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A Virtual Resiliency Intervention for Parents of Children with Autism: A Randomized Pilot Trial

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Abstract

Parents of children with Autism experience high levels of stress. Resiliency is the ability to cope and adapt when faced with stressful events. This randomized, waitlist controlled pilot trial examines the feasibility, acceptability, and preliminary efficacy of an adapted virtual mind-body group intervention for parents of children with ASD. The intervention was feasible and acceptable. The immediate treatment group showed no difference in distress and greater improvement in resiliency and stress reactivity/coping relative to the delayed treatment group, (M difference 5.78; $p = .038$ and M difference 7.78; $p = .001$ respectively). Findings showed promising feasibility, acceptability, and preliminary efficacy for parents of children with ASD.

Keywords

Autism; Autism spectrum disorder; Mind body; Resiliency; Stress; Parent

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Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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Background

Parents of children with autism spectrum disorder (ASD) are at elevated risk for chronic stress (Hayes and Watson 2013; Miodrag and Hodapp 2010). Factors such as perceived lack of control over their child's behavior, concerns about their child's intellectual functioning and mastery of adaptive behaviors, worries about their child-parent relationships, time and caregiving demands, their children's high rates of exposure to adverse childhood experiences, and uncertainty about their child's future can engender feelings of anxiety and distress (Bermúdez et al. 2015; Rivard et al. 2014; Hutchison et al. 2016). In addition to these emotional challenges, parents of children with ASD also face a number of financial concerns; in the United States the costs associated with caring for a child with ASD are about four times greater for medical expenditures and about 8–9 times greater for general expenditures compared to the costs of caring for a child without ASD (Shimabukuro et al. 2007). These challenges are further compounded by a sense of social isolation, as parents often lack the necessary supports that would allow them to access important healthcare and academic services, and develop treatment and future-related plans for their children with ASD (Lindly et al. 2016; Solomon and Chung 2012). Taken together, these experiences may compromise parents' emotional health.

The stressors associated with parenting a child with ASD have additional negative consequences for parent and child health outcomes. Parents of children with ASD are likely to display atypical cortisol patterns, a biological marker of increased stress (Lovell et al. 2015; Padden et al. 2018). Heightened stress is related to poor health outcomes from autonomic nervous system dysfunction in this growing population, such as maternal depression in parents of children with ASD (Foody et al. 2015; Weitlauf et al. 2014). Moreover, there are likely negative indirect effects of parental stress on child outcomes. Recent studies demonstrate that higher parental stress levels while raising a child with ASD are correlated with child behavioral and conduct problems, poorer parent–child interactions (Hutchison et al. 2016; Valicenti-McDermott et al. 2015), and lower autism services use for young children with ASD (Lovell et al. 2015; Davis and Carter 2008; Firth and Dryer 2013; Hall and Graff 2011; Huang et al. 2014; Karp et al. 2018). These studies suggest that programs to address the consequence of stress might be helpful to parents and their children.

Resiliency refers to the ability to maintain adaptive functioning in the face of trauma and the chronic stressors of daily living and is considered a dynamic process that can be enhanced through resiliency skills training (Connor and Davidson 2003; Park et al. 2013).

Interventions to improve stress management and increase resiliency in parents of children with ASD have the potential to improve both emotional and physical well-being for parents and their children with ASD. Several previous trials have examined the use of stress management and relaxation techniques as one approach to increase resiliency for caregivers and educators of individuals with autism. Many of these trials showed promise for resiliency-related outcomes including enhanced well-being and decreased distress for intervention groups compared to control groups (Benn et al. 2012; Lunskey et al. 2017; Dykens et al. 2014), though other studies have shown no significant group differences in other outcomes (e.g., mindfulness, self-compassion; Benn et al. 2012; Lunskey et al. 2017).

The populations that were the target of these interventions included parents of adults with autism or other developmental disabilities (Lunsky et al. 2017; Dykens et al. 2014) and parents and educators of children with special needs (Benn et al. 2012). Thus, research has not yet explored the benefits of resiliency training for parents of children with autism specifically, though the results of these existing studies suggest that stress management and relaxation techniques may be useful, given the overlap between parents of children with autism and the populations studied to date.

Our work complements and builds on existing research by adapting and testing an empirically-supported, comprehensive, manualized intervention, the Stress Management and Resiliency Training-Relaxation Response Resiliency Program (SMART-3RP), for parents of children with ASD (Park et al. 2013). The SMART-3RP targets a broad array of (1) relaxation elicitation techniques, (2) stress awareness skills and stress management techniques, and (3) positive psychology strategies to increase resiliency and improve one's ability to manage the chronic and daily stressors (Park et al. 2013). This program has been used successfully to improve resiliency outcomes in populations of patients with monoclonal gammopathy of undetermined significance and multiple myeloma (MG + MM) (Denninger et al. 2018), parents of children with learning disability (Park et al. 2018), veterans (Sylvia et al. 2015), palliative care clinicians (Mehta et al. 2016), and interpreters in cancer care (Park et al. 2017). These trials have demonstrated the feasibility and acceptability of the SMART-3RP across diverse patient populations, as well as the efficacy of the program for improving resilience (Park et al. 2013), distress (Denninger et al. 2018; Park et al. 2018; Sylvia et al. 2015), perceived stress (Mehta et al. 2016), perspective taking (Mehta et al. 2016), and stress reactivity (Park et al. 2017). Sylvia and colleagues reported no change in resilience for veterans (2015). Overall, the SMART-3RP has shown promising health and mental health effects for other populations with chronic health conditions (Denninger et al. 2018; Park et al. 2018; Sylvia et al. 2015; Mehta et al. 2016).

This study is unique in that it focuses on the use of a resiliency intervention based on elicitation of the relaxation response and enhancement of stress awareness and stress management techniques (i.e., the SMART-3RP), in a group of parents of children with ASD. This study builds on recent trends in the use of telemedicine by using a telehealth platform to extend program's reach by accommodating parent's busy schedules (i.e., eliminating travel time) and reducing physical barriers to psychosocial care. A narrative review of interventions that target improvements in mental health for parents of children with ASD suggest that the study described here is unique for several reasons: exclusive focus on parents of children with ASD, virtual group platform, stress management and relaxation response focus, randomized design, and follow-up after the immediate treatment period (Da Paz and Wallander 2017). Some existing studies include some, but not all, of these characteristics.

The main goals of this study are to determine the feasibility, acceptability, and preliminary efficacy of the adapted, virtually-delivered SMART-3RP for parents of children with ASD, using a randomized controlled trial with a wait list control group design. Based on the results of a previous study of this intervention (Mehta et al. 2016) and the investigators' experience implementing group behavior health programs, we defined feasibility as having

enrollment above 50% cutoff, average attendance at over half of the sessions, and 50% of enrollees completing T2 assessment. We hypothesized that our feasibility outcomes would meet these cut-offs. Additionally, we examined the feasibility of collecting hair samples to further characterize cortisol activity, a biomarker of stress, in this sample using a novel, less invasive methodological approach that aligns with the remote delivery of the intervention. We assessed acceptability based on responses to open-ended questions about the program and questions about the content and duration of the program, and hypothesized that these responses would indicate acceptability (e.g., satisfaction and enjoyment of the program). We examined pre-post changes in resiliency-related primary outcomes, specifically distress, resiliency, and stress coping for the immediate vs. delayed treatment groups. We hypothesized that the intervention would reduce distress, improve resiliency and stress coping/stress reactivity compared to the control group. Exploratory outcomes included psychosocial processes related to stress management (e.g. anxiety, depression) and growth enhancement (e.g. empathy, social support).

Methods

The study was conducted at an academic medical center in Boston from November 2016 to January 2018. IRB approval was obtained from this healthcare system.

Waitlist Controlled Pilot study

Participants and Recruitment—Participants were parents of children with ASD recruited through clinics and community organizations that serve children with ASD. Interested parents completed a pre-screen survey accessed using a link embedded in recruitment materials or they contacted the study research coordinator who screened parents over the phone. Eligible parents were scheduled for a phone consent and orientation to the telemedicine platform. All parents were 18 years or older, proficient in English and willing to engage in an online intervention. The study did not include any inclusion criteria related to parental stress levels at baseline. To keep the focus on the stressors related to parenting a child with ASD, parents were excluded if they had a child with a severe emotional or physical disorder in addition to ASD or another disability. If parents reported regular use of corticosteroids, they were excluded as this would influence our measurement of hair cortisol. The study included 51 participants two of whom were fathers. The average age was 45 years ($sd = 7.6$), the majority (80.4% were married or partnered) and most were non-Hispanic white (82.4%). (See Table 1.)

Intervention—The SMART-3RP is an eight-session mind–body intervention, beginning with 1 intake session, that aims to decrease distress and increase growth enhancement (Park et al. 2013). Mind–body interventions refer to those that aim to unite the body and mind to promote health and healing through a variety of practices such as relaxation techniques, mindfulness meditation, and yoga (Dusek and Benson 2009). The SMART-3RP incorporates three core skills-training components: mind–body practices, cognitive-behavioral therapy skills, and positive psychology approaches (depicted in the left-hand column of Fig. 1). First individuals learn how to elicit the relaxation response, defined as the physiological state of decreased sympathetic nervous system activation. From a state of relaxation, individuals are

better able to notice and manage stress and experience psychosocial growth, thereby promoting overall resiliency. These intermediary processes of stress management and growth enhancement are depicted in the middle column of Fig. 1 and indicate the processes of the SMART-3RP intervention components (Park et al. 2013; Dusek and Benson 2009 See Fig. 1). Figure 2 provides an outline of the SMART-3RP intervention sessions, highlighting the specific relaxation response (RR) elicitation strategies (e.g., breath awareness, body scan), cognitive-behavioral therapy strategies (e.g., creating adaptive perspectives), and positive psychology skills (e.g., using humor) that are used in each session in alignment with this theoretical framework. In each session, participants learned new ways to elicit the RR, use adaptive coping strategies to address stress and improve adaptive and healthy behaviors. Additionally, participants were encouraged to practice the skills throughout the week.

