

Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study

Randomized Clinical Trial: Stage IB

Boston University School of Social Work

Principal Investigator: Hyeouk Chris Hahm

You are invited to participate in the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study conducted by Dr. Hyeouk Chris Hahm at the Boston University School of Social Work (BUSSW).

Your participation in this study is entirely voluntary. Please read the information below and ask any questions you may have before deciding whether or not to participate. We are inviting you to participate in this research because we feel that your experience as an Asian-American woman can contribute much to our understanding and knowledge of mental and sexual health in this population.

PURPOSE OF THE STUDY

Short-term goal of the study: (1) To adapt a program for Asian-American women that educates women on safer sex practices, mental health, and abstinence from substance use; (2) to determine how practical and safe this new program is in a pilot randomized clinical trial (RCT); and (3) to test if this program is effective.

Long-term objective of the study: It is our aim that these efforts will ultimately lead to the reduction of sexual risk behaviors, suicidality, and psychiatric symptoms among Asian-American women.

If you are interested in participating in the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, you will be asked to complete a screening and assessment to determine your eligibility.

PROCEDURES

- There is a set of eligibility requirements that each woman must meet in order to participate in this study. These requirements are for research purposes only.

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IRB Protocol Number: 3177

Consent Form Valid Date: 8/11/15

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- To see if you meet the eligibility requirements, we ask that you complete an eligibility screening that will take about an hour to complete. This in-person preliminary screening and assessment will be audio recorded. The recording will be safely stored in a password-protected server and carefully assessed by researchers. If you are eligible, you will be notified several weeks later whether or not you have been selected for the study.
- If you meet all of the eligibility criteria:
 - We will contact you to ask you to confirm your interest in participating in the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study.
 - You will be randomly selected (by chance, i.e. through a coin toss) to participate in eight 1 hour and 45 minute group sessions to learn about and discuss mental health, sexual health and substance use with other Asian American women ages 18-35.
 - You will also be asked to participate in a Focus Group Feedback Discussion after the eight sessions. This meeting will provide you the opportunity to comment on the effectiveness of the AWARE intervention and discuss the potential improvements that you have noticed as a result of the intervention.
 - Once we have determined that you would like to enroll in the study, we will assign you to one of the groups in the study. There will be several groups that will be conducted, so you may have to wait several months before your group starts. If you are assigned to a group that has to wait, you will be contacted by phone at 3 weeks after assignment and at 6 weeks after assignment to check on your health status during that time. During the waiting period, you are also allowed to participate in any other form of mental health treatment.
 - If you are not eligible, we will let you know. If you are not eligible and you give us permission, we will contact to you in the future, to see if you would be interested in participating in future studies.
- If you are selected by chance to participate in the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, here is a list of important things about participation in the study that you should know:
 1. Participation includes 8 group sessions that will meet once a week for one hour and 45 minutes.
 2. Participation is voluntary and if you do not wish to answer any particular question, or you decide to drop out, or you do not want to be part of this study, there will be no penalty for choosing those options.
 3. If you do decide to participate you will receive \$26 for each session that you attend, up to a total of \$208. You will also receive \$4 for transportation costs associated with attending the sessions.
 4. You will also be paid \$20 for a 45 minute baseline evaluation that will be conducted at a separate appointment prior to the start of the study. You will also receive \$4 for transportation costs associated with attending the evaluation.
 5. There will be 10–12 women in the group which will be led by a trained therapist.

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6. You will be assigned to one of the groups in the study. Multiple groups will participate in the study, so participants may have to wait several months before their group begins the study.
7. The group will take place at BUSSW in a private, comfortable meeting room.
8. The group will discuss sexually transmitted diseases and safe sex practices, mental health, and substance use and will seek your thoughts about these and other similar topics concerning Asian American women.
9. While you are participating in the 8 weekly group sessions, you will receive daily text messages from the group leader every day.
10. You will be required to keep a weekly Adverse Events Log.
11. Participation will include meeting one-on-one with a research team member or access a secure website to complete 75 minute outcome assessments upon completion of the last session and 3 months after the last session. You will receive reminder e-mails about these outcome assessments. You will receive an additional \$20 for completing each of the two outcome assessments. You will also receive \$4 for transportation costs associated if you are attending the assessments in-person. Compensation will be provided in cash if the assessment is completed in-person or in the form of a gift card if conducted online.

POTENTIAL BENEFITS OF PARTICIPATION

There are no benefits to you from taking part in this research. Your participation and feedback will help the research community to understand how mental health, sexual health, and cultural issues affect the health and health behaviors among Asian American women.

POTENTIAL RISKS AND DISCOMFORT

Some of the questions we may ask and topics we may cover in the group sessions may cause feelings of discomfort. In addition, some of the questions in the screening and assessment interview may also cause feelings of discomfort.

- A trained researcher will administer the screening and assessment in a private room at BUSSW. The researcher will remind you prior to the screening and assessment that you may stop at any time, for any reason, without negative consequences. You do not have to answer questions you do not wish to answer.
- A trained therapist will conduct the 8 group sessions in a private room at BUSSW. At each session you will be reminded that you may stop at any time, for any reason, without penalty. You do not have to answer questions that you do not wish to answer. The therapist is trained to help you with uncomfortable feelings and will also be able to advise and/or provide you with local resources of social services and support should you need further help.
- Text messages will be sent once a day, at around noontime with stories or messages that might cause uncomfortable or negative feelings.

PROTECTION OF PRIVACY

AWARE Consent Form

Last modified March 29, 2013

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It is our utmost responsibility to keep any and all information gathered during the study confidential.

