

Intradermal Thumbtack Needle Alleviates Depressive Symptoms and Resets Executive Control System Function in Young Patients With Subthreshold Depression: A Study Protocol of a Randomized, Controlled, and Single-Blind Trial {1}

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Study protocol

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Abstract

Background: Subthreshold depression is the prodromal stage of a depressive episode, which is characterized by depressive symptoms but fails to meet the diagnostic criteria for depression. At present, there is no recognized therapy for subthreshold depression worldwide. Studies have also shown that acupoint stimulation can significantly decrease depressive symptoms by modulating different executive control systems, such as reward circuits and motivational circuits. In this proposed study, our objective is to evaluate the efficacy of intradermal thumbtack needle therapy, a continuous and effective acupoint stimulation therapy, on subthreshold depression and generate hypotheses on the mechanism by which this therapy resets executive control system function in young patients with subthreshold depression.

Method: In this randomized controlled trial, all eligible participants are diagnosed with subthreshold depression. Participants are randomly assigned to two groups at a ratio of 1:1 and receive either intradermal thumbtack needle or sham intradermal thumbtack needle therapy. The primary outcome is self-reported depression severity on the 9-item Patient Health Questionnaire (PHQ-9) from baseline to 6 weeks. The secondary outcomes include the Short Form Survey (SF-12) and the Generalized Anxiety Disorder Assessment (GAD-7) complementarity. Two psychological paradigms, the Attention Network Test (ANT) and the Psychomotor Vigilance Task (PVT), and functional magnetic resonance imaging (fMRI) will be used to evaluate the mechanism. These two psychological paradigms will explain the mechanism from the perspective of executive control in psychology, and fMRI will reflect the change in functional reset of the executive control system from an imaging point of view. The results are obtained at the start of treatment and the end of treatment. The entire duration of the study will be approximately 12 months.

Discussion: This study is designed to evaluate the efficacy of intradermal thumbtack needle on StD patients. Additionally, mechanisms by which this therapy resets executive control system function will be studied

Trial registration: NCT04319562. [ClinicalTrials.gov] [registered before start of inclusion; 24 March 2020] {2a and 2b}

Full Text

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Table

Table1 Measurements to be taken at each point in trial

	Study period						
	Enrolment	Invention		Follow-up			
	-1 week	0 week	6 weeks	1 month	3 months	6 months	12 months
CES-D	x						
The M.I.N.I	x						
PHQ-9		x	x	x	x	x	x
SF-12		x	x	x	x	x	x
GAD-7		x	x	x	x	x	x
Two psychological paradigms		x	x				
fMRI of 40 participants		x	x				

*Recommended content can be displayed using various schematic formats. See SPIRIT 2013 Explanation and Elaboration for examples from protocols.