Participants were consented and oriented in a one-on-one call. All enrollees attended a group intake session. The intervention was delivered in 8 1.5 h virtual sessions. The virtual platform allowed for participants to see each other and for everyone to see presentation slides. Sessions took place weekly during consecutive weeks. Sessions were conducted through a secure, HIPAA-compliant online group videoconferencing program. Clinical psychologists, trained to implement the SMART-3RP conducted the intervention and participated in weekly clinical supervision to assure the quality and adherence to the SMART-3RP model.

We built upon a version of the SMART-3RP manual that was designed for parents of children with learning disabilities (Park et al. 2018). We modified the intervention to the needs of parents of children with ASD based on parent and professional in-depth interviews (e.g. clinicians, school personnel, and staff of advocacy organizations.) These qualitative interviews were conducted from June to July 2016 with two clinicians, one individual from an ASD-related professional group and nine parents of children with ASD. Intervention modifications included using examples related to having a child with ASD and addressing issues that are common for parents of children with ASD such as child sleep issues impacting parental sleep.

Design

Randomization—We randomly assigned participants from January to June 2017. Participants were randomly assigned (1:1) to participate in the SMART-3RP immediately after enrollment (immediate group [IG]) or after 3 months of waiting (wait-list control group [WLC]) using a random plan generator. The intervention was conducted with 3–8 participants each and participants were randomly assigned to intervention or wait-list control groups. Intervention and wait-list control groups were offered a day or evening time and we allowed individuals to choose whether they would attend a day or evening slot during their randomized time period. We offered day and evening sessions for each intervention time period to accommodate different parent schedules. We ran eight groups (four immediate and four delayed).

All participants completed three sets of questionnaires at enrollment (T1), 3 months post-enrollment (T2), and 6 months post-enrollment (T3) (Fig. 3). Parents were asked to supply hair samples at time 1. All questionnaires were administered via email through a secure,

electronic data capture tool, Research Electronic Data Capture (REDCap). Informed consent and authorization was obtained and documented through use of a written consent form approved by the Partners Human Research Committee (PHRC) and signed by the participant during a video conferencing consent procedure with the study coordinator or qualified study staff.

Stress Biomarker: Hair Sample Procedure—All participants were asked to provide hair samples to measure cortisol activity (“stress hormone”). Hair grows approximately 1 cm/month, and each cm provides a snapshot of cumulative cortisol secretion over the past month. Hair sampling offers the benefit of providing a more integrated measure of chronic stress, while being less burdensome, invasive, and easier to collect than saliva sampling, which requires subjects to provide several samples throughout the day (Meyer et al. 2014; Meyer and Novak 2012). Hair cortisol tests compared favorably to salivary cortisol tests (D’Anna-Hernandez et al. 2011). Consistent with hair sample collection procedures outlined by Dr. Jerrold Meyer’s laboratory at the University of Massachusetts, Amherst, study participants were instructed to cut a small sample of hair (approximately 150 strands, which is about the density of a small pencil eraser) from the back of the head, closest to the scalp. They were instructed to mail the hair back to us in the packing materials provided, along with the date and time the sample was collected. We collected approximately 3 cm of hair in length, which reflects cortisol concentration levels over approximately 3 months. During the consent meeting, a study staff member demonstrated how to cut the hair sample. Participants were compensated \$20 for the hair sample. Samples were analyzed in duplicate by Dr. Meyer’s laboratory using a commercially available enzyme immunoassay (EIA) kit.

Assessments

Baseline Demographic—The demographic questionnaire is a ten-item self-report survey that collects information about parent age, gender, race, ethnicity, and relationship and employment status. Child variables such as age, specific ASD diagnosis, and number of children living in the household were also collected.

Feasibility and Acceptability—We recorded enrollment numbers (number of subjects approached and screened), number of sessions attended, and number of subjects completing each assessment. We conducted a brief survey at the post treatment time point. We asked both groups post treatment how often they practiced the RR and for feedback about the program in open ended questions.

Outcomes Assessed T1, T2 and T3

Measures for our primary and exploratory outcomes were selected in alignment with our theoretical framework (Fig. 1). These measures are widely used, well-validated measures with strong psychometric properties that have been previously established and described; we provide details of psychometric properties for measures that are not widely known, and provide references to indicate the validation of well-known measures.

Primary Efficacy Outcomes

Distress: Visual Analogue Scale (VAS)–Distress: The VAS–Distress is based on a one-item analog scale asking about distress: “How much distress do you experience?” (NCCN clinical practice guidelines 2007). Respondents rated their current levels of distress on a scale of 0–10, with higher scores indicating greater distress. The VAS was correlated with the Hospital Anxiety and Depression Scale at (.66 anxiety subscale, .45 Depression subscale, and .65 total scale) in a French Study (Lesage et al. 2012).

Resiliency: Current Experience Scale (CES): The CES is a 25-item measure of resiliency adapted from the Post Traumatic Growth Inventory, to reflect current functioning in the domains of appreciation for life, adaptive perspectives, personal strength, spiritual connectedness, relating to others, adaptive health behaviors (Tedeschi and Calhoun 1996). We scored the CES based on the work of Tedeschi and Calhoun, with higher scores indicating greater resilience. As it reflects current functioning, it can be administered across multiple time-points to assess for change over time, thus capturing resilience as a dynamic growth process (Deshield et al. 2016). The CES has shown good internal consistency reliability, as well as good convergent validity in terms of expected correlations with related measures of psychological well-being (Luberto et al. 2017).

