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Authors

Klusaritz, Heather

Maki, Julia

Levin, Elise

et al.

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A community engaged approach to the design of a population-based prospective cohort study to promote bladder health

Heather Klusaritz, PhD, MSW¹, Julia Maki, PhD², Elise Levin, PhD, MSc³, Amy Ayala, MPH², Jesse Nodora, DrPH⁴, Tamera Coyne-Beasley, MD, MPH⁵, Jeni Hebert-Beirne, PhD, MPH³, Terri H. Lipman, PhD, CRNP⁶, Aimee James, PhD, MPH, MA², Emily Gus, MPH⁷, Shayna D. Cunningham, PhD⁸,

Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium

¹Department of Family Medicine and Community Health, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

²Division of Public Health Sciences, Department of Surgery, Washington University in St. Louis, St. Louis, MO

³Division of Community Health Sciences, School of Public Health, University of Illinois Chicago, Chicago, IL

⁴Herbert Wertheim School of Public Health & Human Longevity Science, University of California San Diego, La Jolla, CA

⁵Department of Pediatrics, University of Alabama at Birmingham School of Medicine, Birmingham, AL

⁶Department of Family and Community Health, University of Pennsylvania School of Nursing, Philadelphia, PA

⁷Division of Urology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

Correspondence should be addressed to: Shayna D. Cunningham, PhD, Department of Public Health Sciences, University of Connecticut School of Medicine, 263 Farmington Avenue, Farmington, CT 06030, 860-679-7642, scunningham@uchc.edu.

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⁸Department of Public Health Sciences, University of Connecticut School of Medicine, Farmington, CT

Abstract

Introduction: Community engagement is increasingly recognized as a critical component of research, but few studies provide details on how to successfully incorporate community perspectives in urological research. This manuscript describes the community engagement strategy used by the Prevention of Lower Urinary Tract Symptoms Research Consortium (PLUS) to design RISE FOR HEALTH (RISE), a multi-center, population-based, prospective cohort study to promote bladder health.

Methods and Results: The PLUS Community Engagement Subcommittee, guided by a set of anti-racist community engagement principles and practices, organized, implemented, and communicated findings for all RISE community engagement activities. Community engagement was conducted through a diverse network of community partners at PLUS clinical research centers called Rapid Assessment Partners (RAPs). Via online surveys (4), virtual discussion groups (14), and one-on-one interviews (12), RAPs provided input on RISE processes and materials, including in-person visit procedures, specimen collection instructions, survey data collection instruments, recruitment materials, the study website, and the study name. This process resulted in significant changes to these aspects of the study design with reciprocal benefits for the community partners.

Discussion: Meaningful community engagement improved the design and implementation of RISE. PLUS will continue to engage community partners to interpret the RISE study results, disseminate RISE findings, and inform other PLUS studies toward the development of interventions to promote bladder health. Future urological studies would also benefit from community participation in determining priority research questions to address.

Keywords

community engagement; participatory research; bladder health; equity

Introduction

A growing body of literature supports the role of community engagement in all phases of the research process including hypothesis generation, proposal development, research implementation and dissemination. Community engagement is the bidirectional, mutually beneficial process of working collaboratively with and through groups of people affiliated by geographic proximity, a health issue, or similar situations¹. It requires working in partnership with the community in a relationship of transparency and trust to draw on the expertise of all partners to address pressing real-world problems affecting the health of the community partners. This process requires an ongoing relationship among researchers and community representatives throughout the course of the research and beyond². Communities are best positioned to define the most pressing problems for their members. Engaging community members and centering their lived experience increases the relevance and cultural rigor of the research and the likelihood of generating meaningful results^{3,4}. It promotes the legitimacy and trustworthiness of the research, especially the appropriateness

and acceptability of the study design and protocols^{5,6}. Moreover, community engagement is essential for translating research findings into new health promotion programs and policies to improve population health and reduce health disparities⁷.

Community engagement ranges across a spectrum from one way outreach, consultation, involvement, collaboration, to shared leadership². While the relative roles of community partners and academic researchers differ across the discovery continuum, all community engaged research contrasts with the traditional research approach in which academic investigators define and control all aspects of the research project and only seek interaction with the community for recruitment and enrollment of research participants⁷. Identifying *what* community engagement strategies are most effective for engaging *which* specific stakeholders and *when*, to best advance scientific knowledge, is an ongoing challenge in community-engaged research⁸. It is essential that communities are not engaged to simply “check a box” but that community voice impacts key decisions in the research process. Community-based participatory research (CBPR) is one intensive form of engagement in which community members are equal partners who share decision-making and ownership for all aspects of the research³. Building trusting, productive relationships and working in a transparent and democratic manner requires considerable effort and time. For many studies, the breadth and depth of community engagement falls lower on the spectrum but is nonetheless worthwhile. Cohort studies offer an important area of research on which to focus strengthening engagement strategies⁹.

RISE FOR HEALTH (RISE) is a large, multi-center, population-based, prospective cohort study being conducted by the Prevention of Lower Urinary Tract Symptoms Research Consortium (PLUS) across nine clinical research centers. RISE aims to identify risk and protective factors for bladder health and lower urinary tract symptoms (LUTS) and to estimate the distributions of bladder health and bladder health knowledge, attitudes, and beliefs in women of all ages across the life course. Although community engagement is increasingly recognized as a critical component of research, few studies provide details on how to successfully incorporate community perspectives in urological research¹⁰. This paper describes a unique community engagement strategy used by PLUS to design the RISE study. This strategy is a part of a larger community engagement infrastructure and approach for the PLUS Consortium, which will be described in a forthcoming publication.

Materials & Methods

The PLUS Community Engagement Subcommittee, comprised of investigators and research coordinators at each clinical research center with experience or interest in community-engaged research, organized, implemented, and communicated findings for all community engagement activities to address key aspects of the RISE study design. This work was guided by a set of anti-racist community engagement principles and practices detailed in the PLUS Community Engagement Toolkit. “Community” was defined broadly as the general population in the metropolitan areas of the consortium’s nine clinical research centers. “Engagement” was defined as the involvement of community members in the design of the RISE.

Community engagement was conducted through the network of the PLUS Consortium's Rapid Assessment Partners (RAPs), a group of center-specific community partners maintained through mutually beneficial relational activities. PLUS works to reach across intersecting ecological levels from individual to community, and represent diverse backgrounds and experiences. RAPs include women over 18 years of age who represent various stakeholder constituencies and communities with diversity across socio-demographic characteristics and lived experiences, identified via clinic populations, previous PLUS or other research activities, or from the community at large.

Requests for community input on RISE were submitted to the Community Engagement Subcommittee by work groups focused on specific aspects of the study design (e.g., measurement, recruitment, etc.). Three types of community engagement approaches were used to solicit input: online surveys, virtual discussion groups, and one-on-one interviews. For each community engagement request, PLUS clinical research centers invited their local RAPs to participate. Invitations and instructions for participation were sent to RAPs who then indicated their interest in participating. These invitations explicitly stated they were being asked to contribute to the design of a research study, not to be a study participant or to participate in an educational session. RAPs were compensated for all engagement activities with electronic gift cards. The decision to use a survey, virtual discussion group, interview, or a combination of these approaches was made by the Community Engagement Subcommittee based on the type of information requested. Although RAP demographic information was not formally collected or tracked, we conducted intermittent assessments to assure that our RAPs included diversity of representation across the life course, race-ethnicity, and lived experiences, and filled gaps when needed.

Online surveys completed by RAPs using Qualtrics software (Provo, UT) solicited feedback on the study name, in person visit instructions, specific instruments, and marketing and recruitment materials for the RISE study. RAPs were asked to provide feedback on factors like readability, ease of survey completion, sensitivity of topics, the extent to which the content would resonate with their culture and community of origin, perceived barriers to survey completion, survey questions they felt would be problematic, and length of time it took to complete the surveys. In instances in which the wording of questions did not resonate with their community or culture of origin, RAPs provided suggestions for re-wording.

During virtual discussion groups, RAPs reviewed the study name and website, in-person visit instructions, specific instruments, and marketing and recruitment materials for RISE. In some cases, discussion groups were held as a follow up to allow a deeper dive into survey findings. Discussion groups were held by videoconference via the Zoom platform. To promote participation across time zones, occupations, and socioeconomic status, the time at which sessions were held varied, or were offered at two different times of day, and RAPs could join via telephone or video. RAPs were emailed or mailed the content for discussion and asked to review ahead of the virtual session. During the virtual sessions, which were each facilitated by one of the PLUS Community Engagement Subcommittee members and a note taker, the content for discussion was shared on the screen and RAPs were asked to provide feedback on the extent to which the content would resonate with their culture

and community of origin, readability, ease of completion, sensitivity of topics, and concerns regarding participation or completion.

One-on-one interviews were conducted with RAPs to get input on the in-person visit procedures such as the feasibility and appropriateness of the proposed data collection procedures. Interviews were conducted similarly to small group discussions but allowed for greater privacy given the sensitive nature of the discussion, if preferred by the community partner. Interviews took place by phone or videoconference via Zoom, based on stated preference.

For each activity, an analytic report was written by a Community Engagement Subcommittee member, summarizing the RAP members' feedback, and provided to the investigators in the consortium charged with the design of the respective study component. Those investigator teams reviewed the content and made decisions about whether and how to alter the study materials as recommended.

Results

During the development of RISE, community partners provided input on seven study design topic areas to inform in-person visit procedures, specimen collection instructions, survey data collection instruments (baseline survey modules and first year follow-up survey modules), recruitment materials, the study website, and the study name (Table 1). Qualitative feedback was collected with 14 virtual discussion groups and 12 one-on-one interviews. Quantitative and qualitative feedback was obtained with four online surveys. RAPs represented up to six PLUS clinical research centers per community engagement request, with between 7 and 121 community partners providing input on each topic. One way to show respect and emphasize the value of community member (i.e. RAP) participation is through compensation. We provided compensated between \$5 and \$25 per activity depending on the nature of the activity. Because our community engagement is grounded in longstanding partner relationships, RAPs often provide input on more than one aspect of the study design. In some cases, we sought additional input from community members outside of our networks to increase diversity of perspectives, including inviting individuals with no prior experience with PLUS or bladder health research. Members provided vital, thoughtful, and detailed input, including suggested changes to study procedures the study name, and the style of recruitment materials, as well as recommendations to improve language, content, and readability throughout all participant facing study materials. Significant changes were made as a result of their efforts. For example, in response to feedback that catheterization would prevent many people from participating, PLUS weighed this against the benefit of the procedure and decided to remove it. Another example of a significant community engagement-influenced change is the adaptation made to the one year follow up survey to include trigger warnings for questions on previous traumatic experiences. Investigators weighed removing or substituting these items, however RAP members emphasized the importance of keeping these questions despite their highly sensitive nature. Some recommendations were not implemented due to scientific or pragmatic reasons, for example PLUS chose not to make changes to some items on existing instruments that have been previously validated with the target study

population. RAPs have shared in informal communications with Community Engagement Subcommittee members that they value the opportunity to learn about bladder health, contribute to research on this topic, and the connections they have made to other community partners from across the country.

Discussion

Community engagement is particularly important for the PLUS consortium. PLUS is about the promotion of bladder health for women. Our goals are to: 1) Learn what a healthy bladder is; 2) Determine potential ways to prevent bladder problems before they happen; and 3) Find the best ways to have strong bladder health. Our research findings are intended to advance both science and practice. By actively involving women with diverse demographics and experiences early and often we help ensure the relevance and positive impact of our research efforts.

During its initial five years, the PLUS consortium established a strong community engagement approach and infrastructure. This was first integrated into the Study of Habits Attitudes Realities and Experiences (SHARE), which used focus groups to explore adolescent and adult women's experiences, perceptions, beliefs, knowledge, and behaviors related to bladder health across the life course¹¹. Now in its second five-year funding cycle, PLUS has launched RISE, a large population-based, prospective cohort study using self-administered quantitative surveys and in-person clinical exams. Between these two funding cycles, PLUS has become more sophisticated in its approach and involvement of community stakeholders. We make the case that for multidisciplinary, clinical and population science studies, including large multi-site studies, community engagement can be achieved and that there is both research and practical value.

Our community engaged processes for the RISE study design highlight important considerations for researchers who wish to pursue community engagement. First, a research group needs to clearly establish its approach and plan for community engagement, how it will be prioritized, and provide clarity about how priorities and resources are aligned with overarching goals of the research. Our consortium prioritizes community engagement as a strategy to dismantle racist structures and work towards health equity. Second, processes and policies need to be agreed upon by all parties and in place to guide decision making when there is disagreement between researchers and community partners. For example, we found differing opinions among RAP members and between RAP members and study investigators regarding the inclusion of money in marketing materials (Table 1). Our research consortium has a Community Engagement Toolkit and RAP Scope of Work that outline how input gathered from RAPs will be used in consortium decision making, which helps guide decisions when differences of opinion arise. Finally, to be done well, community engagement requires an investment of resources. It is our recommendation that at minimum resources are invested in a coordinator role and compensation for participants. Sufficient investigator effort allocated for engagement planning and implementation is also vital for success.

Current literature supports the active involvement of key stakeholders in research. Boyer and colleagues¹² describe a comprehensive, multilevel (i.e., patients, providers, community), approach which spans from short-term (e.g., one-time survey of listening session) to sustained (e.g., advisory, research team membership, co-investigators) stakeholder involvement. The authors conclude that with the appropriate preparation and on-going commitment, broad stakeholder involvement is feasible, can be done expeditiously, and can produce findings that are both more relevant and useful to the field and end-users.

In the area of patient-centered real-world evidence Oehrlein, et al.¹³, propose 13 recommendations to guide future research. The recommendations are organized into four categories (Refinement of the research question, Development of the research protocol, Translation of research findings, and General recommendations). Most important among this list is the second recommendation to: “Prioritize patient-identified questions aligned with study objectives/audience” (Table 3, P. 7). For experienced community-engaged researchers, active involvement of stakeholders in the formation of study questions, the nexus of all discovery, is a clear litmus of meaningful participation¹³. It is also very much in line with current developments in academia on diversity, equity, and inclusion (DEI) which name community engagement as critical to antiracist science. In the next phase of highly structured community engagement approaches, such as CBPR, expansion lies in work to “Engage for Equity”, also known as E2¹⁴. Initiated in 2006, E2 research attempts to identify best practices for power-sharing in CBPR and/or community-partnered research that are most likely to produce impactful health outcomes.

We recognize several limitations to the community engagement strategy described in this paper. First, despite the clear advantages of in person engagement for relationship building, we were unable to conduct in-person engagement during the COVID-19 pandemic. All community engagement for RISE design was conducted by phone, web, or virtually via videoconferencing software. Although this presented challenges for generating excitement and connection, participants expressed verbally during meetings and by email that they found the experience both enjoyable and productive, suggesting that our efforts to overcome this limitation were successful. Relatedly, we recognize that virtual or online engagement has limitations for equitable access to participation. Access to technology (e.g., high speed internet, videoconferencing-capable devices, etc.) is inequitably distributed across socio-demographic populations, such that conducting our engagement online or virtually has the potential to exclude low income and other marginalized populations. However, we also recognize that equal or greater equity issues would be created by exposing community members to COVID-19 by asking them to participate in in-person engagement activities, and ultimately decided to err on the side of immediate public health and safety. Secondly, our engagement activities were conducted only in English. Although some of our community members are bilingual (Spanish/English), we have thus far only communicated with them in English. Plans are underway to expand our ability to engage in Spanish for some or all engagement mechanisms. Third, significant differences exist in regulatory processes across sites, which resulted in some sites not being able to provide compensation for community engagement for RISE. Thus, several sites were unable or significantly limited in their ability to participate in engagement activities; we continue to work to overcome this issue. Finally, PLUS work with community partners currently falls in the middle of the community

engagement spectrum⁷. Ideally, community partners would have been involved at the outset as equal partners in the conceptualization of the study, including the generation of research questions. Although there would undoubtedly be significant benefits for the quality of the research, as well as for the communities we serve, we were limited by funding, investigator effort, and variable experience with and appreciation of community engagement across the PLUS sites. Despite this limitation, we found value in the level of community engagement we were able to accomplish with our resources.

Conclusion

Community engagement is an essential strategy to understand community perspectives, increase the relevance and cultural rigor of research, and the likelihood of generating meaningful results and interventions^{3,15}. While we did not employ the most intensive form of community engagement, CBPR, our engagement efforts allowed our investigators to share with and learn from our community partners in ways that shaped, enriched, modified, and improved the design and implementation of our urologic research. It was worth the investment. We will continue to engage our community partners in the interpretation of results, dissemination of findings, and the development of interventions to promote bladder health.

