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Pilot study protocol for a novel perioperative mind-body intervention for peripheral vascular interventions

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Abstract

Background: A novel mind-body intervention (MBI) targeting vascular surgery patients undergoing peripheral vascular interventions (PVIs) under procedural sedation and analgesia (PSA) was recently developed, but has yet to be clinically tested. An exploratory randomized controlled trial is 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 will be screened for enrollment. Exclusion criteria include urgent or emergent procedures, prior ipsilateral lower extremity amputations (including digit amputations) and non-English speakers. 30 patients will be enrolled and randomized 1:1 to either

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Conception and design: CP, GY
Analysis and interpretation: CP, GY, AD, JM, NZ, JB, SS, ME
Data collection: CP, AD, JM, NZ, JB, SS, ME
Writing the article: CP, GY
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This study was approved and deemed exempt by the Mass General Brigham institutional review board (Protocol #: 2021P002072), and registered on clinicaltrials.gov (NCT05837481).

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DISCLOSURES
None.

a perioperative MBI on the day of surgery (n = 15), or a standard of care control (n = 15). There would be no restriction on anesthesia practice, and collected data will include perioperative pain and sedation requirements and qualitative feedback from both the patients and perioperative staff.

Conclusions: This protocol delineates a pilot randomized controlled trial to test the feasibility and acceptability of a novel perioperative MBI for patients undergoing PVIs under PSA.

Keywords

Perioperative meditation; Integrative medicine; Vascular surgery; Conscious sedation; Mind-body intervention; PROMIS; STAI; MAIA

The mere thought of surgery can generate fear and anxiety in patients, which can impact their clinical care in terms of perioperative hemodynamics.[1] This effect can be compounded for procedures performed under procedural sedation and analgesia (PSA, also known as conscious sedation), because patients are typically asked to perform tasks such as lying still or holding their breath. The incidence of perioperative anxiety during coronary angiograms has been reported to be between 30% and 80%,[2,3] and a recent nationwide survey of vascular surgeons who perform endovascular peripheral vascular interventions (PVIs) confirmed that this issue is similarly prevalent during PVIs and is associated with poor results such as increased radiation exposure and contras administration, and at times even the abortion of the procedure.[4]

The use of perioperative mind-body interventions (MBIs) offers a novel approach to reducing intraoperative anxiety and sedation requirements. Existing research has shown that techniques such as guided imagery, cognitive coping strategies, relaxation and hypnosis, and music interventions can be modestly effective in reducing anxiety and pain in surgical patients, though such therapies have all been generic and not specifically designed for any particular surgery.[5–7] The Obesity-Related Behavioral Intervention Trials (ORBIT) framework is a means of behavioral treatment development that involves a progressive process, prespecified clinically significant milestones for forward movement, and return to earlier stages for refinement and optimization.[8] Using this framework, we recently developed a perioperative MBI that was tailor-made for vascular surgery patients undergoing PVIs under PSA, with the goal of decreasing patient anxiety and increasing intraoperative compliance (with instructions from the surgeons).[8,9] The program uses mind-body techniques such as diaphragmatic breathing (where one uses the diaphragm as opposed to the intercostal muscles to breathe predominantly) body scan (an introspective practice in which focused attention is progressed from one part of the body to another), and guided imagery (focusing on a positive mental image or scene). Details of the intervention development (phases Ia and Ib in the ORBIT framework) have been previously described.[10]

This prospective randomized controlled trial (RCT) is the next step (phase IIb) in the ORBIT framework and was designed to test the feasibility and acceptability of implementing this novel perioperative MBI.

METHODS

Study design.

This study is a prospective, randomized, controlled, assessor-blinded, pilot trial with one intervention arm and one control arm. The study population includes adult patients undergoing PVIs under PSA.

Eligibility criteria.

Patients who are ≥18 years and planning to undergo an endovascular procedure for peripheral vascular disease (both arterial and venous) with an anesthetic plan for PSA will be eligible for inclusion in the study. Exclusion criteria include patients with (1) preexisting psychiatric disorders such as anxiety, panic disorder, depression, psychosis, or bipolar disorder; (2) prior history of lower extremity amputation ipsilateral to the intervention extremity (including digit amputations); (3) inability to consent for the surgery themselves (and as such require a proxy); (4) an urgent or emergent surgery; (5) a hybrid procedure (concurrent open surgical and endovascular procedures), and (6) a primary language other than English.

Because patients with preexisting anxiety or depression diagnoses may be at higher risk of relaxation induced anxiety—a phenomenon where patients paradoxically experience heightened, as opposed to decreased, levels of anxiety during relaxation training—we will exclude patients with significant psychiatric comorbidities including any anxiety disorders, similar to other MBI trials.[11–14] Given the relative simplicity of our MBI, we will not exclude participants with neurological conditions, although we will exclude any patients who lack the capacity to consent for the surgery (which includes patients with significant cognitive deficits). Furthermore, given that our MBI involves a body scan of the entire ipsilateral lower extremity, any patients with a previous amputation on the ipsilateral lower extremity would not be able to participate and thus are excluded.

Recruitment.

Vascular surgical attendings that perform PVIs at four hospitals, namely Massachusetts General Hospital (MGH), Newton Wellesley Hospital (NWH), Salem Hospital (SH), and Southern New Hampshire Medical Center (SNHMC) will be notified of this study before enrollment of any patients. Providers will opt in to allow their patients to be approached regarding the study. Potential study participants will be identified via regular monitoring of the upcoming operating room schedules of all four hospitals by research staff. After a patient is identified and meets enrollment criteria per chart review and communication with the appropriate clinical teams, the research team will reach out to them in person if they are admitted to the hospital or via phone call no later than the morning before their procedure to introduce the study in detail.

Study sites.

