Project Title: Assessing the Feasibility of a New Prevention to Reduce Alcohol-related Sexual Revictimization of College Women
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Adult Consent to Participate in a Research Study

Title of research study: Prevention of Alcohol-related Sexual Victimization in College

Version Date: 07/11/2022

Investigator: Dr. Kathleen Parks

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you have indicated that you have encountered one or more unwanted sexual experiences and regularly consume alcohol.

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 research study is to develop and test whether a combined group and online intervention is effective in reducing rates of unwanted sexual experiences and improve health behaviors. The intervention is designed to help women learn skills to improve health behaviors and more effectively manage risky life situations. The results of this study may help reduce the risk of unwanted sexual experiences and improve health behaviors for young college women.

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

Participants in the Blue Wellness Project will be enrolled in this research study for a period of approximately 7 months, with the intervention period lasting about 1 week. We will ask you to complete online assessments prior to and following your intervention, and again approximately 3- and 6-months after completing the intervention.

The initial assessment will be administered prior to your first in-person intervention session. You'll be asked questions about yourself and your lifestyle including your alcohol use, dating behaviors, and unwanted sexual experiences You will then participate in a study intervention,

involving two in-person group sessions, approximately 1 week apart, and two individual online educational sessions.

The study interventions will provide you with information on improving your Health and Lifestyle or Managing High Risk situations. Each in-person session will be approximately 1.5 hours long and take place on UB's North Campus (Amherst). These in-person sessions will be audio recorded so that research staff can review the sessions in order to ensure that each session is presented consistently to all participants. These recordings will not be used for data collection and will be destroyed after they are checked for consistency. The 2 individual online educational sessions will take about 30 minutes each.

Immediately after the last in-person session, you will be asked to complete an online post-intervention assessment. Approximately 3- and 6-months after you participate in the group sessions, you will be asked to complete an online assessment. These assessments will assess your current drinking and dating behavior and health, and will ask you to provide your opinion about the intervention you received. These assessments will take about 20 min. each.

More detailed information about the study procedures can be found under ***"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?

Some people report discomfort answering questions or engaging in a discussion about their personal life in a group setting or on the questionnaires or other material you will be asked to complete.

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 in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include benefitting from health-, drinking- or dating-related information that you receive in the group sessions or online trainings.

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

Participation in research is completely voluntary. You may choose not to enroll in this study. If you choose not to enroll in this study, this will not negatively affect you at the University at Buffalo in any way. Your alternative to participating in this research study is to not participate.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Blue Wellness research team at 716-887-3307 (bluewellness@buffalo.edu) or Dr. Kathleen Parks, the Principal Investigator at 716-887-3301 (kparks@buffalo.edu) You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

How many people will be studied?

We expect to enroll about 100 people in this research study, here in this area.

What happens if I say yes, I want to be in this research?

This research study will be conducted at the University at Buffalo's North Campus (Amherst). You will receive an intervention designed to help women improve health behaviors or to identify and manage high-risk situations. Thus, you will receive either a Health and Lifestyle intervention or Managing High Risk intervention. The study intervention that you receive will be chosen by chance, like flipping a coin. Neither you nor the study staff will choose which intervention you get. You will have an equal chance (50/50 chance) of being given either intervention. You will not be told which intervention you are getting; however, the study staff will know. After completing your initial intervention, if you would like to receive the other intervention, you will have that option.

This project has *Pre-Intervention, Intervention* and *Post-Intervention* phases.

Pre-Intervention Phase

As part of the study, you will complete an online pretreatment assessment in which you will be asked about your alcohol use, health behaviors, dating experiences, unwanted sexual experiences, and other psychological factors. It will take approximately 30 minutes to complete.

Intervention Phase

The intervention will occur over a 1-week period. You will be asked to attend 2 in-person group sessions, each lasting about 1.5 hours that are spaced approximately 1 week apart. The in-person sessions will include a brief set of interactive measures that you will be asked to complete on a laptop computer, followed by a presentation and group discussion. In between these group sessions, you will be asked to complete 2 individual online educational sessions on your own computer or smart phone, that will provide you with important information. Each of these online sessions will take about 30 minutes to complete. In total, the study intervention phase should take about 4 hours of your time.

Post-Intervention Phase

After you have completed the second group session, you will be asked to complete a post-intervention assessment, and two follow-up assessments approximately 3- and 6-months after completion of the last group session. All of these assessments will be done online and should take approximately 20 minutes each to complete.

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

If you take part in this research, you will be responsible for completing the initial online assessment, attending the 2 in-person group intervention sessions, completing 2 online trainings, and completing the post intervention and 2 follow-up assessments online.

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

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

If you decide to leave the intervention after it has begun, we would still like you to participate in the research assessments.

You have the right to refuse to answer particular questions during the assessment surveys and during the group sessions. If you choose to withdraw from participation, your data up until that point will be retained by the researchers but no further data will be collected.

If you decide to leave the research, please contact the research staff so that Dr. Parks can speak with you to ask if you are withdrawing from all phases of the study or just the intervention phase and insure that we fully understand your desire to withdraw.

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

Some people report discomfort answering questions or engaging in a discussion about their personal life in a group setting or during the surveys or other material you will be asked to complete. You may experience this type of discomfort or negative memories when completing the surveys and participating in the group sessions. In our previous research, this has happened less than 10% of the time. It is fine for you to participate a lot, some or not at all in the group sessions.

While a breach of confidentiality may be a risk, we describe below the detailed procedures that we use to ensure your confidentiality as a research participant. Breach of confidentiality of your personal data is highly unlikely given these procedures. The greatest risk to breach of confidentiality is through the group discussions, however, during these discussions you will not be asked to share any of your own personal information.

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 or education records, to people who have a need to review this information. We cannot promise complete secrecy. Group members will be instructed that the discussions that occur during the group sessions are to remain confidential, that is, that they should not discuss the information from the group sessions in a way that identifies other members of the group. Organizations that may inspect and copy your information include the IRB, the Department of Health and Human Services that is funding this research, and other representatives of this organization. The sponsor, monitors, auditors, and the IRB will be granted direct access to your records to conduct and oversee the research. By signing this document, you are authorizing this access.

Your information collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

We may publish the results of this research. However, we will keep your name and other identifying information confidential; they will not be used in any published materials.

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.

All information you provide during your involvement in the project will be strictly confidential. Only an ID number will appear on data files. A list linking your name and ID number will be kept in a separate password protected file on the University at Buffalo's secured Box Drive. Only authorized project personnel will have access to the data collected. Your identity will not be revealed in any description or publication of this research.

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

In the event that you inform project staff of life-threatening actions such as thoughts or intention to harm yourself (i.e., suicide) or others (i.e., homicide), elder abuse, child abuse or intent to drive while legally intoxicated, the researchers may need to inform the appropriate authorities.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care providers, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from this research study without your approval. Possible reasons for removal include failure to disclose information at the screening or pre-intervention assessment that would have rendered you ineligible for the study, the presence of psychological symptoms that make it very difficult for you to participate in the study, or failure to follow through on study requirements.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

Who is paying for this research?

This research is being funded by the National Institute on Alcohol Abuse and Alcoholism at the Department of Health and Human Services.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you for the research assessments, however, <u>you will not be paid to attend the group sessions or complete the online sessions</u>. You will be paid as follows: $30 for completion of the pre-intervention assessment; $30 for completion of the post-intervention assessment, $40 for completion of the 3-month assessment and $50 for completion of the 6-month assessments to compensate you for your

time and effort. You will receive these payments through a Focus Blue Card that you will receive at the first in-person group session.

The Study Card Program Group, under The University at Buffalo's Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a Reloadable Focus Blue Card, which is a prepaid debit card. When you complete a visit, the amount outlined above will be automatically approved and applied to your U.S. Bank Focus Blue Card balance. After you attend the first in-person group session or after you complete each assessment survey (i.e., post-intervention), your payment will be available no later than the next business day. The Study staff will provide you with additional information about how the bank card works. In order for U.S. Bank to be able to reimburse you using the Focus Blue Card, only your first and last name (required), physical address (required), and birth date (required) will be shared with U.S. Bank. The Study Card Program Group, under The University at Buffalo Office of Financial Management, will also have access to this information. By agreeing to use the U.S. Bank Card service, you are authorizing the release of this information to U.S. Bank and authorizing access to this information to Study Card Program Group, under The University at Buffalo Office of Financial Management. No protected health information will be shared with the U.S. Bank or the Study Card Program Group. **Please note that a fee of $2 per month will be deducted from your card balance after 365 days of card inactivity. Your card will be considered activated as of the day you receive it.**

Consent for Audio-recording

☐ By initialing, I give permission to be audio-recorded as part of the in-person group discussions.

Signature Block for Capable Adult

Typing your name below acts as your signature documenting your permission to take part in this research. By signing this consent form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Typed Name	Date