Research paper

Enhancing behavioral treatment for women with pelvic floor disorders: Study protocol for a pilot randomized controlled trial

Bayley J. Taple [a,*], James W. Griffith [a], Claire Weaver [a], Kimberly S. Kenton [b]

[a] Northwestern University Feinberg School of Medicine, Department of Medical Social Sciences, 625 N. Michigan Ave., 27th Floor, Chicago, IL, 60611, USA
[b] Northwestern University Feinberg School of Medicine, Department of Obstetrics and Gynecology, Arkes Pavilion, 676 N. St. Clair St., Suite 950, Chicago, IL, 60611, USA

ABSTRACT

Approximately one in four American women report bothersome urinary symptoms (e.g., urgency, frequency), which greatly impact quality of life, including mental health. Bidirectional relationships have been found between urinary symptoms and anxiety, such that urinary symptoms worsen emotional distress (i.e., anxiety and depression), and in turn anxiety can exacerbate these symptoms. Current methods to treat urinary symptoms, such as physical therapy and medications, do not address their emotional impact. As such, our multidisciplinary team is conducting a randomized control trial (RCT) of cognitive-behavior therapy (CBT) using the *Unified Protocol* (UP) versus supportive therapy in the context of integrated behavioral treatment in the urogynecology context. Women with bothersome urinary symptoms and anxiety are recruited from the Northwestern Medicine Integrated Pelvic Health Program (IPHP) —a transdisciplinary clinic including urogynecologists, urologists, colorectal surgeons, nurses, and physical therapists— and Northwestern Medicine Urology. Participants are randomized to one of two interventions: UP or supportive therapy. All participants attend therapy once per week for 12 weeks. Assessments of urinary symptoms, anxiety, and other indicators of psychological and physical functioning are completed at baseline, mid-treatment, post-treatment, and at 3- and 6-month follow-ups using patient-reported outcomes. The study has been preregistered on clinicaltrails.gov (ID: NCT03623880) and is currently ongoing.

1. Introduction

Urinary symptoms are common and affect many aspects of an individual's quality of life, including mental health. Nearly one in four women experience urinary symptoms [1], which can include urgency, frequency, incontinence, nocturia, and overactive bladder [2]. These symptoms often cause anxiety as well as depression – risk factors for developing urinary symptoms [3]. Similarly, urinary symptoms can be exacerbated by emotional distress, which encompasses anxiety, depression, and other maladaptive emotional reactions to stress. Women with incontinence are both more likely to have baseline anxiety and to develop anxiety as a result of their incontinence. One in five women will have surgery for pelvic floor disorders with 30% needing a second surgery for the same condition [4,5]. Yet, current methods to treat incontinence focus on the physical symptoms incurred and do not address the emotional impact that urinary symptoms may have on women. Therefore, more research is desperately needed on non-surgical treatments for

these problems that target both physical and mental health symptoms. We propose to implement a novel behavioral intervention to improve quality of life in women suffering from urinary symptoms.

Many studies have shown that urinary symptoms are associated with anxiety and depression [6–10]. An epidemiological study of lower urinary tract symptoms (LUTS) reported that 26.6–38.2% of women with at least one LUTS and 53.3% of women with multiple LUTS endorsed clinical levels of anxiety on the Hospital Anxiety and Depression Scale – Anxiety Subscale (HADS-A) [1]. Moreover, 13.3–26.3% of women with one LUTS and 37.6% of women with more than one LUTS endorsed a clinical level of depression on the HADS – Depression Subscale (HADS-D) [1]. Furthermore, in an observational study of women with LUTS, greater urinary incontinence was associated with higher levels of depression and anxiety as measured by the Patient-Reported Outcomes Measurement Information System (PROMIS) [11]. Of note, the most common anxiety disorder associated with urinary urge incontinence is panic disorder [12,13], perhaps related to these patients having an

increased sensitivity to internal sensations.

Behavioral interventions aimed at reducing symptoms of anxiety as well as physical symptoms have been examined in individuals with irritable bowel syndrome (IBS). The IBS patient population also experiences hypersensitivity to physical sensations and heightened levels of anxiety [14], and these individuals often have comorbid urinary symptoms [15]. Several studies have demonstrated that CBT reduces both gastrointestinal symptoms (e.g., visceral sensitivity, urgency, and pain) and anxiety in patients with IBS [16–22]. Therefore, investigating the application of CBT for women with urinary symptoms and co-occurring anxiety as a potentially viable treatment approach is needed.

Research on CBT for individuals with a primary medical diagnosis of a pelvic floor disorder is lacking. The existing evidence base for behavioral interventions includes mindfulness-based stress reduction (MBSR) [23,24] and physical therapy techniques (e.g., pelvic floor exercises). These treatment studies for urinary symptoms, have not addressed the co-occurring symptoms of anxiety. Previous studies have examined MBSR for women with urinary urge incontinence. Baker et al. (2012 & 2014) found that urinary symptoms decreased with treatment [23,24]. These studies did not measure co-occurring symptoms of anxiety at baseline nor assessed for changes in anxiety following treatment. Others have proposed methodology investigating the effectiveness of hypnosis compared to pharmacotherapy for women with urinary urgency incontinence [25]. Hypnotherapy targets the central nervous system, but does not address maladaptive behavioral patterns that may exacerbate anxiety and urinary symptoms (e.g., preemptive voiding).

The current study addresses how treatment of emotional distress affects anxiety, and in turn urinary symptoms. Although there is a strong connection between anxiety and urinary symptoms, evidence on their causal connections remain unexplored [6–10]. By experimentally manipulating the trajectory of anxiety through treatment, this study will also give insight into anxiety as a mechanism of urinary symptoms. To our knowledge, this study will be the first to apply an empirically-supported, transdiagnostic cognitive- and behaviorally-based treatment to women suffering from urinary symptoms, carried out in accord with high quality psychotherapy trials.

Cognitive-behavior therapy (CBT) is a frontline treatment for anxiety, so it is an obvious choice of intervention for a population with anxiety and depression. The *Unified Protocol for Transdiagnostic Treatment of Emotional Disorders* (UP) [26] broadens access to evidence-based mental health treatment to patients who might otherwise be missed by the healthcare system. CBT has well-developed protocols and thus can be administered to women of all ages and of all economic backgrounds. The intervention is time-limited and inexpensive, requiring only twelve visits with the behavior therapist and a low-cost workbook that is widely available. Delivering CBT in the medical setting, such as in primary care, has been used successfully in previous studies [27–30], but therapy is not embedded within urology and urogynecology patients at some medical centers, such as our own (Northwestern Medicine). This project will facilitate systemic change by bringing a behavioral intervention directly to the patient, as opposed to referring the patient out to another service (e.g., a psychiatry department) or institution. This study can also bring systematic change to the practice of medicine by advancing other possible treatment avenues (i.e., CBT) at the disposal of doctors who are treating women with pelvic floor disorders.

1.1. Purpose

The purpose of this proposal is to test a novel behavioral treatment – the *Unified Protocol for Transdiagnostic Treatment of Emotional Disorders* (UP) [26] – to enhance quality of life in women with pelvic floor disorders. An advantage of the UP is that it is all-purpose and usable with various forms of emotional distress (e.g., symptoms of anxiety), rather than a specific diagnosis. Unfortunately, many women with pelvic floor disorders may not receive effective behavioral treatment, such as CBT,

because urogynecologists, urologists, and other medical professionals may not be aware of providers in their community who offer this treatment. Anxiety is treatable using behavioral procedures, and effective treatment would increase women's emotional health and help to reduce urinary symptoms (e.g., incontinence, frequent urination). Women with pelvic floor disorders are often seen in the urogynecology or urology clinic, which makes this an ideal setting for offering additional interventions that may improve their quality of life. We will enhance treatment options by 1) providing evidence for an all-purpose cognitive-behavior intervention (i.e., the UP), 2) offering and integrating treatment in the urogynecology clinic, maximizing convenience, and 3) improving clinical outcomes for these patients.

1.2. Specific aims

1. To demonstrate that the UP is an effective form of therapy for women with lower urinary tract symptoms.
2. To use baseline characteristics in moderation analyses to determine which women will be most likely to have a positive response to therapy. This aim is exploratory to phenotypically describe participants and generate future hypotheses; any results will be subject to replication.
3. To conduct exploratory analyses using mediation to test a possible causal chain of events – Does treatment lead to lower anxiety, which in turn leads to fewer urinary symptoms?

1.3. Hypotheses

1. We hypothesize that the UP will reduce anxiety and urinary symptoms in women suffering from lower urinary tract symptoms, both at post-treatment and follow-up.
2. The UP will be compared to an active control condition, supportive therapy. Supportive therapy, a bona fide approach that is often used in clinical settings (e.g., in support groups). This treatment does not overtly focus on anxiety, and thus is not expected to reduce anxiety and urinary symptoms to the same degree as the UP. We expect that the benefits of the UP will be greater than benefits of supportive therapy.

2. Method

2.1. Inclusion and exclusion criteria

Women 18 years of age or older are eligible to participate. They must have one or more urinary symptoms, including frequency, nocturia, urgency, leakage, hesitancy, straining, or dribbling. Women who present with clinical signs of anxiety based on the physician exam, have any documented anxiety disorder in the medical record and/or are taking medication for anxiety will be eligible for the study. Women must consent to randomization to treatment, and be willing to complete 12 sessions of treatment, as well as to complete baseline, mid-treatment, and outcome questionnaires. Those that screen positively for an alcohol or substance use disorder (based on the medical record) will be excluded from the study. Any women with blood in the urine, a positive urine culture, or other signs of possible infection will be deferred until they have been evaluated and treated as needed. Women who are pregnant or who have given birth within the past 6 months will be excluded from the study. Other exclusion criteria include serious disease that would impede participation (e.g., Alzheimer's dementia, Parkinson's disease); recent (within 6 months) pelvic or endoscopic surgery, urethral stricture, pelvic malignancy, current chemotherapy or other cancer therapy, pelvic device or implant complication; recent (within 12 months) Botox injection to the bladder or pelvic structures; or difficulties communicating in English. Women who are currently in their own psychotherapy are ineligible for the study. Inclusion and exclusion criteria are summarized in Table 1.

In addition, participants must be willing to defer from usual treatment for urinary problems until after completing the 12-week therapy intervention. For these women with LUTS, there are multiple treatment options that can be tried sequentially, including the management of anxiety. If the person consents to be in the study, they agree to receive psychotherapy before trying an alternative management strategy. LUTS are not life threatening, so waiting to start an alternate therapy will render deferment of usual treatment, but cause no harm. The participant will of course have the choice not to agree to the study and pursue other treatments, or no treatment, if they wish. If a patient is eligible, they will then be given the opportunity to provide informed consent.

2.2. Sample size

This study will include up to 40 participants (see Fig. 1 for CONSORT diagram). Through a waitlist-control RCT, the UP has been shown to have quite large effects (Cohen's *d* values of 1.7 or greater) [31]. For this preliminary study, we have chosen a slightly more conservative estimate for Cohen's *d* of 1.5, which represents 1.5 standard deviations between the treatment effect of the UP versus the control group. Based on a power analysis [32], we would require 16 women per group, in the data analyzed, to detect a treatment effect with >98% power with a Type I error rate of $\alpha = 0.05$, two-tailed. Study withdrawal is estimated at roughly 20%, leaving an estimated final sample of 32 participants for data analysis (see Fig. 1). In addition, we also conducted a sensitivity power analysis: given 80% power with a Type I error rate of $\alpha = 0.05$, two-tailed, an effect size of Cohen's $d = 0.9$ would be required in this pilot study. As this is a pilot study, an additional goal of this study is to estimate the effect size in this population for future trials.

