

Do mindfulness exercises improve patient experience during urodynamic testing?

Submission date 25/04/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/05/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/04/2019	Condition category Signs and Symptoms	☐ 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
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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

Primary study design
Interventional

Study design

Single-center randomized controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Urodynamic, urinary incontinence, anxiety, physical discomfort

Interventions

This 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?
Basic results		09/04/2019	09/04/2019	No	No