**List specific timepoints in this row.

Figures

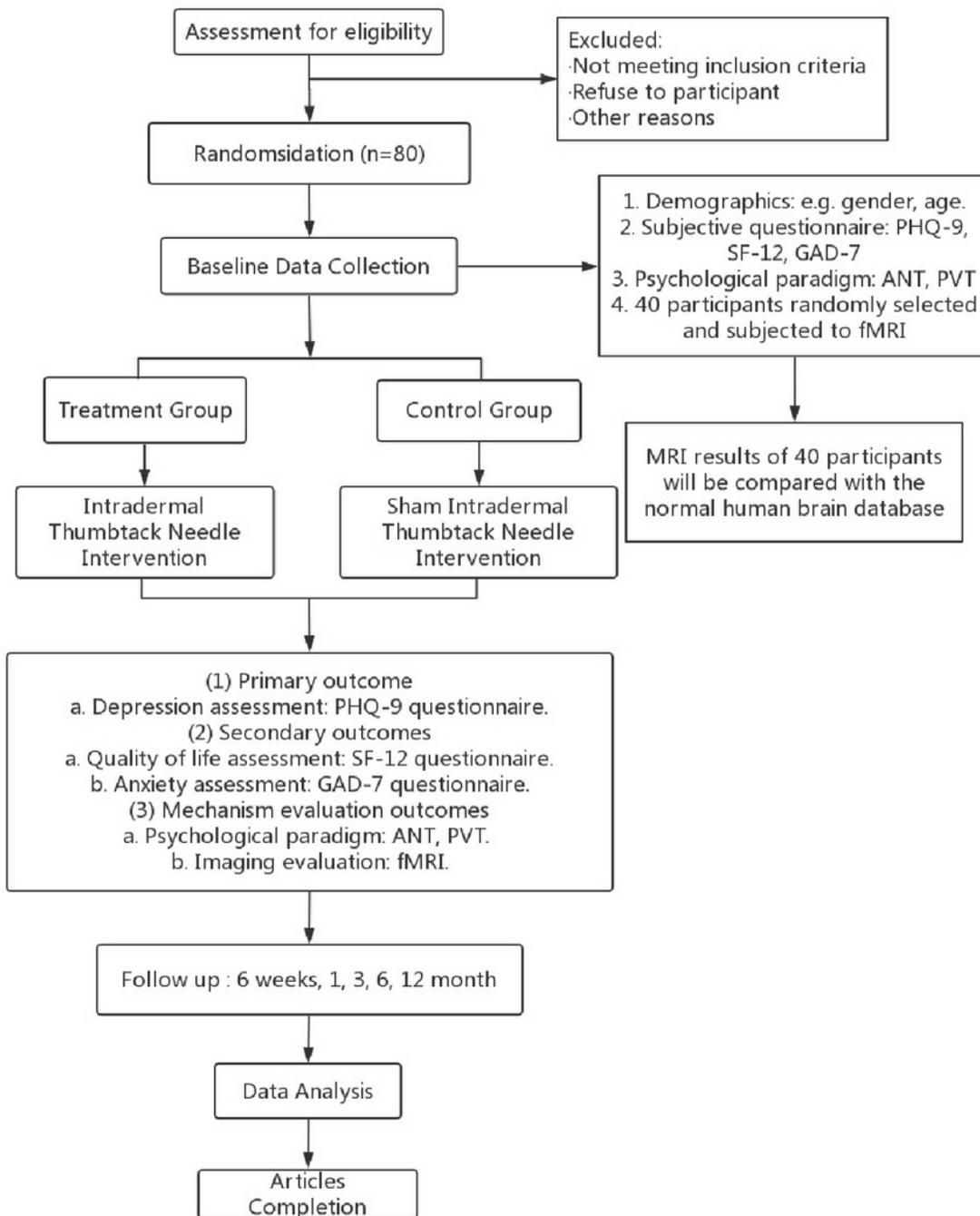


Figure 1

The study diagram

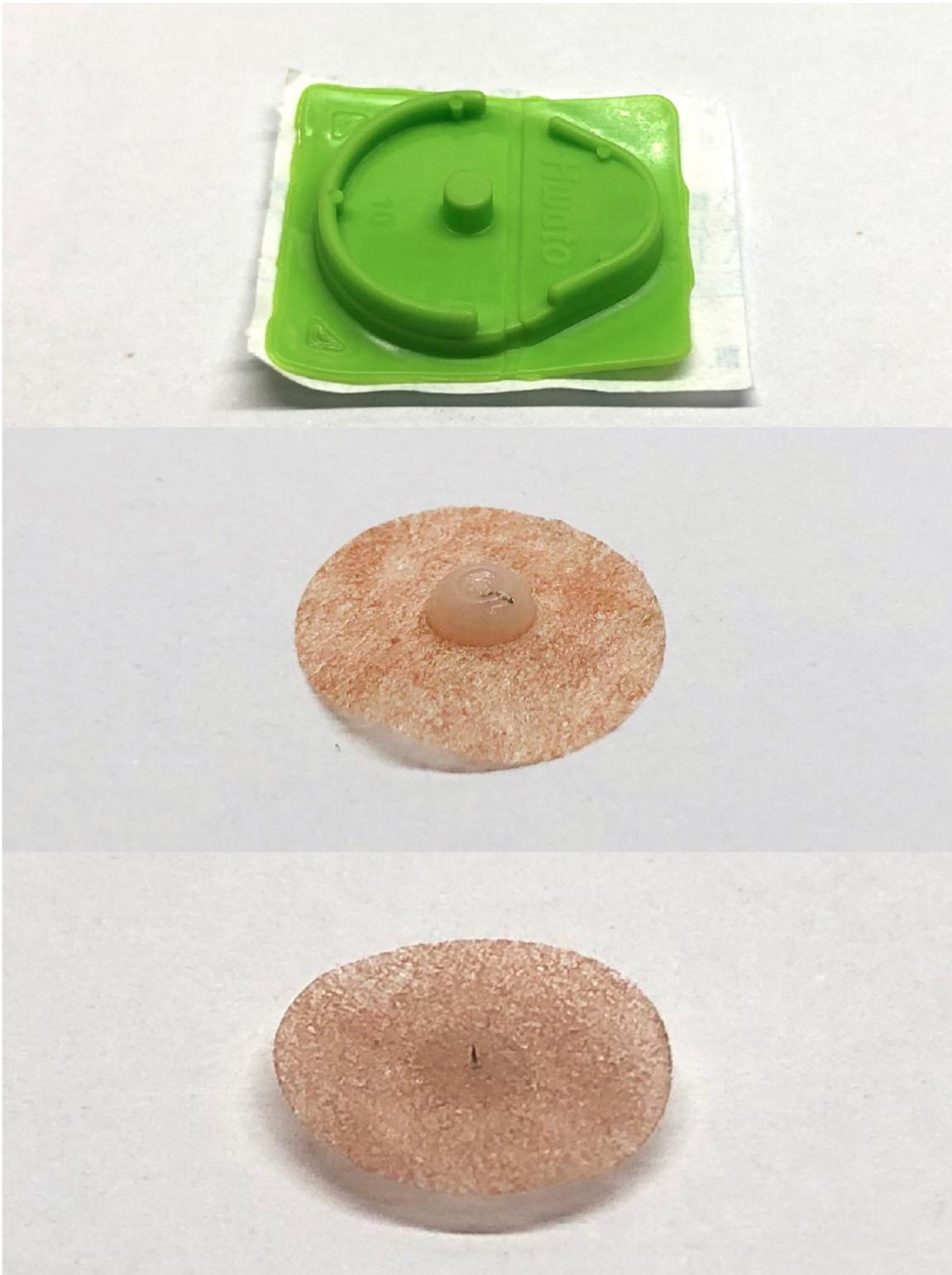


Figure 2

The specification of the needle used in the back shu point is $\phi 9$ mm, 0.20 \times 1.5 mm (Seirin® PYONEX; Seirin Corporation, Shizuoka, Japan), whereas that in the auricular point is $\phi 9$ mm 0.20 \times 0.6 mm (Seirin® PYONEX; Seirin Corporation, Shizuoka, Japan).

