COVER PAGE

Official Study Title: Binge Eating Syndrome Treatment for Older Women (BESTOW)

NCT number: NCT05806788

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Concise Summary

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future**.** We are making a new program for binge eating among older adult women. Binge eating is when someone eats an unusually large amount of food in one sitting while feeling out of control of their eating at that time. Currently, most binge eating intervention studies include younger women, and there are no binge eating interventions designed specifically for older women (ages 60+). Because there is no research for a binge eating intervention ("program") for older women, the purpose of this study is to develop and evaluate a group program designed to help older women with their binge eating and improve their eating habits.

For more information, please see the *Why is this Study being Done* section below.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?

During this study, you will be asked to complete several questionnaires. The program involves 6 group sessions that will each last about 60-90 minutes (1 session a week over 6 weeks). Additionally, you will be asked to give your feedback on the program at the end of the study, 1 month after the study, and 2 months after the study. Benefits of this study include potential improvement in your eating behaviors as well as overall health and wellness.

If you do not wish to participate in this study, other options include seeking an evaluation from a psychologist or counselor, a nutritionist, or participating in another study.

For more information, please see the ***What will be done if you decide to be in the research*** section below.

3. How much time will I spend on the study?
The first assessment (today) is approximately 60-90 minutes. Each group session (6 total sessions – 1 per week over the course of 6 weeks) will be approximately 60-90 minutes. You will have home activities or skills to try in between sessions ("homework"). We will also ask you complete a questionnaire and interview right after finishing the program (within a week of completing the group program); this questionnaire will take approximately 15-30 minutes to complete, and the interview will be approximately 30-60 minutes. Additionally, you will be asked to complete a follow-up survey and interview both 1 month after the end of the program and 2 months after the end of the program; these questionnaires will take 10-15 minutes each and the interviews will take 20-45 minutes each.

4. Could taking part in the study help me and are there risks?
This study is considered to be minimal risk. However, due to the nature of the questions asked in surveys and topics discussed in groups, participants may experience feelings of distress in discussing these topics.

For more information, please *see* ***How could you or others benefit from your taking part in this study*** section below. For details and a list of risks you should know about, please see the ***What are the risks of participation in the research*** section below.

5. What else should I consider before I make my decision?
This is a 6-week program, so you may want to consider if you are able to commit to weekly sessions for 6 weeks (if you are not able to make a session, make-up sessions will be offered).

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Consent to be part of a Research Study
To be conducted at
University of Texas Health Science Center at San Antonio (UT Health San Antonio)

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study is Dr. Lisa Smith Kilpela, PhD, of the Department of Medicine at UTHSCSA.

Funding

The National Institutes of Health (NIH)/ National Institute on Aging (NIA), a federal agency that promotes scientific research, is funding this study. This organization is providing money to UTHSCSA so that the researchers can conduct the study.

Purpose of this study – "Why is this study being done?"

The purpose of this study is to develop and evaluate a group intervention ("program") designed to help older women (ages 60+) improve eating behaviors, particularly binge eating. Binge eating is when someone eats a large amount of food in one sitting, while feeling out of control of their eating at the time. We want to gather feedback from older women about this program (e.g., what works, does not work, what is missing) and see how women respond to this program. How women feel about their eating can also impact other aspects of their lives, such as physical and mental health. So, we are also interested in the effect that participating in the study has on participants' health and wellness, such as mood.

You are asked to participate in this research study for a new program to help with binge eating that is designed for older adult women. Currently, most research studies include only younger people in treatments for eating disorders, and there is no binge eating treatment designed specifically for older women. Some women may choose to seek one-on-one therapy or nutritional counseling to help with their eating issues. Because there is no research for a binge eating program for older women, this study will help to develop and evaluate a new group program for older women experiencing binge eating.

The researchers hope to learn whether this program helps women develop healthier eating habits and how it may change the way women think about themselves and their health behaviors, broadly.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are an adult woman who is at least 60 years of age, who has experienced binge eating (i.e., eating an unusually large amount of food in one sitting and feeling that your eating was out of control at that time) at least weekly over the past month, and who has expressed interest in participating in a new program using group sessions to help with your eating behaviors.

