Int Urogynecol J. 2016 Oct 17. [Epub ahead of print]

Methodology for a trial of brain-centered versus anticholinergic therapy in women with urgency urinary incontinence.

Komesu YM[1,2,3], Rogers RG[4], Sapien RE[4], Schrader RM[5], Simmerman-Sierra T[6], Mayer AR[7], Ketai LH[4].

Author information

[1]Health Sciences Center, University of New Mexico, Albuquerque, NM, USA. ykomesu@salud.unm.edu.
[2]Health Sciences Center Department of Obstetrics and Gynecology, University of New Mexico, MSC10-5580, Albuquerque, NM, 87131-0001, USA. ykomesu@salud.unm.edu.
[3]University of New Mexico, Albuquerque, NM, 87131-0001, USA. ykomesu@salud.unm.edu.
[4]Health Sciences Center, University of New Mexico, Albuquerque, NM, USA.
[5]Clinical and Translational Science Center, University of New Mexico, Albuquerque, NM, USA.
[6]Hypnotherapy Academy of America, Albuquerque, NM, USA.
[7]Mind Research Network, Albuquerque, NM, USA.

Abstract

INTRODUCTION AND HYPOTHESIS: We describe the rationale and methodology for a study comparing mind-body treatment and pharmacotherapy in women with urgency urinary incontinence (UUI). To explore brain associations in UUI, a subset of patients will also undergo functional magnetic resonance imaging (fMRI). We hypothesize that hypnotherapy, a mind-body intervention, will be at least as effective as pharmacotherapy in treating UUI. We also hypothesize that fMRI findings will change following treatment, with changes potentially differing between groups.

METHODS: We describe the development and design challenges of a study comparing the efficacy of hypnotherapy and conventional pharmacotherapy in the treatment of UUI. The study randomizes women to either of these treatments, and outcome measures include bladder diaries and validated questionnaires. Sample size estimates, based on a noninferiority test (alpha = 0.025, beta = 0.20), after considering dropout subjects and subjects lost to follow-up, indicated that approximately 150 woman would be required to test the hypothesis that hypnotherapy is not inferior to pharmacotherapy within a 5 % noninferiority margin. The study will also evaluate fMRI changes in a subset of participants before and after therapy. Challenges included designing a study with a mind-body therapy and a comparison treatment equally acceptable to participants, standardizing the interventions, and confronting the reality that trials are time-consuming for participants who have to make appropriate accommodations in their schedule.

RESULTS: Study enrollment began in March 2013 and is ongoing.

CONCLUSIONS: We describe the design of a randomized controlled trial comparing mind-body therapy and pharmacotherapy in the treatment of UUI and the challenges encountered in its implementation.

KEYWORDS: Anticholinergics; Complementary alternative integrative medicine; Hypnosis/hypnotherapy; Randomized controlled trial or RCT methodology; Women with urgency urinary incontinence

PMID: 27752750 DOI: 10.1007/s00192-016-3169-3

[PubMed - as supplied by publisher]

PFD WEEK 2018
OCTOBER 9-18, 2018 * HYATT REGENCY CHICAGO * CHICAGO, IL
AUGS
Advancing Female Pelvic Medicine and Reconstructive Surgery

Paper 8: Hypnotherapy or Pharmacotherapy for Urgency Urinary Incontinence Treatment in Women. The Hyp-hOP Randomized Clinical Trial

Thursday, October 11, 2018

03:20 PM - 03:30 PM

Hyatt Regency Chicago - Riverside East

Objective: To determine whether hypnotherapy effectively treats urgency urinary incontinence (UUI) compared to pharmacotherapy.

Methods: This investigator-masked trial randomized women with non-neurogenic UUI to hypnotherapy or medication, enrolling those with ≥3 UUI episodes/week. Primary outcome: 3-day diary UUI episodes. Hypnotic susceptibility testing categorized participants into low, medium & high susceptibility. Hypnotherapy group received 8 weekly hypnotherapy sessions, 1 optional “booster” session & audio-recordings. Medication group received 1 medication counseling session, 8 weekly follow-up sessions & extended release anti-muscarinics x 1 year. Follow-up occurred at 2, 6 & 12 months. Multivariable analysis compared groups with respect to UUI, $P<0.05$.

Results: 152 women were randomized (74 hypnotherapy/78 medications); 142 completed 2-month & 140 completed 12-month follow-up (Table 1). Groups did not differ in any characteristics, including age (57.6±12.8, 59.5±10.3 years, P=0.34) & hypnotic susceptibility (P=0.46). Most had high (N=101) or medium (N=31) susceptibility, few had low (N=10). Unadjusted between group comparisons showed no UUI differences at baseline & follow-up; both groups improved (Table 1).

Regression analysis revealed hypnotic susceptibility & baseline UUI influenced follow-up UUI. Due to a 3-way interaction (groupxtimexhypnotic susceptibility), least squares means best described UUI episodes. At 2 months, there were no UUI differences between groups. At 6 months, medium hypnotic susceptibility participants treated with hypnotherapy had fewer UUI episodes compared to medication; 1.2 (0.6-2.5) vs. 3.3 (1.8-6.0), ratio 0.36, 95% CI 0.14-0.94. At 12 months, high hypnotic susceptibility participants treated with hypnotherapy had fewer UUI episodes compared to medication; 2.1 (1.5-3.7) vs. 3.7 (2.5-5.6), ratio 0.56, 95% CI 0.32-0.98] (Fig. 1).

Conclusions: Hypnotherapy & medication both effectively treated UUI at 2--12-month follow-up, with median UUI decreasing ≥ 85%. In those with medium-high hypnotic susceptibility, hypnotherapy was superior to medication at longer follow-up, offering a durable alternative therapy for UUI.

Authors

Yuko M. Komesu, M.D.
University of New Mexico

Robert Sapien, MD
University of New Mexico

Ronald Schrader, PhD
University of New Mexico

Loren H Ketai, MD
University of New Mexico

Rebecca G. Rogers, MD