

PERCEPTIONS AMONG BREAST CANCER PATIENTS RECEIVING ELECTROACUPUNCTURE FOR NEUROSPYCHIATRIC SYMPTOMS IN A CLINICAL TRIAL

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Background

- Patient perceptions toward participating in acupuncture clinical trials are not well characterized in the U.S.
- We conducted a pilot clinical trial administering electroacupuncture (EA) to breast cancer patients and survivors targeting a neuropsychiatric symptom cluster and conducted a secondary analysis on patient perceptions to participating in the study.

Methods

- **Study Design**: A sham-controlled, randomized, patient-assessor double-blinded study. Participants were randomized (1:1) to receive either the verum (vEA) or sham electroacupuncture (sEA). Participants underwent once weekly treatment visits for 10 weeks during which their compliance and perceptions toward the study were monitored.
- Participants: We recruited 36 breast cancer (BC) patients and survivors from various clinics in the University of California, Irvine Health system. Participants were included based on the following eligibility criteria:
 - <u>Inclusion Criteria:</u> diagnosed with cancer and received cancer treatment, ≥16-years-old, life expectancy ≥ 6 months, and complaints of cognitive impairment, fatigue, insomnia, depression, and/or anxiety
 - <u>Exclusion Criteria:</u> needle phobia, presence of psychiatric or bleeding disorders, presence of a pacemaker, epilepsy, received acupuncture therapy within 3 months of participating, and/or breast feeding or planning to get pregnant during study period.
- Data collection tools: A satisfaction questionnaire was given to participants upon completion of all 10 treatments. Participants were asked which treatment they think they received, their views on the efficacy of the treatment as well as their acceptability of participating in an EA study.
- Statistical Analysis: Descriptive statistics were performed to measure the demographic backgrounds of the participants along with their perceptions toward their compliance, blinding, and acceptability of participating in the study.