This study will enroll approximately 25 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 7 in-person visits: 1 visit for consent and taking the first survey (this current visit), and then 6 group sessions. You will be asked to attend an additional 3 visits (in-person, by phone, or HIPAA compliant zoom) with the researchers or study staff. All procedures described below will be only for research purposes.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study.

- **Screening Procedures** - After consent, we will administer the Mini-Mental State Exam (MMSE) which consists of a series of questions to confirm your eligibility to participate. This will take approximately 5 minutes.
- The results of the screening procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Assignment to Study Groups

When it is determined that you are eligible for the study, you will be assigned to a group for the intervention based on how your availability matches that of other eligible women.

Study Procedures:

As a participant, you will undergo the following procedures:

Assessment Visit #1

This visit (today) is your 1st in-person visit for obtaining consent to participate. After consent, we will take your height and weight, waist and hip circumference, and you will complete a set of online questionnaires ("survey") through our secure online survey system, Qualtrics. This visit will take about 60-90 minutes (including taking the survey). The survey asks about your mood, how you feel about

your body, different parts of your health (e.g., behaviors, physical activity, and quality of life), and life experiences. We ask that you complete this survey while you are here with us for your first visit. You may complete the survey on a provided UT Health laptop or you may also complete this survey on paper instead and our researchers will collect upon completion. If you do not have time after completing the consent form, you may complete the survey at home. If you do so:

- We will provide a direct link for you to access the questionnaire by email. We have a way to send this by secure email. At your consent visit (today), we will confirm the email address you would like to use to receive the link, and we will send it while you are here today. If you would like, we can walk through logging into the survey. If you do not have an email address, we will give you a link to use and show you how to use the link to access the survey.

Group Intervention ("Program"): The Binge Eating Syndrome Treatment for Older Women (BESTOW)

After you have completed your first visit and survey, you will come in for your first scheduled group session for the BESTOW program. The study team will clearly communicate with you the exact dates and times of the sessions. You will be asked to attend a group session once a week for 6 weeks (for a total of 6 group sessions). Each group session will last approximately 60-90 minutes. Groups will include 3-6 women. Once the first session begins, this becomes a *closed group*, meaning no new persons will be added to the group for the rest of the program. Your group will include the same women throughout the study. The goal of the BESTOW program is to help women improve their eating habits and to stop binge eating. The BESTOW program involves discussions as well as written and behavioral activities, such as monitoring your stomach feelings before and after you eat, identify coping skills, plan for how you can use coping skills when you feel cravings but are not actually hungry, and thinking about your long-term goals for health and wellness. You will also be asked to complete activities, or 'homework,' in between sessions that will help to stop binge eating and to improve eating habits. Examples of homework include monitoring your fullness, using the coping skills and plan that you made during a session, and reading resources for healthy eating. All group sessions will be audio recorded and transcribed to be rated for "adherence," "competence," and "fidelity," which means that we want to see how closely the BESTOW provider follows the BESTOW program.

Assessment Visit #2

At the end of your last group session, you will be asked to complete a 2nd survey (Assessment #2). This survey will be very similar to the 1st questionnaire you completed in the 1st assessment visit. You will complete a set of online questionnaires through our secure online survey system, Qualtrics, that asks about your mood, how you feel about your body, different parts of your health (e.g., behaviors, physical activity, and quality of life), and life experiences. You may also complete this survey on paper instead that our researchers will collect upon completion. This survey will take approximately 30 minutes to complete. If you need to leave immediately after the group session ends and complete the questionnaire later, you may do so. We ask you complete the questionnaire online within 1-7 days of the last group session.

Also, as a part of Assessment #2, we will want to hear your feedback about the BESTOW program, so that we can learn more about how to make it better, or to add or remove any parts of the program. This interview will happen within 0-7 days after the last group session, and you will be asked to come back to UT Health for this session OR talk by phone or Zoom (based on your preference) with Dr. Lisa Smith Kilpela. During this interview, you will be asked to provide feedback on the intervention.