2.3. Recruitment methods

Participants will be recruited by research coordinators through the IPHP. If an IPHP clinician identifies a patient as meeting the eligibility criteria, a research coordinator will be called in to speak with the participant about the study. Coordinators will follow a recruitment script. In addition, recruitment flyers and postcards will be placed in the waiting area of the IPHP, and will be shared with IPHP clinicians.

2.4. Consent process

The consent process will be carried out by the research coordinators at the IPHP. Written informed consent including HIPAA authorization will be obtained at same visit as screening and determination of eligibility. All participants will be asked about their understanding of their participation, and will have an opportunity to ask questions about the study prior to agreeing to participate. Participants will be free to consult with others (e.g., family members) prior to providing informed consent. Participants will provide written informed consent before beginning the study. Participants will be informed that they are free to withdraw from the study at any time without consequence. Ongoing consent will not be formally assessed after participants provide informed consent, but research team members will be trained to discuss any questions that may arise and the procedure if a participant chooses to withdraw from the study.

2.5. Randomization, blinding, and study design

This is a pilot study to test pre-post changes associated with the UP, urinary symptoms, and anxiety. Women eligible for the study will be randomized to treatment based on a predetermined list created using the *blockrand* package in R [33,34]. Randomization will occur by blocks,
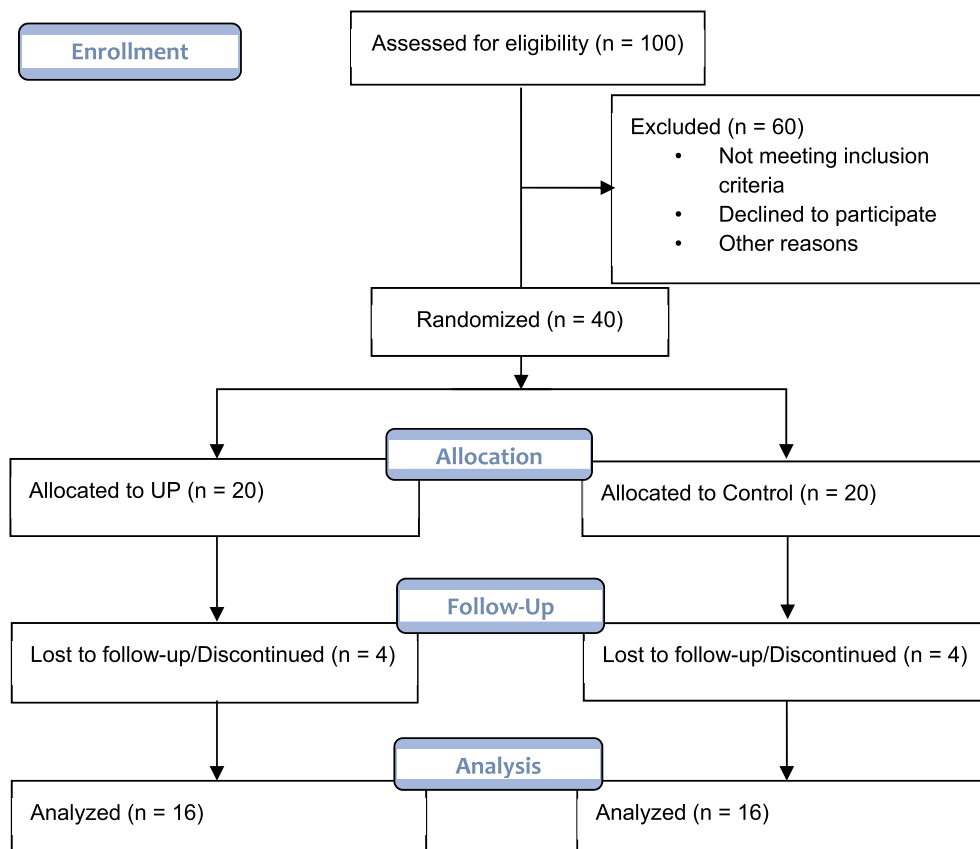

Fig. 1. Study design CONSORT flow diagram.

