Pilot Study Protocol: Healthy Vision Initiative

A 12-Week Phase 2 Pilot Study Evaluating Digital Health Integrations for Anxiety and ADHD Symptom Reduction

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1. Administrative Information & Standards

This protocol is structured in accordance with the **NIH/FDA Phase 2 and 3 Interventional Study Protocol Template** to ensure comprehensive reporting and adherence to International Council for Harmonisation (ICH) E6 Good Clinical Practice guidelines. It follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) recommendations for clinical trial transparency.

2. Background & Rationale

Anxiety and ADHD are among the most prevalent mental health conditions, often impacting attention, emotional regulation, and daily functioning. While traditional treatment methods remain essential, digital health interventions (DHIs) offer scalable, accessible tools to support behavioral change and symptom management.
The Healthy Vision Initiative by Pixel Parqour integrates evidence-based techniques—such as guided breathing, attention training, and structured behavioral prompts—into an interactive digital platform. The objective of this investigation is to evaluate the clinical efficacy and feasibility of these tools in real-world environments.

3. Study Objectives

Objective Type	Description
Primary	To assess whether sustained use of Pixel Parqour's digital health platform leads to measurable, statistically significant reductions in anxiety (GAD-7) and ADHD

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	(ASRS) symptoms over 12 weeks.
Secondary	• Evaluate user engagement and adherence benchmarks. • Measure changes in wellbeing and functional daily activities. • Assess feasibility for expansion into Phase 3 clinical trials. • Generate preliminary data for SBIR/STTR grants and peer-reviewed publication.

4. Study Design & Methodology

Design Type: Randomized, Controlled Trial (RCT) Pilot.
Hypothesis: It is hypothesized that participants in the Full Integration Group will demonstrate a statistically significant reduction in symptom scores compared to the Waitlist Control ($p < 0.05$).
Study Arms:

- **Full Integration Group:** All platform features enabled, including AI-assisted coaching.
- **Single-Module Group:** One focused intervention (e.g., breathing or attention training).
- **Waitlist Control Group:** Access to general wellness content only.

5. Statistical Power & Sample Size Determination

A power analysis was conducted using G*Power 3.1. To detect a **medium effect size** (Cohen's d = 0.5) with an alpha of 0.05 and a power of 0.80 across three study arms, a total sample of N=159 is required. To account for a projected **20% attrition rate**, the target recruitment is set at **N=200** ($n \approx 67$ per group).

6. Participant Population & Recruitment

Target Population: Adults (18+) experiencing clinically significant symptoms of Anxiety or ADHD.
Inclusion/Exclusion: Participants must meet screening thresholds for GAD-7 or ASRS and own a compatible smartphone. Exclusion criteria include acute psychiatric instability or current participation in conflicting intervention studies.
Recruitment Strategy: Participants will be sourced from **University research departments**, clinical referrals, and digital outreach in Atlanta, GA, and the surrounding metropolitan area.

7. Schedule of Activities

Activity	Screening	Baseline	Week 4	Week 8	Week 12
Informed Consent	X				
GAD-7 / ASRS Assessments	X	X	X	X	X
Usage Analytics Review			X	X	X

8. Data Management & HIPAA Compliance

The platform utilizes a **Privacy by Design** infrastructure. All Protected Health Information (PHI) is managed according to the following standards:

- **Storage:** Data is hosted on HIPAA-compliant cloud infrastructure with **AES-256 encryption** both at rest and in transit.
- **De-identification:** All datasets shared with academic partners will be de-identified per the **HIPAA Safe Harbor method**.
- **BAA:** Business Associate Agreements are executed with all third-party data processors.

9. Ethical Considerations & Safety

Informed Consent: Required for all participants, including a dedicated HIPAA Authorization form. Participants may withdraw at any time without penalty.
Safety Monitoring: The protocol includes an automated **Crisis Resource Bridge**. Integrated failsafes trigger an emergency response or referral if GAD-7 score spikes or high-risk keywords are detected in AI coaching sessions.

10. Contact Information

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