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Do mindfulness exercises improve patient experience during urodynamic testing?

Submission date
25/04/2018

Recruitment status
No longer recruiting

Registration date
08/05/2018

Overall study status
Completed

Last Edited
09/04/2019

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Fort Sam Houston
United States of America
78234

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures

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

Overall study start date
29/09/2016

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
30

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

Sponsor details
3551 Roger Brooke Dr
Fort Sam Houston
United States of America
78234

Sponsor type
Government

ROR
https://ror.org/00m1mwc36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Plan to submit for publication by June 2018.

Intention to publish date
30/04/2019

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