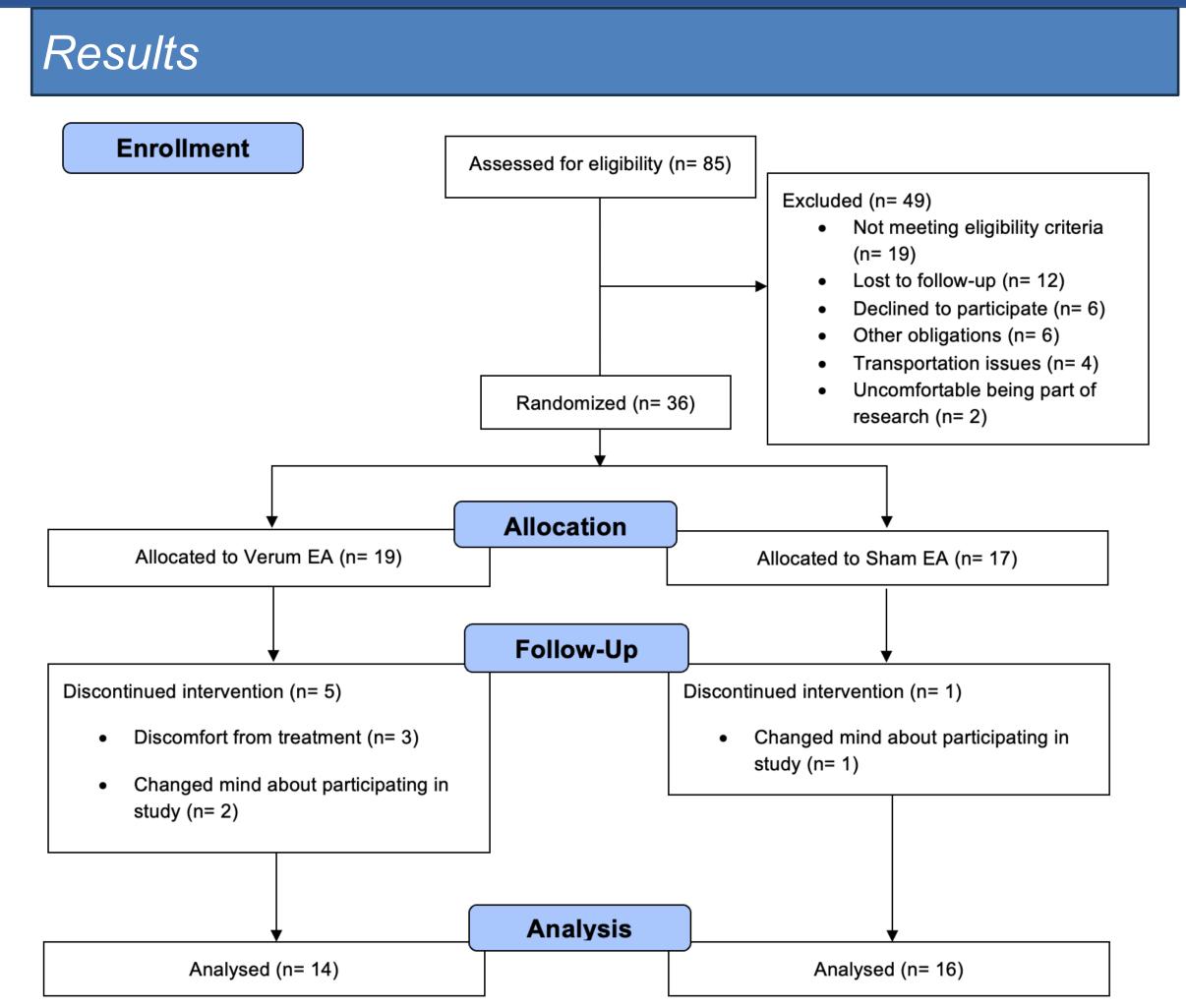


Figure 1. CONSORT diagram outlining the recruitment and compliance trends of participants for our clinical trial.

Table 1. Patient reported guesses of which treatment they received after completion of all 10 treatments.

Total Evaluable Participants (N = 30)	Correctly Guessed Treatment Type	Incorrectly Guessed Treatment Type	Unsure of Which Treatment Type They Received
vEA (N = 14)	7 (50.0%)	2 (14.3%)	5 (35.7%)
sEA (N = 16)	5 (31.3%)	6 (37.5%)	5 (31.3%)

Table 2. Patient reported outcome categories for acceptance in participating in an EA trial.

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Acceptance Category	vEA (N=14)	sEA (N=16)		
Satisfaction from receiving EA	14 (100%)	16 (100%)		
Perceived Benefit from EA	12 (85.7%)	13 (81.3%)		
Perceived Effectiveness in Managing Symptoms	12 (85.7%)	12 (75.0%)		
Overall Experience with EA	Better than expected 7 (50.0%) Same as expected 6 (42.9%) Worse than expected 1 (7.1%)	Better than expected 11 (68.8%) Same as expected 5 (31.3%)		
Worthwhile to participate in an EA trial?	13 (92.9%)	16 (100%)		
Recommend EA to others?	13 (92.9%)	16 (100%)		
Consider EA again outside of a trial?	13 (92.9%)	15 (93.8%)		

Table 3. Patient reported reasons for liking and disliking participating in an EA trial for both the vEA and sEA treatment arms.

Note: For N, some patients did not provide reasons for liking or disliking the study while some reported multiple reasons

Reasons for Liking EA	vEA Responses (N=14 (%))	sEA Responses (N =16 (%))
Relaxation	9 (64.3%)	9 (56.3%)
Symptom Improvement	2 (14.3%)	3 (18.8%)
Other Health Benefits	2 (14.3%)	1 (6.3%)
Experience with Acupuncturist	1 (7.1%)	1 (6.3%)
Participating in a research study	1 (7.1%)	1 (6.3%)
Reasons for Disliking EA	vEA Responses (N=14 (%))	sEA Responses (N=16 (%))
Expected Adverse Events	9 (64.3%)	7 (43.8%)
Transportation	0 (0%)	3 (18.8%)
Other	3 (21.4%)	3 (18.8%)

Conclusion

- A majority of patients in this study, regardless of treatment allocation, reported favorable perceptions toward participating in an EA trial and receiving the EA intervention.
- Reasons for disliking the EA intervention were adverse events and timing of EA
 appointments during the week. Participant attrition was influenced by physical
 discomfort from the intervention and the inability to balance study participation with
 other life obligations.
- Our findings provide a basis for diminishing the possibility of placebo effects from EA for future neuropsychiatric-driven EA clinical trials.