- using humor to enhance resiliency. We revisit the Energy Battery that we competed in our first session, and reflect on our current battery. We reinforce their use of setting goals in support of maintaining resiliency.

Session Content

Humor and Coping
- Laughter
- More Humor Strategies

Staying Resilient
- Tips for Staying Resilient

In-Session Exercises

RR Practice: Idealized Self

Energy Battery, Take 2

Finding Humor in Your Life

Laughter

Mini of the Week: Tonglen

Program Review

Review of RR Practice Note
Review of stress and Coping Logs
Review first session energy battery

SMART-3RP Development

The process of developing the Benson-Henry Institute's SMART-3RP is further described in Dr. Elyse Park's article, The Development of a Patient-Centered Program Based on the Relaxation Response: The Relaxation Response Resiliency Program (3RP). The current program that will be used in this study is an adapted version of the original program, and is tailored to the needs of parents of children with ASD.

Differences in the adapted program include:
-Examples in each exercise tailored to parents
-An introduction at the beginning of the program about parental stress, and how we hope to provide useful stress management skills to help parents of children with ASD.
-A list of recommended resources for parents if they are interested (list serves etc)

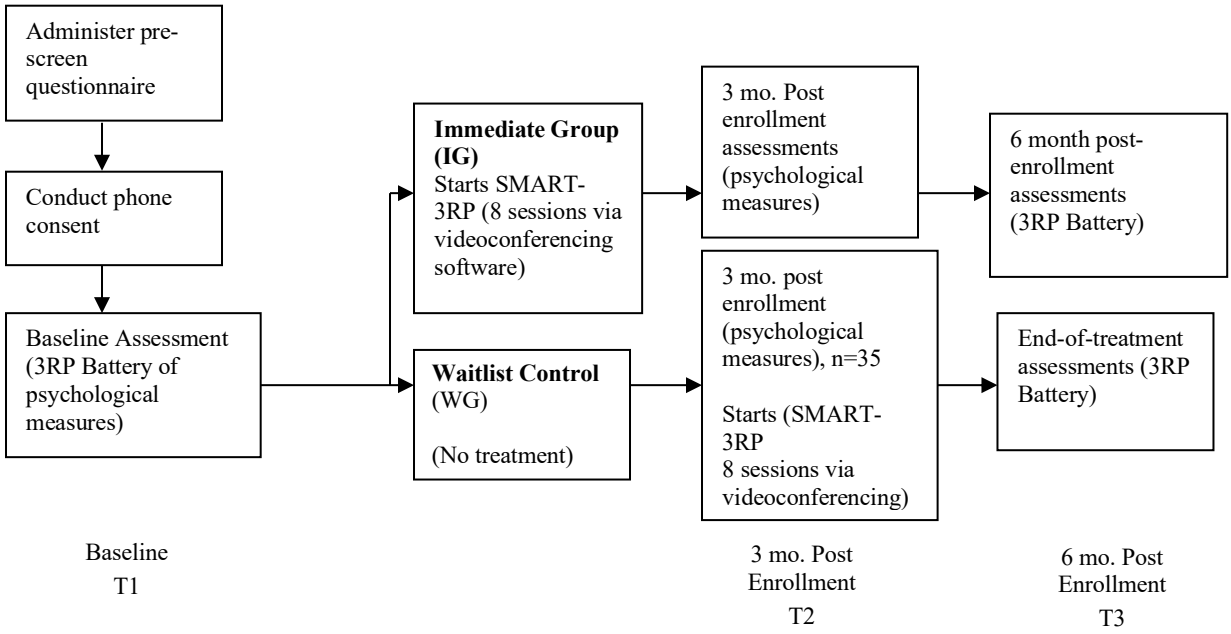
Participants randomized to Immediate or Waitlist will participate in the SMART-3RP program. Participants in the Immediate arm will be encouraged to practice the skills taught in the program

during the 3 month follow up period after completion of the 8 session SMART-3RP. Participants in the Waitlist arm will wait for approximately 3 months before beginning the SMART-3RP.

Participants in both groups will be given questionnaires at the same timepoints (baseline, 3 month post enrollment, and 6 month post enrollment). Study staff will email these questionnaires to the participants via the REDCap system. Participants who have not responded within two weeks of each time point will be contacted by telephone to ensure receipt of study data.

Figure 1 (below) illustrates the administration of questionnaires in both groups.

Figure 1. Study Design.



Remuneration

Participants will be given a $20 gift certificate for completing 3 mo. survey and another $20 gift certificate for completing the 6 mo. survey assessment.

Participants may also be compensated up to $40 for their hair samples ($20 for the first and $20 for the second). Compensation will be provided for those who have already submitted at least their baseline hair sample, and for all future participants interested in completing their hair samples.