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Multi-Principal Investigators: Linda Brubaker, MD; Elizabeth R. Mueller, MD, MSME

Investigators: Marian Acevedo-Alvarez, MD; Colleen M. Fitzgerald, MD, MS; Cecilia T. Hardacker, MSN, RN, CNL; Jeni Hebert-Beirne, PhD, MPH; Missy Lavender, MBA.

Northwestern University - Chicago IL (U01DK126045)

Multi-Principal Investigators: James W. Griffith, PhD; Kimberly Sue Kenton, MD; Melissa Simon, MD, MPH; Investigator: Julia Geynisman-Tan, MD;

University of Alabama at Birmingham - Birmingham, AL (U01DK106858)

Principal Investigator: Alayne D. Markland, DO, MSc

Investigators: Tamera Coyne-Beasley, MD, MPH, FAAP, FSAHM; Kathryn L. Burgio, PhD; Cora E. Lewis, MD, MSPH; Gerald McGwin, Jr., MS, PhD; Camille P. Vaughan, MD, MS; Beverly Rosa Williams, PhD.

University of California San Diego - La Jolla, CA (U01DK106827)

Principal Investigator: Emily S. Lukacz, MD

Investigators: Sheila Gahagan, MD, MPH; D. Yvette LaCoursiere, MD, MPH; Jesse Nodora, DrPH.

University of Michigan - Ann Arbor, MI (U01DK106893)

Principal Investigator: Janis M. Miller, PhD, APRN, FAAN

Investigators: Lisa Kane Low, PhD, CNM, FACNM, FAAN.

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Multi-Principal Investigators: Bernard L. Harlow, PhD; Kyle D. Rudser, PhD

Investigators: Sonya S. Brady, PhD; Haitao Chu, MD, PhD; Cynthia S. Fok, MD, MPH; Peter Scal, PhD; Todd Rockwood, PhD.

University of Pennsylvania – Philadelphia, PA (U01DK106892)

Principal Investigator: Multi-Principal Investigators: Diane K. Newman, DNP FAAN; Ariana L. Smith, MD

Investigators: Amanda Berry, MSN, CRNP; Heather Klusaritz, PhD, MSW; Ann E. Stapleton, MD; Jean F. Wyman, PhD.

Washington University in St. Louis - Saint Louis, MO (U01DK106853)

Principal Investigator: Siobhan Sutcliffe, PhD, ScM, MHS

Investigators: Aimee S. James, PhD, MPH; Jerry L. Lowder, MD, MSc; Melanie R. Meister, MD, MSCI.

Yale University - New Haven, CT (U01DK106908)

Principal Investigator: Leslie M. Rickey, MD, MPH

Investigators: Marie A. Brault, PhD (Dec. 2020-); Deepa R. Camenga, MD, MHS; Shayna D. Cunningham, PhD.

Steering Committee Chair: Linda Brubaker, MD. UCSD, San Diego. (January 2021-)

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TABLE 1

Community partner input on the RISE FOR HEALTH (RISE) study design

RAP topic or purpose	Main goals and questions	Format	CRCs engaged	Community members engaged	Main findings	Outcome of findings
1 In-person visit procedures	Identify potential challenges and potential solutions to recruitment for the proposed in-person visit. Consider the language used for recruitment and explaining potential study procedures in an accessible and honest, but non-off-putting way.	Virtual one-on-one and small group discussions	5	44	Allow for same-day return of stool and/or urine samples to avoid women having to store samples in their home refrigerators. Make the stool sample and catheterization optional. Many women will not consider participating if these are required. Make explicit in the consent form what biological samples will and won't be used for (e.g., samples will not be used for drug testing or genetic testing). Allow women the option of a female provider for the pelvic exam, make sure the provider is trained and coached to be extremely patient, gentle, and thoughtful about the participants' comfort, and make sure the protocol is trauma-informed. Use careful consideration for logistical aspects of the visit, including allowing for early/late/weekend appointments, visit length and wait times, and distance/accessibility of the clinic.	Some study procedures, including catheterization, were removed from the protocol. Language suggestions were incorporated into the consent, recruitment materials, and scripts.
2 Study name	Provide feedback and preferences for eight potential study name options.	Survey and virtual group discussion	5	115 (survey) 8 (group discussion)	Quantitative survey responses suggested some names were preferred over others. In some cases, support was divided, with some members having strong positive feelings about a name, and others having strong negative feelings. The virtual group discussion provided a greater depth of insight into feelings for or against particular names. Members quickly identified with the name RISE and pointed out the drawbacks of other names.	RISE was adopted as the study name.
3 Baseline survey modules	Provide feedback on clarity, appropriateness, length, and problematic areas of the baseline surveys. Explore familiarity with specific terminology. Identify missing questions or question areas of interest to members.	Virtual group discussions	5	30	Members desired additional explanation of the purpose of the questions and whether and how they relate to bladder health. Particularly for questions that felt very personal or required a lot of investment to complete, members indicated that they would need a strong justification for providing the information. Members brought forward concerns for privacy with sensitive information being shared both through the mail system and digitally. Additionally, groups pointed out areas where skip patterns, terminology, and instructions could be improved.	Changes were made to improve the clarity of questions and improve terminology. Additional language was added to introductory paragraphs to explain the purpose for and value of the questions being asked.
4 Recruitment materials	Provide feedback on participant-facing recruitment materials, including the study website, invitation letters, mailing envelopes, flyers, and return postcards. Explore the clarity, visual appeal, and organization of the various materials as well as how compelling they might be	Survey and virtual group discussion	6	121	Community members were pleased with the general design and language of the recruitment materials. Several areas with room for improvement were discussed, including improved visual appeal and teaser on the envelope, clarifications in wording and spacing in the letter, flyer, and postcard, and improved layout of the magnet. Community members indicated a preference for one version of the invitation letter over another. Members were evenly split in their opinions about including either a magnet or two \$1 bills in the initial mailing envelope.	Changes were made to recruitment materials to improve clarity, spacing and layout, and language. The invitation letter format preferred by community members was adopted. After lengthy discussions, a decision was made to retain the two \$1 bills in the initial

RAP topic or purpose	Main goals and questions	Format	CRCs engaged	Community members engaged	Main findings	Outcome of findings
5 Specimen collection instructions	Provide feedback on ease of interpretation of instructions, images, and confidence (participants) could do the sample collection if given the instructions.	Survey and virtual group discussion	6	34	Members indicated that some of the languages could be too complicated for individuals without a medical background, and feedback suggested that people of color, people over 40, and people with less than a bachelor's degree may have been less confident about their ability to complete the tests than their counterparts. Improvements were suggested for the organization/flow of the Peezy specimen kit. Members also suggested improvements to esthetics and readability.	Changes were made to the language of the instructions to reduce the reading level of the materials, and improve esthetics.
6 RISE website	Provide feedback for the RISE website.	Virtual, group discussion	5		Overall members were pleased with the website. They found it to be clear, easy to navigate, and appealing to the eye. Suggestions for improvement included increased diversity of photos, greater emphasis on the importance of the study, more contact information, and improvements in the layout of the mobile version of the website.	Additional photos were added to the front page of the website with a scroll bar to ensure diversity was represented by all viewers. Changes were made to increase the emphasis on the importance of the study.
7 1-year follow-up survey modules	Learn the average length of time to complete each survey section. Understand if any sets of questions were particularly hard or upsetting to answer. Provide feedback on the relative value and priority of sets of questions.	Survey and virtual group discussion	4	22 (survey) 9 (discussion group)	Sections took a mean of 23 min to complete and a range of 9–130 min. Many members felt that the section on adverse life experiences was upsetting, uncomfortable, or hard to answer. Members ranked all sections as moderately to highly valuable, and despite their discomfort taking it, the section on adverse life experiences was ranked the most valuable.	The section on adverse life experiences was shortened and additional introductory language was added for the purpose of warning participants it may be challenging to complete, and making it clear they can skip the section if needed. Additionally, a guide (specific to each CRC) was developed to offer mental health resources to participants.
8 1-year follow-up survey modules	Identify any questions that were confusing or difficult to answer. Explore the relative priority of questions and sections.	Virtual group discussion	2	7	Despite changes to the adverse life circumstances section, members still felt uncomfortable with the content. However, they also saw high value in the questions, especially knowing that the PLUS Consortium is led and run by women, and supported the idea of having a mental health resource list. Additionally, members provided feedback on survey wording and formatting to help clarify. For example, bolding or underlining certain words throughout sections and providing definitions.	Changes were made to improve clarity and provide additional definitions and explanations.

Abbreviations: CRC, clinical research center; PLUS, Prevention of Lower Urinary Tract Symptoms; RAP, Rapid Assessment Partner.