Table 1
Summary of inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
1. Female	1. Blood in the urine, positive urine culture, signs of infection
2. Age 18 years or older	2. Pregnant, or 6 months or less postpartum
3. Presence of one or more of the following urinary symptoms in the past 12 months and currently seeking treatment: frequency, nocturia, urgency, leakage, hesitancy, straining, or dribbling	3. Psychosis, dementia, or other cognitive impairment that would preclude participation
4. Willing and able to provide informed consent	4. Recent (within 6 months) pelvic or endoscopic surgery, urethral stricture, pelvic malignancy, current chemotherapy or other cancer therapy, pelvic device or implant complication
5. Anxious presentation and/or history of anxiety	5. Recent (within 12 months) Botox injection to the bladder or pelvic structures
6. English speaking	6. Currently in psychotherapy
7. Willing to defer usual treatment for urinary problems	7. Current alcohol or substance use disorder
	8. Difficulty communicating in English

with varying block sizes, in accord with recommended methods for RCTs [35–37]. The randomization key will be linked to a unique study ID number, as well as to a blind labeled treatment condition (i.e., Group1 or Group 2). Following the consent process, research coordinators assign participants to condition based on the randomization key. Research coordinators are blind to condition. Therapists are not blind to condition because they provide the treatment specific to each group. Participants are blind to condition until they meet their therapist for the first session, yet participants are not informed whether they are in the intervention or active control condition. In fact, all participants are told they will receive psychotherapy, but will be randomized to type of therapy. To minimize potential bias, once data collection is complete, data will be provided to an independent data analyst blind to treatment condition.

2.6. Measures

Participants will be asked to complete questionnaires at baseline, mid-treatment (after 6 sessions), post-treatment (after 12 sessions), at a 3-month follow-up, and at a 6-month follow-up. Baseline, mid-treatment, and post-treatment assessments will be completed on tablets with a link from REDCap, though participants will have the option to

respond on paper forms. Both follow-up assessments will be carried out online with a link sent via email. The primary outcome tool for this study will be the six-item Urinary Distress Inventory (UDI-6), which is a sub-scale of the Pelvic Floor Distress Inventory (PFDI-20), as a measure of urinary symptoms [38]. We will also measure anxiety as a primary outcome, using the anxiety subscale from the NIH Patient Reported Outcomes Measurement Information System (PROMIS-29) profile, which has high levels of reliability and validity [39]; this form is brief and easy to complete. Secondary measures include all other subscales from the PROMIS-29 profile [40] (depression, fatigue, pain, physical function, sleep disturbance, and social roles), trauma history assessed with the PTSD Checklist for DSM-5 with Life Events Checklist (PCL-5) [41], the Mini-IPIP, a 20-item short form of the International Personality Item Pool measure of the Big Five personality traits [42], the Ruminative Responses Scale (RRS) short form [43], and the Patient Global Impression of Improvement (PGI-I) – a one item self-report assessment of improvement of urinary symptoms [44]. In addition, at both follow-up assessments, participants will be asked whether they have received any treatment outside of the study for their urinary symptoms and/or their anxiety. Any treatment participants receive outside of the study will be tracked in this manner and included in data analyses. Measures and timing of assessments are summarized in Table 2.

2.7. Intervention

Participants will be scheduled to come to an individual treatment session once per week for 12 weeks, at a convenient time for them, on the Northwestern Medicine campus. This arrangement maximizing convenience for the participants. As described above, participants will be randomized to one of two therapy conditions: the UP or supportive therapy. All sessions, in both conditions, will be 45 min in duration. If a participant misses or cancels a session, it will be rescheduled.

