

A Pilot Participatory Program Evaluation of a Virtual Trauma Support Program for Autistic
Adults
NCT05862467
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Data Analytic Plan

For aim 1, we will examine the efficacy of WET in reducing PTSD (and related mental health symptoms) via pre-post change analyses. Our primary outcomes will be pre-post change in self-reported total PTSD symptoms on the PCL-5, evaluated using paired samples t-tests with effect sizes reported as Hedges' g , and pre-post change in self-reported co-occurring mental health symptoms (depression, anxiety, adjustment, loneliness), also evaluated using paired samples t-tests with Hedges' g effect sizes. The same analyses will be conducted with the one and six month follow-up assessments to evaluate whether treatment gains are maintained longitudinally.

For aim 2, we will examine whether WET is associated with changes in objective biobehavioral health metrics and self-reported physical health outcomes. Our primary objective metrics are Fitbit obtained past week number of steps, average sleep duration, and average resting heart rate. Subjective health metrics are self-reported past week pain levels and sleep quality. Pre-post change will be evaluated via paired samples t-tests with Hedges' g effect sizes; analyses will also be conducted with one and six month follow-up assessments.

For aim 3, we will examine treatment satisfaction from autistic adults who experienced the program. In particular, this will involve completing a comprehensive treatment feedback form regarding their satisfaction with each aspect of the program, as well as suggested recommendations for enhancing the program in the future. Qualitative information on treatment experiences will also be collected via a semi-structured interview post treatment completion (week 6 above).

Additional exploratory analyses will include evaluation of (1) pre-post change on secondary outcomes, (2) rate and pattern of change across the study, and (3) how baseline factors relate to magnitude and rate of change. Additional post-hoc analyses may be conducted.

Summary of Study Protocol

The goal of this single-group clinical trial is to learn about the initial efficacy and feasibility of telehealth-delivered Written Exposure Therapy (WET) for autistic adults with traumatic stress symptoms. The main questions the investigators aim to answer are:

- Do symptoms of posttraumatic stress disorder (PTSD) and co-occurring mental health concerns decrease after receiving WET?
- Do biobehavioral health outcomes, including objective (Fitbit indicators of activity, sleep, and heart rate) and subjectively-reported health variables (e.g., sleep, pain, health-related quality of life), improve after receiving WET?
- How do autistic adults experience WET, and how can this program be modified and enhanced in the future in collaboration with autistic adults?

Participants will complete the following as part of the study, which is completed entirely over telehealth.

- Participants will first complete an initial assessment, involving brief measures of cognition and autistic traits, as well as interviews and questionnaires about PTSD, mental health, and physical health. If eligible, participants will proceed to the following steps:
- Eligible participants will then start wearing a Fitbit, to be used for the duration of the study.
- Participants will then participate in 5 weekly virtual visits involving the WET protocol, including weekly brief assessment of PTSD and mental and physical health.
- Then, participants will complete a sixth virtual visit the following week where PTSD, mental and physical health, and treatment feedback are assessed.
- Lastly, participants will complete virtual visits 1 and 6 months later involving re-assessment of PTSD and mental and physical health.

Therefore, this is a pre-post single group design, where all participants will receive WET to establish initial efficacy and feasibility. Investigators will also consult with an autistic advisory board throughout the project, and make adaptations as recommended in consultation with autistic adults. The goal is to better understand the initial efficacy and feasibility of WET for supporting autistic adults who have experienced trauma.

Primary and Secondary Outcome Measures Include:

Posttraumatic Symptom Checklist for DSM-5 (PCL-5)

Patient Health Questionnaire (PHQ-9)

Anxiety Scale for Autism-Adults (ASA-A)

University of California Los Angeles (UCLA) 3-Item Loneliness Scale

Brief Adjustment Scale (BASE-6)

Brief Experiential Avoidance Questionnaire

Difficulties in Emotion Regulation Scale, Short (DERS-16)

Ultra-Brief Self-Stigma of Seeking Help (SSOSH-3) Scale

Camouflaging Autistic Traits Questionnaire (CATQ)

Pittsburgh Sleep Quality Index (PSQI)

PROMIS Pain Intensity Short Form scale

PRMIS Pain Interference Short Form scale

Fitbit (Average past week daily steps, sleep duration, resting heart rate)

Autism Spectrum Quality of Life Scale
World Health Organization Quality of Life Scale
Autism Spectrum Identity Scale