

1. Title

Predictive Modeling and Non-Invasive Sensory Interventions for Autistic Flare-Ups Using Passive Wearable and Environmental Data

2. Principal Investigator

TBD

3. Purpose of Study

This exploratory pilot study aims to evaluate the feasibility of using passive biometric, behavioral, and environmental data streams to develop predictive models of acute behavioral episodes ("flare-ups") in children with autism spectrum disorder (ASD). A secondary goal is to assess the acceptability and safety of gentle sensory interventions delivered via wearable or mobile devices to interrupt or mitigate the severity of these episodes.

4. Background and Rationale

Autistic behavioral episodes are often unpredictable and vary by individual. Many families rely on manual observation and reactive strategies to manage stressors. Recent advances in wearable biometric monitoring, EEG neurofeedback, and mobile computing create an opportunity to passively gather multi-modal data for personalized episode modeling and closed-loop support.

This study will investigate:

- Whether biometric and environmental data can be passively collected and aligned to identify precursor patterns to flare-ups.
 - Whether predictive alerts and/or gentle sensory interventions (audio/haptic/visual) are tolerated and helpful.
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5. Study Design

Type: Observational + Interventional (low-risk)

Duration: 12 months

Sample Size: 10–20 families with children ages 7–14 with a formal ASD diagnosis

Phases:

- **Phase 1 (Months 1–3):** Baseline passive data collection, no intervention.
 - **Phase 2 (Months 4–8):** Real-time risk modeling and caregiver alerts.
 - **Phase 3 (Months 9–12):** Optional gentle intervention (vibration, sound cue, visual distraction) delivered when flare-up risk exceeds threshold.
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6. Devices & Data Types

Signal	Device	Use
Heart rate, HRV, EDA	Fitbit or Oura Ring	Stress detection
Skin temp, motion	Smartwatch	Shutdown prep or restlessness
Location, app usage	Smartphone	Contextual load, overstimulation
EEG	Mendi / Flow Neuroscience / Elemind	Attention, overload
Audio patterns	Phone mic (non-recorded, pattern only)	Sudden noise detection

All devices used will be FDA-exempt, commercially available wellness monitors.

7. Data Privacy and Security

- All data encrypted on-device and transmitted via TLS 1.3
- Personal identifiers removed; pseudonymized ID used for modeling

- Data stored in HIPAA-compliant encrypted cloud storage (e.g. Google Cloud Healthcare)
 - No raw audio or GPS coordinates stored — only event patterns or derived context
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8. Inclusion/Exclusion Criteria

Inclusion:

- Formal ASD diagnosis
- Age 7–14
- Verbal or non-verbal, but must have caregiver communication
- Family willing to use device package and complete weekly logs

Exclusion:

- History of seizure disorder (if EEG device used)
 - Implanted medical devices contraindicating neurostimulation (in Phase 3)
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9. Risk and Mitigation

Risks are minimal and non-invasive:

- Skin irritation from wearables (monitored, opt-out option)
 - Stress from alert or stimulus (customizable, caregiver-controlled)
 - Data privacy: encrypted and access-restricted, fully opt-out
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10. Consent Process

- Full written informed consent from parent or guardian
 - Age-appropriate assent from child, where feasible
 - Ongoing right to withdraw at any time without consequence
 - Clear option to disable sensors or pause data at will
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11. Outcomes & Evaluation

Primary:

- Accuracy of flare-up prediction model (sensitivity/specificity)
- Number of successful predictive alerts

Secondary:

- Family-reported satisfaction and stress reduction
 - Number and outcome of sensory interventions
 - Child's subjective comfort and tolerance of system
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12. Dissemination

Findings will be shared with families, submitted to peer-reviewed journals, and presented at relevant autism and neurotechnology conferences. No identifying information will be published.

13. Funding

[To be determined or disclosed — private grant, university seed fund, crowdfunding, etc.]

14. IRB Approval

Protocol will be submitted to an Institutional Review Board for full ethical review under minimal risk classification.