The four hospitals (MGH, NWH, SH, and SNHMC) comprise the sites where our vascular surgery division at MGH conducts clinical operations. MGH is a 1000-bed quaternary care center located in the center of Boston, at which >30,000 operations are performed

annually, where PVIs performed by vascular surgeons are generally performed in a hybrid operating room. NWH is a 270-bed community-based teaching medical center located in the western suburbs of Massachusetts in the town of Newton, where PVIs performed by vascular surgeons are generally performed in an interventional laboratory shared with interventional radiologists. SH is a 200-bed community-based medical center located on the North Shore of Massachusetts in the town of Salem, where PVIs performed by vascular surgeons are generally performed in a hybrid operating room. SNHMC is a 188-bed community-based medical center in Nashua, New Hampshire, and serves the Greater Nashua population, where PVIs performed by vascular surgeons are generally performed in an interventional laboratory shared with interventional radiologists. None of these hospitals have PVIs performed in any associated office-based laboratories or ambulatory surgical centers.

Study intervention.

The iterative development of our novel, PVI-targeted MBI has been described in our previous paper.[10] In short, this MBI takes the form of a meditation program with elements of mindfulness and guided imagery and will involve two sessions of guided meditation, the first session while the patient is in the perioperative holding area and the second session after the patient has been positioned on the operating room table. The content of the sessions includes a primer and introduction to the program and its concepts, guided diaphragmatic breathing, body scan meditations of the ipsilateral leg (from toes to upper thigh), and guided imagery of the ipsilateral leg. Both sessions will be delivered via a set of wireless headphones (with bone-conduction technology so they do not cover the patients' ears), with the associated audio recording being played from an institutionally secured iPad. Research staff will be physically present next to the patient and following the script on the iPad to track the patient's progress during the MBIs.

Randomization and blinding.

Block randomization of the study patients will be performed, with each hospital being a separate block. Each block will have a 1:1 ratio of intervention and control patients. A mobile application "Randomizer for Clinical Trial Lite" will be used by research staff to perform the random assignments.[15] After the relevant anesthesia and surgical procedure consents are obtained, patients will be randomized in the preoperative holding area. Regardless of which group the patient is assigned to, the research staff will accompany the patient into the operating room and stay with the patient up until patient is appropriately positioned on the operating table, but before the induction of anesthesia. By this point, if the patient had been randomized to the intervention group, both sessions of the MBI would have been completed. The vascular surgeon would then be advised that the patient was ready for their PVI. As such, the vascular surgeon performing the procedure will be blinded to the allocation of the patient (intervention vs control), at least until after the vascular surgical procedure has been completed and they had filled out the postprocedure provider questionnaire (delineated elsewhere in this article).

Primary outcome.

The primary outcome of the study is feasibility of implementing a meditation routine in the perioperative period. Feasibility is predefined as an enrollment rate of >80% and a study completion rate of >80%.

Secondary outcomes.

Secondary outcomes of this study will include perioperative anxiety, interoceptive awareness, and quality of life, as well as acceptability of the intervention, which will be evaluated through questionnaires of both patients and providers.

Patients will self-report their quality of life, levels of state anxiety and interoceptive awareness using three well-established instruments; quality of life via the Patient-Reported Outcomes Measurement Information System (PROMIS)-10, state anxiety via the State-Trait Anxiety Inventory (STAI)-6 and interoceptive awareness via Multidimensional Assessment of Interoceptive Awareness (MAIA) questionaries (Figs 1 and 2).

The PROMIS-10 is a tool developed by the National Institutes of Health to measure self-reported physical, mental, and social health, including symptoms, function, and general perceptions of health and well-being, and has been previously validated in patients with cardiovascular disease.[16,17] This metric will be administered at baseline before the procedure and at outpatient follow-up 2 to 4 weeks after the procedure.

The STAI-6 is a shortened version of the full state STAI, which includes six questions with a Likert scale from 1 to 4, for a range of 6 to 24. The original STAI has two components: a state portion that evaluates the current state of anxiety a patient has in a clinical setting, and a trait portion that evaluates how the patient generally feels unrelated to the clinical setting. The shortened STAI only takes a few minutes to complete and is highly correlated with the full state STAI.[18] The STAI-6 will be administered immediately before and after the procedure.

The MAIA is self-reported multidimensional instrument with eight separately scored scales. The three scales each have between three and seven questions that combine to provide an assessment of a patient's interoception (awareness of bodily sensations).[19] Each subscale can be separately administered with the retention of its psychometric features; we will administer the first subscale "Noticing" because it contains the most relevant items to our investigation and is less likely to overburden patients. The MAIA (Noticing subscale) will be administered immediately before and after the procedure.

Postprocedure patient questionnaire.

After their operation and after they are deemed ready for discharge, patients will be asked a series of close-ended questions regarding their experience during the PVI. Specifically, patients will be asked to self-rate their ability to hold their breath whenever they were asked to and for the duration that they were asked to during the procedure, as well as their ability to keep their body still during the procedure. Additionally, patients in the intervention arm will be asked if they understood the content of the MBI program, and if they were able to perform the tasks asked of them during the MBI. Finally, patients in both arms of the study

were asked to rate their overall experience during the PVI. These questions will be delivered in the form of a visual analogue scale (Figs 3 and 4).

Postprocedure provider questionnaire.

The questions asked of providers will be much more limited compared with those in the patient questionnaire and are meant to be able to be completed in less than 2 minutes. We will assess the opinions of providers regarding the MBI through a five-question, closed-end questionnaire. These questions will assess the provider's perception of intraoperative patient compliance (both with breath holds and keeping still), the patient's anxiolytic and analgesic requirements, and the need for additional administration of iodinated contrast and/or radiation to complete the procedure (relative to a patient who was fully compliant with intraoperative on-table instructions). These questions will be delivered in the form of a visual analogue scale (Fig 5).

Follow-up patient questionnaire.

Roughly between 2 and 4 weeks after their procedure, patients will be assessed regarding their perioperative experience. This will be via a semistructured interview and will also include using eight questions from the Hospital Consumer Assessment of Healthcare Providers and Systems, which is a standardized survey that measures patients' perceptions of their hospital experience (Figs 6 and 7 Table)

Data management.

All data will be recorded and managed using REDCap electronic data capture tools hosted at Mass General Brigham. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources.[20,21] Any paper forms created will be kept in a cabinet secured in the offices within the division of vascular surgery at MGH.

Study termination criteria and safety considerations.

Individuals may withdraw from the study at any time without impact to their care. They may also be discontinued from the study at the discretion of the investigator for lack of adherence to intervention or study procedures or adverse events or if at any point their participation is deemed to be a safety risk. It will be documented whether or not each patient completes the study. Any adverse events will be tracked and reported according to the policies of our institutional review board. Should the patient's participation in the trial be terminated early, the rest of their care and their vascular intervention will proceed as if they had not been in the trial. Safety data will be reviewed biweekly by the core investigator team, and the study itself will be terminated should there be serious adverse events resulting directly from the intervention.

Statistical analysis.

Statistical analyses will be performed using STATA 15 statistical software (College Station, TX). Given that this is a pilot study to assess the feasibility and acceptability of an intervention and to gather preliminary data to inform the design of a future trial, most of the statistics will be descriptive and there will not be any power analysis for this study. Where relevant, demographic or other categorical data will be analyzed using *t* test or Fishers exact test as appropriate Interval measurements (STAI-6 scores) will be analyzed by using the *t* test or Mann-Whitney *U* test as appropriate.

DISCUSSION

This article delineates the protocol for a pilot RCT to assess the feasibility and acceptability of a novel MBI targeting patients undergoing PVIs under PSA. In the context of the ORBIT framework, this proof-of-concept study is the next phase after the initial design and refinement of our MBI.[8]

This protocol allows us to test the intervention in different hospital systems, as well as to maximize the feedback gathered from a vascular surgical provide standpoint. It also allows us to test the integration of our randomization and blinding process within various operating room workflows-with particular focus on the surgeons being separate from the patients during the MBI implementation. For these reasons, we will include four hospitals within our vascular surgery clinical network and all vascular surgeons with the relevant associated operative privileges within these centers.

One notable limitation of our study is that because our MBI is in English, we may exclude a more racial/ethnically diverse population. Particularly given the known racial and ethnic disparities in the treatment of peripheral arterial disease in the United States,[22] the results of our study may not be widely generalizable.

Based on the ORBIT framework, this pilot RCT will inform the next steps for our novel MBI, the need for further phase Ia and Ib work, and the eventual design of the future phase III efficacy trial.[8] Importantly, this study will add to the existing mind-body literature by providing valuable information on the feasibility and acceptability of a novel perioperative MBI for patients undergoing PVIs under PSA.

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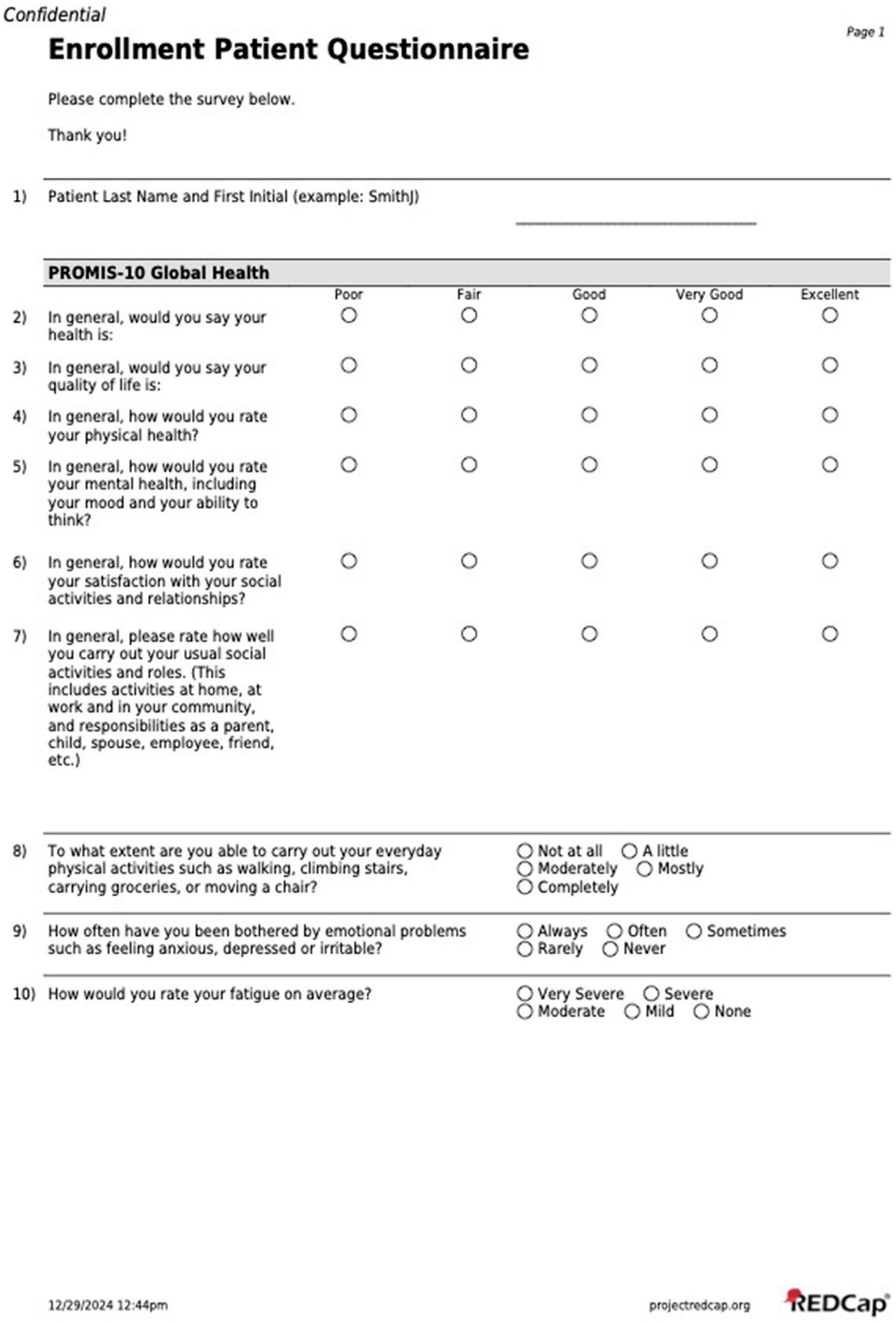

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Page 1

Enrollment Patient Questionnaire

Please complete the survey below.

Thank you!

