Consent to Participate in Research

Title of Research: Healthy Weight in Lesbian & Bisexual Women/Women's Health and Mindfulness (WHAM)

Introduction

You are being asked to participate in a research study. Before you decide if you want to take part in this study, you need to read this form so that you understand what the study is about and what you will be asked to do. This form also tells you who can be in the study, the risks and benefits of the study, how we will protect your information, and who you can call if you have questions. Please ask about anything you don't understand before you decide.

Purpose

The Women's Health and Mindfulness (WHAM) is a research study paid for by the Office of Women's Health. The study is being conducted by RTI International and Lyon-Martin Health Services. The purpose of this study is to improve the health, nutrition and physical activity of lesbian and bisexual women. You are one of approximately 80 lesbian and bisexual women being asked to participate in this intervention study.

Procedures: What is involved in being in the WHAM program?

First, a short interview is used to see if you meet the requirements to join the study:

- Identify as a lesbian or bisexual woman
- 40 years old or older
- Speak English
- Have a body mass index (BMI) over 27.5

If you agree to join, you will be asked to come to a 12 week group program that meets 1 time per week with 10-12 other women. The groups will be led by a licensed therapist. The meeting will take place at Lyon-Martin Health Services or another community center that may be more convenient for you. We will also hold sessions for exercise and movement lead by a trainer that will take place each week. The groups will focus on stress, nutrition, physical activity. They will use a technique called mindfulness as a tool to help you make changes to improve your health. Each week will have a special topic for discussion and some activities for you to practice what you are learning.

This is a new program and we are testing how well it works to improve women's health. To do this, some women who join will start the program very soon and others will be asked to start about four months from now. This will be decided by chance (like the flip of a coin) using a computer program. After your interview today we will learn whether you are in the group starting soon or starting later. If you are in the later start group (4 months from now), you will be do an extra visit with us when the program is done. You will be paid $25 for each visit.

In the beginning and at the end of the intervention, you will be asked questions about your health including your stress levels, what kinds of foods you eat, and your physical activity levels. This interview will be done by a member of our staff and you will be interviewed in a private location. You will also be asked to complete a health assessment that includes having your blood pressure taken and testing your blood for your cholesterol levels and your blood sugar levels. The blood will be drawn by a medical assistant either at Lyon-Martin Health Services or at one of our partner labs. You can choose what is most convenient for you from a list we will give you. The blood draw is most accurate if you haven't eaten before the test (called a "fasting blood draw"). You may want to get the blood test first thing in the morning. You will get the results of the tests.

Also, some women in both groups will be chosen by chance to wear an accelerometer (a small device the size of a quarter that measures your activity level). This is worn on your waist or wrist. These women will wear the accelerometer for one week at three points during the program and also keep a daily physical activity log. This will help us learn how much movement and physical activity women get. For each week, these women will be paid $20 (for a total of $60 over the program).

Study Duration

Your participation in the intervention will last 12 weeks. The group session each week will be 2 hours long. The physical activity sessions, which you are encouraged to attend each week, will be 1 hour long. You may spend up to three hours a week in program activities (or up to a total of 36 hours over the 12 weeks). The interview and health assessment visits at the beginning and end of the program will take approximately 45 minutes to one hour each. The first one is a bit longer because we review the consent form and collect contact information from you.

Participants who cause serious disruption during the group sessions will be asked by the project director to stop coming to groups and will be discontinued from the study.

Possible Risks or Discomforts

Some of the questions you will be asked are personal. It is possible that some of the topics may make you uncomfortable. You can always feel free not to talk about an issue or you may take a break at any time.

The primary potential risk is a loss of confidentiality due to sharing of personal information during group activities such as the weekly intervention sessions. Participants will be reminded that, though confidentiality will be emphasized within the group, we cannot guarantee confidentiality and that this should be understood in choosing what information to share within the group.

There may be slight pain from the needle in your arm during your blood draw. A bruise may be left at the spot where the arm is stuck. There is a slight chance of swelling of the vein and/or blood clots, but this is extremely rare. All blood draws will be done by a medical professional.

In addition to the risks and discomforts listed here, there may be uncommon or previously unknown risks. You should report any problems to the researcher.

Benefits

You will receive free services for participating in this study. These include a one-on-one appointment with a registered dietician (nutritionist) and 16 free group sessions with a certified personal trainer. You will also receive free blood tests to screen for cholesterol levels and diabetes. You will get the results of your tests.

Payment for Participation

You will receive $25 cash for completing each interview ($50 total for "start now" group and $75 total for "start later" group). Women who are chosen by chance to wear the accelerometer, which records movement and physical activity, will be paid $20 for each week they complete (up to three; total $60).

Confidentiality

Many precautions have been taken to protect your information. Other personal information like your address and phone numbers will be stored separately from the answers you provide in any of your assessment forms. If the results of this study are presented at scientific meetings or published in a journal, no information will be included that could identify you or your answers personally.

Information from your health assessment will be used to create a chart for the study at Lyon-Martin Health Services. If you choose, the information from your health assessment can also be copied and included in your regular Lyon-Martin Health Services chart if you are currently a patient. These charts will be kept in a locked file cabinet and only accessible to study staff members and no other Lyon-Martin Health Services staff.

The Institutional Review Board (IRB) at RTI International has reviewed this research. An IRB is a group of people who are responsible for making sure that the rights of participants in research are protected. The IRB may review the records of your participation in this research to assure that proper procedures were followed. A representative of the IRB may contact you for information about your experience with this research. This representative will be given your name, but will not be given any of your confidential study data. If you wish, you may refuse to answer any questions this person may ask.

Future Contacts

We may wish to contact you about future studies. If you are contacted in the future, you will be able to make a decision about participating at that time. Your participation in any future studies is completely voluntary.

Your Rights

Your decision to take part in this research study is completely voluntary. You can refuse any part of the study and you can stop participating at any time. You can refuse to answer any question. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

Your Questions

If you have any questions about the study, you may call Alexandra Minnis at (415) 848-1323 at RTI International or Natalie Ingraham via Lyon-Martin Health Services at (415) 565-7667. If you have any questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature (or mark) below indicates that you have read (or been read) the information provided above, have received answers to your questions, and have freely decided to participate in this research, including to be audio-recorded if you participate in a focus group. By agreeing to participate in this research, you are not giving up any of your legal rights.

_____	_____
Date	Signature (or Mark) of Participant
	_____
	Printed Name of Participant

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above-named individual.

_____	_____
Date	Signature of Person Obtaining Consent
	_____
	Printed Name of Person Obtaining Consent