

Virtual Recruitment and Retention in a Multisite Clinical trial: Descriptive analysis of strategies used to engage Women Veterans with urinary incontinence

Susan Alton Dailey

susan.altondailey@va.gov

Durham VA Health Care System

Katherine Van Loon

Durham VA Health Care System

Emily Malone Boyd

University of Alabama at Birmingham

Hannah Howell

University of Alabama at Birmingham

Karen M. Goldstein

Durham VA Health Care System

Camille P. Vaughan

Atlanta VA Healthcare System

T. Mark Beasley

Emory University

Alayne D. Markland

VA Salt Lake City Healthcare System

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Abstract

Background Urinary incontinence (UI) is a common condition among women has a significant impact on quality of life. In addition to typical risk factors for UI (e.g. pelvic floor trauma), women Veterans have additional risk factors associated with military service such as repeated heavy lifting and restricted bathroom access. Accessing care for UI can be hindered by lack of knowledge about treatment options, embarrassment, and inconvenience. Remote delivery of UI self-management education can overcome some of these barriers to care. Establishing evidence for remote delivery of UI treatment through clinical trials will be critical to informing patient-centered care, but it is unknown how to efficiently and effectively recruit women Veterans into such studies. In this paper we describe recruitment and retention strategies employed during a pragmatic clinical trial comparing the effectiveness of two virtual care delivery modalities of behavioral treatment for urinary incontinence.

Methods We reviewed and analyzed descriptive recruitment data from a three-site sequential, multiple assignment randomized clinical trial conducted within the Department of Veterans Affairs Health Care System between April 2020 and September 2023. We explored how the study design, procedures, and modifications of study processes impacted recruitment and retention of participants.

Results We met the overall recruitment and retention goal of randomizing 286 women for this study within the planned timeframe. The majority of study participants were identified through administrative medical records. Regular reminders, study staff's flexibility with scheduling, and the use of technology such as Docusign and remote study interventions contributed strong recruitment and retention results.

Conclusions Using recruitment strategies and study design choices intended to address barriers experienced by the target study population can result in reaching recruitment and retention targets more efficiently. Remote strategies for study recruitment and retention show a lot of promise for recruiting and retaining women in trials, but they do require additional study staff time, which should be taken into consideration during study planning.

Trial Registration: [Clinicaltrials.gov: NCT04237753](https://clinicaltrials.gov/ct2/show/study/NCT04237753)

Background

Urinary incontinence (UI) has significant impacts on quality of life, with UI contributing to depression and psychological distress as well as social isolation.¹ Among women Veterans (WVs), up to 20% report symptoms of UI.^{3–6} In addition to the risk factors known among the non-Veteran population (childbirth, obesity, hypertension, and age), WVs may be at increased risk due to conditions they experience during their military tours, such as carrying heavy equipment and inadequate access to bathrooms.^{7,8} With a median age of 52, aging WVs are one of the fastest growing segments of the Veteran population. Thus, rates of UI are expected to increase, and having accessible woman-centered treatment available will be essential.

Existing treatments for UI include medications, behavioral and physical therapies, drug treatments, and surgery, in addition to products that help women manage symptoms (i.e. pads).^{9,10} Yet even with these options, only 35% of women with UI receive treatment.⁵ Barriers to care for UI include inconvenience, cost, lack of knowledge and awareness of treatment options, embarrassment, and the perception that UI is a normal part of life for women who are postpartum or postmenopausal.^{11–13} Rurality is also associated with a delay in seeking treatment.^{14,15} In addition to the barriers to care for the general population, cited challenges in rural areas range from lack of choice in providers, lack of anonymity in seeking care, and distance to urban centers where more care is available¹⁶. The rates of UI, combined with barriers to accessing treatment, suggest that options for remote treatment modalities could be beneficial.

Recruitment into clinical trials can be challenging in general, and more so for women, older women, and WVs who are often underrepresented in clinical trials.^{17–19} The specific barriers to recruiting older populations into intervention studies that have been identified in the literature include challenges such as comorbidities, access to transportation, physical mobility difficulties, and reliance on family members or caregivers who might feel that participation in a study is a burden.²⁰ Recruiting WVs can be difficult due to their status as a numerical minority (9%) and can require navigating women-specific clinics and primary care providers, which can present additional challenges to researchers.^{21,22} Fully remote implementation of a pragmatic clinical trial has the potential to overcome several of these barriers to recruitment.²³ Yet, the benefits and challenges associated with recruiting women into fully remote trials have not been explored.

In this paper, we describe recruitment and retention strategies employed during a pragmatic clinical trial designed to compare the effectiveness of two virtual care delivery modalities of behavioral treatment (mobile application and video-based consultation) for UI in WVs at three clinical sites within the Department of Veterans Affairs (VA). The possible benefits of remote recruitment and virtual interventions for this study are of particular interest because they may offer solutions to the barriers to recruiting women and older populations into studies.¹⁹

Methods

We reviewed and analyzed descriptive recruitment data across sites, intervention arms, and over the course of the study to better understand how the study design, procedures, and modifications impacted recruitment and retention of participants.

Study Overview. Women Veterans at three study sites in the southeastern US who had received care at a primary care clinic in the past 6 months, were 18 years and older, and had persistent UI symptoms for at least 3 months were recruited to participate in a pragmatic clinical trial comparing two models of virtual care designed to promote behavioral self-management of symptoms. [Figure 1. Recruitment and Retention Process Diagram]. Study recruitment began in June of 2020 at two sites; the remaining site

began recruitment in July of 2020. All recruitment was completed in March of 2023. The standardized components of the behavioral interventions and the study design have been described previously in the study protocol manuscript and elsewhere (Goode et al., 2020; Markland et al., 2023). Based on a determination by the VA Central Institutional Review Board (CIRB) that site-level IRB review was most appropriate, the study protocol was reviewed and approved by the VA Medical Center's Institutional Review Boards at each site and was registered with clinicaltrials.gov: NCT04237753.

Intervention conditions and outcomes assessment. Study participants were randomized to one of two conditions: MyHealtheBladder (MHB) in which daily sessions were delivered through a mobile application, or VA Video Connect (VVC), a one-time video-based consultation with a continence expert. Participants in both arms accessed study materials and assessments through the Tonic for Health platform, a secure internet portal that allowed study participants to easily engage in research.²⁴ The MHB intervention consisted of 8 weeks of daily self-paced activities covering information and strategies for behavioral self-management of UI; participants could make up any missed sessions for up to 2 weeks after they were assigned. The VVC intervention consisted of a 60-minute virtual clinical assessment with an experienced continence provider and relevant self-management guidance. All participants were assessed for response to treatment using the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-UI-SF).²⁵ At 8 weeks post-baseline, non-responders were rerandomized to remain with the previously assigned treatment or to receive a one-time booster of a video-based consultation with a continence provider. The primary outcome was assessed via online survey at 12 weeks post-baseline. At no point during the study did the participants come for an in-person interaction.

Recruitment. We used three strategies to identify potentially eligible participants: 1) administrative data based on ICD-10 codes from the electronic health record (EHR) pulled at the start of the study, 2) referrals from designated women's health primary care providers after they received education about the study and eligibility criteria, and 3) flyers and brochures, specifically designed with photos of WVs, placed in VA primary care clinics in locations frequented by WVs. (Fig. 1. Recruitment Flowchart)

For the first recruitment strategy, the lead site accessed VINCI, the VA Informatics and Computing Infrastructure (VINCI), a VA Health Services Research (HSR) resource that provides a secure, central analytic platform for performing IRB approved administrative data acquisition. VINCI was used by our team to access Corporate Data Warehouse (CDW) data for recruitment.

Study staff at each site conducted chart reviews of EHR information for potentially eligible participants to identify any exclusion criteria, such as homelessness or UI treatment in the last 3 months. Eligible women were sent a letter by the study team inviting them to participate. After the initial letter was sent and women had an opportunity to opt out of further contact, each woman received up to 3 phone calls from the study team to gauge interest and screen for eligibility.

Consent Process. If eligible and interested, participants began the enrollment process for the study by phone. Per the protocol, at the start of the study, participants reviewed the consent form and HIPAA authorization form with study staff over the phone. Procedures for obtaining informed consent differed across sites as the study was reviewed by each site's institutionally affiliated IRB. At Sites A and B, if participants gave verbal agreement, they were then mailed these forms to review. At Site A participants signed and returned both forms; at Site B participants were only required to sign and return the HIPAA form. At Site C the study team documented verbal consent and HIPAA authorization. In April 2021 Docusign was approved for use and Site A and Site B transitioned to having participants review and sign HIPAA and consent forms electronically.

Once consented, participants completed a baseline ICIQ-UI and demographic survey by phone, and we scheduled the next study call to occur within 7 days. Between calls the participant was assigned a study ID and randomized to a study arm. During the next call the study team member walked the participant through the process of logging into the Tonic platform where they could access study assessment and intervention materials.

