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Comprehensive pelvic muscle assessment: Developing and testing a dual e-Learning and simulation-based training program

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Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium

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ETHICS STATEMENT

This manuscript is the original work of the authors and has not been submitted for publication elsewhere.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

CONFLICTS OF INTEREST

Melanie Meister, Lisa K. Low, Julia Geynisman-Tan None, Alayne Markland, Sara Putnam, Kyle Rudser, Ariana L. Smith, and Janis M. Miller declare no conflict of interest.

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Abstract

Objective: The Prevention of Lower Urinary Tract Symptoms (PLUS) research consortium launched the RISE FOR HEALTH (RISE) national study of women's bladder health which includes annual surveys and an in-person visit. For the in-person exam, a standardized, replicable approach to conducting a pelvic muscle (PM) assessment was necessary. The process used to develop the training, the products, and group testing results from the education and training are described.

Methods: A comprehensive pelvic muscle assessment (CPMA) program was informed by literature view and expert opinion. Training materials were prepared for use on an electronicLearning (e-Learning) platform. An in-person hands-on simulation and certification session was then designed. It included a performance checklist assessment for use by Clinical Trainers, who in collaboration with a gynecology teaching assistant, provided an audit and feedback process to determine Trainee competency.

Results: Five discrete components for CPMA training were developed as e-Learning modules. These were: (1) overview of all the clinical measures and PM anatomy and examination assessments, (2) visual assessment for pronounced pelvic organ prolapse, (3) palpatory assessment of the pubovisceral muscle to estimate muscle integrity, (4) digital vaginal assessment to estimate strength, duration, symmetry during PM contraction, and (5) pressure palpation of both myofascial structures and PMs to assess for self-report of pain. Seventeen Trainees completed the full CPMA training, all successfully meeting the a priori certification required pass rate of 85% on checklist assessment.

Conclusions: The RISE CPMA training program was successfully conducted to assure standardization of the PM assessment across the PLUS multicenter research sites. This approach can be used by researchers and healthcare professionals who desire a standardized approach to assess competency when performing this CPMA in the clinical or research setting.

Keywords

comprehensive pelvic muscle assessment; pelvic examination; pelvic floor myofascial pain; pelvic muscle strength; pelvic organ prolapse; pubovisceral (pubococcygeus) muscle; women's health

1 | INTRODUCTION

Over the last decade, research has revealed new, expanded knowledge regarding pelvic muscle (PM) complexity,¹ anatomic specificity, physiologic functioning, and potential for specific muscle injury² (e.g., tears) or pain³ (e.g., myofascial). Improved imaging techniques have refined the assessment and identification of the range of PM changes, injuries, and recovery associated with life course events (e.g., childbirth).⁴⁻⁸ There remains a need to estimate PM health (optimal to poor) using clinical examination that draws on this new knowledge to support ongoing research and advance clinical care. However, standardization of PM assessment including training materials and quality control is lacking.

The Prevention of Lower Urinary Tract Symptoms (PLUS) research consortium is comprised of eight clinical centers and a scientific and data coordinating center focused on advancing science to understand bladder health (BH) and prevent lower urinary tract symptoms (LUTS) in adolescent and adult women.⁹ The PLUS consortium launched the RISE FOR HEALTH (RISE) national study of BH which includes annual surveys and an in-person visit.¹⁰

During RISE study development, the need arose for a process to clearly identify and prioritize which PMs to assess (e.g. levator ani [LA] consisting of the pubovisceral [PV; pubococcygeus], puborectalis, and the iliococcygeus and the obturator internus [OI] muscles)^{1,11} in the in-person visit and how to standardize a replicable training approach to PM assessment. Hence, the PLUS research consortium was motivated to develop an overall, standardized, replicable clinician training program for comprehensive pelvic muscle assessment (CPMA). We describe our process, products (e.g., electronic-Learning [e-Learning] modules), and group testing results from the education and training methods developed and used by Clinical Trainers in the PLUS RISE CPMA program.

2 | MATERIALS AND METHODS

The PLUS research consortium was established to create the evidence base for the promotion of BH and prevention of LUTS by using a transdisciplinary approach that integrates discipline-specific perspectives and extends this knowledge to generate a fundamentally new aspect of scientific inquiry.⁹ The team of PLUS investigators ($n = 22$) spans a range of perspectives and areas of expertise in the healthcare of adolescent and adult women. The research protocol for the PM assessment was developed by PLUS investigators, including physical medicine and rehabilitation physicians, urologists, and urogynecologists, nurse practitioner continence specialists, nurse-midwife, primary healthcare providers, geriatricians, and epidemiologists. The steps of the planning process and launch of the training are described.

2.1 | Planning Task 1: Literature review

The team's first task was to conduct a literature search for the most current understanding and knowledge regarding the following:

- a. PMs anatomical detail and complexity,
- b. the function of discrete components,
- c. evidence on muscle injury type and prevalence, and
- d. evidence of muscle and myofascial pain.

Once informed by the literature, the group used consensus to identify as comprehensively as practical, the PM examination components deemed most important for the RISE study (Table 1) and to develop two case report forms: (1) for compiling data from the PM assessment, and (2) for providing detailed instructions on the PM assessment procedure itself (available in Supporting Information: Materials).

2.2 | Planning Task 2: e-Learning module development

A content lead for each of the four exam components was responsible for gathering any additional required materials (e.g., figures, diagrams, videos, and references) and drafting an e-Learning module with a voice-over presentation. An e-Learning platform was selected to accommodate investigators and research staff from the eight sites across the United States. Each module was determined as complete only after initial review and discussion with the entire team, with iterative improvements and a final team review for establishing consensus regarding module accuracy and completeness. All modules were designed for self-administration using a personal computer.

