A Novel Perioperative Mind-body Intervention For Peripheral Vascular Interventions: Pilot Study Protocol

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Background

A novel mind-body intervention targeting vascular surgery patients undergoing peripheral vascular interventions (PVIs) under procedural sedation and analgesia (PSA) was recently developed, but had yet to be clinically tested. An exploratory randomized controlled study with 1:1 allocation was planned to test the novel intervention in patients undergoing PVIs under PSA.

Methods

Patients undergoing PVIs under PSA by vascular surgeons across four hospitals in Massachusetts and New Hampshire would be screened for enrollment. Exclusion criteria would include urgent or emergent procedures, prior ipsilateral lower extremity amputations and non-English speakers.

Results

30 patients would be enrolled, with 15 patients in the intervention group and 15 controls. The intervention group would receive two sessions of preoperative guided meditation on the day of surgery, while the control group would receive standard of care. There would be no restriction on anesthesia practice, and collected data would include perioperative pain and sedation requirements, and qualitative feedback from both the patients and perioperative staff

Schema:

<table>
<tr><td rowspan="5">Patient consents to vascular procedure AND consents to trial</td><td></td><td rowspan="5">Randomize</td><td rowspan="2">=></td><td rowspan="2">Intervention group: Guided meditation program preoperatively</td><td rowspan="2">=></td><td rowspan="5">Vascular Procedure</td></tr>
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<tr><td></td><td>=></td><td>Control group: No guided meditation preoperatively (standard of care)</td><td>=></td></tr>
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Conclusion

This protocol delineates a pilot randomized controlled study to test the feasibility and acceptability of a novel perioperative guided meditation program for patients undergoing PVIs under PSA.

Study Visits:

Timing	Location	Procedure/Data Collected
At least one day prior to day of vascular intervention: When decision is made to proceed with vascular intervention	Outpatient Clinic vs Inpatient Ward	Screening and consent for enrollment into trial Preoperative Quality of Life survey (PROMIS-10)
Day of vascular intervention: 30 minutes preoperatively, after surgical and anesthesia consents are obtained	Pre-operative holding area	Randomization Pre-meditation STAI-6 if randomized to intervention arm Guided Meditation if randomized to intervention arm Pre- procedural STAI-6 Pre-procedural MAIA (Noticing subscale)
Day of vascular intervention: 2 hours after vascular intervention	Post-anesthesia care unit	Post-procedural Patient Questionnaire Post-procedural Provider Questionnaire Post-procedural MAIA (Noticing subscale)
Outpatient follow-up Typically between two weeks to one month after procedure	Outpatient Clinic	Follow-up Patient Questionnaire Followup Quality of Life survey (PROMIS-10)