2.7.1. Cognitive-behavior therapy

This study uses the second edition of the *Unified Protocol for Trans-diagnostic Treatment of Emotional Disorders* (UP) [26]. Participants randomized to this condition are given the UP workbook. The UP is a modular therapy that draws upon various forms of CBT to unify the most important tools into one protocol. CBT has been a leading treatment for depression and anxiety for decades, but historically has focused on specific disorders (e.g., major depression, social anxiety disorder, panic disorder). The UP includes a variety of general-purpose techniques to

Table 2
Timing of assessments.

Measure	Estimated Completion Time	Baseline	Session 6	Session 12	3 Month Post-Treatment Follow-up	6 Month Post-Treatment Follow-up
Medical history and physical exam	0 (part of regular medical visit and extracted from EMR)	X				
Demographic questionnaire	1 min	X				
Single Item Literacy Screener (SILS)	<1 min	X				
Brief Medication Questionnaire (BMQ) [45]	3–5 min	X			X	X
Primary outcome 1: PROMIS Anxiety subscale of profile (4 of 29 items below)	See below for entire profile	X	X	X	X	X
Primary outcome 2: Urinary symptoms using the Urinary Distress Inventory (UDI-6) of the Pelvic Floor Distress Inventory (PFDI)	1–3 min	X	X	X	X	X
Secondary outcomes:						
• PROMIS Profile (29 items)	5–10 min	X	X	X	X	X
• PGI-I	5–10 min	X	X	X	X	X
	<1 min			X	X	X
Secondary correlates:						
• PTSD Checklist for DSM-5 with Life Events Checklist (PCL-5)	10 min	X				
• Mini-IPIP	3–5 min	X				
• Ruminative Response Scale (RRS)	1–3 min	X				
Follow-up treatment questions	1–3 min				X	X

help people cope more skillfully with emotionally stressful situations. One example of a strategy for dealing with emotional situations is reappraising negative thoughts (e.g., "If I get nervous at work, the stress I feel will be temporary and won't kill me" rather than "I can't deal with my life"). The UP focuses on managing stress in general, but its techniques are readily adaptable to women coping with urinary symptoms. For example, a woman might have catastrophic thinking about urine leakage (e.g., "What if someone notices that I've leaked?"). These catastrophic thoughts can result in strong fear responses, as well as potentially problematic behaviors (e.g., avoidance of social situations, skipping work). In general, the UP teaches people to track emotions, thoughts, and behaviors in an effort to identify maladaptive patterns. In addition, people learn to restructure their thoughts, and to more confidently confront situations that they find challenging. Towards the end of treatment, patients learn to prevent relapses by continuing to practice therapy skills. Participants in the UP group will be asked to complete specific homework assignments outside of therapy sessions. Homework will be completed in their therapy workbook, and they will be instructed to bring their workbook to each session. Participants will be able to keep their workbook.

2.7.2. Active control

Supportive therapy [46,47] is a non-directive form of psychotherapy that has been widely used as a control condition in therapy studies [48–51]. Many of the elements of supportive therapy may be beneficial to some participants, just as pill placebos benefit some participants in drug trials. As such, it is an excellent control condition because it is not merely placebo. Supportive therapy is widely-used in clinical community settings. In this condition, rather than cognitive-behavioral exercises (e.g., thought records) supportive therapy allows for discussion of maladaptive thoughts if this is a primary concern of the patient. That said, there are important philosophical differences between supportive therapy and CBT. For example, supportive therapy does not challenge defensive/avoidant behavior unless they are grossly maladaptive, whereas CBT emphasizes approach and exposure as a means to address anxiety. Supportive therapy is an ideal match to the UP because it allows for careful control over both the length of and number of sessions. The protocol for supportive therapy includes 1) education about urinary symptoms, anxiety, and depression, 2) discussion of patient goals, 3) sharing of concerns in a nonjudgmental environment, 4) discussion of the possible connections between urinary symptoms and anxiety, 5) exploration of emotions and relationships, and 6) reflective listening. Unlike the UP, participants in supportive therapy will *not* be given a therapy workbook or planned homework.