1) Patient Last Name and First Initial (example: SmithJ) _____

PROMIS-10 Global Health

		Poor	Fair	Good	Very Good	Excellent
2)	In general, would you say your health is:	○	○	○	○	○
3)	In general, would you say your quality of life is:	○	○	○	○	○
4)	In general, how would you rate your physical health?	○	○	○	○	○
5)	In general, how would you rate your mental health, including your mood and your ability to think?	○	○	○	○	○
6)	In general, how would you rate your satisfaction with your social activities and relationships?	○	○	○	○	○
7)	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	○	○	○	○	○

8) To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
○ Not at all ○ A little ○ Moderately ○ Mostly ○ Completely

9) How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
○ Always ○ Often ○ Sometimes ○ Rarely ○ Never

10) How would you rate your fatigue on average?
○ Very Severe ○ Severe ○ Moderate ○ Mild ○ None

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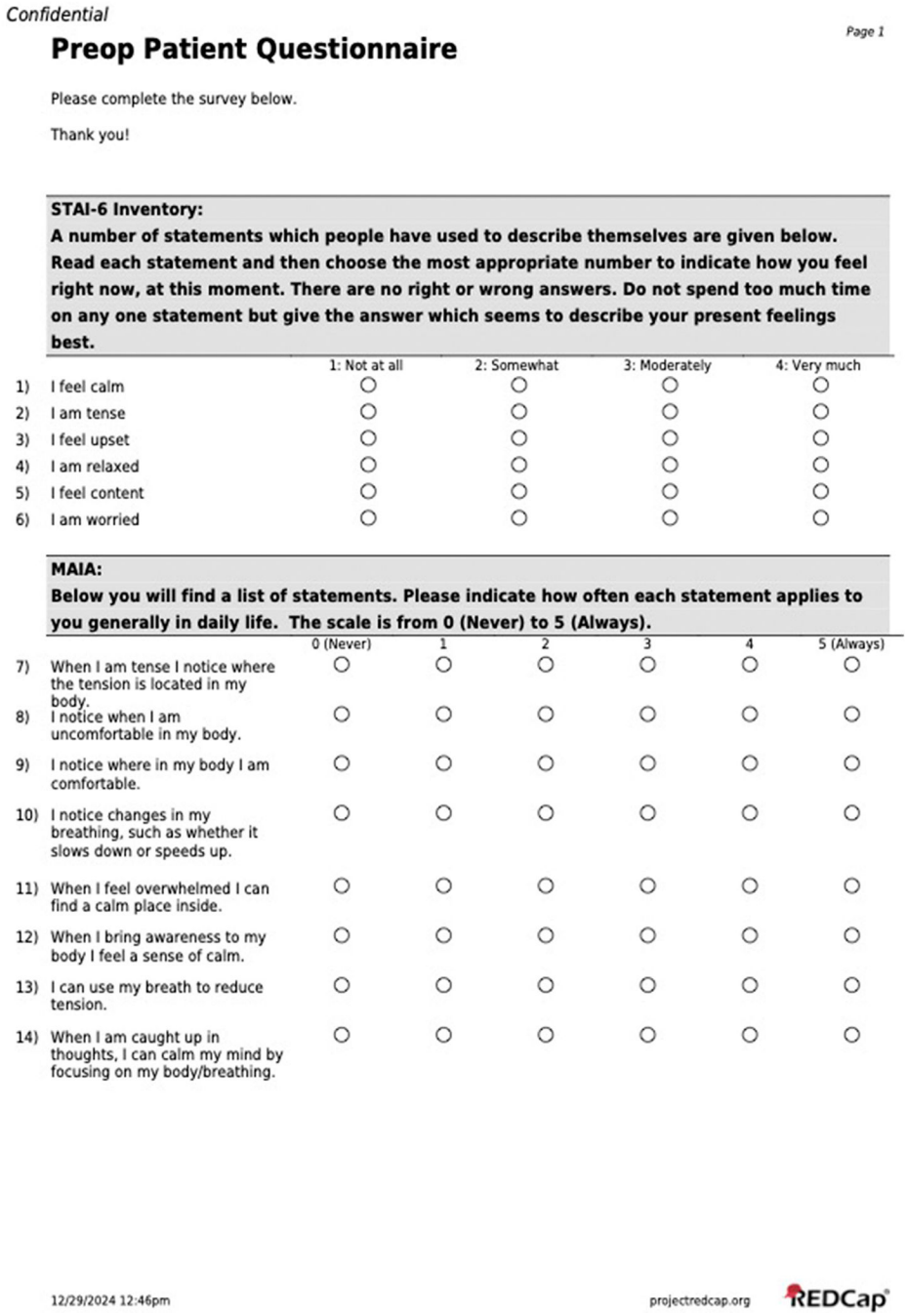
Fig 1.
Enrollment patient questionnaire.



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Page 1

Preop Patient Questionnaire

Please complete the survey below.

Thank you!

STAI-6 Inventory:

A number of statements which people have used to describe themselves are given below. Read each statement and then choose the most appropriate number to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		1: Not at all	2: Somewhat	3: Moderately	4: Very much
1)	I feel calm	○	○	○	○
2)	I am tense	○	○	○	○
3)	I feel upset	○	○	○	○
4)	I am relaxed	○	○	○	○
5)	I feel content	○	○	○	○
6)	I am worried	○	○	○	○

MAIA:

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life. The scale is from 0 (Never) to 5 (Always).

		0 (Never)	1	2	3	4	5 (Always)
7)	When I am tense I notice where the tension is located in my body.	○	○	○	○	○	○
8)	I notice when I am uncomfortable in my body.	○	○	○	○	○	○
9)	I notice where in my body I am comfortable.	○	○	○	○	○	○
10)	I notice changes in my breathing, such as whether it slows down or speeds up.	○	○	○	○	○	○
11)	When I feel overwhelmed I can find a calm place inside.	○	○	○	○	○	○
12)	When I bring awareness to my body I feel a sense of calm.	○	○	○	○	○	○
13)	I can use my breath to reduce tension.	○	○	○	○	○	○
14)	When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	○	○	○	○	○	○

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Fig 2.

Preoperative patient questionnaire.