Stress Reactivity/Coping: Measure of Current Status (MOCS-A): The MOCS-A is a 13-item self-report measure developed to assess participants’ current self-perceived status on: the ability to relax at will, recognize stress-inducing situations, restructure maladaptive thoughts, be assertive about needs, and choose appropriate coping responses as needed (Carver 2006). We use the total score which can range from 0 to 52, and higher scores indicate greater self-perceived proficiency with these skills. Average alphas for subscales ranged from .71 to .89 (Antoni et al. 2006).

Exploratory Outcomes

Worry: Penn State Worry Questionnaire (PSWQ)—The PSWQ is a widely used, well-validated 16-item self-report measure that assesses the trait of (or the tendency towards) worry in individuals (Meyer et al. 1990). Total score is calculated by summing 11 items and the reverse-scores of five items so that higher scores reflect increased worry. Cronbach’s alpha of 0.93 was reported for subjects with anxiety disorders, suggesting good internal reliability. Correlations between the PSWQ and the Self-Analysis Questionnaire (SAQ-Form 9) subscales were significant, (P s < 0.001: Tension: $r = 0.54$; Anxiety: $r = 0.35$; Depression: $r = 0.39$), suggesting good convergent validity (Brown et al. 1992).

Depression and Anxiety: The Patient Health Questionnaire–4 (PHQ–4)—The PHQ-4 is a validated four-item brief self-report measure that assesses symptoms of depression and anxiety to assist clinicians in the diagnosis and treatment of the disease, widely used in clinical and research settings (Kroenke et al. 2009). The measure was created using two anxiety items from the Generalized Anxiety Disorder-7 item (GAD-7) and two depression items from the PHQ-8 to allow for quick measurement of symptoms based on the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual Fourth Edition (DSM-IV). Higher scores indicate greater symptoms of depression and

anxiety. Cronbach's alphas were .83 and .92 at baseline and end of treatment, respectively, among primary care patients at 32 practices in Scotland. Yet with strong internal consistency the measure differs from the depression subscale of the Hospital Anxiety and Depression Scale (HADS-D) regarding its measure of depression severity (Cameron et al. 2008). Pearson's correlations of the PHQ-9 were .90 with the Hopkins Symptom Checklist depression subscale and .78 with the Hamilton Rating Scale for Depression among 135 adults with traumatic brain injury (Fann et al. 2005).

Social Support: Medical Outcome Study Social Support Survey (MOS-SSS)—

The MOS-SSS is a 19-item self-report survey that measures the functional aspects of social support based on four dimensions: tangible support (material aid and assistance); affectionate support (love and affection); positive social interaction (engaging in entertaining activities with others); and emotional/informational support (feedback, guidance and information) (Sherbourne and Stewart 1991). Total scores range from 19 to 95, and higher scores reflect higher levels of social support. The scale is reliable ($\alpha > .91$), stable over time, and has good construct validity.

Positive Affect: Positive and Negative Affect Schedule–Positive Subscale (PANAS-P)—

The PANAS is a widely used measure of general affect, with strong and well-described psychometric properties (Watson et al. 1988). The PANAS-P is a 20-item measure that assesses global dimensions of positive and negative affect. In the current study, we administered the ten-item positive affect subscale (PANAS-P) to assess positive emotions. Scores are calculated by summing the items for a scale with a range of 10–50. Internal consistency ranged between .86 and .90 for positive affect. Test–retest reliability (1 week) was .79 for positive affect. The PANAS has strong reported validity with such measures as general distress and dysfunction, depression, and state anxiety. The PANAS has been used in research on mind–body interventions (West et al. 2004; Vadiraja et al. 2009; Danhauer et al. 2009).

Perspective Taking Subscale: Interpersonal Reactivity Index (IRI)—The IRI is a well-validated 28-item self-assessment of cognitive and affective components of empathy (Davis 1980, 1983). The IRI internal reliability is reported at .70 to .78 (Davis 1980). We used the seven item sub-scale on perspective taking asking endorsement of items such as “I try to look at everybody's side of a disagreement before I make a decision.”

Mindfulness: Cognitive and Affective Mindfulness Scale–Revised (CAMS-R)—

The CAMS-R is a 12-item self-report measure of trait mindfulness (i.e., the ability to be mindful in everyday life), which shows appropriate reliability and validity (Feldman et al. 2007). Respondents report upon four subscales of mindfulness components (attention, present-focus, awareness, and acceptance/non-judgment) using a 4-point Likert scale from 1 (rarely/not at all) to 4 (almost always). Scores on the scale are summed, with higher scores reflecting greater mindfulness.

Parental Stress: Parental Stress Scale—The Parental Stress Scale is an 18-item measure that uses a five-point scale to assesses positive and negative experiences of parenting, as well as parental stress levels (Berry and Jones 1995). Respondents are asked to

report how strongly they agree or disagree with each item (disagree (1) to strongly agree (5)). Positive items include topics on emotional benefits, self-enrichment, personal development, whereas negative items explore demands on resources, opportunity costs, restrictions. Positive items are reverse scored. Scores range from 18 to 90, with higher scores indicating greater parental stress.