2.7.3. Fidelity of intervention

For participants who provide consent, therapy sessions will be audio recorded. Recordings of CBT sessions will be reviewed by the principal investigator, a licensed clinical psychologist, to ensure fidelity of treatment and for supervision purposes. Fidelity will be evaluated using the Cognitive Therapy Rating Scale (CTRS) [52], which assesses general characteristics of the therapy as well as CBT specific factors, and is a validated measure of assessing therapist adherence to CBT.

2.7.4. Study therapists

Therapists for both treatment arms will be qualified clinical psychology PhD students. Graduate student therapists will have current and/or prior experience providing therapy. Therapists will be randomized to one intervention condition and only see participants randomized to that same condition. Thus, therapists will be trained on either the UP or supportive therapy though didactics, role playing, and background readings, and will be closely supervised by a licensed clinical psychologist. A certified-UP clinician trained therapists in the UP condition. Therapists will attend supervision once per week, held separately for each condition. In addition, they will have completed CITI training to ensure ethical practice of research for human subjects.

3. Analysis plan

3.1. Primary analyses

We will create hierarchical linear models (HLM) to test the primary hypotheses of the study. One model will determine the effect of type of therapy on anxiety. A separate model will determine the effect of type of therapy on urinary symptoms. The dependent variables for these models will be the UDI-6 subscale of the PFDI-20 and anxiety as measured by the anxiety subscale of the PROMIS Profile-29. The structure of the HLM model is shown below. Note that these models create a response profile for each person across all time points as described in the protocol.

Level 1.

$$Y = P0 + P1\ (T2) + P2\ (T3) + P3\ (T4) + P4\ (T5) + E$$

Level 2.

$$P0 = B00 + B01\ (\text{Condition})$$
$$P1 = B10 + B11\ (\text{Condition}) + R1$$
$$P2 = B20 + B21\ (\text{Condition}) + R2$$
$$P3 = B30 + B31\ (\text{Condition}) + R3$$
$$P4 = B40 + B41\ (\text{Condition}) + R4$$

The dummy variables P1–P4 are dummy codes for the five time points. These will allow us to determine the degree of change from baseline. Each of the "P" coefficients is influenced by Level-2 variables. T2 - T5 are dummy variables of the time differences from baseline. E, R1-R4 represent error terms in the model. Condition will be dummy coded (UP = 1, supportive therapy = 0).

We have two primary endpoints and therefore we will have two models. For both anxiety (PROMIS T score) and urinary symptoms (UDI-6), the full model (see above) will be compared to a reduced model with all of the terms involving condition removed (i.e., B01, B11, B21, B31, and B41). If this comparison is significant ($p < .05$), then we will test individual parameters at a Type I error rate of alpha = .05 (two-tailed). Note, these tests will only be carried out if the full-reduced model comparison is significant. The key prediction for anxiety is that parameters B21, B31, and B41 (representing the effect of UP at post-treatment and beyond) will be significant and negative (representing fewer symptoms). The key prediction for urinary symptoms is that parameters B21, B31, and B41 (representing the effect of UP at post-treatment and beyond) will be significant and negative (representing fewer symptoms). Although we have specific predictions based on null-hypothesis testing, we will also inspect, interpret, and report all aspects of the model, including effect sizes.

3.2. Missing data

All participants with baseline data will be included in the modeling using an intent-to-treat approach. The HLM approach described above can accommodate cases with missing follow-up data.