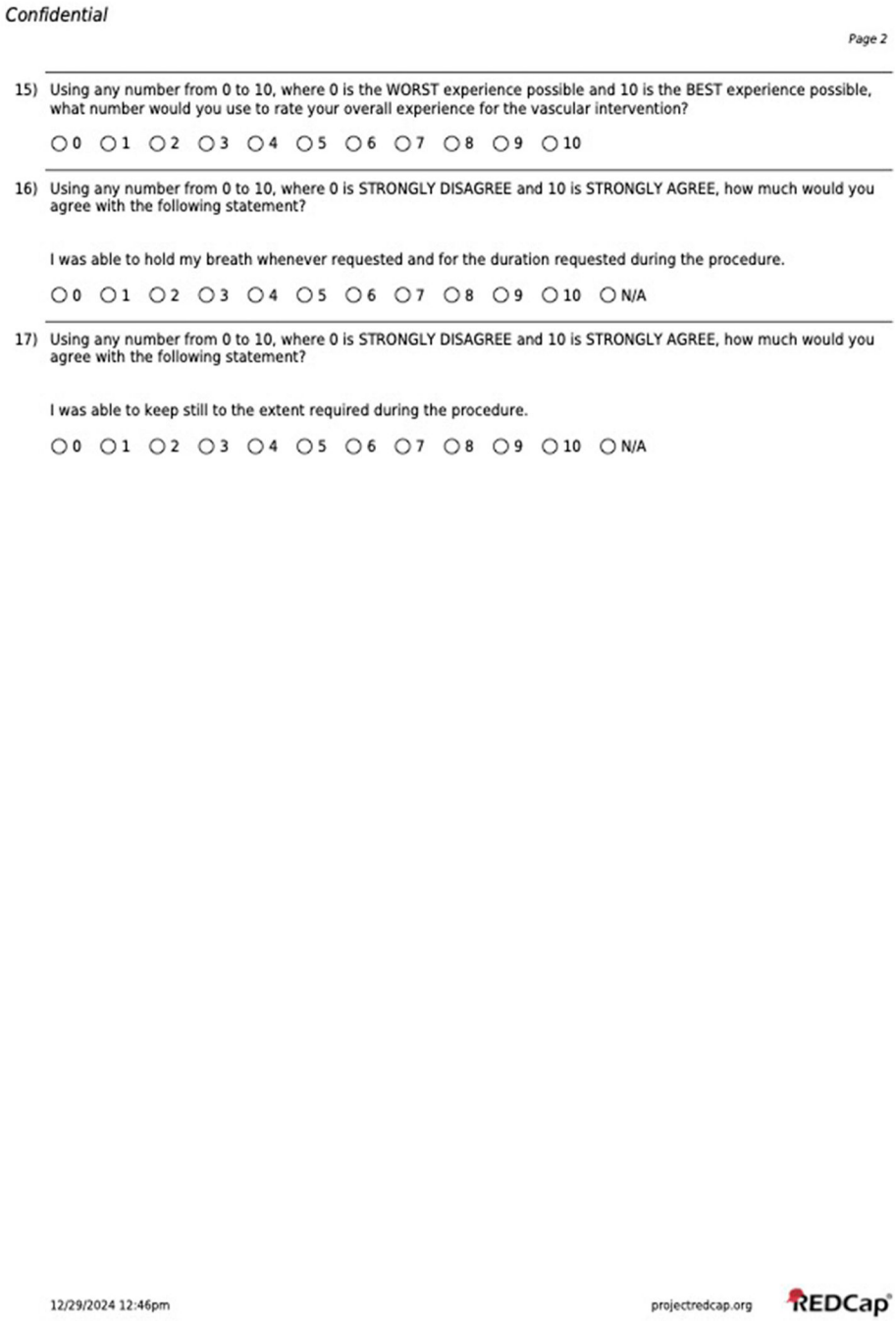
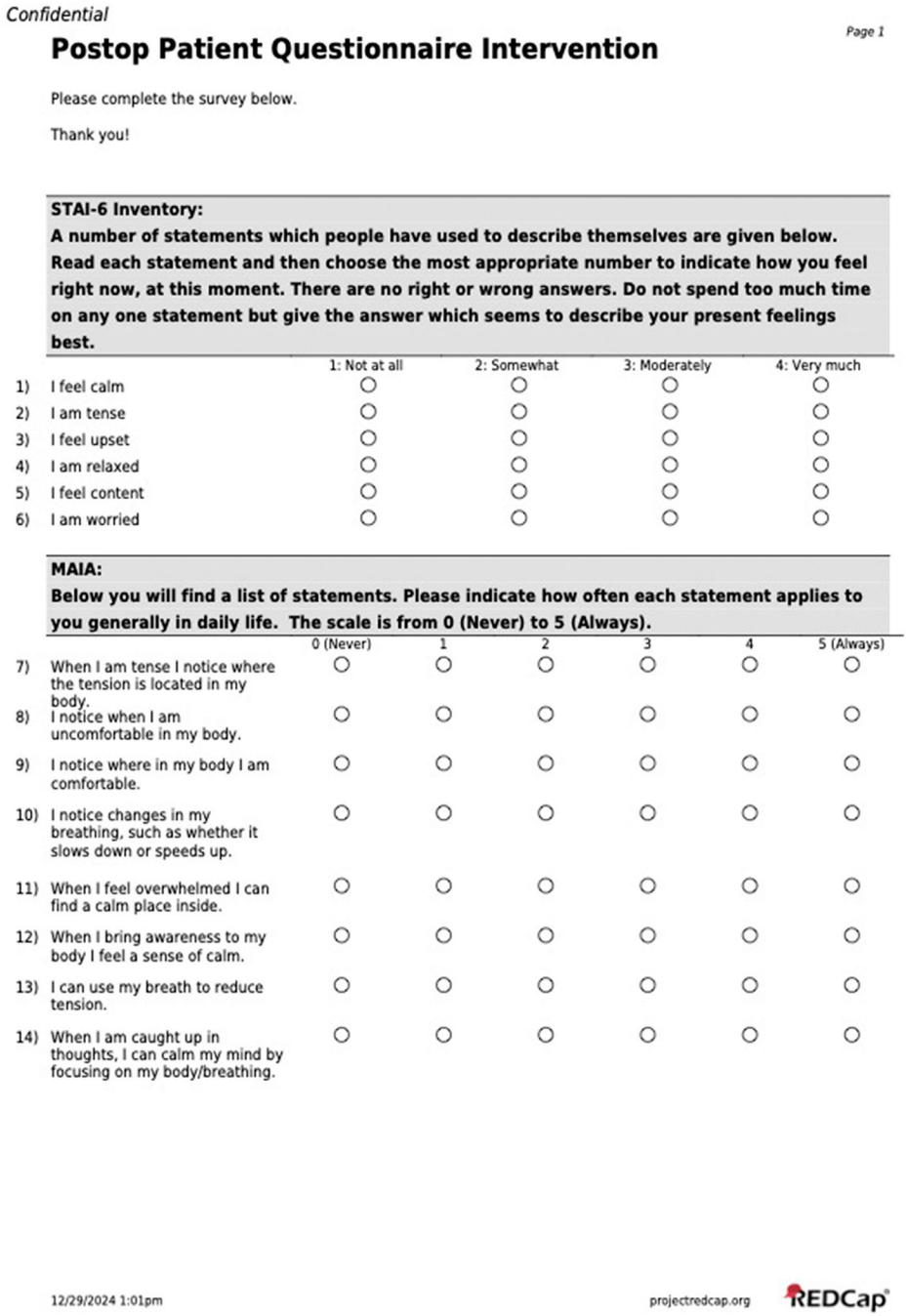