Analyses

Primary Analyses—We assessed study feasibility based on rates of enrollment, intervention session attendance, and survey retention post intervention. Potential risk factors for study attrition were explored by comparing study completers and non-completers at T1 demographic characteristics, using independent samples t tests for continuous characteristics and Chi square or Fisher's exact test for categorical characteristics.

We assessed intervention acceptability by reviewing participant quantitative and open-ended feedback among immediate treatment participants at T2. We first reported demographic characteristics of the immediate and delayed treatment groups. We also reviewed the univariate distributions of cortisol at T1. Although hair cortisol data were positively skewed and had a few outliers ($Z > 2.5$), we reported means and standard deviations in their original units to facilitate interpretation and comparison with other populations.

Preliminary Efficacy Assessments—We then used all available cases with pre and post data to test between-group (immediate versus delayed treatment) differences in change scores for our psychosocial variables (T2 score—time 1 score) using independent samples t tests. Using the intent-to-treat principle, we re-ran the t tests of group differences using multiple imputation (five imputed datasets) to estimate missing T2 data.

We followed our main tests of group differences with additional exploratory analyses, using all available cases to further characterize potential intervention efficacy. First, we evaluated T1–T2 changes in psychosocial factors within each randomized group, using paired samples t tests. Second, we explored potential maintenance of intervention benefits by evaluating changes in psychosocial factors within the immediate treatment group during their follow-up period (T2–T3) using paired samples t tests. Finally, to explore a potential moderator of intervention efficacy in preparation for a future trial, we conducted a series of Pearson correlations to explore whether parenting stress at time 1 was associated with T1–T2 change scores in the immediate treatment group. All analyses were conducted in IBM SPSS version 23 and were tested at $p < .05$. We focus our interpretation on effect sizes.

Results

Feasibility

Figure 4 shows the 113 parents who were screened with 64 entering randomization and 51 completing the baseline surveys and 25 assigned to the immediate group and 26 in the delayed group. Primary reasons for non-enrollment ($n = 49$) included inability to reach parent for subsequent screening ($n = 41$) or lack of parent interest following screening ($n = 8$). Among enrollees, 13 participants (seven immediate group and six delayed group) withdrew prior to completing the time 1 survey, leaving a total of 51 study participants.

Fully, 65% of intervention participants completed 6 sessions. Among time 1 participants, 42/51 (82.4%) completed the T2 survey and 34/51 (66.7%) completed the time 3 survey, with similar proportions of attrition between the immediate and delayed treatment groups at T2 and T3 (Fig. 1). Among 72% of intervention group participants who completed the post-intervention survey, 83% reported practicing RR exercises at least “a few times a week.”

We were able to obtain hair cortisol concentrations for 34 individuals at time 1 showing (67% response among the 51 who completed time 1 questionnaires) a mean hair cortisol concentration of 10.3 (SD = 12.2) pg/mg for the immediate intervention group and 9.8 (SD = 8.7) pg/mg for the delayed intervention group. These concentrations are consistent with values previously reported in other adult populations (10.8 pg/mg) (Gidlow et al. 2016). Primary reasons for missing hair samples include the participant having too short or no hair, having recently color treated hair, corticosteroid use, or the participant declining to provide a hair sample.

Demographic factors did not differ between immediate and delayed intervention groups at time 1, except that the delayed intervention group was marginally more diverse than the immediate intervention group with respect to race identification (Table 1).

Acceptability

Post-intervention, group participants reported being comfortable in the group sessions, and 73% said the sessions were the right length 70% felt that eight sessions were the right number of sessions. In response to open ended questions, parents generally noted that they found the virtual intervention to be quite helpful. For example one participant noted, “I really liked it! It provides a wonderful opportunity to so many. Providing delivery this way—especially in a group—could be very powerful and long-lasting to some who may not otherwise make time to drive someplace. I sincerely hope this program is further developed and shared with other therapeutic venues to connect with the millions of parents and family members who would benefit from this.” Others stated that the practice of RR techniques and the connection with other parents were particularly useful, “I really liked the in-session RR exercises. I participated in things I might not have done on my own (e.g. guided imagery) and processed the experience with others. It was validating that I was doing it ‘right’ or that others had similar feelings after participating (especially debriefing whether or not it worked for them/me).” Some parents noted that they wanted a shorter program while others wanted it to be longer.

Preliminary Efficacy

Based on between-group differences in change scores from time 1 to time 2, the immediate intervention group showed greater improvement in resiliency (CES) and stress reactivity/stress coping (MOCS-A) relative to the delayed intervention group, reflecting a medium effect size. (See Fig. 3 for the study design and Table 2 for the results). For distress (VAS), the immediate intervention group showed a small, but non-significant improvement in distress.

Among other measures of efficacy, the immediate intervention group showed greater improvements in depression/anxiety (PHQ-4), social support (MOS-SSS), and mindfulness

(CAMS-R) relative to the delayed intervention group, with medium to large effect sizes for all differences. The immediate intervention group showed small to medium improvements in the remaining secondary outcomes (worry [PSWQ], positive affect [PANAS-P], and empathy [IRI]) relative to the delayed intervention group, although these differences did not reach statistical significance. Results of pooled analyses using multiple imputation for time 2 missingness showed a similar pattern of results (not shown).

