UNIVERSAL MIND

modul8 infinity Randomized Controlled Trial

Scientific Briefing for Research and Institutional Partners

Version 1 - Partner Review Brief
31 August 2026

This briefing describes a proposed randomized controlled trial. It is not a registered or ethics-approved clinical trial protocol. Final design decisions will be developed with research, clinical, and statistical partners.

RCT TITLE & PLATFORM IDENTIFICATION

Trial Title:	The **modul8 infinity** Study: A 4-Arm Randomized Controlled Trial of Adaptive Sound and Visual Interventions for Rapid Stress Reduction, Social Connection, and Empathy
Platform Lead:	Universal Mind
Vision Statement:	*modul8 infinity* represents our underlying platform capability—exploring the frontier of real-time targeted gene expression and epigenetic modulation through prescription sound radiation, EMDR, and silent mantra, together as one — paired with pioneering hyperspectral computer vision research toward contact-free, non-invasive inference of gene expression in real time.

THE *modul8 infinity* STUDY

A Double-Blind Randomized Controlled Trial of Mental Health Embedded in Entertainment & Its Real-Time Gene Expression Signatures

Developed by Universal Mind

Executive Summary & Clinical Mission

The **modul8 infinity** trial evaluates a scalable, non-pharmacological digital intervention—combining 10-minute electronic music streams with embedded saccadic eye-movement stimulation (EMDR), isochronic brain entrainment, and silent mantra—to measure immediate physiological and transcriptomic stress reduction.

Our Mission

To provide free, accessible, and evidence-backed digital support for individuals navigating anxiety and PTSD. Designed specifically to serve as an immediate bridge between scheduled therapy appointments and to complement existing medication regimens, this platform aims to increase equitable access to care, foster social connection and empathy, and establish direct referral pathways to clinical support—ideally through strategic integration with national youth mental health networks such as Headspace Australia.

1. Trial Architecture & Arm Design

A 4-arm, double-blind, randomized controlled trial delivered seamlessly via the Universal Mind online platform. Automated platform routing ensures participants and researchers remain blinded to arm allocation.

Arm A (Full Active modul8 infinity):

Livestream Electronic Music + Active EMDR + Active Isochronic Entrainment + Silent Mantra

Arm B (Visual Sham):

Livestream Electronic Music + Static Visual (No EMDR) + Active Isochronic Entrainment + Silent Mantra

Arm C (Auditory Sham):

Livestream Electronic Music + Active EMDR + Flat Audio (No Entrainment) + Silent Mantra

Arm D (Full Control Sham):

Standard Livestream Music + Static Visual + Flat Audio (No active features)

1.1 Phased Study Execution & Stage-Gated Rollout

To optimize capital efficiency, ensure participant safety, and de-risk technical pipelines early, the study is structured across three adaptive, stage-gated phases. Advancement to each subsequent phase requires meeting defined operational and statistical milestones.

Phase 1: Proof-of-Concept & Technical Validation (N=10)

Focus: Validate digital platform delivery, rPPG signal integrity, buccal RNA extraction quality (Fisher Biotech), and local Python TELiS bioinformatic pipelines.

Exploratory Sub-Study: Conduct the initial UNSW FabiLab scRNA-seq optical feasibility protocol on a subset (N=5–10).

Gate Criteria: 100% pipeline completion, zero safety/adverse events, and confirmed RNA data quality.

Phase 2: Signal Detection & Parameter Refinement (N=50)

Focus: Evaluate initial statistical trends across all 4 arms for psychometric, autonomic (HRV), and candidate gene transcriptional shifts (*OXTR, DRD2, NR3C1*, etc.).

Gate Criteria: Demonstrable effect-size or directional significance ($p<0.05$) in post-session autonomic parameters or target transcript shifts in Active Arm A versus Shams.

Phase 3: Definitive Efficacy & Clinical Translation (N=100)

Focus: Execute the fully powered double-blind RCT to establish definitive clinical efficacy for journal publication (*Frontiers in Psychiatry* / *Nature Digital Medicine*) and present data for Headspace AU integration.

2. Target Cohorts

Focusing on populations experiencing acute or elevated stress:

Young Veterans:

PTSD / acute anxiety screening

Young Indigenous Australians:

Community-guided support frameworks

General Cohort:

Presenting with elevated state anxiety

3. Biometric Capture Engine (rPPG Integration)

To ensure frictionless remote data collection, biometrics are captured non-invasively via contact-free remote Photoplethysmography (rPPG) integrated into the platform stream (licensed via the SaMD-certified Shen.AI engine).

Capture Windows:

Baseline pre-session (T minus 2 mins to T0), continuous passive stream during the 10-minute session, and immediate post-session (T plus 10 mins).

Validated Biomarker Outputs:

- **Cardiovascular:** Heart Rate (HR), Blood Pressure (BP) estimation
- **Autonomic Nervous System:** Heart Rate Variability (HRV parameters: RMSSD, SDNN, LF/HF ratio) to track immediate parasympathetic activation (vagal tone)
- **Hemodynamics & Respiratory:** Oxygen Saturation (SpO2) and Baroreflex Sensitivity estimates

3.1 Cognitive, Affective & Connection Endpoints (CANTAB Integration)

To quantify immediate shifts in executive function, social empathy, and felt connection, the platform integrates web-administered cognitive micro-surveys powered by Cambridge Cognition's validated CANTAB digital platform alongside rapid connection surveys.

Assessment Windows:

Baseline pre-session (T minus 5 mins) and immediate post-session (T plus 15 mins).

Validated CANTAB & Psychometric Modules:

- **Spatial Working Memory (SWM):** Evaluates visual-spatial working memory capacity, executive strategy, and cognitive retention under acute stress (Connection to Self / Internal Regulation).
- **Emotion Recognition Task (ERT):** Quantifies facial empathy and social-emotional acuity by testing the subject's ability to decode subtle facial expressions across primary affective states (Social Connection & Empathy).
- **State Connection & Empathy Scale (IOS / SSCS):** A 3-item visual micro-survey assessing felt warmth, authentic self-presence, and interpersonal resonance.
- **Multi-Layer Triangulation:** Correlates CANTAB facial empathy scores and connection deltas (Δ) directly against rPPG autonomic recovery (vagal tone) and candidate transcriptomic markers (*OXTR* and *CD38*).

4. Transcriptomic Protocol & mRNA Seq

Primary Non-Invasive Specimen Collection:

Buccal swab sampling using kits sourced from Fisher Biotech for simple, self-administered cellular collection without requiring invasive phlebotomy.

Pipeline Optimization:

Active exploration of lollipop-based microfluidic collection (such as CandyCollect) pending initial assay validation and feasibility prototyping with Garvan's Kinghorn Centre for Clinical Genomics.

Sampling Timeline & Gene Panel:

Matched baseline (T0) and post-session (T plus 10 mins) buccal swabs to capture immediate-early transcriptional responses and TFBS activity across candidate targets:

- **Neuropeptides, Neurotransmitters, Oxytocin Signaling & Pro-Social Pathways:** OXTR, CD38, DRD2, SLC6A4, NMDAR
- **Immune & Stress Markers:** IL6, DOCK2, NR3C1, CD38

4.1 Downstream Bioinformatics: TELiS Promoter Mapping

To determine the upstream cellular signaling pathways driven by the *modul8 infinity* intervention, raw transcriptomic data will undergo **TELiS (Transcription Element Listening System)** bioinformatic analysis.

Mechanism:

Rather than assessing gene expression in isolation, the TELiS computational pipeline scans the upstream promoter regions of differentially expressed genes against transcription factor binding motif (TFBM) databases (JASPAR/TRANSFAC).

Time-Domain Profiling:

Evaluates temporal waves of transcription factor activation (e.g., CREB, NF-κB, GR) controlling candidate neurotransmitter, neuropeptide, and immune targets across the T0 to T+10m window.

Pipeline Architecture:

Dry-lab execution via local Python bioinformatic pipelines developed in collaboration with Garvan's Kinghorn Centre for Clinical Genomics, with potential academic cross-validation alongside UCLA Social Genomics Core research frameworks.

4.2 Exploratory Sub-Study: Optical & Single-Cell Genomics (UNSW Collaboration)

To establish proof-of-concept for non-invasive, computer-vision-based gene expression tracking, a nested exploratory sub-cohort (N=5–10) will evaluate single-cell transcriptomic dynamics alongside facial optical flow.

Single-Cell Profiling (scRNA-seq):

High-resolution single-cell transcriptomic profiling targeting OXTR expression and autofluorescence dynamics, executed via the UNSW FabiLab **HyperSeq** protocol.

Optical & Hyperspectral Alignment:

Synchronized alignment of facial region-of-interest (ROI) blood flow dynamics—captured via research grade hyperspectral cameras during the 10-minute intervention—against scRNA-seq ground truth.

R&D Objective:

To train downstream machine learning algorithms capable of detecting acute *OXTR* transcriptional shifts through contact-free facial optical analysis.

Hyperspectral CV Extraction Architecture:

Passive facial frame recording during the stream is processed asynchronously via offline spectral reconstruction algorithms (extracting 31 hyperspectral bands from standard RGB optical frames) to train non-invasive ML models against UNSW single-cell transcriptomic ground truth without impacting stream performance.

Geometric ROI Optimization:

Evaluation of 2D equilateral triangular meshes and 3D tetrahedral volumetric spatial modeling within the facial ROI during Phase 1 to reduce spatial-temporal compute complexity, lower inference GPU overhead, and establish a lightweight geometric architecture for real-time spectral tracking.

