

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

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ASD Study Aims

| <i>Type</i> | <i>Specific Aim</i> | <i>Hypothesis</i> | <i>Measure</i> | <i>Statistical Test Type</i> |
|-------------|--|--|--|---|
| Primary | To develop and determine the feasibility and acceptability of an 8-session Relaxation Response Resiliency program for parents of children with ASD | The SMART-3RP virtual delivery will be feasible to implement and acceptable to parents of children with ASD. | <ul style="list-style-type: none"> • assessing the number of sessions attended • adherence to Relaxation Response Practice • Participant Feedback Survey | |
| Primary | To test the effectiveness of a pilot waitlist controlled trial on improving resiliency and on improving stress reactivity, growth enhancement, and parental stress | Patients randomized to the Immediate group will report significantly greater scores on the primary outcomes and on the secondary outcomes at 3 mo. post enrollment | <ul style="list-style-type: none"> • General Self-Efficacy Questionnaire (GSE) • Current Experiences Scale (CES) • Visual Analogue 0-10 scales (stress, distress, coping, and physical discomfort) (VAS) • Measure of Current Status-A (MOCS) • Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) • Parental Stress Scale (PSS) • Baseline-3 mo. scores on primary and secondary outcome measures between the Immediate and waitlist control group | <ul style="list-style-type: none"> • paired samples t-tests to compare within group differences from 3 mo. to baseline • independent samples t-tests to compare the difference between the Immediate group's 3 months post enrollment and baseline assessment results |

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| Secondary | to investigate the extent of pre-post changes in primary and secondary outcomes among participants randomized to both conditions | Scores on primary and secondary outcome measures will improve from pre-post intervention. | • Immediate: assessments from baseline-3 mo.; Waitlist: from 3-6 mo.) | • paired samples t-tests to compare all primary and secondary assessments from pre-post SMART 3-RP |
| Secondary | to assess whether end-of-treatment improvements will be sustained improvement on primary and secondary outcome measure from 3 to 6 mo. post enrollment | These end-of-treatment effects will be sustained at 6-mo. post enrollment. | | • paired samples t-test to assess within-group differences in long-term outcomes compare measure at the 6 months assessment to measures at the 4 month assessment for the Immediate group |
| Secondary | To pilot test the end-of-treatment effects of the SMART-3RP on parents' stress levels | 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. 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. | <ul style="list-style-type: none"> • mixed effects models to test hair cortisol concentrations (HCC) • Pearson Correlation to examine the association of HCC with each of our psychological outcomes • measuring basal HPA axis and SNS activity | |