Tailoring Online Continence Promotion

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University of Wisconsin-Madison Consent to Participate in Research and Authorization to Use Protected Health Information for Research

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Study Title for Participants: Women on the Go

Formal Study Title: Tailoring Online Continence Promotion

Lead Researcher: Drs. Megan Piper (email: mep@ctri.wisc.edu; phone: 608-265-5472; mailing address: 1930 Monroe Street, Suite 200 Madison, WI 53711) and Heidi Brown (email: heidi.w.brown@kp.org)

Institution: University of Wisconsin School of Medicine and Public Health and Kaiser Permanente

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Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

Even though lots of online programs (websites) exist to support us in making healthy choices, the majority of these websites are not used regularly.
The purpose of this research study is to test two versions of the Women on the Go program to see which version helps women stay engaged with the website.
We also hope to learn which version of the Women on the Go program helps women make behavior changes to improve or prevent bladder and bowel symptoms.

What will I need to do in this study?

The research team will ask you to complete four questionnaires about your bladder and bowel health and about using the online program. You may also be invited to complete an optional interview with one of our study team members.
The version of the program you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what version you get. You will have an equal chance of being given each version.

We expect that you will be in this research study for 6 months.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

How long will I be in this study?

You will be part of the study for about 6 months.

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
Comfortable having researchers ask questions about your bladder and/or bowel health. Willing to participate in the study for 6 months. Interested in contributing to scientific knowledge even though you may not benefit directly from the study.	May not have time to complete study questionnaires. Feel uncomfortable or embarrassed answering survey questions about your bladder and/or bowel health.

Do I have to be in the study? What happens if I say yes, but I change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

Let the researchers know if you choose to leave the study.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

There is no single standard treatment for bladder or bowel incontinence. As part of their regular health care, people might take medicine, see a physical therapist, see a nutritionist, wear a device, have an office procedure, have surgery, or choose to have no treatment at all.

People who access the Women on the Go program will learn about these treatments and may choose to seek medical treatment for bladder or bowel incontinence.

People who take part in this study will not get any medical treatment from the study.

This study is not part of your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at Megan Piper, PhD at (608) 265-5472

If you have concerns about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. UW Staff not part of the study team will work with you to address concerns and assist in resolving any complaints.

If I take part in the study, what will I do?

If you decide to participate in this research study, you will be asked to:

1. Be randomly assigned to one of two versions of the Women on the Go program.

2. Use the Women on the Go program at least once per week for 3 months.

3. Complete electronic (email) research surveys 4 times over 6 months.

4. Consider an invitation to participate in a telephone or video interview about your experience.

1. What does being randomly assigned to one of two versions of the Women on the Go program mean?
We are testing two versions of the Women on the Go program because we do not know which one will work better. The version of the program that you get will be chosen by chance, like flipping a coin. Neither you nor the research team will choose which version you get. You have a 50/50 chance of getting each version.

2. What is involved in using the Women on the Go program?
The Women on the Go program is a website with information about how to change your habits to improve bladder and bowel health. Both versions of the program involve these activities:

You will be mailed a paper booklet that you can use to help you track your progress. You can choose whether or not you use this booklet.
You will be asked to create a free account with the Women on the Go program using your email address. You will create your own password and you can use the program as often as you want to. The program records data about which pages you have visited and how often you visit them.
You will get an email from the Women on the Go program every week for 12 weeks. The emails are meant to help remind you to log into the program. The types of emails you receive will be different depending on which version of the program you are assigned, but the number of emails is the same in both versions.
If you choose not to create an account with the Women on the Go program, you will not be able to participate in this research study.

3. How long will the surveys take? How often will they be? What are they about?
   The electronic surveys will take about 20-30 minutes each.
   You will be asked to complete a research survey today within this website.
   You will receive emails inviting you to complete research surveys again in 4 weeks, 12 weeks, and 24 weeks.
   The surveys ask questions about yourself and your health, your attitudes and behaviors, and your opinions about the Women on the Go program, some of the questions ask about bladder, bowel, and sexual health. You can choose not to answer any questions that make you feel uncomfortable.
   You may receive up to 3 reminder invitations for each email survey.
   You will receive $25 after you complete each research survey (in the form of an electronic gift card or paper check.)

4. What happens if I am invited to participate in a telephone or video interview?
About 30 - 40 of the 500 people in this research study will be invited to participate in a telephone or video interview to learn more about their personal experiences with the program.

If you are selected for an invitation, the research team will send you an extra email asking for permission to contact you to schedule an interview that will last no more than 30 minutes by telephone or video.

The interview will include questions about your experience with the program, what made it easier or harder for you to use the program, and how the program could be changed to make it easier and more helpful for people in the future. You can choose to skip any question you do not wish to answer.

Your voice will be recorded but not your face or picture. Only the researchers will have access to the recording. What you say will be written down word for word to create a transcription. The transcription will be saved but the recording will be destroyed. No information that could identify you will be included in the transcription.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Name
Contact information (mailing address, phone number, email address)
Things you tell the researchers about your health

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

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the Lead researcher, Dr. Megan Piper, in writing (1930 Monroe Street, Suite 200 Madison, WI 53711).

Will being in this study help me in any way?

Being in this study will not help you directly. But your participation in the study may benefit other people in the future by helping us learn more about how to improve the Women on the Go program.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

What are the study risks?

There is a risk that your information could become known to someone not involved in this study. You may also feel embarrassed or uncomfortable completing questions about your health.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for

monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed above for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research or share it with other researchers without additional consent from you.

What risks and benefits are associated with open access data sharing?

Any research data collected from you, excluding your personally identifiable information, could be included in the open access data sharing. However, even with your identifiable information removed, there may be a risk of you being identified. Anybody in the world can have access to information in an open access database. If you tell other people that you participated in this study, you may increase the chance that someone will be able to link your data to you.

We do not know how likely it is that your identity could become re-connected with information shared through open access. As of today, we believe there is a low risk that most de-identified study data could be used to re-identify you. However, data that cannot be used to identify you today could be used to identify you in the future.

If you decide to withdraw from the study after consenting to open data sharing, we will not have any way to know who has already used your data before you withdrew and will not be able to prevent continued use of your data.

There is no direct benefit to you from placing your data in an open access database. If you agree to open access data sharing, this will help a wider range of researchers make discoveries that may help others in the future.

Will information from this study go in my medical record?

None of the information we collect for this study will be put in your medical record.

What else do I need to know?

Will I receive anything for participating?

We will pay you $25 after you complete each survey (today, in 1 month, in 3 months, and in 6 months). You will be asked to provide your email address to receive an electronic gift card for each of these payments. If you choose to leave

the study, or if we remove you from the study for any reason, you will not receive any additional payments.
If you are invited for and complete a telephone interview, you will receive an additional $25 electronic gift card.

Permission to communicate about the study by email

We are requesting your email address so we can send your 1 month, 3 month, and 6 month surveys. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Megan Piper, PhD at 608-265-5472.

How many people will be in this study?

We estimate that about 500 people will participate in this study.

Who is funding this study?

Funding for this study is provided by the National Institutes of Health.

Publication of study protocol and results statement

A description of this clinical trial is available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

You have read this consent form.
You have had a chance to ask questions about the research study, and the researchers
have answered your questions.
You want to be in this study.

By checking the box below and typing my name below, I am electronically signing this consent form and agree to participate in the research study.

☐ _____

(check this box) First and last name