The University of Minnesota REDCap web interface was assigned as the e-Learning platform. The modules were voice-over PowerPoint presentations and were designed for easy access online at any time and were available to download. In brief, the five modules and components include (1) an overview of all the clinical measures and PM examination assessments, (2) pelvic organ prolapse (POP) assessment without and with Valsalva while also evaluating for any urinary or stool leakage during Valsalva, (3) palpatory assessment of the PV (pubococcygeus) muscle to estimate muscle integrity, (4) PM strength digital vaginal assessment for duration and symmetry, and (5) PM and internal hip myofascial pain with palpation examination that incorporates self-reported pain with pressure over specific muscles (LA and OI) areas. Full details are shown in Tables 1 and 2.

2.3 | Planning Task 3: In-person training process for certification in PM assessment

To complement the e-Learning modules, the RISE in-person team also designed an in-person training and certification process. This was to confirm and document skill acquisition and skill consistency across Trainees preparatory to the RISE study. Each Trainee would first complete all five e-Learning modules as a prerequisite.

The in-person training and certification process was envisioned as a 1-day simulation experience using gynecology teaching assistants (GTA) who received training before the session and the use of the PM assessment Certification Checklist of the PM Assessment

(Appendix 1) for the Trainee and the Standardized PM Checklist for the GTA (Appendix 2). To recruit Trainees, the planning team asked each of the eight PLUS clinical research sites for the RISE study to identify at least two individuals as their Trainees. Each Trainee would be an advanced practice provider (e.g., nurse practitioner, certified nurse midwife, physician assistant) or a physician, who conducts pelvic examinations as a regular component of their practice.

A competency assessment checklist was prepared for use by the Clinical Trainer with detailed steps of the process indicated. A second assessment, using the GTA checklist, was conducted by the GTA indicating whether components of the exam were completed consistently between the Trainer and Trainee. The planning team decided a score of 85% was required for passing the in-person hands-on PM assessment. However, it was also decided that those unable to successfully certify by achieving 85% during a first assessment process could undergo remediation (review of the necessary elements on the checklist and feedback with the evaluator) and be allowed a second certification opportunity within the same day.

The competency process was led by four expert clinicians (two physicians, one nurse practitioner, and one midwife) with prior experience in one or more parts of the PM assessment. Each of these clinicians would serve as a Clinical Trainer and is further referred to as such here. Each Clinical Trainer, as with all Trainees, would be required to complete all five e-Learning modules before leading the training and certification processes. Each Clinical Trainer would also be fully oriented to the highly detailed performance Certification Checklist of the PM assessment (Appendix 1) developed by the planning team to use as the tool to standardize the in-person training process, set expectations, and determine pass or fail of Trainees via a quantified scoring system. The checkoff list would be inclusive of the case report form developed for recording PM assessment data.

Several components of the PM assessment were recognized as not feasible for direct visualization by the Clinical Trainer such as the LA assessment and the myofascial pain assessment. Therefore, the planning team designed alternative Trainee feedback and evaluation, which included feedback from trained GTAs. The GTAs were volunteer staff at the clinical simulation center that hosted the 1-day training simulation and had prior training and competency in educating healthcare professional students in pelvic exams process and procedures. The GTAs served in the role of standardized patients but also with an evaluative capacity constructed per a performance standardized checklist of items (Appendix 2) that only they could perceive with accuracy. The details of the hands-on component of the CPMA are found in Table 2. Before the in-person training session and per request, the GTAs were provided with an overview of the entirety of the PM examination (Table 3).

The process established for the GTAs and Clinical Trainers to ensure baseline competency (Figure 1) was as follows:

- a. Expert Clinical Trainers review the PM exam with the lead GTA so she could ascertain specifics of the assessment (e.g., degree of finger pressure on the muscle as exerted by the expert Clinical Trainer) to establish intertrainer reliability of the PM assessment process.

- b. Each Clinical Trainer conducts each PM component with the lead GTA for her to provide feedback about consistency between Clinical Trainers.
- c. Each Clinical Trainer would then conduct all PM exam components with the GTA specifically assigned to her/him for later work with Trainees. The goal would be to demonstrate the exam to the GTA and establish the benchmark exam (including all components, expected sites of touch, and pressure for each component).
- d. For each new Trainee and across every component, the GTAs would complete a standardized checklist (Appendix 2) that assessed if a step of the exam was completed or not and how consistent the exam component was to the Clinical Trainer's criterion exam.
- e. For the competency assessment certification, Clinical Trainers would be responsible for completing a competency certification checklist (Appendix 1) of the Trainees in performing each component of the comprehensive PM assessment in a 1:1 ratio (Clinical Trainer/Trainee).

The GTA assessment then served as an audit process and was used to provide feedback to the Trainees during the examination process as a summative review of the full assessment process and to correct the level of pressure.

Throughout the training process, to the extent possible, the planning team's goal was to simulate the setting for a typical clinical research exam setting. Thus, it was decided that each PLUS clinical site would be asked to identify a person on their research staff (research coordinator [RC]) to attend the in-person training in the role of assistant to their site's Trainees, further simulating and establishing the dynamic that would occur during the RISE study's PM examination between the PM assessor and RC (chaperone and data recorder).

2.4 | Logistics of the in-person training

The site of the in-person portion of the training program was the University of Minnesota Health Sciences Education Center in Minneapolis, MN. This location is a state-of-the-art clinical simulation center that is staffed by experts in clinical training processes and procedures and with enough space to allow for a clinical examination space for each Clinical Trainer/ Trainee/Assistant team. The center staff includes trained GTAs who participate in health professional trainee education in the performance of gynecologic pelvic examinations.

The intention of the first step of the in-person training session was to confirm the Clinical Trainer's expectations and establish intertrainer rater reliability before going into the competency assessments of new Trainees. This step was accomplished using one GTA who provided feedback to the four Clinical Trainers as a way to confirm intertrainer reliability. The staffing model to support the training process included four GTAs who would be paired with the four Clinical Trainers to form an expert training team. Each expert Clinical Trainer/GTA team then used detailed checklists to assess the competency of the PM assessment with each new Trainee. Hereafter, we refer to this total program for training in CPMA as the PLUS consortium's CPMA Training Program.

2.5 | Data analysis

Assessment results for this report are limited to module completion rates, certification pass rates presented as a number, and percent of Trainees passing by overall scores. We also report these descriptive statistics stratified by the various components.

3 | RESULTS

Results from the planning process included consensus on the need for five discrete e-Learning modules to incorporate all components of the CPMA.

The five PM modules were made available to all PLUS members who would be participating in the in-person visit, which included content not related to PM assessment. A total of 40 PLUS members took at least some portion of the e-Learning training with 36 completing all 5 PM modules as confirmed by a Trainee e-signature documented in the e-Learning platform. Of the total 36 completers, 17 were Clinical Trainees for the PM assessment certification process during the in-person training. Other completers included the RCs who served as in-person examination chaperones and data recorders for the results of the PM examination.

All participants who completed the full in-person training ($N = 17$), including the initial four Clinical Trainers, met or exceeded the pre-specified overall 85% pass rate for the overall PM assessment, with an average passing rate of 96.3%. The average pass rate for each examination component was: 95.2% for the POP assessment, 97.5% for the PV muscle integrity exam, 96.2% for the PM strength exam, and 95.6% for the pelvic floor and internal hip myofascial pain for the palpation screening exam. The Trainees were also evaluated on how a description of the research exam process for the participant was conducted (average score 94.1%) and professionalism/communication (average score 98.0%) during the exam process.

From the GTA patient models' assessments, the overall "yes" versus "not done" for the Trainees ($n = 17$) as a percentage for each component's details (as listed in the Appendix) were: (1) Introduction of the examination, 78% yes; (2) the POP assessment, 97% "yes"; (3) the PV muscle integrity exam, 85% "yes"; (4) the PM strength exam, 83% "yes"; and (5) the pelvic floor myofascial pain assessment, 89% "yes." Eighty percent of Trainees established the reference pressure on the model's thigh before performing the internal component of the pelvic floor myofascial pain examination. The GTAs assessed the Trainee's pressure during palpation of each muscle during the myofascial pain assessment as "less pressure," "greater pressure," or "equal pressure" as compared to the Clinical Trainers. The reported percentage of Trainees using less pressure than the Clinical Trainer's pressure was 7%, equal pressure was 31%, and greater pressure was 62%.

4 | DISCUSSION

We present the novel CPMA Training Program developed by the PLUS research consortium that included Gynecology Teaching Assistants in sufficient detail to reproduce it for use in research and other settings that require high-quality training in PM assessment.

Standardization and current knowledge application in assessment measures are critical for accurate interpretation of scientific results, but also for application to clinical and community-based populations. Standardization of training for these broad applications relies on simplicity without loss of comprehensiveness or rigor, and a balance of feasibility and burden matched against the opportunity to gain accurate assessments for research purposes and clinical applications as indicated.

Extensive efforts have been taken to validate instruments used for outcome assessment in the RISE for Health study including validation of the Bladder Health Index.²⁹ Similarly, the pelvic examination protocol was designed using the best available evidence and expert opinion with rigorous e-Learning and centralized in-person training for all clinical evaluators to ensure consistency across participants and sites.

We used existing validated measures whenever possible for the evaluation of PM integrity, function, and pain with the additional focus of creating a physical assessment process (relative to its application in the RISE study) yet simplistic enough to be reproducible in a standardized manner. The long-term outcome expected is generating accurate information and minimizing participant burden.

For example, our method for prolapse evaluation follows guidelines for standard clinical POP measurements^{23,30} using prolapse beyond the hymen as a dichotomous outcome and simplifying the presence or absence of prolapse. There is good evidence that clinically significant and bothersome prolapse does not occur until it is beyond the hymen. As the RISE study is aimed at evaluating BH in community-dwelling women, rather than women with known pelvic floor disorders, we elected not to perform a detailed pelvic organ prolapse quantification examination; thus, minimizing participant and evaluator burden. Similarly, there are numerous validated and reliable methods to assess PM strength.^{18–21} Our protocol selected the Modified Oxford assessment²⁴ with its standardized, validated scoring measure for the strength assessment which also aligns with the current understanding of muscle function.

Standardized, validated assessments of PV integrity and pelvic myofascial pain are published but not widely adopted yet.^{26–28} The PV muscle integrity assessment was included as an estimate of prior tear away from its origin (which is chronic).^{5,6} Measurement was simplified as the presence or absence of the PV muscle as a categorical outcome with the option for “equivocal” if the examiner was uncertain.¹³ There is evidence that loss of PV muscle fibers (tear) indicates/or is associated with LUTS and prolapse. The RISE study will determine if a physical assessment estimate of PV loss is associated with measures of BH.

In the PM functional strength measure, we relied on techniques well-documented in the literature, slightly modified to align with modern understandings of anatomical landmarks. Because our goal was “comprehensive” assessment, we additionally included PM muscle pain assessment, which has typically not been evaluated in research contexts or clinical settings focusing on BH. PM pain with palpation has been associated with LUTS symptoms.²⁵

One of the most innovative highlights of our PM exam is combining integrity (tear), strength and pain in the assessment and planning to explore all three with BH. Putting these many components of PM assessment together in a single training program is a strength of our work. In addition to a comprehensive assessment process based on the latest knowledge and understanding of PM anatomy and function, an additional strength of our methods is the use of e-Learning and centralized in-person training and evaluation using experienced women who volunteer as models for pelvic exams and were trained GTAs. A priori metrics were set to ensure adequate training and consistency across examiners. Postexam assessments and immediate feedback from GTAs yielded high pass rates from Trainees.

