

# Do mindfulness exercises improve patient experience during urodynamic testing?

<b>Submission date</b> 25/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/04/2019	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Urodynamic study (UDS) is a series of tests that evaluate bladder and urethral function. UDS involves placing catheters into the bladder and rectum that can be uncomfortable. Several interventions have been attempted to reduce the unpleasantness associated with UDS without success. A new technique that has been shown to reduce chronic bladder pain is mindfulness. The aim of this study is to see whether incorporating mindfulness exercises before UDS results in less pain, anxiety and discomfort.

### Who can participate?

Patients aged 18-80 scheduled to undergo UDS for urinary symptoms

### What does the study involve?

Participants are randomly allocated to one of two treatment plans. One treatment plan includes undergoing mindfulness exercises before the UDS evaluation. Participants are guided through a mindfulness meditation exercise by a licensed professional where they are asked to focus their attention on their breathing, physical sensations, and thoughts. This exercise lasts for about 10 minutes and does not involve any physical activity other than sitting and breathing. The other treatment plan includes simply undergoing the UDS evaluation. After the UDS evaluation, participants are asked questions about their emotional and physical experiences during the UDS procedure, including pain, anxiety and discomfort.

### What are the possible benefits and risks of participating?

Participants may experience less discomfort, anxiety and/or pain associated with UDS. There is no guarantee they will receive any benefit from this study other than knowing that the information may help future patients.

### Where is the study run from?

Brooke Army Medical Center (USA)

### When is the study starting and how long is it expected to run for?

September 2016 to April 2018

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Forrest Jellison

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Forrest Jellison

**Contact details**  
Division of Urology  
3551 Roger Brooke Dr  
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## Additional identifiers

**Protocol serial number**  
C.2016.202d-IRB approval number

## Study information

**Scientific Title**  
Incorporation of mindfulness exercises to reduce anxiety and pain during urodynamic testing: a pilot randomized controlled trial

**Study objectives**  
The objective of the study is to investigate whether mindfulness techniques improve patient's perceptions of UDS testing:  
Objective 1: To evaluate changes in anxiety symptoms during UDS testing  
Hypothesis: Anxiety will improve during UDS testing with prior mindfulness intervention  
Objective 2: To evaluate changes in pain intensity during UDS testing  
Hypothesis: Pain will improve during UDS testing with prior mindfulness intervention

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Regional Health Command-Central (RHC-C) Institutional Review Board, 29/09/2016, Protocol C.2016.202d

**Study design**  
Single-center randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Urodynamic, urinary incontinence, anxiety, physical discomfort

## **Interventions**

This is a single center randomized trial with the urologist performing the urodynamic testing blinded or masked. Participants are randomly assigned to one of two treatment plans. One treatment plan includes undergoing mindfulness exercises prior to the UDS evaluation. Participants are guided through a mindfulness meditation exercise by a licensed professional where they are asked to focus their attention on their breathing, physical sensations, and thoughts. This exercise will last for approximately 10 minutes in which participants will not be asked to engage in any physical activity other than sitting and breathing. The other treatment plan includes simply undergoing the UDS evaluation. After the UDS evaluation, participants will be asked questions about the urodynamic procedure. They will be asked to answer questions on a UDS and anxiety questionnaire which pertain to their emotional and physical experiences during the procedure. They will rate the amount of discomfort on a scale of 1-10 during the procedure on a visual analog pain scale.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Anxiety as measured by state-trait anxiety inventory (STAI-6). The STAI-6 form consists of six feelings, negative feelings (tense, upset, worried) and positive feelings (calm, relaxed, content), that are measured with a Likert scale. Higher scores are associated with higher levels of anxiety. Measured three times during the same clinic visit for UDS testing: at baseline, about 10 min later, and after the UDS testing.

## **Key secondary outcome(s)**

Measured three times during the same clinic visit for UDS testing: at baseline, about 10 min later, and after the UDS testing:

1. Pain as measured on the visual analog scale
2. Emotional and physical discomfort as measured by a urodynamic questionnaire

## **Completion date**

18/04/2018

## **Eligibility**

### **Key inclusion criteria**

Adults (Department of Defense [DoD] beneficiaries and active duty military patients aged 18-80) scheduled for urodynamic testing

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

All

**Total final enrolment**

27

**Key exclusion criteria**

1. Age less than 18 years
2. Pregnant, as verified by urine or blood sample
3. Have an alteration in neurologic bladder function
4. Inability to complete forms
5. Inability to provide informed consent

**Date of first enrolment**

01/09/2017

**Date of final enrolment**

30/12/2018

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

Brooke Army Medical Center

San Antonio

United States of America

78234

**Sponsor information****Organisation**

Brooke Army Medical Center

ROR

<https://ror.org/00m1mwc36>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data that is stored is de-identified from the validated questionnaires and demographic information.

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		09/04/2019	09/04/2019	No	No