VI. BIOSTATISTIC ANALYSIS

We plan to conduct a pilot trial of a virtual-based SMART-3RP intervention for parents of children with ASD. Participants in this trial will be randomized to one of two groups: 1) Immediate SMART-3RP intervention, or 2) Waitlist control SMART-3RP group (starting approximately 3 months after enrollment).

The following questions will be assessed:

1) Is the virtual SMART-3RP feasible and acceptable for parents who have children with ASD?

Feasibility will be assessed using attendance and homework completion (i.e. 6/8 sessions and homework completion-See practice note).
Acceptability will be assessed using a Participant Feedback questionnaire (See Feedback questionnaire attached).

2) Is the virtual SMART-3RP program effective for parents of children with ASD?

a) Is there a significant difference in primary and secondary outcome measures between participants in the Immediate and Waitlist SMART-3RP groups at 3 mo. post enrollment?

We will use paired samples t-tests to compare within group differences on primary and secondary outcome measures from 3 mo. to baseline for the Immediate and Waitlist Groups. Primary outcome measures are the General Self-Efficacy Questionnaire (GSE), Current Experiences Scale (CES; from the Post Traumatic Growth Inventory), and the Visual Analogue 0-10 scales (VAS; measuring stress, distress, coping, and physical discomfort). Secondary outcome measures are: the Measure of Current Status-A (MOCS-A; to assess stress reactivity), Cognitive and Affective Mindfulness Scale-Revised (CAMS-R; to assess growth enhancement), and the Parental Stress Scale (PSS; to assess parental stress).

We will then use independent samples t-tests to compare the difference between the Immediate group's 3 months post enrollment and baseline assessment results with the difference between the waitlist group's 3 months and baseline assessment results on primary and secondary outcome measures.

b) Among participants randomized to both conditions, will there be improvements in primary and secondary outcome measures from pre-post SMART-3RP (IG: assessments from baseline-3 mo.; WG: from 3-6 mo.)?

We will use paired samples t-tests to compare all primary and secondary assessments from pre-post SMART-3RP (for the IG, assessments are from baseline-3 mo.; for the WG, assessments are 3 mo. to 6 mo.).

c) Among the Immediate group only, will the changes from baseline to 3 months post enrollment (end of treatment) be sustained at 6 months post enrollment (3 months post treatment)?

We will use paired samples t-test to assess within-group differences in long-term outcomes. We will compare measures at the 6 months assessment to measures at the 3 months assessment for the Immediate group.

3) Will the virtual delivery SMART-3RP be effective in reducing participants' stress levels, measured by hair cortisol?

A mixed effects models approach will be used to examine differences in hair cortisol concentrations (HCC) at baseline (at enrollment) and 3 months (end-of-treatment) for each study arm. Pearson correlation or Spearman's rank correlation will be used to examine the association of HCC with each of our psychological outcomes.

VII. RISKS AND DISCOMFORTS

Participants may feel uncomfortable completing various psychosocial 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, as outlined below. In addition, participants may find it time consuming to practice techniques learned in the intervention or tracking behavior such as elicitation the relaxation response.

Hair cortisol collection: some participants may feel uncomfortable sending us a hair sample. If they feel this way, they will not need to. Participants can still remain in the study if they do not wish to send a hair cortisol sample.

VIII. POTENTIAL BENEFITS

Participants in the current study may observe a reduction in symptoms of parental stress. It is hoped that the intervention will result in a statistically and clinically significant reduction of symptoms across these domains.

The current study may provide support for parents of children with ASD. This intervention may enhance our understanding of the role of mind-body interventions such as the SMART-3RP in parents of children with ASD. This intervention may have widespread implications for types of resources available that may ultimately improve health and well being of parents and children with ASD.

IX. MONITORING AND QUALITY ASSURANCE

All study staff will complete required Partners human subjects trainings prior to the start of study procedures. All interventionists and assessors will have advanced training in interviewing and

assessment. Participants will be informed that they may refuse to answer questions that make them feel uncomfortable. Participants will be advised to wear headphones and sit in a quiet place during each virtual session. Participants will also be asked not to share the contents of the group with anyone else.

Electronic information will be stored in REDCap (Research Electronic Data Capture), a free, secure, and HIPAA-compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group (based at the PHS Needham corporate datacenter).

REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group. The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Data will be stored on password protected computers that will be stored in secure locations at all times. Paper data files (with coded subject identification) will be stored in a locked filing cabinet. Only research staff will have access to these data locations.

A unique anonymous identifier will be assigned to each subject; subsequently, all data collected will be associated exclusively with this identifier. This includes all questionnaires administered over the course of the study, as well as home practice logs.

Data Management and Quality Control Procedures

To maximize accuracy and security, all survey data will be collected and stored on REDCap. Research staff will ensure that proper consent has been obtained before sending the REDCap survey to each participant.