For example, what was helpful to you? What was not helpful? What was missing? This interview will be approximately 30-60 minutes, and it will be recorded so that we can keep track of the recommendations to change or keep parts of this new program. The recordings will be stored securely, and we will not use your name or personal information to store the records (see below for details).

Assessment Visit #3
Approximately 1 month after your last BESTOW session, you will be asked to complete a shorter online questionnaire, asking questions about your mood and different parts of your health (e.g., behaviors, and quality of life). We will provide a direct link for you to access the questionnaire by secure email. If you do not have an email address, we will give you a link to use and show you how to use the link to access the survey, or we can mail you a hard copy to complete and return to us.

Additionally, you will be asked to complete another in-person interview with Dr. Kilpela. You may also complete this interview via phone or Zoom (again, based on your preference). This interview will check-in on how you are doing since the BESTOW program ended and help us learn any new feedback about the program that you may have after having been out of the program for 1 month. This interview will be approximately 20-45 minutes.

Assessment Visit #4
Approximately 2 months after your last BESTOW session, you will be asked to complete a final online questionnaire, asking questions about your mood and different parts of your health (e.g., behaviors, and quality of life). We will provide a direct link for you to access the questionnaire by secure email. If you do not have an email address, we will give you a link to use and show you how to use the link to access the survey, or we can mail you a hard copy to complete and return to us.
Additionally, you will be asked to complete a final in-person interview with Dr. Kilpela. You may also choose to complete the interview by phone or Zoom instead. This interview will check-in on how you are doing since the BESTOW program ended and help us learn any new feedback about the program you may have. This interview will be approximately 20-45 minutes.

Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. You will be audio recorded by the conferencing platform being utilized for virtual interview (i.e., Zoom platform). Our Zoom account is HIPAA-compliant, but we cannot guarantee privacy and confidentiality due to the nature of the research environment.

In summary:
This study includes:

- Assessment Visit #1 (Today!)
    - Consent
    - 1st survey
- BESTOW Group Sessions
    - 1 session a week for 6 weeks (6 total sessions); each session 60-90 minutes
- Assessment Visit #2 (In-person OR Virtual)
    - At the END of Session #6:
        - Complete another survey (like an exit survey)
    - Within 0-7 days after the last BESTOW session, you will be asked to complete a phone interview with Dr. Kilpela to get your feedback on the intervention (30-60 minutes)

- Assessment Visit #3 (In-person OR Virtual)
    - 1 month after the last BESTOW session, you will be asked to:
        - Complete a follow-up survey
        - Complete a follow-up interview (20-40 minutes)
- Assessment Visit #4 (In-person OR Virtual)
    - 2 months after the last BESTOW session, you will be asked to:
        - Complete a final survey
        - Complete a final interview (20-40 minutes)

The research team would like to communicate with you regarding your participation via text message. In order to do this, we will share your name and phone number with Twilio. Standard text messaging rates will apply if you do choose to receive the text messages.

Please indicate your willingness to receive study-related text messages:

□ **Yes,** I agree to receive texts from the research team
□ **No,** I do not agree to receive texts from the research team

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for mental health care when your participation in this study ends.

Future Use of Your Information Collected as Part of Your Participation

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

Risks – "What are the risks of participation in the research?"

Your participation in the study should not subject you to any physical risk or harm; however, there are some risks to participation in the research. Because the questionnaires and interview deal with personal issues, you might be subject to some stress. If you need help as a result, it will be offered to you. You may contact the researchers for more information.

Risks from the specific research procedures (interventions, or procedures)

There are risks to taking part in this research study. Be sure to tell study staff immediately about any negative effects that you have while taking part in the study.

The following section will describe the risks related to your participation in this research study.