4.3 Phase 3 Exploratory Sub-Study: Cellular Mitotic Stability Protocol

To evaluate cellular mitotic stability - whether a multi-week, non-pharmacological digital therapeutic combining rhythmic electronic music, visual saccadic eye movements (EMDR), and silent mantra reduces systemic replication stress and protects healthy tissue, a Phase 3 exploratory sub-study (N=100) tracks cellular mitotic stability.

Clinical & Strategic Objective:

Bridges psychological trauma recovery and systemic mental health resilience. Proving that digital stress reduction shields rapidly dividing healthy tissues from cortisol-driven replication errors provides a non-invasive tool to demonstrate how relieving severe psychological distress directly preserves structural cellular integrity and mitigates premature tissue aging.

Expanded Phase 3 Sampling Protocol:

- **Day 1 Baseline (Swab 1):** Pre-session buccal swab establishing baseline mRNA profiles and baseline mitotic error rates.
- **Day 1 Post-Session (Swab 2 at T+10 min):** Captures immediate-early transcriptomic shifts across primary neurotransmitter and oxytocin signaling pathways (OXTR, DRD2, SLC6A4) alongside broader target panels processed via local Python TELIS bioinformatic pipelines.
- **Days 2–27 (Active Home Program):** Participants stream the 10-minute *modul8 infinity* intervention multiple times per week.
- **Day 28 Cumulative Outcome (Swab 3):** Evaluates newly matured epithelial cell layers that underwent mitosis during the multi-week trial.

Core Laboratory & Imaging Pipelines:

- **High-Content Cellular Imaging (Garvan Imaging Platform):** Processes Swabs 1 and 3 via automated microscopy on fixed, DAPI-stained epithelial cells to automatically score micronuclei frequencies, karyorrhexis, and nuclear abnormalities.
- **Single-Cell Alignment (UNSW FabiLab):** Cross-validates a sub-cohort (N=5–10) using scRNA-seq to map single-cell transcriptomic dynamics against systemic mitotic stability outcomes.

Primary Metric of Success:

A statistically significant reduction in micronuclei frequencies and nuclear abnormalities in Active Arm A compared to Sham Control Arms (B, C, D) by Day 28, confirming physical, systemic cellular preservation driven by mental health recovery.

5. Intervention Technical Specifications

Visual Saccadic Stimulation (EMDR):

Grid layout featuring 10 or more animated GIFs combining high-contrast fashion-style animations by Xaviera Lopez with complex hexagonal geometry by Hexeosis, driven by controlled rotational saccadic motion paths — per Dr Francine Shapiro's original saccadic eye-movement discovery (1987) — the psychologist who founded EMDR therapy — not limited to left–right oscillation.

Isochronic Acoustic Architecture:

7.38088 Hz Isochronic beat frequency paired with a 111.011 Hz carrier tone and a 528.088 Hz constant sine wave overlay.

Silent Mantra:

Contemplative silent mantra curated by Saajz Azura (Bless My Life), delivered via integrated on-screen visual/rhythmic cues.

6. Media, Storytelling & Participant Engagement (Vogue Campaign)

To capture the lived experience of trial participants and share the human narrative behind the research (for potential media features such as Vogue), the platform implements an optional, ethically isolated video journal pathway.

Dual-Consent Model:

Participation in the RCT clinical trial and participation in the media/video journal are entirely decoupled. Declining the video journal has zero impact on trial eligibility or clinical care.

Media Production Compensation:

Participants who opt to record short video entries (e.g., vertical short-form/reel updates) are compensated specifically for their time and creative production efforts, managed separately from clinical data collection.

Editorial Authority & Trial Integrity:

Participants retain final approval rights over any video footage prior to public release. Video recording actions occur strictly outside the immediate 10-minute intervention window to preserve double-blind parameters.

7. Governance & Institutional Partners

Institutional Status Note: *The original 2019 trial framework was designed in discussion with key institutional leads (primarily Garvan Institute and early partnership discussions with Professor McGorry of Orygen). The protocol specifications below represent the updated 2026 digital and transcriptomic architecture currently being presented to partner institutions for formal re-engagement, HREC ethics approval, and operational onboarding.*

Platform & Protocol Lead:	Universal Mind
Principal Research & Genomics Lead (Proposed):	Garvan Institute of Medical Research / Kinghorn Centre for Clinical Genomics *(mRNA sequencing, local TELiS Python bioinformatic pipelines, TFBS analysis)*
Clinical & Youth Mental Health Alignment (Proposed):	Orygen / Center of Excellence in Youth Mental Health *(Clinical framework oversight and cohort-specific guidance)*
Single-Cell Genomics & Systems Biology Lead (Proposed):	UNSW Sydney / FabiLab *(scRNA-seq protocol execution and optical exploratory sub-study)*
Veterans Mental Health Advisory (Proposed):	Phoenix Australia
Ethics & Governance Oversight:	The Ethics Centre / Designated HREC

8. Budget Estimates & Capital Allocation

In-Kind Platform Contribution: The *modul8 infinity* digital streaming engine, automated 4-arm sham delivery architecture, and web interface are **100% built and fully funded** by Universal Mind ($0 software development cost to the trial).

