HEARTTOUCH PROGRAM

HeartTouch Trial Protocol Outline

Effects of manual therapy combined with structured breathing on heart rate variability and carryover outcomes: a randomised controlled trial

A SPIRIT-style working outline — design, outcomes, and open decisions

Protocol version	Outline v0.1 — November 2026 (working draft for review, not for submission)
Program developer	David T Abbott, Core Therapy Center — proposed Co-Investigator / Consultant and Intervention Lead
Principal Investigator	To be appointed — a faculty PI at the host institution (see Section 14)
Host institution / sponsor	To be confirmed. The funding award, if made, goes to the institution, not to an individual
Source document	HeartTouch Program synopsis, Research Edition (October 2026), especially Section 13, Research direction
Status	Pre-protocol outline. No site, funder, registration, or ethics approval is in place yet

How to use this outline

This outline follows the structure of the SPIRIT 2013 statement (Standard Protocol Items: Recommendations for Interventional Trials), the structure ethics committees, funders such as the National Institutes of Health (NIH), and trial registries expect a protocol to follow. It states the design of the proposed trial. It is not a literature review, and it does not re-argue the evidence for the program — that material stays in the HeartTouch Program synopsis.

Two conventions run through the document:

- **"Decision needed"** marks a specific choice that has not yet been made, or data that have not yet been supplied. Nothing in those boxes has been filled in by assumption. Section 15 gathers every one of them into a single checklist for review.
- **"To be specified (TBS)"** means the item is named at outline level and still needs a full written specification before the protocol can be submitted anywhere.

The purpose of this draft is review: to make the goal of the trial sharper, expose where the design is strong, and show exactly which decisions would most strengthen it — population, control condition, primary outcome and timepoint, and dose — before any funding application is built on top of it.

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Protocol at a glance

Element	Outline position
Design	Parallel-group, two-arm, individually randomised controlled trial; outcome assessor blinded
Intervention	HeartTouch session: manual therapy plus a named, structured breathing protocol, delivered trauma-informed
Comparator	Credible control condition — type not yet chosen (see Section 5)
Primary outcome	Heart rate variability (HRV), recorded before, during, and after the session to Task Force (1996) standards
Key secondary outcomes	Resting blood pressure; client-reported felt safety and comfort; pain; range of motion; mood; function; Body Oxygen Level Test (BOLT) score; carryover at follow-up
Population	Not yet defined — see the decision in Section 4
Follow-up	Beyond the session, to measure carryover — duration not yet set
Setting	Host institution to be confirmed; University of Colorado Anschutz is the intended home explored in the synopsis

1 Background and rationale

Heart rate variability — the variation in time between successive heartbeats — is a non-invasive index of autonomic regulation. The 1996 Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology set the standards for its measurement, physiological interpretation, and clinical use, and Shaffer and Ginsberg (2017) published the modern review of its metrics and norms. In the neurovisceral integration model (Thayer and Lane, 2009), vagally mediated HRV reflects the regulation of physiological, affective, and cognitive processes, and low HRV is associated with poorer self-regulation and higher disease risk.

Manual therapy and structured breathing are each used in practice to influence autonomic state. Brief structured breathing has controlled-trial support in its own right: in a remote randomised trial, Balban and colleagues (2023) found that daily five-minute breathwork, particularly exhale-focused cyclic sighing, improved mood and reduced respiratory rate more than an equivalent period of mindfulness meditation. Breathing re-education in the Buteyko and Oxygen Advantage traditions adds a specific, teachable protocol — nasal, light, and slow breathing — with a simple repeatable measure, the Body Oxygen Level Test (BOLT).

What does not yet exist is a controlled trial of the combined HeartTouch intervention: manual therapy delivered together with structured breathing, with HRV recorded before, during, and after the session, and with participants followed beyond the session to test whether any change carries over into pain, range of motion, mood, and daily function. The program has been trialled informally in practice over six years using HRV biofeedback devices around massage and manual

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