Title Sensory Habituation in Autism Spectrum Disorders

NCT Number NCT06247176

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Study Design

A between-subjects design will be used with two groups of 20 participants each ASD with hyperresponsivity (ASD-RE; n=20) and those with ASD and hyperresponsivity who will experience VR but will not see the aversive stimuli (ASD-CTL; n=20). A between- subjects design will be used to identify the difference in habituation between the groups, in addition to within-subject analysis. Participants will be randomly assigned to group. Note these are final sample sizes; we have planned for attrition in the budget. All groups will be matched on age and sex. Participants need to have a pre-existing diagnosis of autism that will be confirmed using ADOS-2, and clinical judgement. If they do not, we will provide them a full diagnosis at the first visit and will be performed by the ASD Diagnostics team at MMI. Their diagnostic evaluation is a two-part process, with a clinical interview and a testing. The interview is with the parent/guardian and the child, asking questions about the child's development. The testing will include a variety of tests looking at cognitive, social, emotional, speech, and adaptive skills. In total, an evaluation will take up to 4 hours. Participants will complete 4 phases in up to 6 visits: 1) Mock MRI experience, surveys, and assessments, 2) pre-exposure MRI scan, 3) VR exposure, 4) post-exposure MRI. This would total 7 hours and 45 minutes at maximum and 5 hours and 15 minutes at minimum. Prior studies have included studies with 3-4 visits, up to 4 hours each.

Statistical Design for Stated Outcome Measures.

All data will be inspected to ensure that statistical assumptions are met (e.g., normality, skewness, kurtosis, outliers). In the case of non-normal distributions, data will be transformed, or non-parametric analysis methods will be used. We will compare the groups on demographic variables using chi-square tests and t-tests, as appropriate. We plan to balance the groups on participant characteristics, but if there are any differences ($p > .20$) then we will include those variables as covariates in all analyses. Additionally, we will perform a sensitivity analysis that compares people with ASD on medication and not on medication. All of the data analyses described below will be performed in R.

BOLD Response during Visual Stimulation A linear mixed model will be used with time (pre/post) and groups (ASD-RE /ASD-CTL) as fixed factors and participant as a random factor for each of the ROIs. Post-hoc t-tests will be performed for all significant interactions.

Connectivity during Visual Stimulation A linear mixed model will be used with time (pre/post) and groups (ASD-RE /ASD-CTL) as fixed factors and participant as a random factor for each of the ROIs.

Heart Rate A linear mixed model will be used with time (pre/during/post) as a fixed factor, participant as a random factor, and physiological response habituation measure as a predictor variable, for the activation and connectivity habituation measures to identify if the change in physiological response predicts the changes in the brain.

Electrodermal Activity A linear mixed model will be used with time (pre/during/post) as a fixed factor, participant as a random factor, and physiological response habituation measure as a predictor variable, for the activation and connectivity habituation measures to identify if the change in physiological response predicts the changes in the brain.

Skin Temperature A linear mixed model will be used with time (pre/post) as a fixed factor, participant as a random factor, and physiological response habituation measure as a predictor variable, for the activation and connectivity habituation measures to identify if the change in physiological response predicts the changes in the brain.