Limitations and challenges to developing the in-person part of the CPMA training included the inability to rigorously validate PM assessment using test–retest reliability or validity testing of exam measures within a single-day training program. However, the training resources and materials are available for replication testing of this process to extend into train-the-trainer models and further validity testing. Future studies beyond this initial development of the CPMA training program should include test/retest reliability testing, inter-/intra-rater reliability of exam measures and indicators of their validity, and evaluation of sustainment of competence following the initial assessment. With the building blocks in place, e-Learning modules, in-person training processes, use of checklist assessments of Trainee by Clinical Trainer and GTA and initial success indicated by our findings, the field is now primed for undertaking these next steps. A potential limitation to the use of the process is the cost of the training process. This should be proactively planned into research budgets during the proposal phase.

5 | CONCLUSIONS

As the PLUS research consortium prepared to initiate the RISE study, the need for a comprehensive PM assessment training program was a necessary component of the in-person examination process to support new insights and discoveries related to BH and the prevention of LUTS. Through a process of literature review and expert-generated procedures, a comprehensive PM assessment training program was developed that was based on current knowledge and understanding of PM anatomic and physiologic function. The RISE CPMA training program was successfully conducted to assure standardization of the PM assessment process across the PLUS multicenter research study. These resources and tools are available for use by others who have a need for a standardized clinician training program in PM assessment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in the Supporting Information of this article.

APPENDIX 1: CERTIFICATION CHECKLIST FOR THE RISE COMPREHENSIVE PELVIC MUSCLE ASSESSMENT

Passing Score ≥102 Trainee’s Total Score: _____ /120 points

Trainee Name: _____ Research Site: _____
 Certifying Trainer: _____ Date Certified: _____

To evaluate performance: score each category that is marked using the following rubric:

- 4 Performs flawlessly
- 3 Requires one minor cue for performance
- 2 Requires one minor recommendation to improve performance
- 1 Requires >1 minor or 1 major recommendation to improve performance
- 0 Unsafe or requires >1 major recommendation to improve performance

Points for passing criteria indicated for each section. A score of “1” on any items requires repeating that section. A score of “0” on any section requires remediation and participant will not be certified but retested.

SKILL: Pelvic Examination	Score	Comments
Preparation-Required Review:		
Review RISE Manual of Operations	NS	
View Powerpoint presentations	NS	
View Instructional Videos & Relevant Publications	NS	
CONDUCT Practice with Volunteers at your site (if possible)	NS	
Section I. Preparation of Participant		
Performs hand hygiene, dons gloves appropriately, applies lubricant		
Explains examination procedure: <i>“Hello [participant’s name], I am (examiner’s name and profession [MD, NP etc], I am an investigator [or principal investigator] at/with the [research site] being a participant in this study. Thank you so much for being a participant in this study. Now I am going to do a pelvic examination. I do not use a speculum for this exam. First, I will be looking at the outside of your vagina and asking you to cough. Then, I will insert one finger into your vagina to test the strength of your muscles. I will put pressure on different</i>		

SKILL: Pelvic Examination	Score	Comments
<i>areas in your vagina to determine the muscle tone and if you have any discomfort. At any time during the exam you can ask to stop. Please also let me know if there is any pain or discomfort during the exam. You are in control of the process. Is it OK if I begin the exam?</i>		
Asks participant if she needs to void		
Positions comfortably in supine position, hips and knees flexed.		
Maintains proper draping of participant during exam		
Passing Score Section 1: /20		
Section 2. Observation of Perineum for POP		
Explains examination procedure to participant <i>"First, please let your knees fall to the side. I am going to start by looking at the opening of the vagina and then while you strain, push or bear down like you are moving your bowels."</i>		
Asks participant to bear down while observing the perineum		
Passing Score Section 2: /8		
Section 3. Internal Examination-PV Muscle Integrity		
Informs participant that the internal examination will be performed next. <i>"I will be feeling the muscles inside the vagina. I will not use a speculum but will place 1 finger in your vagina. I will examine the muscles on each side of your pelvis."</i>		
Index finger is placed at the expected anatomical location of the midmuscle body of the PV as felt about 2 cm inside the vaginal sidewall, with the finger curled to the right or left		
Sweeps slightly up and back down using the finger pad at each point to palpate for fullness of the PV muscle body. It is allowed to ask the woman to attempt a pelvic floor muscle contraction as a check on impression regarding felt fullness.		
Repeats exam bilaterally		
Completes CRF for PV muscle integrity scoring related to PV muscle		
Completes CRF for pain during PV palpatory assessment, including assessing for indicators of pain from both observation and verbal confirmation from the woman		
Passing Score Section 3: /24		
Section 4. Internal Examination-PM Functional Strength		
Informs the participant of the next part of the internal examination, pelvic muscle strength test. <i>"Next, I will examine the muscles around your vagina. I will ask you to squeeze these muscles around my fingers. You may know this as a Kegel contraction."</i>		
Inserts 1–2 gloved, lubricated index (and middle) fingers (pads down) into the vagina. Inserts fingers (posterior) to depth of proximal interphalangeal joint. Rests fingers on muscle belly of LA -midline		
Uses correct instructions for LA contraction and relaxation <i>"I am going to count to 3 and when I say 3, I want you to tighten and squeeze your pelvic floor muscle and hold it as I count to 5. I am going to have you do this 3 times."</i> Explains she is to "pull in" or "lift up" the floor of her vagina or to imagine she is trying to control passing wind or pinching off a stool.		
At a count of 3, asks participant to tighten/squeeze and hold for 1,2,3, 4, 5 and asks her to relax.		
Accurately evaluates LA muscle contraction/relaxation midline		
Repeats exam bilaterally (right & left side) repeating same instructions		
Completes CRF for PM strength section		
Passing Score Section 4: /28		
Section 5. Obturator Internus and Levator Ani Myofascial Pain Screening Examination		
Introduces the participant to the myofascial pain exam		

SKILL: Pelvic Examination	Score	Comments
<i>"Now, I would like to move to the next step of the assessment focused on assessing the muscles of your pelvic floor for any pain or discomfort with pressure. I will be pressing on 4 muscles during a vaginal examination." Is it ok to proceed?</i>		
<p>Orients the participant to the internal examination by pressing on midthigh to provide a reference pressure that will be applied on the exam <i>"First, I will first press on your thigh to let you know how the pressure will feel when I press internally (inside you). Do you feel my finger on your thigh? (palpate mid-thigh) This is as firmly as I am going to be pressing on the muscles. Is there any pain or discomfort? If not, this will be a "0" on a scale of "0-10". Please let me know if you experience pain or discomfort and rate that pain or discomfort on a scale of 0 to 10. No pain or discomfort would be a 0 and severe pain or discomfort is a 10."</i></p>		
<p>Informs participant that 1 finger will be inserted vaginally. <i>"I will begin the exam by inserting 1 finger into your vagina and begin with the muscles on your RIGHT side, then will test the muscles on your left side. "</i></p>		
<p>Asks participant if pressure applied to RIGHT OI induces pressure-only vs pain or discomfort. **Trainee directs hand/finger to the 10-11 O'clock position. <i>"When I press on this muscle, if it only pressure, a "0" or is there pain or discomfort? If there is pain or discomfort, please rate it on a scale of 1-10. "Mild" pain or discomfort would be a 1,2 or 3, "moderate" pain or discomfort a 4,5 or 6, and "severe" pain or discomfort a 7,8,9, or 10."</i></p>		
<p>Trainee may move knee of RIGHT knee medially-laterally-medially to help identify OI muscle.</p>	NS	
<p>Asks participant if pressure applied to RIGHT LA induces pressure- only vs pain or discomfort. **Trainee will direct hand/finger to the 7-8 o'clock position. (During application of pressure) <i>When I press on this muscle, is there pressure or pain/ discomfort?</i> <i>(May reorient to pain scales "If there is pain or discomfort, please rate it on a scale of 1-10. "Mild" pain or discomfort would be a 1,2 or 3, "moderate" pain or discomfort a 4,5 or 6, and "severe" pain or discomfort a 7,8,9, or 10."</i></p>		
<p>Asks participant if pressure applied to LEFT OI induces pressure-only vs pain or discomfort. **Trainee will direct hand/finger to the 1-2 o'clock position. (During application of pressure) <i>When I press on this muscle, is there pressure or pain/ discomfort?</i> <i>(May reorient to pain scales "If there is pain or discomfort, please rate it on a scale of 1-10. "Mild" pain or discomfort would be a 1,2 or 3, "moderate" pain or discomfort a 4,5 or 6, and "severe" pain or discomfort a 7,8,9, or 10."</i></p>		
<p>Asks participant if pressure applied to LEFT LA induces pressure-only vs pain or discomfort. **Trainee will direct hand/finger to the 4-5 o'clock position. (During application of pressure) <i>When I press on this muscle, is there pressure or pain/ discomfort?</i> <i>(May reorient to pain scales "If there is pain or discomfort, please rate it on a scale of 1-10. "Mild" pain or discomfort would be a 1,2 or 3, "moderate" pain or discomfort a 4,5 or 6, and "severe" pain or discomfort a 7,8,9, or 10."</i></p>		
<p>Passing Score Section 5: /28</p>		
Section 6: OVERALL: Professionalism/Communication		
<p>Develops a professional rapport with the participant.</p>		
<p>Speaks at an appropriate pace</p>		
<p>Demonstrates appropriate closure after exam</p>		
<p>Passing Score Overall Section 6: /12</p>		
<p>Total Score (Passing 102/120 points)</p>		

APPENDIX 2: STANDARDIZED PM CHECKLIST FOR GTA ASSESSMENT OF THE TRAINEE

Instructions: There are 5 components to this exam, Introduction and 4 parts. We are asking you to evaluate and complete the specific section after each component.

First Part: Introduction			
Did the Trainee explain each step of the PM examination prior to beginning:			
<u>Introduction</u>	Overall purpose of the Pelvic examination	Yes	No
	Explained that there will be 4 parts: pelvic organ prolapse, pelvic muscle integrity, strength and presence of pain	Yes	No
	Asked for permission to examine	Yes	No
	Asked if you needed to void	Yes	No
	Provided a cover for privacy	Yes	No
	Placed you in a comfortable position with hips and knees flexed.	Yes	No
	Put on gloves and used lubricant	Yes	No
	Explained the examination can be stopped at any point and to report any pain or discomfort during any part of the examination	Yes	No
	Second Part: POP		
Did the Trainee explain each step of this examination prior to beginning:			
<u>Introduction</u>	What is done to observe for pelvic organ prolapse (knees fall to the side, will look at area around vagina)	Yes	No
	Asked to bear down	Yes	No
Compared to the Trainer, did the Trainee gave you instructions on what to do, – asked you to bear down?		Yes	No
Third: PV Integrity			
PV Muscle Integrity Portion of internal examination			
Did the Trainee explain each step of the examination prior to beginning:			
<u>Introduction</u>	Purpose of the PV internal exam and insertion of 1 lubricated finger	Yes	No
	Palpation should not be painful	Yes	No
	Examination can be stopped if too uncomfortable	Yes	No
Compared to the Trainer, did the Trainee press on the middle of the right side of your vagina?		Yes	No
Compared to the Trainer, did the Trainee sweep her finger slightly up and back down the side wall of your vagina?		Yes	No
Compared to the Trainer, did the Trainee test both sides?		Yes	No
Fourth Part: Pelvic Muscle Strength			
Did the Trainee explain each step of the examination prior to beginning:			
<u>Introduction</u>	Purpose of the pelvic muscle strength exam	Yes	No
	Palpation should not be painful	Yes	No
	Examination can be stopped if too uncomfortable	Yes	No

Compared to the Trainer, did the Trainee rest finger on the middle of your vagina?		Yes	No
Compared to the Trainer, did the Trainee use correct instructions for LA contraction and relaxation?		Yes	No
Compared to the Trainer, did the Trainee ask you to “pull in” or “lift up” your pelvic floor/vagina or to imagine trying to control passing wind or pinching off a stool.		Yes	No
Compared to the Trainer, did the Trainee count to 3 and asked to tighten/squeeze and hold for 1, 2, 3, 4, 5 and then to relax?		Yes	No
Compared to the Trainer, did the Trainee do this 3 times (middle of vagina and left and right side)?		Yes	No
Fifth Part: Myofascial Tenderness Portion of examination			
Did the Trainee explain each step of the examination prior to beginning:			
Introduction	Purpose of the PFMP with palpation exam		Yes No
	Palpation of skeletal muscle should not be painful		Yes No
	Will establish pressure reference on thigh		Yes No
	Explain that (4) pelvic muscles will be examined: 1) With a similar pressure as applied to thigh, 2) Mid belly and then along length of muscle		Yes No
	Explain pain score: 0 = Pressure, no pain or discomfort 1-3 = Mild pain/discomfort 4-6 = Moderate pain/discomfort 7-10 = Severe pain/discomfort		Yes No
	Examination can be stopped if too uncomfortable		Yes
Compared to the Trainer, did the Trainee establish reference pressure on mid-thigh?			
Mid quadriceps, RIGHT thigh		Yes	No
Compared to the Trainer, was the pressure applied to the muscles by the Trainee:		Less Equal Greater	
		RIGHT mid-thigh	Less Equal Greater
Compared to the Trainer, did the Trainee identify each muscle correctly?			
RIGHT obturator internus		Yes	No
RIGHT levator ani		Yes	No
LEFT levator ani		Yes	No
LEFT obturator internus		Yes	No
Did the Trainee palpate the muscle first in the middle of the muscle and then along the muscle length?			
RIGHT obturator internus		Yes	No
RIGHT levator ani		Yes	No

LEFT levator ani	Yes No	
LEFT obturator internus	Yes No	
Compared to the Trainer, was the pressure applied to the muscles by the Trainee:		Less Equal Greater (please circle one)
RIGHT obturator internus	Mid muscle belly	Less Equal Greater
	Length of muscle	Less Equal Greater
RIGHT levator ani	Mid muscle belly	Less Equal Greater
	Length of muscle	Less Equal Greater
LEFT levator ani	Mid muscle belly	Less Equal Greater
	Length of muscle	Less Equal Greater
LEFT obturator internus	Mid muscle belly	Less Equal Greater
	Length of muscle	Less Equal Greater

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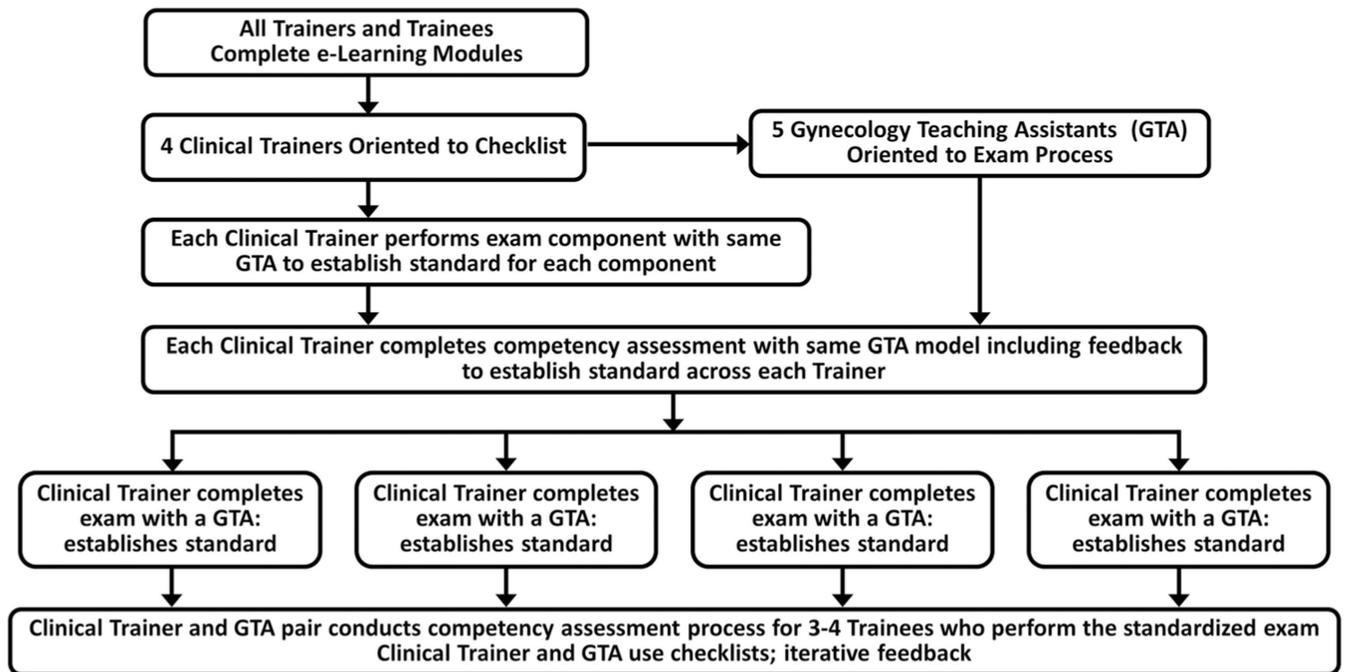


FIGURE 1.
Comprehensive pelvic muscle assessment training process

Components of RISE pelvic assessment

TABLE 1

Exam component	Assessment approach	Comment/rationale
<p>Evaluation for prolapse and incontinence</p> <p>Pubovisceral (PV) muscle integrity. Note: PV nomenclature aligns with the muscle naming convention as opposed to the alternative name pubococcygeus. Muscle “origin” denotes attachment at an unmovable anchoring site and muscle “insertion” reflects attachment at a site that responds to muscle contraction with movement.</p> <p>LA muscle strength and endurance</p>	<p>Visual inspection of the presence of prolapse protruding beyond the introitus at rest and/or with Valsalva.</p> <p>Palpatory assessment will estimate the extent of the PV muscle body integrity where it passes the vaginal sidewall bilaterally.^{1,13-16} The degree of detachment (tear) for the origin of the pubic bone can vary from none to complete loss on either side of the bilateral muscle structure.</p> <p>Transvaginal digital palpation is used to assess the PMs and surrounding areas during contraction to determine the duration and symmetry of muscle contractions.</p>	<p>Damage to the levator ani musculature and ligamentous support of the pelvic organs may result in vaginal prolapse.¹²</p> <p>Prevalence of PV muscle tear ranges from 13% to 36% of women who have had a vaginal delivery with a higher prevalence associated with older maternal age and obstetric variables indicative of a more complex vaginal birth.^{5-8,17} A PV muscle tear has been identified as a risk factor for two important pelvic floor disorders: pelvic organ prolapse and possibly stress urinary incontinence.^{5,6}</p>
<p>Pelvic floor myofascial pain with palpation</p>	<p>Palpation to determine presence of obturator internus (OI) and LA myofascial pain with palpation. Myofascial pain is characterized by the presence of trigger points or tenderness on a scale of 0 to 10 with palpation of the OI and LA muscles bilaterally.^{3,23}</p>	<p>The recommended position of the examining digit(s) is to place the palmar surface of the examining finger on the LA.^{11,18-22} Pressure or stretch is applied perpendicular to the muscle fibers to assess tone. A contraction is felt as a tightening, lifting, and squeezing action under the examining finger as per the modified Oxford scale.</p> <p>Pelvic floor myofascial pain may occur in conjunction with, or as sequelae of disease of the urinary, genital or musculoskeletal systems, or it may arise independently and has been observed in patients with LUTS and pelvic floor dysfunction.^{24,28}</p>

Abbreviation: LA, levator ani; PM, pelvic muscle; RISE, RISE FOR HEALTH.

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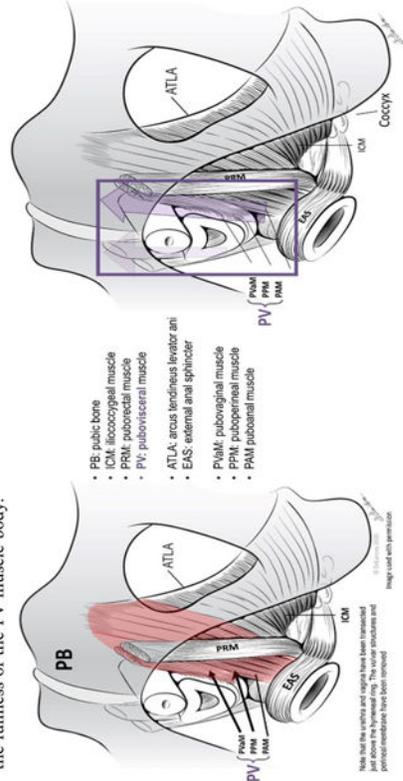
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TABLE 2

Description of the RISE pelvic examination

Component	Description
1	Introduction to pelvic examination

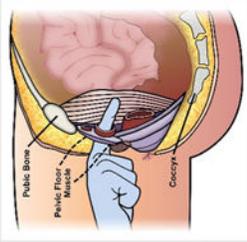
- Review of the pelvic muscles (PM).
 - Brief description of the examination (Supporting Information: Pelvic Examination Instructions Case Report Form).
 - Instructed to report any pain or discomfort with any component of the pelvic exam and that the exam component can be stopped at any point.
 - Positioned in dorsal lithotomy for viewing the perineum and vagina and performing the internal vaginal examination.
- 2 Prolapse screening exam
 - Visual assessment for the presence/absence of prolapse protruding beyond the introitus at rest and with Valsalva.
 - Any leakage of urine and/or stool will be noted.
 - If the prolapse is present, perform manual reduction for the remainder of the exam.
 - 3 Pubovaginal muscle integrity exam
 - The index finger is placed at the anatomical location of the mid-muscle body of the PV as felt about 2 cm inside the vaginal sidewall (typically to first and no more than second knuckle).
 - Finger curled to the right or left.
 - Lightly press against the vaginal sidewall and sweep slightly up and down using the finger pad to palpate for the fullness of the PV muscle body.



- If the PV muscle body cannot be clearly felt, the above procedure can be repeated while the woman attempts a PM contraction.
- During the upward sweep, assesses for continuous soft tissue resistance interposed between the lateral vaginal wall and its origin of attachment at the pubic bone.

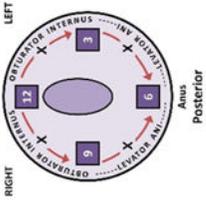
- The absence of the muscle body will be felt as a bony area at the inferior pubic ramus, and there will be pronounced thinness of the PV muscle more dorsally.
- Three scoring categories: The body of the muscle is definitively felt, and that side is graded as “PV muscle present.” If the muscle body is not felt, and instead there is a sense of indentation and/or feeling of the hardness of the pubic ramus, that side is graded as PV muscle “absent.”
- If unable to confidently ascertain that the PV muscle body is either “present” or “absent,” that side is scored as “equivocal.”
- Both sides scored.

4 Pelvic muscle strength assessment



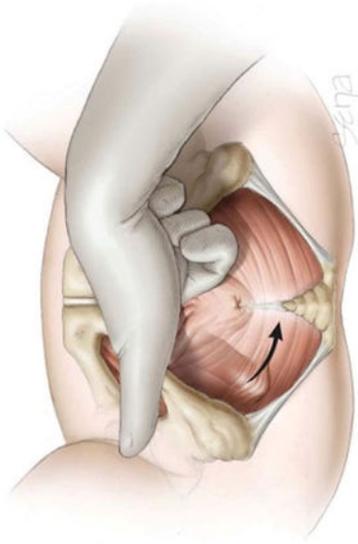
- The index finger is inserted on a mid-sagittal plane 4–8 cm (approximately 2 inches) into the vagina, the levator ani (LA) muscle can be palpated just inside the hymenal ring.
- Muscle is tested at the midline (6 o'clock position) and bilaterally (right and left sides) at the 4 o'clock and 8 o'clock position, at the muscle belly.
- At a count of 3, the participant contracts the muscle for 5 s followed by relaxation.
- “Tactile feedback,” to activate PM stretch receptors, can provide a quick, but very slight stretch to the muscle by pressing down towards the perineal body between the vagina and rectum can be used to: (1) identify the muscle to contract, (2) understand how to contract the PMs, and/or (3) improve the contraction in the case of very weak PMs.
- Modified Oxford grading scale is used for scoring.

5 Pelvic floor myofascial pain with palpation, including levator ani (LA) and obturator internus (OI) palpation exam



- Standardize the pressure that is applied to the muscles during the examination by pressing on the participant's mid-thigh (the belly of quadriceps femoris) to provide a reference pressure. Moderate to firm pressure is used, similar to the pressure that would “blanch” the evaluator's nail bed on a desk top. The participant is asked if this elicits “pain” or “discomfort.”
- Orientation is visualized with a clock face overlying it, the RIGHT OI identified between 10 and 11 o'clock and LEFT OI between 1 and 2 o'clock, RIGHT LA identified between 7–8 o'clock, and LEFT LA between 4 and 5 o'clock

- OI—palpation of the mid-muscle belly is performed with the index finger of the dominant hand inserted 3–4 inches (8–10 cm) from the introitus, (up to the metacarpophalangeal joint of the first finger).
- LA—palpation of the mid-muscle belly of the LA is palpated within 1–4 inches (8–10 cm) from the introitus (typically metacarpophalangeal joint of first finger).
- Apply pressure in the center of the muscle belly, then in a sweeping motion along the length of the muscle in the direction of the orientation of that muscle from near the pubic bone and move along the length of the muscle.
- Proceeds clockwise from 12 to 6 o'clock; right OI, right LA, left LA, and left OI.



Levator Ani



Obturator Internus

Abbreviations: RISE, RISE FOR HEALTH; PV, pubovisceral.

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TABLE 3

RISE training, GTA pelvic examination description

We are asking you to undergo four pelvic examinations for an NIH-funded research study on women. The examination is to test the muscles that surround your vagina. The only way to test them is to insert one finger into your vagina. These examinations will be done by an examiner (Trainer) or Trainee who is a doctor or nurse practitioner who has experience in performing pelvic examinations. The trainee will be observed by an experienced clinician (doctor or nurse practitioner) to ensure the exam is being done correctly. The reason for the pelvic examination is to check how your internal pelvic muscles, often called “Kegels”, work. There are 4 parts to this pelvic examination. A speculum will not be used. The four parts of the pelvic examination will take approximately 15–20 min. You will be asked to:

- Urinate before you are examined.
- Undress from the waist down and you will be given a gown to wear.
- Lie on an exam table with your feet in stirrups and knees separated.
- 1. Look for pelvic organ prolapse (dropped bladder or uterus)
 - The first part of the exam is to determine if you have a dropped bladder or uterus and it only involves looking at the opening of your vagina.
 - The examiner will ask you to push down like you are moving your bowels and look at the opening to your vagina to see.
- 2. Palpate (touch) for pelvic muscle integrity
 - Involves examining the muscles inside your vagina.
 - To do this, the examiner will place a gloved lubricated finger about 1 inch inside your vagina and lightly press against the center and the left and right sides of your vagina muscles.
 - The examiner will then sweep slightly up and down using one finger to feel for the fullness of the muscle.
- 3. Test for pelvic muscle strength
 - While the lubricated gloved finger is in your vagina, the examiner will lightly touch three different areas in your vagina, the middle, and each side.
 - You will then be asked to squeeze or tighten your pelvic muscles around the examiner’s fingers. To do this you will be asked to pull in the muscle like you are holding back gas.
 - You will be asked to hold the muscle squeeze for 5 s and you will be asked to do this three times.
- 4. Check for any pain or discomfort
 - Before starting this exam, the examiner will first press on your thigh to let you know how the pressure will feel when doing the test inside your vagina.
 - The examiner will assess the muscles for any pain or discomfort.
 - While applying a small amount of pressure on the left and right side of the muscle, the examiner will ask you to rate any pain or discomfort you have on a scale of 0–10, with 0 being none and 10 being the most pain or discomfort.
 - A Trainer will perform the exam at the start of this test so you will know what each part of the exam should feel like. At the end of the exam, you will be asked to compare the trainee’s examination with the examination performed by the experienced clinician.

Abbreviations: GTA, gynecologic teaching assistants; RISE, RISE FOR HEALTH.