Expense Category	Phase 1 (N=10)	Phase 2 (N=50)	Phase 3 (N=100)
Garvan Trial Management Fee *(15% trial operations & oversight)*	~$4,000 AUD	~$10,000 AUD	~$18,000 AUD
Shen.AI SaMD License *(Full HRV, BP, SpO_2 unlock: €1,000/mo)*	~$1,650 AUD *(1 mo)*	~$3,300 AUD *(2 mos)*	~$4,950 AUD *(3 mos)*
mRNA Sequencing & Swab Kits *(Fisher Biotech / Garvan chemistry)*	~$10,000 AUD	~$50,000 AUD	~$100,000 AUD
scRNA-seq Sub-Study *(UNSW HyperSeq FabiLab protocol, N=5–10)*	~$8,000 AUD	*(Integrated)*	*(Integrated)*
Downstream TELiS Bioinformatics *(Local Python / Garvan execution)*	~$1,500 AUD	~$3,000 AUD	~$5,000 AUD
Partner Research Contributions *(Philanthropic allocations to Orygen/Phoenix)*	~$2,500 AUD	~$5,000 AUD	~$10,000 AUD
Music Broadcast Licensing *(APRA AMCOS / PPCA digital stream)*	~$1,500 AUD	~$2,500 AUD	~$4,000 AUD
Ethics (HREC) & Governance *(The Ethics Centre / Institutional review)*	~$5,000 AUD	~$2,500 AUD	~$2,500 AUD
Participant Honorariums / Incentives *(Including optional video journals)*	~$1,000 AUD	~$5,000 AUD	~$10,000 AUD
ESTIMATED TOTAL DIRECT COSTS	**~$35,150 AUD**	**~$81,300 AUD**	**~$154,450 AUD**

Note: Phase advancement is strictly contingent upon meeting defined safety, technical, and signal-detection milestones at each stage.

8.1 Advanced R&D Add-On: Computer Vision & Hyperspectral ML Pipeline

Funding Optionality: Funders may choose to support the core **Clinical Trial (Module A)** alone or include the **Biophysical AI Add-On (Module B)** to advance non-invasive, computer-vision-based gene expression tracking.

Dual-Camera & Spectral Reconstruction Architecture (N=5–10 Sub-Cohort)

Camera 1 (Consumer Baseline):

Standard RGB camera capturing rPPG and facial ROI blood flow dynamics via Shen.AI.

Camera 2 (Ground-Truth Calibration):

High-resolution research hyperspectral camera (400–1000 nm continuous spectrum) capturing deep micro-capillary absorption profiles.

Cross-Domain Time Calibration:

Synchronized alignment of continuous optical absorption spectra, rPPG autonomic parameters, and UNSW scRNA-seq *OXTR* expression data across the 10-minute session.

Geometric ROI Optimization:

Evaluation of 2D equilateral triangular meshes and 3D tetrahedral volumetric spatial modeling within the facial ROI during Phase 1 to reduce spatial-temporal compute complexity, lower inference GPU overhead, and establish a lightweight geometric architecture for real-time spectral tracking.

Module B Capital Budget (Exploratory AI Pipeline)

R&D Expense Category	Phase 1 (N=10)	Notes / Function
Research Hyperspectral Camera Hardware	~$25,000 AUD	Dual-camera research setup (400–1000 nm facial ROI capture)
Spectral Reconstruction SDK / API Access	~$8,000 AUD	Voyage81 / RGB-to-31-band hyperspectral translation licensing
Computer Vision & ML Pipeline Engineering	~$15,000 AUD	Asynchronous model training: Optical spectra ↔ scRNA *OXTR* ground truth
TOTAL MODULE B R&D ADD-ON	**~$48,000 AUD**	*Unlocks proprietary IP for contact-free gene transcription inference via hyperspectral camera — and horizon to gene transcription inference via standard RGB smartphone camera*

Total Program Funding Summary

Module A (Core Clinical RCT - Phase 1):	~$35,150 AUD | $22,350 USD
Module B (Hyperspectral AI Add-On - Phase 1):	~$48,000 AUD | $34,500 USD
Combined Phase 1 Launch Total:	**~$83,150 AUD | $60,000 USD**

Founder & Operational Time: Platform engineering, clinical trial coordination, and data architecture provided by Universal Mind are contributed in-kind ($0 direct charge to the trial budget).

Research Enquiries

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