In follow-up within-group analyses (Table 3), the immediate intervention group showed improvements from T1 to T2 in our proposed primary outcomes (distress, resiliency, and stress reactivity/stress coping) and several secondary outcomes (depression/anxiety, positive affect, empathy, and mindfulness), with no change in worry or social support. In comparison, the delayed intervention group did not show changes in any of the proposed outcomes from T1 to T2 (the two-time periods before the intervention for this group). Finally, results of within-group analysis of change in all proposed outcomes in the immediate intervention group only from time 2 to time 3 showed that the immediate group's time 2 values did not change at time 3 ($p = .15$) suggesting no loss of the intervention effects ($N = 17$).

Exploration of the association of baseline parental stress with time 1 to time 2 change scores for all proposed outcomes in the immediate group ($n = 20$) showed no associations of baseline parental stress with any change scores ($p = .13$).

Discussion and Conclusion

Findings from our randomized pilot trial showed promising feasibility, acceptability, and preliminary efficacy of the SMART-3RP for improving resiliency-related outcomes for parents of children with ASD. Findings about enrollment (57% parents entering randomization and 51 completing the baseline surveys), session attendance (65% of the sample completed at least six sessions), and completion of study assessments (82% of T1 participants completed the T2 surveys) suggest that the program is feasible for this population. Although scheduling was a challenge for some parents, this level of enrollment is encouraging and can help us expand our time offerings for future programs.

Parents generally found the content of the program acceptable and most indicated that they planned to continue practicing relaxation response techniques after the intervention was over. The use of the online format did allow for individuals to join from diverse US geographical locations, required no commute time, and likely reduced the need for child care in order to participate. The video platform for group sessions is an innovative approach in mind-body research. It allows for the benefits of social support and clinician interaction while allowing participation remotely.

The preliminary assessment of efficacy in this pilot study was promising with a medium effect size for many measures. Participants in the immediate intervention group also showed improvements in current distress, although this change did not differ relative to the change in distress in the delayed intervention group nor did it have a large effect size. Other tests of this intervention have seen changes in distress in populations of parents of children with disabilities (Park et al. 2018), veterans (Sylvia et al. 2015), and MG and MM (Denninger et

al. 2018). Perhaps the types of distress that parents of children with ASD experience are difficult to change or fully eliminate. The other primary outcomes did change in the expected direction. Participants in the immediate intervention group showed greater improvements (T1–T2) in resiliency and stress reactivity/stress coping relative to the delayed intervention group, with a medium effect size for the difference between groups. That the resiliency measure was responsive to the intervention seems reasonable since parents were taught resiliency skills and resiliency is the response to stressors and is thus modifiable. If we consider resiliency as the response to daily stress and distress, resiliency is a modifiable factor that may be improved by training in skills such as those included in the SMART-3RP.

In this group of parents, it is likely that many of the child and family-related stressors may have remained unchanged and thus if parents were responding to the VAS measure of distress considering these unchanged stressors rather than their response to stressors, we would not likely see differential change in the groups. That said, other papers examining mindfulness interventions found changes in stress using different measures and somewhat different intervention populations (Benn et al. 2012; Lunsy et al. 2017; Dykens et al. 2014). Further exploration of different measures of distress and comparing the impact of different interventions may be warranted and may suggest whether and how distress can be changed. Expanding on this work to include both self-reported and biomarkers of stress will further our knowledge of the impact of this type of intervention. We also feel that since the primary target was improvements in resiliency, that is an important outcome to consider in future studies as it is more proximate to the intervention and likely more modifiable.

For the other outcomes one of two measures of stress management showed improvements in the expected direction with medium to large effect sizes (depression/anxiety) but the third measure (worry) did not show differences. It may be that given the many demands on this group of parents, worry is inherently present. Perhaps this fits the pattern seen earlier with resiliency changing but not distress where some traits such as worry are difficult to change in a population with many potential sources of stress and worry.

The improvement in depression/anxiety is promising. Amongst the growth enhancement measures, two of the four showed results in the expected or improved direction with medium to large effect sizes (social support and mindfulness but not positive affect or empathy) in the main analyses. The large effects for social support and mindfulness are encouraging, as they were primary focuses of the group intervention. Post hoc, the interventionists suggested that empathy may not have been a strong enough focus of the intervention to pick up change (there was no specific session devoted to the topic of empathy). The lack of change in positive affect may be due to its design, the PANAS-P picking up the state of positive affect thus picking up fluctuation based on how someone is feeling in a short time frame (2 weeks) rather than picking up on global intervention effects. Or perhaps positive affect may not change meaningfully, and the other positive changes in the constructs noted above capture a more accurate picture of this population's psychological well-being.

We saw no difference in intervention outcomes based on the baseline levels of parenting stress suggesting that the intervention was similarly beneficial for individuals with different baseline parenting stress levels. We further saw maintenance of the intervention effects (for

the immediate group) between the time period immediately post intervention and 3 months later. This suggests that the positive effects were maintained.

Limitations

This pilot intervention included a relatively well-educated group of parents with less racial and ethnic diversity than the general population of parents of children with ASD. Next trials of the intervention package will need to employ new strategies to successfully recruit a more diverse sample. This is important both for the generalizability of the findings and to determine whether the intervention works equally well in different subgroups. Second, this study was set up as a pilot intervention and not powered to detect changes in all of the measures. The medium to large intervention effect observed in this study support the importance of testing our proposed intervention outcomes in an adequately powered study, with attention to adjustment for multiple comparisons. Finally, we did see differences in the immediate and delayed treatment group for race. Due to the relatively small overall sample size these difference were due to a small number of individuals. Further work with larger samples will allow for more complex statistical models controlling for differences between groups. Moreover, further work should consider whether the intervention works equally well for different groups of parents (e.g. different racial/ethnic groups, parents from families with different socio-economic status, and mothers vs. fathers).

Conclusion

Overall, this resiliency intervention has promise for improving resiliency in this group of parents who experience high levels of stress and is a growing population. Remote delivery via video conferencing has promise for making the intervention accessible to a broader group of parents.

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Fig. 1.

Conceptual model. *CAMS-R* cognitive and affective mindfulness scale-revised, *CBT* cognitive behavioral therapy, *CES* current experience scale, *CI* confidence interval, *IRI* interpersonal reactivity index, *MOCS-A* measure of current status, *MOS-SSS* medical outcome study social support survey, *PANAS-Pos* positive and negative affect schedule-positive subscale, *PHQ-4* patient health questionnaire-4, *PSWQ* Penn State Worry Questionnaire, *SD* standard deviation, *VAS* visual analogue scale

Session	Session Content
1	Introducing Resiliency and the Relaxation Response <i>RR Practice</i> : Simple Breath Awareness
2	SMART-3RP and The Science of Mind-Body Medicine <i>RR Practice</i> : Single-pointed focus meditation and body awareness
3	The Relaxation Response and Recuperative sleep <i>RR Practice</i> : Body scan and the mini
4	Stress Awareness: Mindful Awareness and Social Support <i>RR Practice</i> : Mindful awareness and mindful body meditations
5	Mending Mind and Body: Thoughts and Movement <i>RR Practice</i> : Yoga, walking meditation
6	Creating an Adaptive Perspective and Healthy Eating <i>RR Practice</i> : Insight imagery and joyful place imagery
7	Promoting Positivity and Physical Activity <i>RR Practice</i> : Contemplation
8	Healing States of Mind, Empathy, and Creative Expression <i>RR Practice</i> : Loving Kindness, I am... at peace meditation
9	Humor and Staying Resilient <i>RR Practice</i> : Idealized Self meditation

RR= Relaxation Response

Fig. 2.
SMART-3RP intervention session content. *RR* Relaxation Response

Fig. 3.
Schema: Waitlist controlled study design

Fig. 4.
Consort diagram

Table 1

Sample demographic characteristics for the total sample, immediate treatment group, and delayed treatment group

Variables	n(%) or M ± SD		p ¹
	Total (n = 51)	Immediate (n = 25)	Delayed (n = 26)
Age (years) [*]	45 ± 7.6	45 ± 7.2	45 ± 8.1
Female	49 (96.1)	25 (100.0)	24 (92.3)
Hispanic/Latino	2 (3.9)	1 (4.0)	1 (3.8)
Race ²			
White	43 (84.3)	24 (96.0)	19 (73.1)
Black or African American	3 (5.9)	1 (4.0)	2 (7.7)
Asian	2 (3.9)	0 (0.0)	2 (7.7)
Native Hawaiian or other Pacific Islander	1 (2.0)	0 (0.0)	1 (3.8)
Other	2 (3.9)	0 (0.0)	2 (7.7)
Marital status ^{3*}			
Married/living as married	41 (80.4)	21 (84.0)	20 (76.9)
Divorced/separated	7 (13.7)	2 (8.0)	5 (19.2)
Never married	2 (3.9)	1 (4.0)	1 (3.8)
Education level ^{4*}			
High school graduate/GED	1 (2.0)	0 (0.0)	1 (3.8)
Some college/technical school	6 (11.8)	3 (12.0)	3 (11.5)
College graduate	43 (84.3)	21 (84.0)	22 (84.6)
Employment status ^{5*}			
Employed for wages	28 (54.9)	14 (56.0)	14 (53.8)
Homemaker	13 (25.5)	7 (28.0)	6 (23.1)
Self-employed	5 (9.8)	2 (8.0)	3 (11.5)
Unable to work	3 (5.9)	1 (4.0)	2 (7.7)
Out of work > 1 year	1 (2.0)	0 (0.0)	1 (3.8)
Number of children in household			
0–1	23 (45.1)	10 (40.0)	13 (50.0)
2	28 (54.9)	15 (60.0)	13 (50.0)

Variables	n(%) or M ± SD			P ¹
	Total (n = 51)	Immediate (n = 25)	Delayed (n = 26)	
Age of child(ren) with ASD ⁶				
2–11	26 (51.0)	10 (40.0)	16 (61.5)	.26
12–16	16 (31.4)	10 (40.0)	6 (23.1)	.23
17	9 (17.6)	4 (16.0)	5 (19.2)	1.00