Data and Safety Monitoring Plan

Adverse Event Monitoring: Throughout the study subjects will be monitored for the occurrence of events defined as any undesirable experience or unanticipated risk. Lack of effect of treatment is not considered an event. All adverse events will be reported on an adverse event form.

The principal investigator 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 Principal Investigator. The Principal Investigator has the responsibility of reporting serious adverse events (death, life threatening illness or injury, serious injury, or permanent disability) to PHRC within 72 hours of notification.

Subject Safety

In the case that an issue related to mandatory reporting or duty to warn arises, we will contact the Office of General Council for advice on how to proceed.

X. REFERENCES

[1] Developmental, D. M. N. S. Y., & 2010 Principal Investigators. (2014). Prevalence of autism spectrum disorder among children aged 8 years-autism and developmental disabilities monitoring network, 11 sites, United States, 2010. Morbidity and Mortality Weekly Report: Surveillance Summaries (Washington, DC: 2002), 63(2), 1.
[2] Shimabukuro, T. T., Grosse, S. D., & Rice, C. (2008). Medical expenditures for children with an autism spectrum disorder in a privately insured population. Journal of Autism and Developmental Disorders, 38(3), 546-552.
[3] Kang-Yi, C. D., Locke, J., Marcus, S. C., Hadley, T. R., & Mandell, D. S. (2015). School-based behavioral health service Use and expenditures for hildren with Autism and children with other disorders. Psychiatric Services, 67(1), 101-106.
[4] Rivard, M., Terroux, A., Parent-Boursier, C., & Mercier, C. (2014). Determinants of stress in parents of children with autism spectrum disorders. Journal of Autism and Developmental Disorders, 44(7), 1609-1620.
[5] Bermudez, M. I. O. E., Sanchez, J. E. J. C., del Sol, M. I., & Sevilla, F. (2015). Parents-perceived and self-perceived anxiety in children with autism spectrum disorder. Educational Research and Reviews, 10(18), 2531-2538.
[6] Hayes, S. A., & Watson, S. L. (2013). The impact of parenting stress: A meta-analysis of studies comparing the experience of parenting stress in parents of children with and without autism spectrum disorder. Journal of Autism and Developmental Disorders, 43(3), 629-642.
[7] Foody, C., James, J. E., & Leader, G. (2015). Parenting stress, salivary biomarkers, and ambulatory blood pressure: A comparison between mothers and fathers of children with autism spectrum disorders. Journal of Autism and Developmental Disorders, 45(4), 1084-1095.
[8] Solomon, A. H., & Chung, B. (2012). Understanding autism: How family therapists can support parents of children with autism spectrum disorders. Family Process, 51(2), 250
[9] Lovell, B., Moss, M., & Wetherell, M. A. (2015). The psychophysiological and health corollaries of child problem behaviours in caregivers of children with autism and ADHD. Journal of Intellectual Disability Research, 59(2), 150-157.
[10] Huang, C. Y., Yen, H. C., Tseng, M. H., Tung, L. C., Chen, Y. D., & Chen, K. L. (2014). Impacts of autistic behaviors, emotional and behavioral problems on parenting stress in caregivers of children with autism. Journal of Autism and Developmental Disorders, 44(6), 1383-1390.
[11] Firth, I., & Dryer, R. (2013). The predictors of distress in parents of children with autism spectrum disorder. Journal of Intellectual and Developmental Disability, 38(2), 163-171.
[12] Hall, H. R., & Graff, J. C. (2011). The relationships among adaptive behaviors of children with autism, family support, parenting stress, and coping. Issues in Comprehensive Pediatric Nursing, 34(1), 4-25.
[13] Davis, N. O., & Carter, A. S. (2008). Parenting stress in mothers and fathers of toddlers with autism spectrum disorders: Associations with child characteristics. Journal of Autism and Developmental Disorders, 38(7), 1278-1291.
[14] Miodrag N., Hodapp R.M. Chronic stress and health among parents of children with intellectual and developmental disabilities. CurrOpin Psychiatry. 2010;23:407-11.
[15] Bermudez, M. I. O. E., Sanchez, J. E. J. C., del Sol, M. I., & Sevilla, F. (2015). Parents-perceived and self-perceived anxiety in children with autism spectrum disorder. Educational Research and Reviews, 10(18), 2531-2538.
[16] Gatzoyia, D., Kotsis, K., Koullourou, I., Goulia, P., Carvalho, A. F., Soulis, S., & Hyphantis, T. (2014). The association of illness perceptions with depressive symptoms and general psychological distress in parents of an offspring with autism spectrum disorder. Disability and health Journal, 7(2), 173-180.
[17] McEwen, BS & Stellar, E. (1993). Stress and the individual. Mechanisms leading to disease. *Arch Intern Med.*153(18):2093-101.

[18] Adam, EK & Kumari, M. (2009). Assessing salivary cortisol in large-scale, epidemiological research. Psychoneuroendocrinology. 34(10): 1423-36.