Fig 3.
Postoperative patient questionnaire (control group).



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Page 1

Postop Patient Questionnaire Intervention

Please complete the survey below.

Thank you!

STAI-6 Inventory:

A number of statements which people have used to describe themselves are given below. Read each statement and then choose the most appropriate number to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		1: Not at all	2: Somewhat	3: Moderately	4: Very much
1)	I feel calm	○	○	○	○
2)	I am tense	○	○	○	○
3)	I feel upset	○	○	○	○
4)	I am relaxed	○	○	○	○
5)	I feel content	○	○	○	○
6)	I am worried	○	○	○	○

MAIA:

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life. The scale is from 0 (Never) to 5 (Always).

		0 (Never)	1	2	3	4	5 (Always)
7)	When I am tense I notice where the tension is located in my body.	○	○	○	○	○	○
8)	I notice when I am uncomfortable in my body.	○	○	○	○	○	○
9)	I notice where in my body I am comfortable.	○	○	○	○	○	○
10)	I notice changes in my breathing, such as whether it slows down or speeds up.	○	○	○	○	○	○
11)	When I feel overwhelmed I can find a calm place inside.	○	○	○	○	○	○
12)	When I bring awareness to my body I feel a sense of calm.	○	○	○	○	○	○
13)	I can use my breath to reduce tension.	○	○	○	○	○	○
14)	When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	○	○	○	○	○	○

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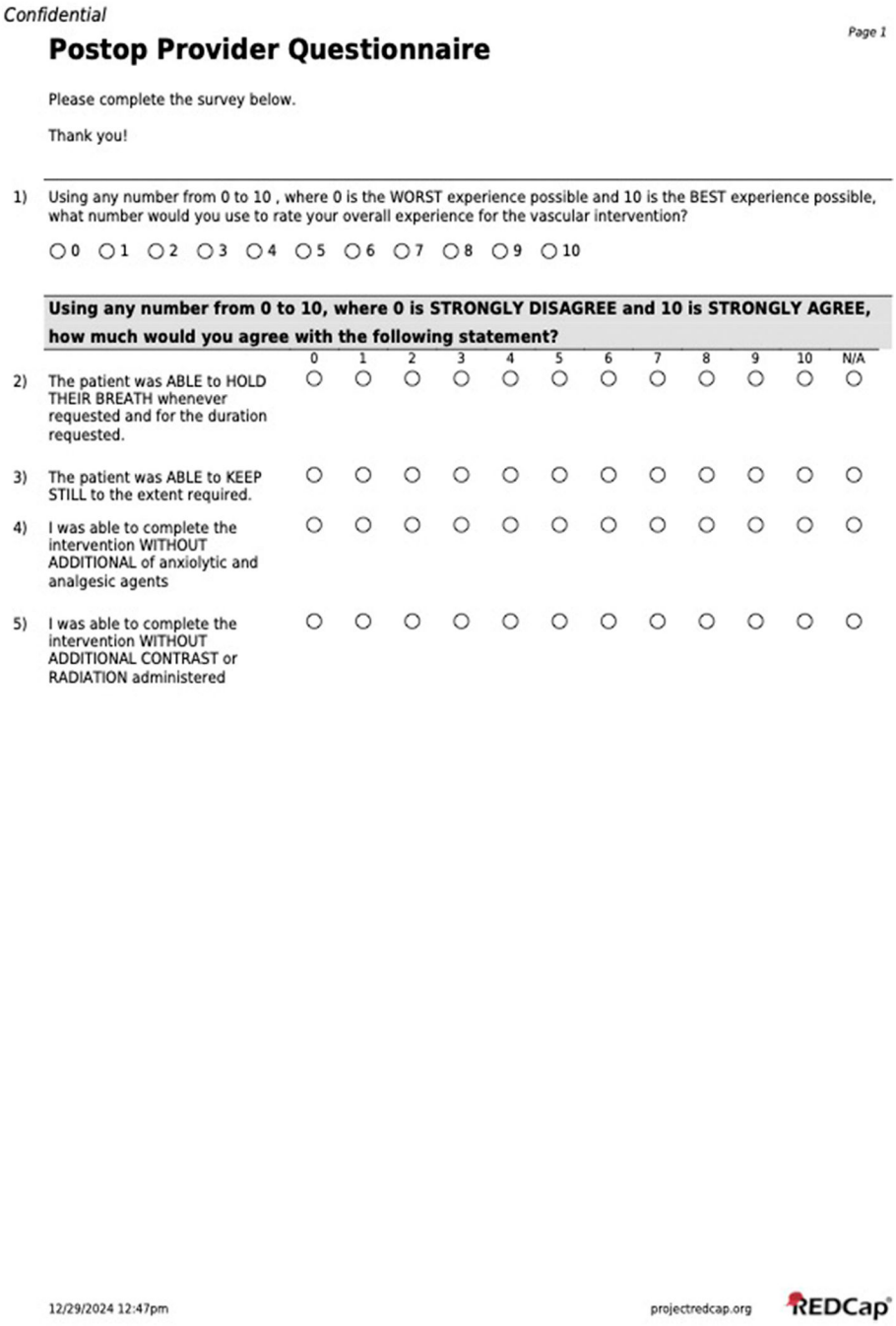
Fig 4.