Depending on the type of device (e.g. smart phone, tablet) a participant was using and their technological proficiency, the study team spent varying amounts of time with participants setting them up to use the Tonic application. We created each participant's account just before the post-randomization phone call, and once they were on the phone, prompted the registration email to be sent to the participant with their username and password. During this phone call, we would explain the log-in process and have the participant attempt to log-in while on the call. Once successfully logged into the app, we helped participants navigate around the site, showing them how to access educational study materials as well as the weekly surveys. This process could include challenges such as the delays in the arrival of registration email and participants having difficulty understanding log-in instructions. When challenges arose, we provided technical support, such as re-sending registration emails or guiding participants to find the study email in their spam folder. This experience of increased staff support is consistent with implementation findings reported by other study teams executing remote trials.²⁶

Study Burden. The study was intentionally designed to reduce the burden on participants to promote engagement and completion of the intervention. The use of Docusign, a service that allows participants to sign documents electronically, the Tonic for Health app, and telehealth appointments were design elements included to allow women to participate fully without attending an in-person study visit.²⁷ We also allowed participants flexibility around call-back times, handing off study calls to other study team members with different schedules or in different time zones.

Retention Strategies. In addition to the virtual nature of this study, we undertook a variety of efforts to promote retention of participants in the study. The study coordinator at the lead site (Site A) sent weekly emails (Appendix, Fig. 1. Sample reminder email) to the study teams at each site listing participants with upcoming or past-due assessments that week who needed reminder calls. This served as an efficient snapshot of participants' status in the study, calls that needed to be made, and when a participant had

reached their final week of reminders before becoming lost to follow-up. We also had weekly meetings to review progress toward quarterly goals and discuss any participants that were at risk of being lost to follow up, often brainstorming solutions for contacting them or ways to make participation easier. For example, if one team was having trouble reaching a participant who was overdue in completing study activities, other study team members shared strategies to try, such as calling at different times versus re-sending reminders through the Tonic app, which the lead site could do. Another adjustment we made was to start collecting 4- and 8- week assessment data for MHB participants by phone for participants who did not get to that point in the online sessions (assessment questions were embedded within the sessions). We made this effort to ensure that outcome measures were collected from as many participants as possible, even those who may not have completed all the MHB sessions.

We also provided flexibility for participants by offering after-hours appointment times for video visits, flexible times for call backs, delaying enrollment in the study if they were interested but too busy to commit when they were first contacted, and providing reminder calls for VVC participants before their appointments with clinicians.

As part of the consent process, participants were given a calendar of study activities to help them understand the breadth of their participation. The calendar was part of the consent documentation that was accessible through DocuSign and we called participants' attention to it when walking them through the consent process, suggesting it could be saved to their computer or printed out for reference. When the study was first in the field, participants were given \$20 incentives at three milestones: after they completed the baseline assessment, at the completion of the study, and if they completed an additional qualitative interview, for a possible total of up to \$60. In May of 2021 an additional payment of \$20 was added for participants invited to complete a second qualitative interview, and in July of 2021 another \$20 incentive was added for participants who completed the 8-week assessments to keep them engaged until the 12-week primary outcome measures were collected.

In June of 2021, we also began sending thank you letters to participants who had completed 12 and 24 weeks in the study to let them know that their participation would help determine which method of remote treatment delivery is most effective for participants.

Variation Between Sites and Changes Over Time. While the general recruitment methods were the same across sites, some variation was introduced between sites during the consent and HIPAA procedures. Site B had a waiver of documented consent but required a signature on the HIPAA form. Site A required signatures for both consent and HIPAA. Site C had waivers of documentation for both the consent and HIPAA forms. Additionally, changes occurred to study procedures over the course of the study. For example, at Site B, the HIPAA form initially had to be mailed and required a wet signature, but in 2021 DocuSign was approved for research use and allowed for electronic signature of the HIPAA forms. [Figure 2. Study Phase, Strategies, and Adjustments]

Two sites in this study offer UI-specific care (continence clinics), and one did not, which may have impacted the number of participants who were currently receiving treatment for UI (and were therefore

ineligible for the study) in the respective treatment areas. At Site B, where there was not a continence clinic, staff periodically presented the study to local clinic staff, giving them an overview of the study and recruitment efforts to date and then encouraging them to refer potentially eligible patients.

Results

Overall recruitment and retention. The overall recruitment goal was 286 women with an anticipated drop-out rate of 25%.²⁸ We succeeded in reaching this goal within the planned timeframe, with a total of 292 participants consented by February 2023 after 33 months of active recruitment. Of the three recruitment strategies used to identify participants, the majority of participants were identified from the CDW data pull (231, 79%). Six participants were excluded post-consent prior to being randomized. Of these, 4 declined participation and 2 were lost to follow-up after consent. Of the 286 randomized women, 188 (66%) completed the 8-week assessment (arms combined), 200 (70%) completed the 12-week assessment, and 178 (62%) completed the 24-week assessment. [Figure 3. Recruitment and Retention Through Study Progression.]

In total, 91 (31%) of the 292 consented participants were dropped or discontinued their involvement in the study. This overall dropout rate was slightly higher than what was anticipated (25%). Of the 91 dropped or discontinued participants, 46 (50%) left before they received the intervention. Six (6.6%) participants were excluded post-consent but before randomization and 40 (44%) were randomized but dropped before baseline data collection. Of those 40, 23 were randomized to MHB and 17 were randomized to VVC. The majority of the participants lost after randomization were lost to follow-up (31).

Recruitment and retention by site. Site A sent 756 recruitment letters to women and study staff were able to contact and phone screen 62%. Site A subsequently consented 111 women (24% of those contacted by letter). At Site B 645 letters were sent and study staff contacted and screened 79% of those women, eventually consenting 101 women or 20% of those who were sent letters. And at Site C, 681 letters were sent out, and study staff were able to contact and screen 44% of those. Site C was able to consent 80 women who received a letter (20%). (Table 1. Consort Table).

Table 1
Consort Table

Recruitment letters sent		Site A	Site B	Site C	Overall
		756	645	681	
Declined or Unable to contact		287	133	379	
Phone Screened		469 (62%)	512 (79%)	302 (44%)	
Did not qualify, declined, or lost to follow-up after phone screen		-358	-411	-222	
Consented/Enrolled		111 (15% of letters, 24% of phone screened)	101 (16% of letters, 20% of ph screened)	80 (12% of letters, 26% of ph screened)	292
Excluded post-consent		5	1	0	6
Randomized		106	100	80	286
MyHealthEBladder (MHB)		51	53	43	147
VA Video Connect (VVC)		55	47	37	139
Rerandomized (after 12-week assessment)		41	25	14	80
MHB_Continue		4	4	2	
MHB_Booster VVC		9	2	1	
VVC_Continue		18	7	6	
VVC_BoosterVVC		10	12	5	
Discontinued/Dropped		27	25	33	85 (29%)
Completed Assessments					
Baseline	MHB	46 (90%)	50 (94%)	28 (65%)	124 (84%)
	VVC	50 (90%)	41 (87%)	31 (84%)	122 (88%)
8-weeks	MHB	35 (69%)	31 (58%)	18 (42%)	84 (57%)
	VVC	44 (80%)	34 (72%)	26 (70%)	104 (75%)
12-weeks*	MHB	39 (76%)	39 (74%)	22 (51%)	100 (68%)

Recruitment letters sent		Site A	Site B	Site C	Overall
		756	645	681	
	VVC	41 (75%)	34 (72%)	25 (68%)	100 (72%)
24-weeks	MHB	36 (71%)	38 (72%)	18 (42%)	92 (63%)
	VVC	37 (67%)	31 (66%)	18 (49%)	86 (62%)

*Participants were allowed to continue in the study even if they did not complete the 8-week assessment as the 12-week assessment was of primary interest.

At Site A 27(24%) of the 111 enrolled participants discontinued the intervention; at Site B 25(25%) of 101 enrolled participants discontinued; and at Site C 33 (41%) of 80 enrolled participants discontinued. All three sites had strong retention at the 8-week assessment in the VVC arm (70% or greater), while MHB retention was weaker: 69% at Site A, 58% at Site B, and 42% at Site C. At the 12-week assessment participation was strong in both arms with Site A and Site B over 70%. At Site C participation in the 12-week assessment was at 51% for MHB and 68% for VVC. At 24-weeks participation was again higher for Site A and Site B at over 66% in both arms, and Site C with 42% completing the MHB 24-week assessment and 49% completing the VVC assessment.

Retention by arm. Among the 286 randomized participants, 147 were randomized to MHB and 139 were randomized to VVC. In the MHB arm, 124 of the 147 (84%) participants completed their baseline assessment, 84 (57%) participants completed their 8-week assessment, 100 (68%) participants completed their 12-week assessment, and 92 (63%) participants completed their 24-week assessment. In the VVC arm, 122 of the 139 (88%) participants completed their baseline assessment, 104 (75%) completed the 8-week assessment, 100 (72%) completed the 12-week assessment, and 86 (62%) completed the 24-week assessment. These proportions show higher retention within the VVC arm at the two earlier milestones (8 and 12-week assessments) and almost equal retention at the 24-week assessment.

Changes in retention over study milestones

The three sites enrolled 111 (Site A), 101 (Site B), and 80 (Site C) participants, with some variation over the course of the study. Site A and Site B ended up with comparable proportions of participants retained at the 8-week, 12-week, and 24-week milestones. A notable difference was that Site B was the only site to retain more participants in the MHB arm of the study at each milestone. Site C experienced lower retention rates, most notably in the MHB arm.

Demographically, about 25% of participants who started the study were between 18–44 years old, 58% were between 45–64, and 16% were over 65 years old. Retention was higher among women between

45–64 years old (58% at the start and 63.2% at the end) and lower among women between 18–44 years old (25% at the start and 20.9% at the end). The proportion of Hispanic participants remained constant throughout the study (6.3% to 6.5%). Among recruited participants, 35.3% were white and 58% were Black, and this remained largely unchanged among retained participants (35.8% white and 56.7% Black). Rurality also remained mostly stable between recruited and retained participants, with a slight shift towards an increase in those in urban settings being retained throughout the study (74.5% to 76.6%). The shift among recruited and retained rural participants was 24.5% to 21.9%. [Table 2. Participant Demographics Compared to Overall Population of Women Veterans Accessing VA Care.]

In comparison to the overall population of women at VA, our study sample was aligned on rurality and ethnicity but differed on race and age. Black women were overrepresented compared to national figures (58% of recruited participants vs. 20% national) and white women were underrepresented in our sample, though this was consistent with the study site's demographics. Women age 18–44 were underrepresented while those ages 45–64 were overrepresented compared to national statistics; however, this aligns with the prevalence of UI in the general population, which increases with age.²

Table 2
Participant Demographics Compared to Overall VA Population of Women Veterans

N	Overall VA WV Population (FY20)	Randomized Participants	Retained Participants
	Varies	286	201
Age, N(%)	2,051,010 ¹		
Mean, range	NR	53, 23–83	54, 23–83
18–44	781,957 (38.1%)	73 (25.5%)	42 (20.9%)
45–64	878,523 (42.8%)	166 (58%)	127 (63.2%)
65+	390,530 (19%)	47 (16%)	32 (15.9%)
Ethnicity N(%)	2,012,760 ²		
Hispanic	197,270 (9.8%)	18 (6.3%)	13 (6.5%)
Not Hispanic	1,815,490 (90.2%)	265 (92.7%)	185 (92%)
Not Reported	NR	3 (1.1%)	3 (1.5%)
Race, N (%)	2,012,760		
White	1,395,496 (69.3%)	101 (35.3%)	72 (35.8%)
Black/African American	402,563 (20%)	166 (58.0%)	114 (56.7%)
Asian	49,386 (2.5%)	1 (< 1%)	1 (< 1%)
More than one	93,307 (4.6%)	8 (2.8%)	5 (2.5%)
Other	51,674 (2.6%)	5 (1.7%)	5 (2.5%)
AI/AN	20,334 (1%)	2 (< 1%)	1 (< 1%)
Unknown/NR	NR	3 (1.1%)	3 (1.5%)
Rurality, N(%)	555,323		
Urban	73%	213 (74.5%)	154 (76.6%)
Rural	24%	70 (24.5%)	44 (21.9%)
Highly Rural	3%	3 (1%)	3 (1.5%)

1. 1.(VetPop2023 National Estimates by Sex and Age Groups 2000 to 2023 | Department of Veterans Affairs Open Data Portal, n.d.)

2. 2.(Women Veterans in 2023: VetPop2020 by Sex and Race/Ethnicity | Department of Veterans Affairs Open Data Portal, n.d.)

Discussion

Overall, we were successful in attaining the target recruitment through iterative adaptations based on observed barriers to recruitment in the context of site specific regulatory and logistic requirements. This success can be attributed to the study team's use of strategies such as a multi-pronged approach for recruitment; clear communication with participants; including incentives for participants; a clear reminder system; and providing flexible study intervention times, which have been determined by prior studies to be effective strategies for recruitment and retention.^{31–33} Some participants reported to study staff anecdotally that they were enthusiastic about participation because the study provided an opportunity to learn about an issue, they did not typically discuss with their providers. Retention may have also been strengthened by positive experiences with the intervention itself—at least one participant recommended the study to a friend (also a Veteran) who then volunteered for the study. The lead site also contributed to strong recruitment and retention efforts through close tracking of recruitment and retention against targets, with timely reminders to staff at all sites to call participants who were past due for logins and assessments which took some of the burden off the secondary sites' study staff.

The remote design facilitated retention by removing logistical challenges, such as travel^{31–33} and addressed some of the barriers cited as reasons WVs may not participate in research, such as dependent care, children, distance to the VA, or discomfort with VA facilities because of prior experiences of trauma.¹⁷ Being able to obtain consent by phone and signatures via DocuSign, as well as participating in the intervention virtually were all strengths made possible through the use of technology. This reinforces the findings of Zhang et al., who reported that remote recruitment contributed to a willingness to participate in cancer trials,³⁴ and Ali et al., who found that fully remote dermatology trials result in higher rates of recruitment and retention.³⁵

There is also some evidence that suggests that WVs respond particularly well to remote trial recruitment and implementation. Whitbourne et al. discuss their success recruiting WVs online for the Million Veteran Program, particularly for WVs between the ages of 60–69, a key demographic for women with UI.³⁶ The authors cite a National Telecommunications and Information Administration factsheet showing Veterans over age 65 as more likely than their non-Veteran counterparts to use the internet.³⁷

While technology enabled many study activities to be more accessible to participants, technical issues with the Tonic app sometimes caused additional challenges to recruitment and retention. Even without app-related technical difficulties, some participants lacked the technological proficiency to access either DocuSign or the Tonic app, potentially resulting in frustration that may contributed to missed assessments throughout the study. We also found that using two databases for participant data to be inefficient: we used an MS Access database for site-level recruitment tracking and a REDCap database accessible only by the main site for assessment data. This disjointed system introduced inefficiencies and human error.

It is worth noting that half (46/91 or 50%) of the withdrawals occurred before participants started the intervention, with the majority being lost to follow up. Participants who dropped out before completing the baseline assessment were split fairly evenly between MHB and VVC, so drop-out before baseline cannot be attributed to a specific treatment arm. Enrollment for this study was intended to be engaging with 3 separate calls to be completed (recruitment/screening, consent, randomization/account set-up). It would be useful for future studies to explore reasons for study drop-out pre-intervention, to track differences between sites such as study staff turnover, HIPAA or consent processes, or study team make-up that might contributed to recruitment and retention rates, or to attempt an exit survey among those who opt to withdraw before the study intervention.

Conclusion

Failure to achieve recruitment and retention targets can cost time and money and can compromise the generalizability of study results. Overall recruitment and retention in this study were successful, which can be attributed to advance considerations of study burden appropriate for both the study topic and the focus on WVs, as well as close monitoring of recruitment and retention of participants that cued the need for mid-study adaptations. Remote strategies for study recruitment and retention show a lot of promise for recruiting and retaining women in trials, however sufficient staff time for support of these strategies needs to be considered during study planning. Future studies may want to intentionally track recruitment and retention measures to help build best practices around recruitment strategies in general and specifically for women study participants.

Declarations

Author Contribution

SAD, KVL, and KMG were responsible for the concept and writing of the main manuscript text. SAD and KVL prepared tables and figures. Critical review of the manuscript: EMB, HH, KMG, CPV, ADM, KMG. Original study statistical analysis: TMB. Funding acquisition: ADM, TMB, CPV.

Data Availability

All data supporting the findings of this study are available within the paper and its Supplementary Information. In this manuscript we describe recruitment and retention strategies for a pragmatic clinical trial; full results for this trial are published here: [doi:10.1001/jamanetworkopen.2025.32111](https://doi.org/10.1001/jamanetworkopen.2025.32111)

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Figures

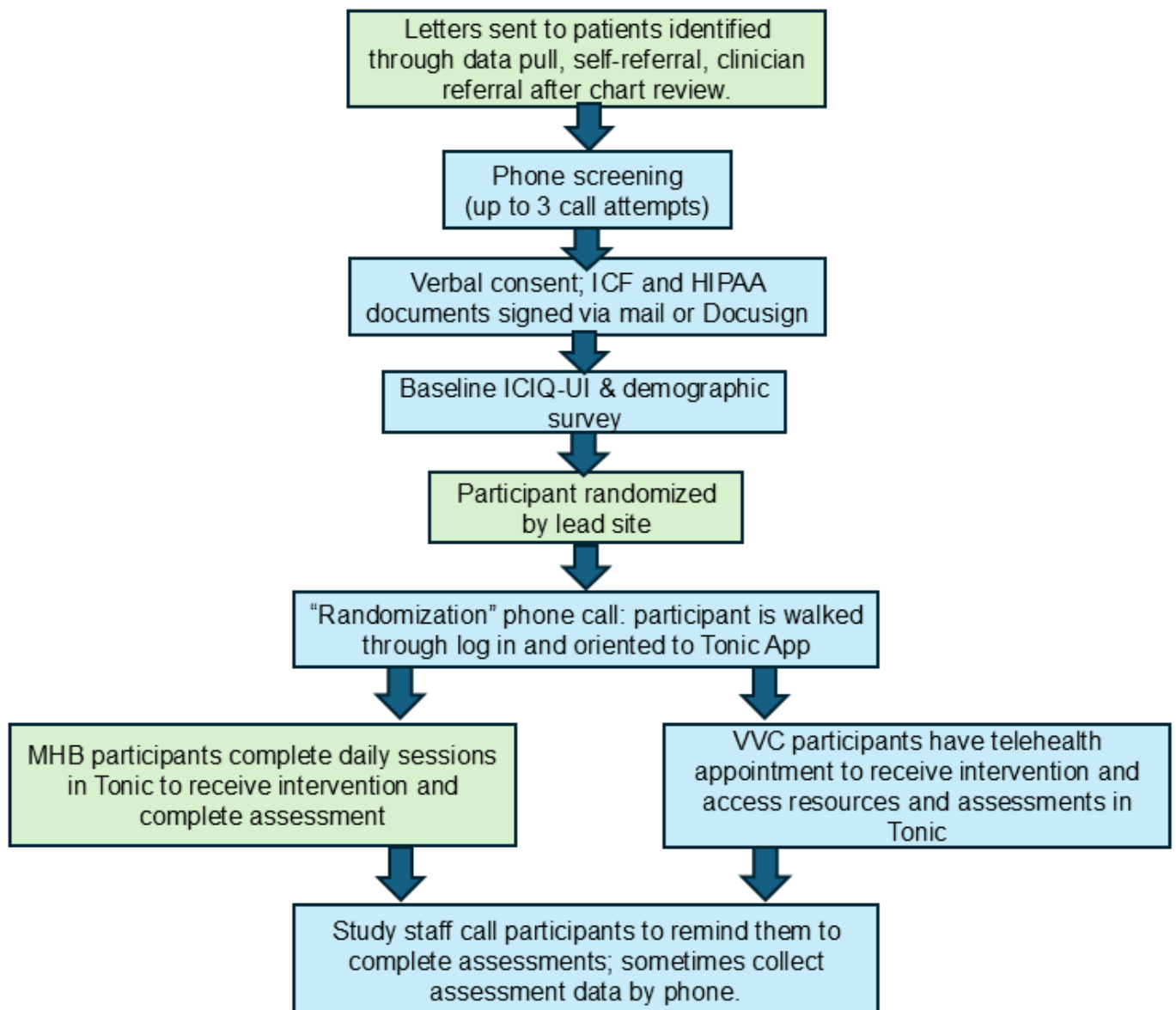


Figure 1

Recruitment Flowchart (contact with participants in blue)

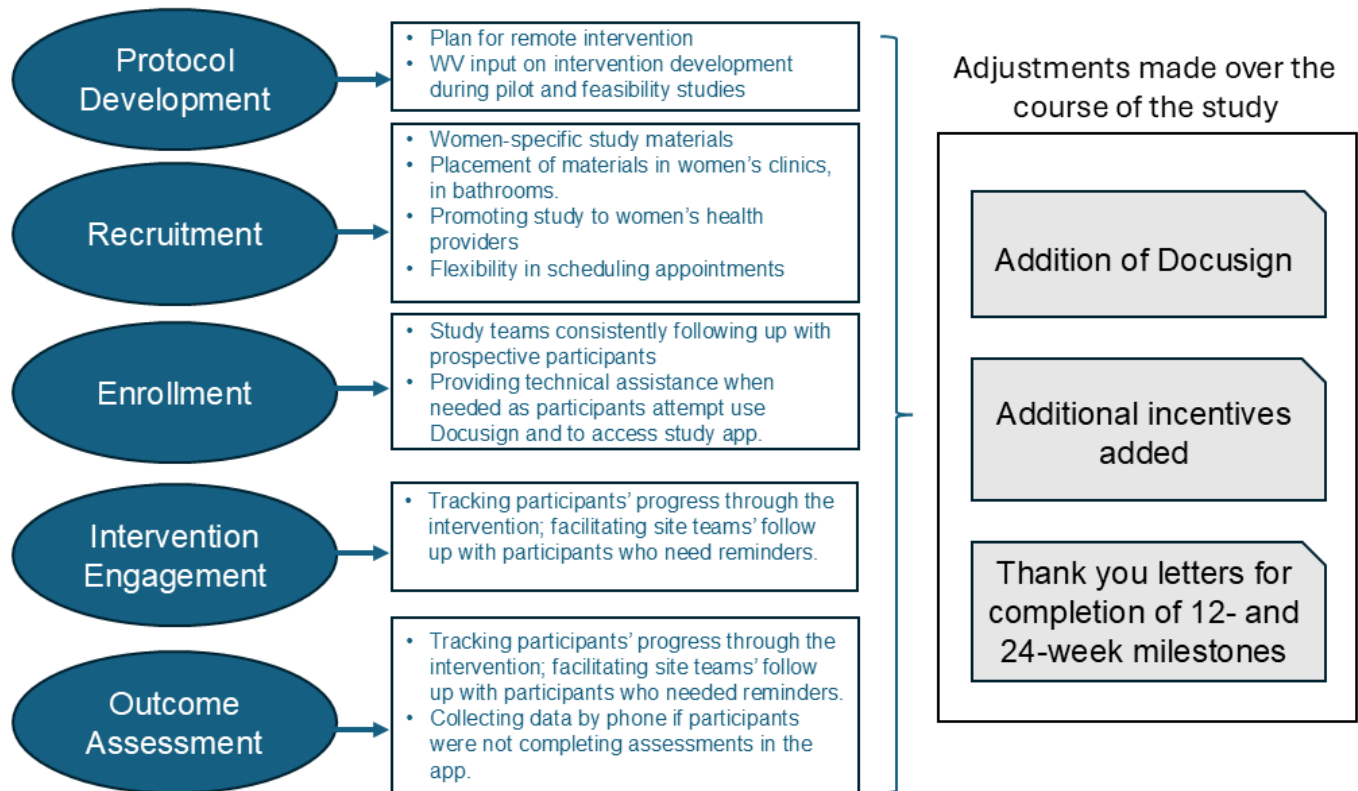


Figure 2

Study Phase, Recruitment Strategies, and Adjustments

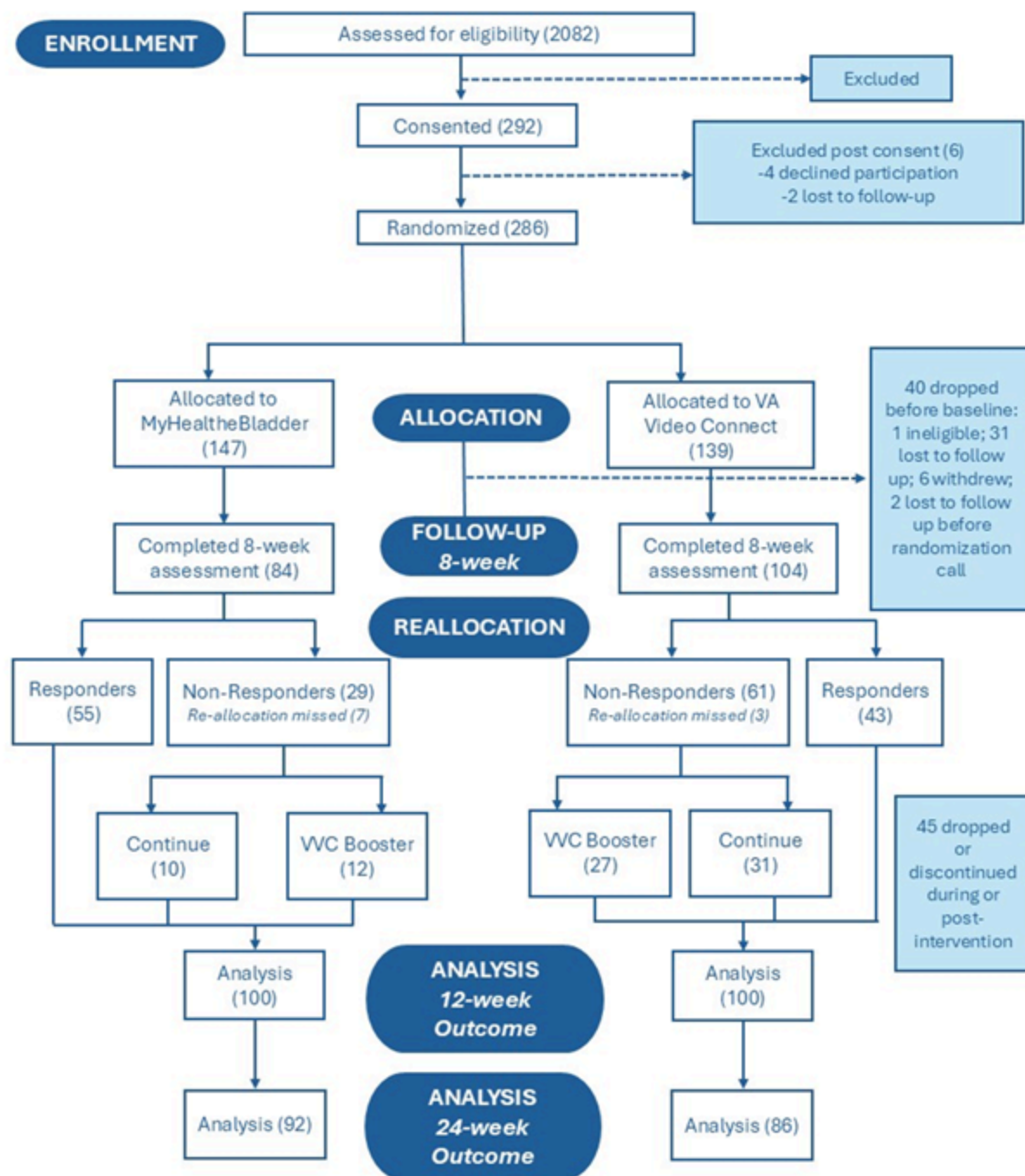


Figure 3

Recruitment and Retention Through Study Progression

Supplementary Files

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