- All the information you provide will be used for research purposes only.
- Your name will be associated with an ID number.
 - The only place where we obtain your name is on this consent form.
 - Your name and ID number will be linked in a password-protected computer document to which only the PI and a limit number of her staff will have access.
 - Your name will not appear on any publication about this research.
 - Your name will not be associated with your answers.
 - It will not be possible to identify you even using groups of answers.
 - Any publications or reports will present information about groups of participants (for example, people aged 21 and over).
 - Your name will be shared in group sessions with the therapist and other participants to promote a comfortable environment. However, anything that is discussed during the group session and your identity will be kept confidential.
 - The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.
- Individual scores on assessments will not be released to anyone, including participants.
- To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services.
 - This Certificate of Confidentiality means that we cannot be forced (for example, by court subpoena) to reveal any of the information that is gathered about you in any federal or state proceedings or local civil, criminal, administrative, legislative, or other proceedings.
 - Staff from the federal agencies funding this project, including the National Institute of Health and other DHHS agencies, may audit this program and see your personal information. Also, this Certificate does not mean that the Secretary of DHHS approves or disapproves of the project.
 - The 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.
 - Please note, however, that if an insurer or an employer learns about your participation, and you give your consent for them to receive research information, the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.
 - You should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or someone else such as instances of child abuse or elder abuse. For example, in the instance that you disclose thoughts about harming yourself or committing suicide, the research staff may ask you more questions about those thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself, the research staff may provide you with

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referrals for treatment, work with you to contact your personal physician, a trusted family member, and/or therapist to discuss your thoughts of harming yourself, or work with you on a plan that may include getting you to a hospital for safety.

- As a participant you may consent, in writing, to disclose information about yourself.
- We will design and use text messages that are closely tied with our weekly session topics to stimulate aspects of psychotherapy outside the weekly group sessions. We will utilize Doc Halo, a HIPAA-compliant secure mobile messaging system that has password-protection controls and has comprehensive privacy controls. Participants may opt to receive the messages through Doc Halo or elect to receive these messages through a regular SMS which will NOT be password protected. The overall mobile messaging system will consist of 2 components: (1) a text-message delivery/receipt platform; and (2) a research team member who can be reached for any technical problem or general questions related to the intervention. This system works for smartphones only. Participants without access to smartphones will be given the option to receive the messages through SMS or may choose not to receive these messages. The entire text communication will be through mobile messaging. We will send text messages (called "AWARE Stories") every day at noon, between the weekly group therapy sessions. We named these messages "AWARE Stories" because we will use actual quotes from API women chronicled in our AWSHIP qualitative data to match the upcoming week's core elements (see "Protection of Human Subjects" for examples). These messages will also include a brief summary of each week's content to reinforce the intervention lesson, a brief summary of the upcoming session, and reminders about the weekly group psychotherapy time. We will test whether satisfaction and utilization of AWARE Stories are correlated with group psychotherapy attendance. Please choose your response by marking "X" in a box below:

I would like to receive messages through the password-protected application Doc Halo.

I would like to receive my messages through a non-password protected SMS.

PARTICIPATION AND WITHDRAWAL

- You do not have to participate in this study.
- You do not have to answer any question that you do not wish to answer.
- If you decide not to participate, or if you decide to stop once you have started the study, there will be no penalty.
- The Principal Investigator reserves the right to withdraw you from the study if your drug and alcohol use, PTSD symptoms, substance abuse disorder, or/and overall psychiatric status become much worse than baseline for two consecutive weeks. This is to ensure that the study is not causing any harm to your health.

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Keeping the potential for a breach in confidentiality at an absolute minimum is a main concern for researchers. The collection of accurate data is essential to the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study success, and not only will be beneficial to the researcher, but will also provide Asian American communities with knowledge and tools necessary to address mental health problems and transmission of sexually transmitted disease within the population.

Compensation: If you are eligible to participate and you complete the study, we will pay you \$26 per session, \$20 per evaluation and \$4 transportation compensation in appreciation of your time, efforts, and energy. Compensation will be provided in cash for participant

Data storage: We will maintain a strict security system to prevent unauthorized access to the data. Audiotapes will not contain any names or identifying information and will be stored on computers. All precautions will be taken so that only Dr. Hahm and research personnel will have physical access to the computers where the data will be stored until downloaded to the SSW server. Each computer will be configured with secure BIOS to boot the computer and the access will be controlled by complex passwords associated with authorized users and with no obvious association to the dataset. The data will be stored on the SSW file server with access restricted to Dr. Hahm and her research personnel, using strong passwords, behind the BU campus Firewall. All data, including audiotapes, will be destroyed after analysis is complete.

Permission to contact about future studies: If you are not eligible for the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, or if you are not randomly selected to participate in the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, we may also conduct future follow-up studies. Do we have permission to contact you about future opportunities to participate in our research? Please choose your response by marking "X" in a box below:

- Yes, I am interested in participating in future studies; please contact me in the near future.
- I'm not sure if I'm interested in participating in future studies at this time. However, you may contact me in the future to ask for this opportunity.
- No, I am not interested in participating in future studies, so please do not contact me.

IF YOU HAVE ANY QUESTIONS OR CONCERNS

Please contact the Principal Investigator of Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, Hyeouk Chris Hahm, PhD, LCSW (617-353-3925) (hahm@bu.edu) with any questions or concerns you may have about this project.

Should you have any questions about your personal rights as a participant in Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, please contact Boston University's CRC Institutional Review Board (617-358-6115).

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Thank you for your time and your participation in this project.

Sincerely,

Hyeyouk Chris Hahm, PhD, LCSW
Principal Investigator
(617) 353-3925
hahm@bu.edu

If you agree to participate in this research project, please sign and date below.

Full Name (please print)

Signature

Date

Signature of Person Obtaining Consent

Full Name (please print)

Signature

Date

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