Postoperative patient questionnaire (intervention group).



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Page 1

Postop Provider Questionnaire

Please complete the survey below.

Thank you!

1) Using any number from 0 to 10 , where 0 is the WORST experience possible and 10 is the BEST experience possible, what number would you use to rate your overall experience for the vascular intervention?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

Using any number from 0 to 10, where 0 is STRONGLY DISAGREE and 10 is STRONGLY AGREE, how much would you agree with the following statement?

		0	1	2	3	4	5	6	7	8	9	10	N/A
2)	The patient was ABLE to HOLD THEIR BREATH whenever requested and for the duration requested.	○	○	○	○	○	○	○	○	○	○	○	○
3)	The patient was ABLE to KEEP STILL to the extent required.	○	○	○	○	○	○	○	○	○	○	○	○
4)	I was able to complete the intervention WITHOUT ADDITIONAL of anxiolytic and analgesic agents	○	○	○	○	○	○	○	○	○	○	○	○
5)	I was able to complete the intervention WITHOUT ADDITIONAL CONTRAST or RADIATION administered	○	○	○	○	○	○	○	○	○	○	○	○

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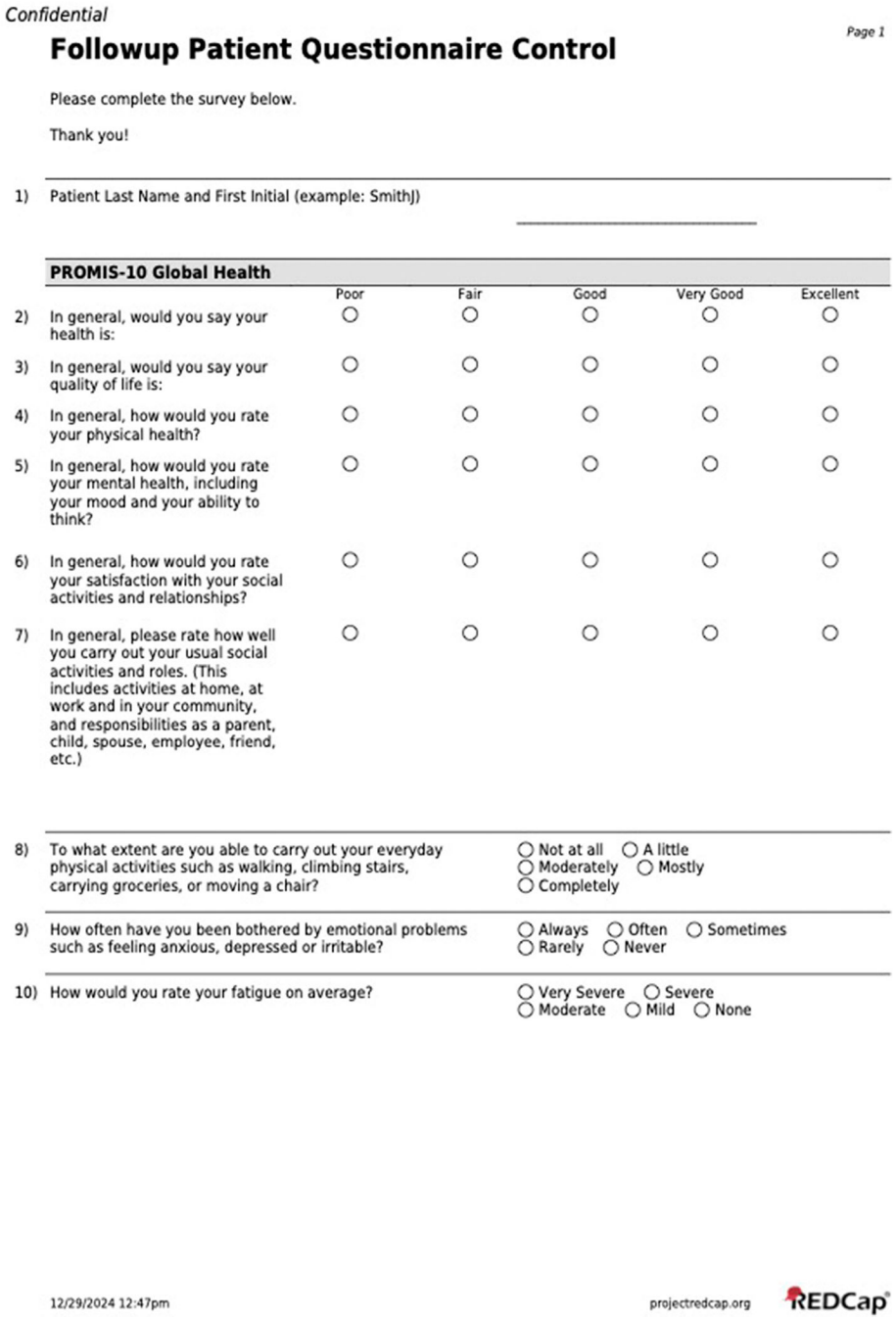
Fig 5.
Postoperative provider questionnaire.



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Page 1

Followup Patient Questionnaire Control

Please complete the survey below.

Thank you!

1) Patient Last Name and First Initial (example: SmithJ) _____

PROMIS-10 Global Health

		Poor	Fair	Good	Very Good	Excellent
2)	In general, would you say your health is:	○	○	○	○	○
3)	In general, would you say your quality of life is:	○	○	○	○	○
4)	In general, how would you rate your physical health?	○	○	○	○	○
5)	In general, how would you rate your mental health, including your mood and your ability to think?	○	○	○	○	○
6)	In general, how would you rate your satisfaction with your social activities and relationships?	○	○	○	○	○
7)	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	○	○	○	○	○

8) To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
○ Not at all ○ A little ○ Moderately ○ Mostly ○ Completely

9) How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
○ Always ○ Often ○ Sometimes ○ Rarely ○ Never

10) How would you rate your fatigue on average?
○ Very Severe ○ Severe ○ Moderate ○ Mild ○ None

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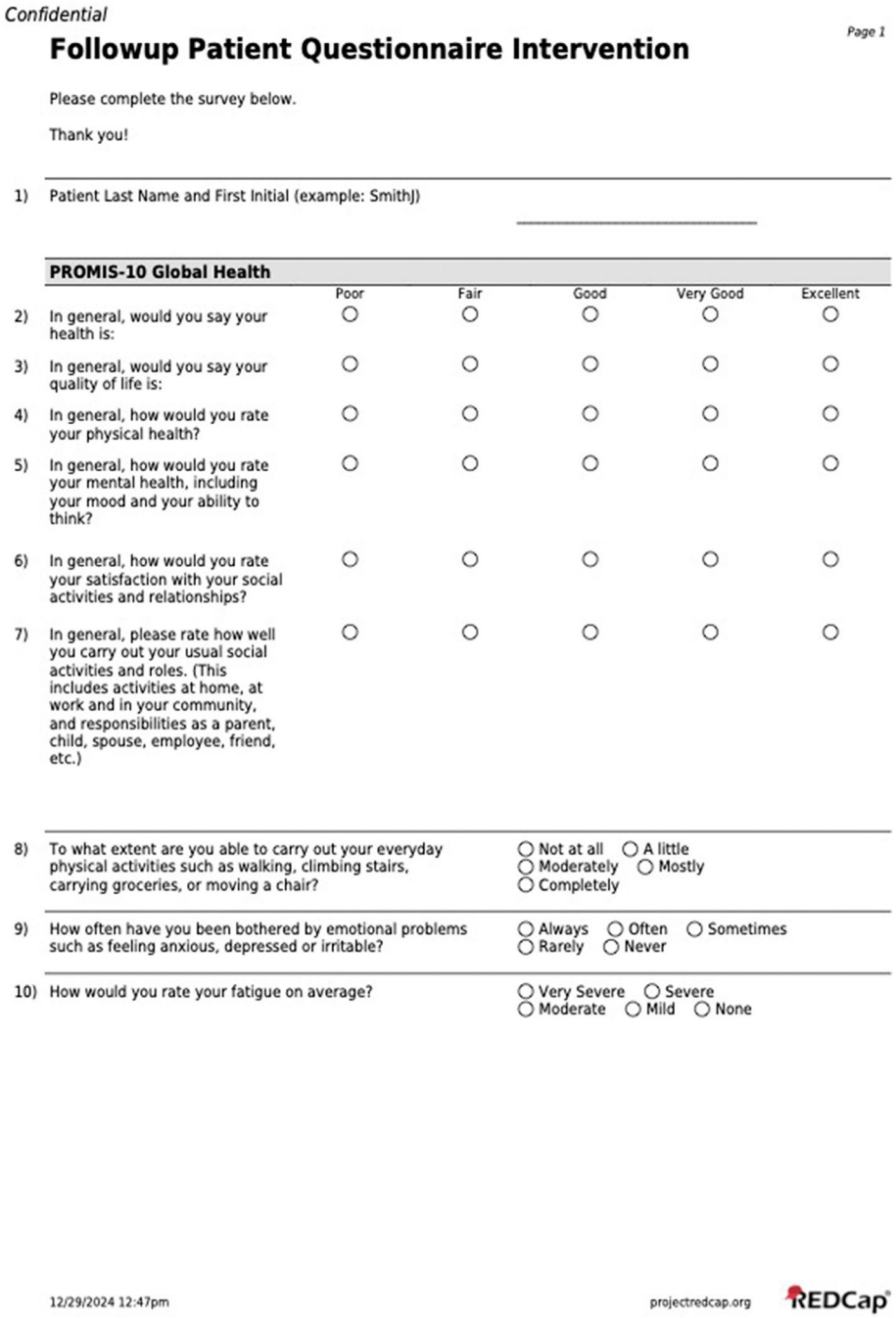
Fig 6.
Follow-up Patient questionnaire (control group).



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Page 1

Followup Patient Questionnaire Intervention

Please complete the survey below.

Thank you!

1) Patient Last Name and First Initial (example: SmithJ) _____

PROMIS-10 Global Health

		Poor	Fair	Good	Very Good	Excellent
2)	In general, would you say your health is:	○	○	○	○	○
3)	In general, would you say your quality of life is:	○	○	○	○	○
4)	In general, how would you rate your physical health?	○	○	○	○	○
5)	In general, how would you rate your mental health, including your mood and your ability to think?	○	○	○	○	○
6)	In general, how would you rate your satisfaction with your social activities and relationships?	○	○	○	○	○
7)	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	○	○	○	○	○

8) To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
○ Not at all ○ A little ○ Moderately ○ Mostly ○ Completely

9) How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
○ Always ○ Often ○ Sometimes ○ Rarely ○ Never

10) How would you rate your fatigue on average?
○ Very Severe ○ Severe ○ Moderate ○ Mild ○ None

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Fig 7.
Follow-up Patient questionnaire (intervention group).

Table.

Study timeline

Timing	Location	Procedure/data collected
At least 1 day before day of vascular intervention: When decision is made to proceed with vascular intervention	Phone call vs inpatient ward	Screening and consent for enrollment into trial Preoperative Quality of Life survey (PROMIS-10) (Fig 1)
Day of vascular intervention: Preoperatively, after surgical and anesthesia consents are obtained	pre1operative holding area	Preprocedural STAI-6 (Fig 2) Preprocedural MAIA (Noticing subscale) (Fig 2) Randomization If randomized to intervention arm: Guided Meditation
Day of vascular intervention: 1–4 hours after vascular intervention	Postanesthesia care unit	Postprocedural STAI-6 (Figs 3 and 4) Postprocedural MAIA (Noticing subscale) (Figs 3 and 4) Postprocedural Patient Questionnaire (Figs 3 and 4) Postprocedural Provider Questionnaire (Fig 5)
Outpatient follow-up Between 2 weeks and 1 month after procedure	Outpatient clinic	Follow-up Patient Questionnaire (Figs 6 and 7) Follow-up Quality of Life survey (PROMIS-10) (Figs 6 and 7)