3.3. Exploratory mediation analysis

We will also carry out mediation analysis in *Mplus* using bias-correct bootstrapped 95% confidence intervals. We will hypothesize that these confidence intervals will not contain zero for the following mediated effects:

- Condition → Mid-treatment anxiety → Post-treatment urinary symptoms
- Condition → Post-treatment anxiety → 3-month urinary symptoms
- Condition → 3-month anxiety → 6-month urinary symptoms

In addition to testing statistical significance, our hypothesis is

directional. Condition (i.e., receiving the UP) should lead to lower anxiety, in turn leading to a reduction in urinary symptoms.

3.4. Additional exploratory analyses

Although our primary focus is anxiety and urinary symptoms, we will conduct HLM analyses on each scale of the PROMIS Profile (depression, fatigue, sleep, pain interference, pain, social function) and other sub-scales of the PFDI (total score, colorectal symptoms, pelvic organ prolapse symptoms). These analyses will be clearly marked as exploratory in all write-ups. We will also create a prediction model of treatment response (i.e., trajectory of symptoms) based on baseline characteristics. These will also be clearly marked as exploratory in all study write-ups. The goal of these exploratory analyses is to identify patient characteristics that predict good versus poor response to treatment.

This randomized controlled trial pilot study emphasizes interdisciplinary collaboration and is the first study to integrate CBT in the urology/urogynecology setting for non-cancerous urologic conditions. This study uniquely employs a transdiagnostic treatment model, such that women with urinary symptoms who also experience anxiety but may not meet diagnostic criteria for a specific psychiatric disorder can still participate and potentially benefit from this treatment. Moreover, the UP [26] treatment applies CBT strategies effective across several diagnostic categories. This study protocol uses longitudinal methods, which engenders the opportunity for mediation analyses to investigate the mechanisms of action among urinary symptoms and anxiety.

3.5. Trial status

This RCT has been preregistered on clinicaltrails.gov (Clinical Trials ID: NCT03623880). The research team initiated the study in March of 2018. Participants were first randomized in September of 2018. Study enrollment occurs on a rolling basis and the intervention phase is ongoing.

3.6. Limitations and future directions

Despite its strengths, this study has several potential limitations: 1) We acknowledge that the expected sample size of $N = 40$ is small; however, this is a pilot study and is intended to serve as preliminary to a full-scale RCT. 2) This study takes place at a reputable medical center in a major metropolitan area; accordingly, results may not generalize to patients in other contexts, such as non-urban settings. We plan on tackling this issue in future studies through community outreach efforts. 3) Both therapy conditions in this RCT require patients to attend 12 visits, which reflects short-term therapy in the community. There is the potential for selection bias to people whose schedules are flexible enough to accommodate this requirement. Perhaps, future studies can evaluate brief treatments (e.g., 8 sessions). 4) All study outcome measures are self-report. We anticipate that the results of this study will give rise to a subsequent clinical trial on a behavioral intervention that allows for laboratory-based measures of change (e.g., inflammatory markers, salivary cortisol) to supplement patient-reported outcomes. 5) Lastly, this study focuses on an existing protocol, the UP. Going forward, we plan to develop and test tailored interventions specific to women with urinary symptoms.

Funding

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100514.

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Definitions of Acronyms (in alphabetical order):

BMQ: Brief Medication Questionnaire
CBT: cognitive-behavior therapy
DSM-5: Diagnostic and Statistical Manual of Mental Disorders
HLM: hierarchical linear models
IPIP: International Personality Item Pool
MBSR: mindfulness-based stress reduction
PCL-5: PTSD Checklist for DSM-5 with Life Events Checklist
PFDI-20: Pelvic Floor Distress Inventory
PGI-I: Patient Global Impression of Improvement
PROMIS: Patient Reported Outcomes Measurement Information System
PTSD: posttraumatic stress disorder
RRS: Ruminative Responses Scale
UDI-6: Urinary Distress Inventory
UP: Unified Protocol for Transdiagnostic Treatment of Emotional Disorders