

Permission to Take Part in a Human Research Study

Title of Research Study: Enhancing Behavioral Treatment for Women with Pelvic Floor Disorders (STU00207124)

Investigator: *James W. Griffith, PhD*

Supported By: This research is supported by the Evergreen Foundation.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a woman 18 years of age or older seeking care at this clinic for urinary symptoms such as urgency or frequency, and you have reported some emotional distress.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to better understand how emotional distress (such as depression and anxiety or nervousness) may contribute to the abnormal urinary sensations you are experiencing. Urinary symptoms are common health issues affecting an individual's quality of life. Emotional distress is treatable using behavioral procedures, and effective treatment would increase women's emotional health and help to reduce urinary symptoms. The main benefit is the possibility of improving your urinary symptoms and emotional distress, as well as providing important information about the relationship between urinary symptoms and emotional distress.

How long will the research last and what will I need to do?

We expect that you will be in this research study for nine months in total. The therapy portion of the study will take place over 12 weeks (one visit per week), then you will complete two follow-up surveys online. The first follow-up survey will take place 3 months after the end of therapy, and the second follow-up survey will take place 6 months after the end of therapy.

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You will be asked to complete 12 therapy sessions in-person. In addition to therapy visits you will be asked to complete five surveys in total: 1) baseline survey before starting therapy, 2) a survey midway through your therapy visits, 3) a survey at the end of your last therapy session, 4) 3-month follow-up online, and 5) 6-month follow-up online.

More detailed information about the study procedures can be found under the section **What happens if I say “Yes, I want to be in this research”?**

Is there any way being in this study could be bad for me?

You may experience emotional distress from answering certain survey questions or discussions pertaining to your urinary symptoms or stress. Participating in the study will allow you to process any concerns or distress in the therapy sessions.

More detailed information about the risks of this study can be found under **“Is there any way being in this study could be bad for me? (Detailed Risks)”**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include feeling that your emotions and urinary issues get better. Another possible benefit to you or others is that we can improve treatment for urinary problems and emotional stress.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Instead of being in this research study, your choices may include: usual treatment for your urinary symptoms (e.g., physical therapy, if appropriate as determined by your doctor).

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 503-3811 or btaple@u.northwestern.edu

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 30 to 40 people here at Northwestern to be in this research study.

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What happens if I say “Yes, I want to be in this research”?

As a participant in this study you will agree to take surveys. The first survey will tell us if you can be in this study. If you can be in the study, you will be asked to come to Northwestern Memorial Hospital for 12 in-person therapy sessions. You will be randomly chosen to get either Cognitive-Behavioral Therapy or Supportive Therapy. Your therapist will be a clinical psychology graduate student, supervised by a licensed psychologist. During the therapy portion of this study (12 weeks), you will not be able to receive the usual treatment for your urinary problems from your urologist or urogynecologist. After completing 12 weeks of therapy, you will fill out follow-up surveys online. Therapy sessions will be audio recorded to see that you get the best quality of care. Your agreement for therapy sessions to be recorded is optional and will not affect your chances of being in the study. If you happen to miss or need to cancel a therapy session, you will be given the opportunity to reschedule your appointment, so that you can participate in all 12 sessions.

There are two parts to this research study: surveys and therapy. These are explained below in more detail:

Surveys (Approximately 15-30 minutes):

- You will be asked to complete a number of surveys about urinary symptoms and emotional distress. Surveys during the study will be given to you on tablets (with the option of completing surveys on paper forms) and collected by research coordinators and therapists, and you will complete follow-up surveys online.
- We think that it will take you 15-30 minutes to complete the surveys.
- You will answer surveys five times during the study: once after signing this form (on a tablet or paper form), once after completing six therapy sessions (tablet or paper), once after completing all 12 therapy sessions (tablet or paper), once at a 3-month follow-up (online), and once at a 6-month follow-up (online).

Therapy (Approximately 45 minutes, once per week for 12 weeks):

- You will participate in 12 individual 45-minute therapy sessions led by a graduate student therapist.
- During the therapy session you will discuss your stress with a therapist. More details about therapy will be given during and after the study. You may ask questions at any time.
- The group you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study doctor/study team will choose what intervention you get. You will have an equal chance of being assigned to any given group.
 - If you are assigned to Cognitive-Behavioral Therapy, therapy includes discussion of thoughts and behaviors.
 - If you are assigned to Supportive Therapy, therapy includes supportive listening and emotional support.