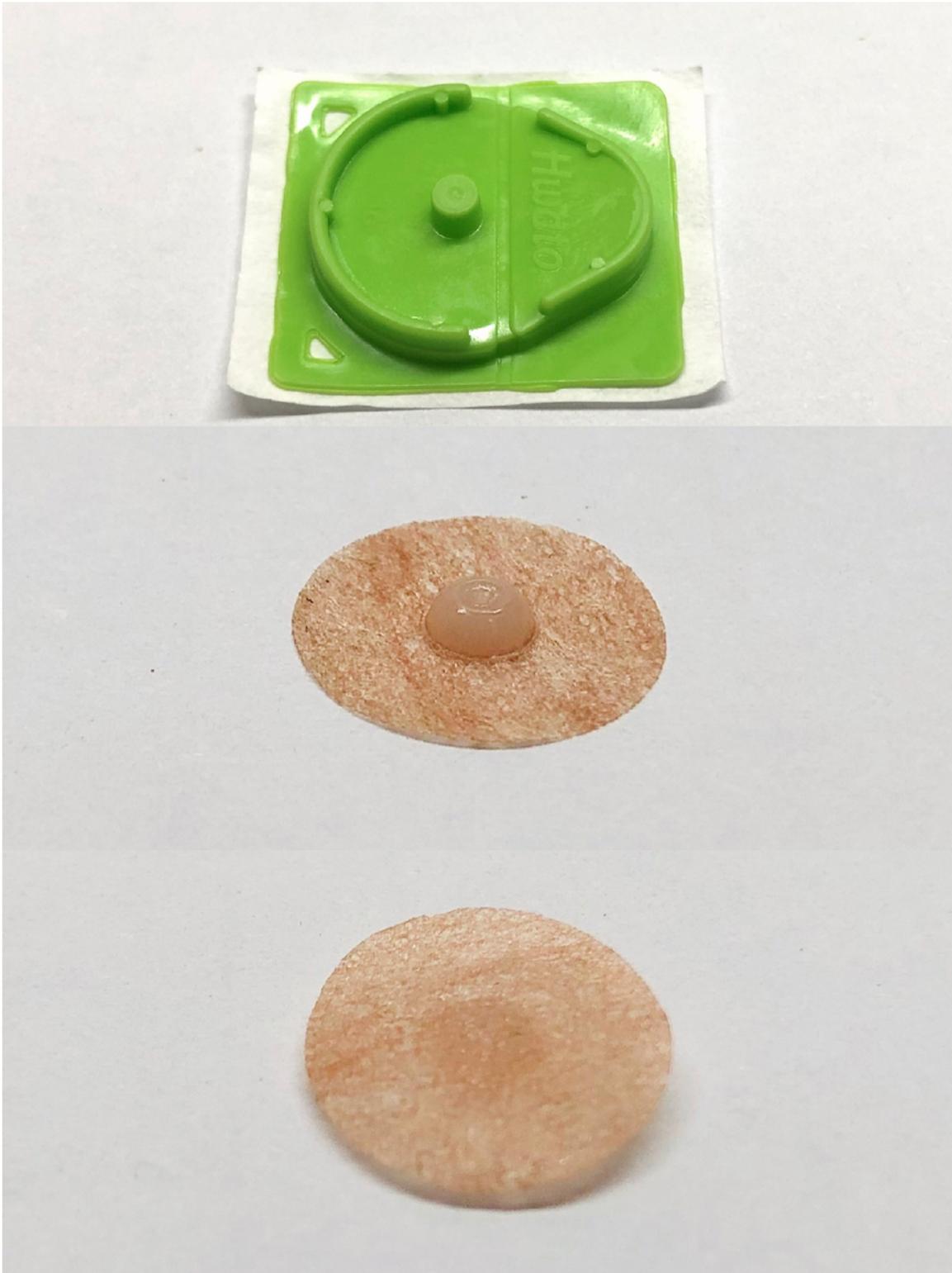


Figure 3

The sham needles will be removed by the therapists after 3 days. Participants are required to receive this intervention twice a week. The specification of the sham needle

Supplementary Files

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- [SPIRITChecklistdownload8Jan13.doc](#)