Sample size (percentage) and p value for difference between immediate treatment group and delayed treatment group

ASD autism spectrum disorder

*Missing n = 1

¹A t test was used to compute the p value for parent age, and Chi square tests were used to compute p values for the remaining categorical variables

²P value is for comparison of White versus all other groups

³P value is for comparison of married/partnership versus all other groups

⁴P value is for comparison of college graduate versus all other groups

⁵P value is for comparison of employed or self employed versus all other groups

⁶One participant had two children with ASD. The P value shows the difference per age category (since that family had children in two different categories)

Table 2

Differences in change scores between the immediate (n = 20) and delayed (n = 22) treatment groups from study enrollment (time 1) to 3 months post-enrollment (time 2)

Variables	M (SD) Immediate	Waitlist	M diff	95% CI	t	p	d
Distress (VAS)	-1.35 (2.50)	-.36 (2.74)	-0.99	-2.63 to 0.65	-1.22	.23	.38
Resiliency (CES)	6.05 (8.04)	.27 (8.04)	5.78	.78 to 10.78		.024	.69
Stress reactivity/stress coping (MOCS-A)	7.60 (7.24)	-.18 (6.66)	7.78	3.45 to 12.12	3.63	.001	1.12
Worry (PSWQ)	-1.25 (2.71)	-.50 (2.13)	-0.75	-2.26 to .76	-1.00	.32	.31
Depression/anxiety (PHQ-4)	-1.80 (2.28)	-.27 (2.53)	-1.53	-3.04 to -.02	-2.05	.047	.64
Social support (MOS-SSS)	4.15 (11.29)	-2.73 (9.70)	6.88	.33 to 13.42	2.12	.040	.65
Positive affect (PANAS-Pos)	3.20 (3.64)	-.36 (7.59)	3.56	0.21 to 7.34	1.91	.06	.60
Empathy (IRI)	2.50 (3.80)	.64 (3.37)	1.86	-.37 to 4.10	1.68	.10	.52
Mindfulness (CAMRS-R)	2.95 (3.47)	.27 (3.53)	2.68	.49 to 4.87	2.47	.018	.77

Bold values indicate $p < .05$

d = Cohen's d (effect size); sample sizes for analyses included study completers at time 2

CAMS-R cognitive and affective mindfulness scale-revised, *CES* current experience scale, *CI* confidence interval, *IRI* interpersonal reactivity index, *MOCS-A* measure of current status, *MOS-SSS* medical outcome study social support survey, *PANAS-Pos* positive and negative affect schedule-positive subscale, *PHQ-4* patient health questionnaire-4, *PSWQ* Penn State Worry Questionnaire, *SD* standard deviation, *VAS* visual analogue scale

Table 3

Changes from time 1 to time 2 within the immediate (n = 20) and delayed (n = 22) treatment groups

Variables	M (SD)		t	p
	Time 1	Time 2		
Distress (VAS)				
Immediate	5.4 (3.0)	4.1 (2.5)	2.42	.026
Control	5.8 (2.3)	5.4 (2.2)	0.62	.54
Resiliency (CES)				
Immediate	71.8 (23.8)	77.9 (23.8)	− 3.36	.003
Control	78.0 (17.5)	78.3 (17.3)	− .16	.87
Stress reactivity/stress coping (MOCS-A)				
Immediate	20.6 (7.0)	28.2 (9.2)	− 4.69	< .001
Control	23.3 (8.3)	23.1 (6.9)	.13	.90
Worry (PSWQ)				
Immediate	9.4 (4.0)	8.1 (3.4)	2.06	.053
Control	8.3 (3.6)	7.8 (3.2)	1.10	.28
Depression/anxiety (PHQ-4)				
Immediate	5.6 (3.3)	3.8 (2.9)	3.52	.002
Control	4.2 (3.1)	4.0 (2.9)	.51	.62
Social support (MOS-SSS)				
Immediate	69.7 (15.3)	73.9 (15.5)	− 1.64	.12
Control	65.9 (19.3)	63.1 (19.5)	1.32	.20
Positive affect (PANAS-Pos)				
Immediate	29.9 (8.7)	33.1 (8.4)	− 3.94	.001
Control	31.7 (8.1)	31.4 (7.2)	.23	.82
Empathy (IRI)				
Immediate	16.3 (6.8)	18.8 (5.9)	− 2.94	.008
Control	18.0 (5.4)	18.6 (4.7)	− .89	.39
Mindfulness (CAMS-R)				
Immediate	37.9 (6.0)	40.9 (5.2)	− 3.80	.001
Control	39.7 (5.7)	40.0 (5.5)	− .36	.72

Bold values indicate $p < .05$

Sample sizes for analyses included study completers at time 2 *CAMS-R* cognitive and affective mindfulness scale-revised, *CES* current experience scale, *IRI* interpersonal reactivity index, *MOCS-A* measure of current status, *MOS-SSS* medical outcome study social support survey, *PANAS-Pos* positive and negative affect schedule-positive subscale, *PHQ-4* patient health questionnaire-4, *PSWQ* Penn State Worry Questionnaire, *SD* standard deviation, *VAS* Visual Analogue Scale