Assessment Visits

Risks and side effects related to the questionnaires and interviews:

Less Likely and Not Serious

In 100 people, approximately 10-20 may have:

- Boredom or frustration from completing the questionnaires
- Mild discomfort or stress from filling out questionnaires and answering questions about personal issues, such as eating habits, body image, mood, and health. If you feel uncomfortable answering questions, one of the investigators will speak with you to help clarify your doubts. Your responses will be kept confidential. You do not have to respond to any question that you do not feel comfortable answering.

Rare and Serious:

In 100 people, less than one may experience

- Breach of confidentiality if your information were accidentally released to individuals outside of the research team. The researchers have taken steps to keep your personal and identifying information strictly confidential. We will use a HIPAA-compliant Zoom account or your telephone or computer to do the interview. Audio recordings will be stored using a de-identified research code. The survey program is a part of a secured system at UT Health SA. We will give you a study ID code that you will use when you complete the survey online, and we will not record your name on the survey. The researchers have taken precautions to store the research information in a secure location and will not record your name or identifying information on the research data that are collected. Once the audio recordings are de-identified, transcribed and verified, they will be destroyed.
- Due to the use of online conferencing systems, your privacy and confidentiality are not guaranteed.

BESTOW Program

Risks and side effects related to participation in the group program:

Less Likely and Not Serious

In 100 people, approximately 10-20 may have:

- Mild discomfort or stress from attending a group program with other participants.
- Inconvenience with timing of attending program sessions.

Rare and Serious:

In 100 people, approximately 3 to 10 may have:

- Feelings of anxiety and stress from attending a group program with other participants.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures. There is no risk to you if you do not complete the withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
The possible benefit of your participating in this study is improving and feeling more in control of your eating habits. This may help you feel better in other ways that are good for your health and wellness. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"
There are other options available to you. Your other choices may include:
There are many other options available to you, but some choices may include:
- Seeking an evaluation from a psychologist or counselor
- Seeking care from a nutritionist or dietitian
- Seeking health care from your doctor or healthcare team
- Participating in another study

Payments – Will there be any payments for participation?
The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of:
- Assessment Visit #1 (1st survey) - $20
- Assessment Visit #2 (exit survey and interview) - $30
- Assessment Visit #3 (1-month follow-up survey and interview) - $30
- Assessment Visit #4 (2-month follow-up survey and interview) - $30

Your name, address, and date of birth will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

In addition to the compensation on the card, you may also elect to receive study-related messages (phone and/or email). These messages will contain information confirming that money has been loaded onto your card. You may also receive reminder messages with information about your next appointment with researchers or study staff.

Please indicate your willingness to receive study-related messages:

- □ **Yes,** I would like to participate (please select the best method(s) for communication)
  - Cell Phone (text messages)
  - Email
- □ **No,** I choose not to participate

Costs – Will taking part in this study cost anything?

There are no costs to you for taking part in this study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: information that is collected during your participation in the study including your medical diagnoses and treatment history; information you give us during your participation in the study from questionnaires, and interviews; and demographic information like your age, race, ethnicity, marital status, and the years of education you have completed.

We will get this information by asking you during your participation in this research study.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The collaborators with the research team, the Clinical Research Core of the San Antonio Claude D. Pepper Older Americans Independence Center (OAIC)
- The members of the local research team
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Health Science Center at San Antonio.
- Twilio texting platform

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location, or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name to identify your health information. Code numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of UTHSCSA for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Lisa Kilpela, UTHSA, Department of
Psychiatry, MC 7792, 7703 Floyd Curl Drive, San Antonio, TX 78229. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access
to your PHI for seven years after the study ends. After this time, it will be destroyed.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Lisa Kilpela, PhD can be reached at 210-450-8121

If primary is not available, contact
[redacted]

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UT Health San Antonio, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

Please indicate whether you give your permission to be videotaped or audio recorded.

☐ Yes

_____ _____

Initials of participant or individual authorized to consent on behalf of the participant Date

☐ No

_____ _____

Initials of participant or individual authorized to consent on behalf of the participant Date

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐Consent and authorization were obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.

The specific means by which the subject communicated agreement to participate was: _____