You will be asked to give us permission to re-contact you for possible participation in other studies.

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What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: attend 12 therapy sessions and complete five surveys across the study period as described above in **What happens if I say "Yes, I want to be in this research"?**

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can ask for permission to use data through the length of your participation in the study. If you choose to leave the research, we will ask you the reason, if you wish to tell us.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?

1) Therapy Experience

- You may feel some negative emotions from talking about personal stress and problems. Therapists will have been trained by the researcher to be sensitive to your discomfort and your concerns. If this happens, you may tell the therapist how you are feeling, or ask to take a break from the session.
- No serious negative effects should come from your therapy.

2) Survey Responses

- We will be asking you more than the normal amount of questions about your urinary symptoms and your emotional stress, so you may experience some discomfort or distress, anxiety, or depression about discussing these issues. You may also feel bored or tired.
- Staff running the study will have been trained by the researcher to be sensitive to your discomfort and your concerns. At any time, if you wish, you can take a break or stop the answering the questionnaires.
- No serious negative effects should come from answering the questionnaires.

3) Data Collection

- There is a potential loss of private information when involved in a research study, but all steps will be taken to minimize the risk as described below.
- There is a small risk to your privacy. Some data collected for research use will be labeled with your name; however, this information will stay at Northwestern. Information that is put in the database or that is sent with your data will be labeled with a specific identification number.

If you are uncomfortable and find the research procedures to be upsetting, you have the option to leave the study at any time. As with any research study, there may be more risks that are unknown or unexpected.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?"**.

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Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you, such as transportation costs and parking. Therapy sessions will take place either in the Integrated Pelic Health Program (IPHP) clinic or our research space on the same campus with the aim of increasing convenience for participants.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include feeling that your emotions and urinary issues get better. Another possible benefit to you or others is that we can improve treatment for urinary problems and emotional stress.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

During the research study, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will provide you with help to get treatment, even if that means loss of privacy.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

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The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you \$100 total for your time and effort. You will be paid \$5 per therapy session with a bonus of \$10 for completing all 12 sessions (\$70 total). You will receive your first payment after your last therapy session via a Stored Value Card (VISA), described below. In addition, you will receive \$15 for completing each follow-up survey (\$30 total), via a virtual gift card which can be used to make online purchases. If you decide to withdraw from the study before completing all 12 sessions, you will be paid the pro-rated amount corresponding to the number of sessions you completed via your preference of a virtual gift card or Stored Value Card.

You will be issued the Stored Value Card (VISA), which is a type of bank debit card with a specific dollar value programmed into it. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card.

You will need to set a PIN to use the card at an ATM. Using the PNC automated service number and Account Access Code provided on the card, follow the prompts to establish a PIN. You may also call this number to obtain the current balance on the card and to verify your activity. A fee will be charged to speak to a live operator. This information can also be checked online at pncprepaidcard.com. Please note that neither PNC nor Northwestern can obtain the PIN if forgotten.

If the card is used at a PNC ATM, there is no fee; however, there will be a \$2.50 charge for non-PNC ATM withdrawals. One card will be issued for the duration of your participation. If your card is lost or stolen, please call the study team on the contact information provided on this consent document.

Please be advised: You will incur a fee if the card is not used in 6 months and a monthly fee for each additional month of non-use. However, as long as there is activity (funds are added or card is used), on the card within 6 months the month period will reset and no monthly fee will be assessed. If the card is used at a restaurant, there will be a 20% "hold" above the tab amount. The card will be declined if used at a gas pump. Rather, the card must be physically presented to the gas station attendant.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record (e.g., demographics, contact information, urinary symptoms)
- Results of physical examinations
- Medical history
- Substance abuse information: substance use history
- Mental Health information: mental health diagnoses

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You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on August 31, 2021. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.

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- Evergreen Foundation, who is sponsoring the study, and that company's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on August 31, 2021.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: James W. Griffith
Institution: Northwestern University Feinberg School of Medicine
Department: Medical Social Sciences
Address: 625 N. Michigan Ave., 27th Floor, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree

I disagree

The researcher may audio record me to aid with quality of therapy and data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

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Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent