STANFORD UNIVERSITY Research Information Sheet

Protocol Director: Dr. Ekene Enemchukwu

IRB Use Only
Approval Date: January 18, 2024
Expiration Date: (Does Not Expire)

Protocol Title: **Improving Overactive Bladder Treatment Access and Adherence through Personalized Behavioral Modifications and Mobile Technology-Based Interventions**

IRB# 72487

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Ekene Enemchukwu, MD, MPH 1000 Welch Rd Suite 100, Palo Alto CA 94304. 650-723-3391 or 650-721-2700.

DESCRIPTION: You are being invited to take part in a research study that is being funded by the National Institutes of Health. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary. This study is about improving access to non-surgical bladder leakage, or urinary incontinence (UI), treatment for women. By participating in this study, we hope to learn the best way to deliver remote non-surgical treatment to women with bladder symptoms.

TIME INVOLVEMENT:
Your participation in this research will last about 3 months. During this time, you will receive an online educational program called MyHealthBladder. You will review educational sessions on a weekly basis for 8 weeks and will be asked to complete a follow-up survey 12 weeks after enrollment. Throughout the study, you will be asked to answer questions online related to your health, and bladder leakage, and track your behavioral training.

We will randomize a total of 30 eligible women to the mHealth application (intervention group) or usual care (control group). Simple randomization will occur using an online randomization program. You have a 50% chance of being randomized to either group.

RISKS AND BENEFITS: There are no known health risks associated with this study. Possible risks of participation are loss of confidentiality or discomfort or fatigue from completing study questionnaires. If, for any reason, you wish not to answer specific questions, you will be able to do so.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Your decision whether or not to participate in this study will not affect your medical care with Stanford.

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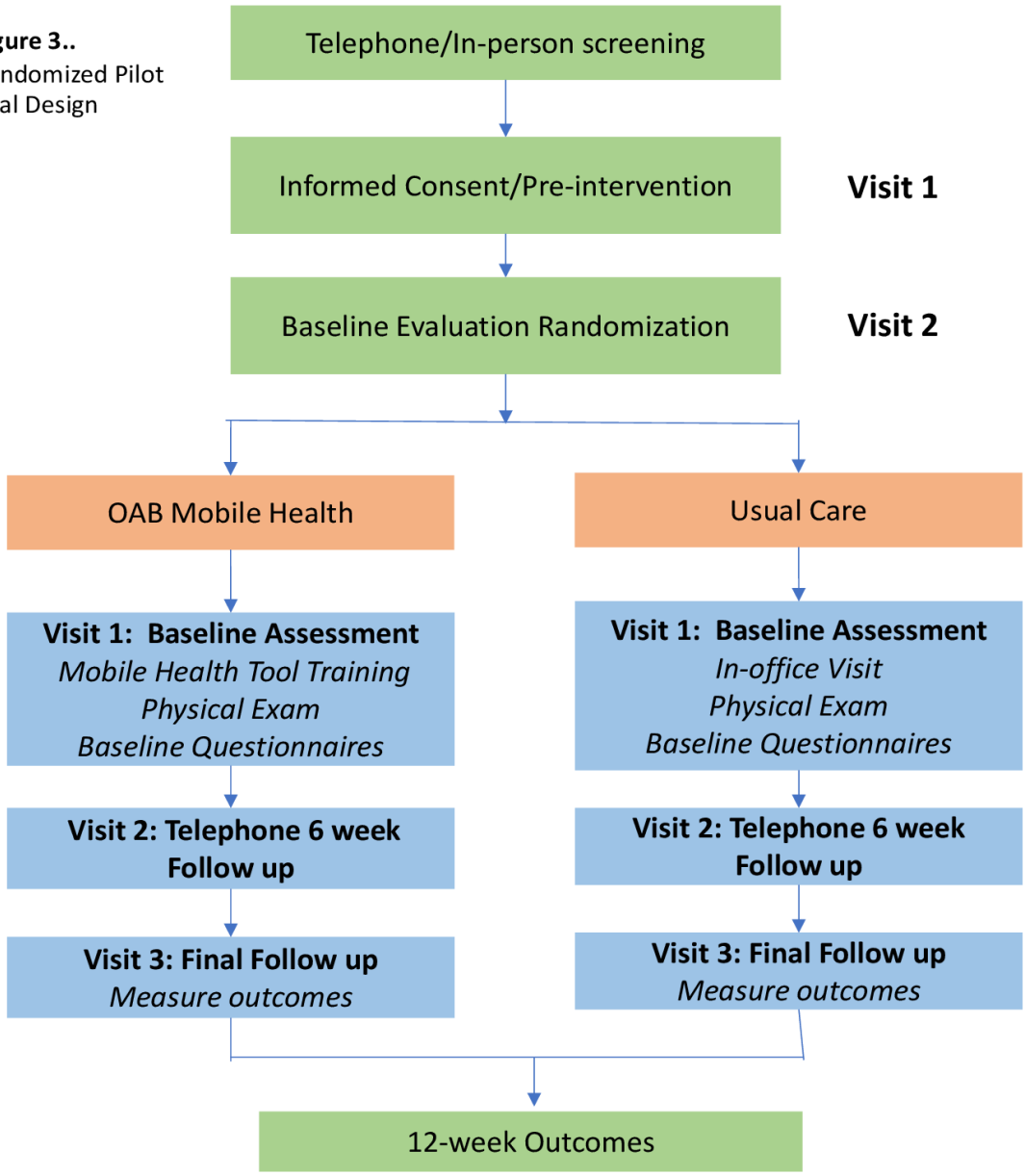
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Figure 3..
Randomized Pilot Trial Design



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PAYMENTS: You will receive $50 as payment for your participation.

SPONSOR: The National Institutes of Health and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) are providing financial support and/or material for this study.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The alternative is not to participate. You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. Your individual privacy will be maintained in all published and written data resulting from the study

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

ClinicalTrials.gov: A description of this clinical trial will be available on 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.

CERTIFICATE OF CONFIDENTIALITY
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.'

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring

the project that is needed for auditing or program evaluation by the National Institutes of Health and the National Institute on Aging, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law in regard to suspicion of participant abuse or neglect or possible harm by the participant to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Information obtained during the course of the study which in the opinion of the investigators (s) suggests that you may be at significant risk of harm to yourself, or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you agree to this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before agreeing to it.

What is the purpose of this research study and how will my health information be utilized in the study?

This study is about improving access to non-surgical bladder leakage, or urinary incontinence (UI), treatment for women. By participating in this study, we hope to learn the best way to deliver remote non-surgical treatment to women with bladder symptoms.

Do I have to agree to this authorization form?

You do not have to agree to this authorization form. But if you do not, you will not be able to participate in this research study Agreeing to the form is not a condition for receiving any medical care outside the study.

If I agree, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

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Department of Urology
Kristine Talavera
800 Welch Road, FC3C81 Palo Alto, CA 94304

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: Name, medical record number, date of birth, demographic information (e.g., gender, and ethnicity), medications, medical history, medical diagnoses and treatments, dates and type of treatment or procedures, progress or follow-up notes, patient's vitals, office visit reports, diagnostic tests (e.g., labs and imaging), reported side effects, changes in symptoms or medication use, duration of treatment response.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Ekene Enemchukwu
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institutes of Health (NIH), National Institute on Aging (NIA) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

- The Society of Urodynamics and Female Pelvic Medicine and Urogenital Reconstruction
- Office for Human Research Protections (OHRP)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and disclosure of your health information will end on 12/16/2050 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- Pregnancy
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:
Questions: If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Protocol Director, Dr. Ekene Enemchukwu at (650) 725 -5746.

You should also contact them at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Kristine Talavera at (650) 723 -0525.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

The extra copy of this signed and dated consent form is for you to keep.

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_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent