

# Texas A&M University Human Research Protection Program

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## Informed Consent

**Study Title:** Comparison of a telehealth versus in-person intervention for adults endorsing binge eating

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**Sponsor:** Texas A&M University

### Why am I being asked to be in this study?

Research studies are done to help find better ways to help people or to understand how things work. You are being asked to participate because you showed interest in our study after reading about the study online or from a flyer. You are also being asked to participate because you are over the age of 18 and have felt you can't control what or how much you are eating.

### Why is this study being done?

People often find comfort in food. Most people find themselves eating more than they normally would every once in a while, or on special occasions. Some people feel like they have lost control of what they are eating and cannot stop, even when they are uncomfortably full. At first, they may think that eating the food will give them comfort or stop them from feeling upset. Often, it does the opposite. This type of eating can cause people to feel physically uncomfortable, guilty, embarrassed, nervous, or sad.

The COVID-19 pandemic has changed the lives of many Americans in different ways. One change it has led to is a switch to speaking with others on virtual platforms, like Zoom or Skype. Many people had to visit their doctor over one of these platforms during the years 2020 or 2021. We want to understand whether it would be helpful to meet with therapists over Zoom or in-person to help people who have that difficult time keeping control over their eating. To do this, you will be randomly assigned to an eating intervention that will take place either online or in-person.

### Where will this study take place?

If randomly assigned to the in-person group, sessions will take place at the TAMU Psychology Clinic on the Texas A&M University campus in College Station, TX:



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4235 TAMU  
Milner, Suite 101  
College Station, TX

Go to: <http://aggiemap.tamu.edu/>

Type / click: Northside Parking Garage (NSG)

Type / click: Milner Hall (MILN) — TAMU Building 0420; 425 Ross St., 77843-4258

If assigned to the online group, you may participate anywhere you'd like as long as you are in Texas, and situated in a quiet, private space.

### **How long will the research last?**

The bulk of this research study will take place over 10 weeks. Before beginning the intervention, we will ask to meet with you over Zoom to review the consent forms, answer any questions about the study, and orient you to features on Zoom. Since we will also be recruiting other participants for this study, there will be, on average, a 1-4 week gap between the consent session and the first session of the study. This is to ensure that we have enough participants for each group. We understand this can be frustrating. We will provide all participants with a separate handout containing local resources for individual psychotherapy and online support groups at the end of the consent session. You may also choose not to take part in the study at any point in time.

### **What will I be asked to do in this study if I agree to participate?**

Your participation in this study will last approximately 10-14 weeks (depending on when you are assigned to a group). Participation starts with a brief training (15-45 minutes) on how to use Zoom to answer the questionnaires, led by 1-2 members of the research staff. You will be provided a handout explaining the study and the week-to-week agenda for the group sessions during the first meeting over Zoom. During this time, you will be guided through this consent form, be oriented to features on Zoom, and learn more about our study. You will also be asked for your preference for a day and time for the group based on a few options. Within the, on average, 1-4 week gap after this consent session mentioned earlier, you will receive an email or phone call about the group you will be asked to participate in (either in-person or online) and the day/time it takes place. You will also be sent reminder emails prior to each session.

The first study visit (**Session 1**) will be attended online and will be scheduled based on your availability. It will last approximately 2 hours. At this time, we will provide more information about the treatment provided to you in this study, and ask you to complete a set of questionnaires. These questionnaires will ask you about your eating habits, emotions, and ways



you think and feel. After this session, we will ask you to participate in eight, 1-1.5 hour weekly group sessions (**Sessions 2-9**), where you will learn new skills to manage your emotions. At the beginning of each session, you will be asked to fill out two questionnaires. Lastly, during the final session (**Session 10**), you will be asked to participate in a group mindful eating and meal activity, which includes eating a meal provided for you by our staff (e.g., Blue Baker; the meal is chosen by you). After the session is over, we will ask you some questions about your experience in the group sessions and ask you to complete another set of questionnaires. This session will take approximately 2.5 hours. The exit interview will be audio-recorded.

The majority of the weekly sessions will be attended by you and other group participants either online through Zoom or in-person at the TAMU Psychology Clinic. If you are selected to participate in the online group, you must email your homework assignment to one of the group facilitators prior to the start of the session. If selected for the group attending in-person, you will be asked to turn the assignment in to one of the facilitators before the start of the session.

Your participation in the group sessions and completing the questionnaires are all for research purposes only. None of these procedures are standard of care (in other words, they would not happen if you were not in the study). We are happy to provide you with updates on the publication of the research generated from this study upon request.

### **What should I know about a research study?**

Your participation in this research is completely up to you. It is your choice whether or not to be in this research study. If you decide you do not want to participate, no one will be upset and there will be no consequences. You can ask all the questions you want before you decide.

### **What happens if I say “Yes”, but I change my mind later?**

If you say yes now, you can still change your mind later without any consequences. Your choice not to be in this study will not negatively affect your present or future status with Texas A&M University.

### **What does it cost to participate in this study?**

There are no direct costs for participating in this study. If you are selected for a group that attends sessions in-person, you will be reimbursed for parking. All session materials will either be emailed to you, provided in-person, or mailed or delivered to your home address (for the online group members for Sessions #2, 3, 4, 5, and 10).

### **What, if any, consequences are there to participating?**



You may feel uncomfortable or experience troublesome feelings or emotions while completing the questionnaires or attending the group sessions. You may refuse to answer any of the questions, and you may take a break at any time during the study. Referrals for psychological services will be available and provided if requested at any time.

Everyone will be asked to respect the privacy of other group members. All participants will be asked not to disclose anything said within the context of the discussion, but it is important to understand that other people in the group may not keep all information private and confidential.

After the final group session, we will ask you to fill out the same forms you completed before you started attending group sessions. Afterward, we will audio-record your responses to questions about your experience participating in the group. Having your voice recorded may make you feel uncomfortable. You may take a break during any part of the study. There is also a potential risk of loss of confidentiality if the research staff member, who is also asked to protect your confidentiality, listens to your audio recording and is able to identify you. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**Will any of the group sessions be recorded?**

No, we are not recording the group sessions, as we believe that may make some participants nervous and disrupt the treatment.

However, it is mandatory that we audio-record your responses to our brief, 15-30 minute interview at the end of the final session (**Session 10**). Most of your responses during this time will be free-response, and to fully capture your unique experiences, we would like to record your answers for our data analyses.

There will be no other time during the intervention that research staff will request to record your voice, face, or body. If there is any indication that a group participant is attempting to record any part of this study, this will immediately result in them being asked to leave the study.

Please indicate below that you understand that we will be asking to record your responses during the brief exit interview:



(Please initial)

\_\_\_\_\_

I give my permission for audio recordings to be made of me during the exit interview portion of this research study.

### **Could this research help me?**

Your feeling of a loss of control while eating may improve while you are in this study; however, this cannot be promised. The skills you learn as a result of your participation may also help you deal with emotional difficulties in other parts of your life. Additionally, being part of a group may help you feel more supported. The results of this study may help people with similar symptoms in the future by helping us to figure out the best way to help people pay more attention to when and why they feel a loss of control while eating.

### **What is the alternative to participating?**

If you do not choose to participate, there are no alternative group treatment options for loss-of-control eating in the Bryan/College Station area. However, we can provide referrals for individual psychotherapy, a local in-person/online support group for eating disorders, or regional/national online support groups.

### **What happens to the information collected for the research?**

The principal investigator will take steps to limit access to your personal information (including research study records). Information about you will be kept confidential to the extent permitted or required by law. People who have access to your information include the principal investigator, group treatment facilitators, and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) and entities such as the Texas A&M University Human Research Protection Program may access your records to make sure the study is being run correctly and that information is collected properly. The information collected as part of this research, even if personal identifying information (e.g., name, date of birth, address, phone number) is removed, will not be used or distributed for future research studies.

### **Will I receive any compensation for being in this study?**

You will receive a \$20 Amazon gift card by attending and completing 1-2 hour's worth of questionnaires for the first session (Week 2), and then another \$20 Amazon gift card for attending the last session of the study where we ask you to fill out the same questionnaires. In addition, based on your attendance in sessions and completion of homework assignments, you will be eligible to receive an extra \$100 gift card. One participant will be randomly selected, out of those that are eligible, to receive this \$100 gift card. The selection and distribution of the gift card will occur after all the groups in the study have completed their sessions.



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**Who can I talk to if I have questions or complaints?**

If you have questions, concerns, or complaints about the research, you may talk to a member of the research team for the Health Behavior Research Group at [hbrg.tamu@gmail.com](mailto:hbrg.tamu@gmail.com) or at 979-845-6152. If your questions, concerns, or complaints that are not being answered by the research team, you want to talk to someone besides the research team, or you have questions about your rights as a research participant, you may call the Texas A&M University Human Research Protection Program (HRPP) by phone at 1-979-458-4067, toll free at 1-855-795-8636, or by email at [irb@tamu.edu](mailto:irb@tamu.edu).

Given this study includes talking and answering questions about some very sensitive topics, we provide all participants with a separate handout containing local resources for individual psychotherapy and online support groups (if you have not received this handout before now, please ask the individual guiding you through this consent form to provide it).

We have some expectations for your participation in this study. Your participation in this research study may be stopped by any member of the research staff without your consent for any of the following reasons:

- If you miss more than 2 group sessions
- If you are actively suicidal, or require a higher level of treatment, such as inpatient care.
- (If selected for an online group) If you turn your camera “off” during a session and it is not due to either a privacy breach or from having received permission to do so by a group facilitator.

We will have a separate group therapy contract that will go into more detail explaining these expectations in **Session 1**.

**Consent**

You have read or have had read to you a description of the research study as outlined above. The investigator or their representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records

\_\_\_\_\_  
**Signature of Research Subject**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**



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**Printed Name of Research Subject**

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**Date**

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**Time**

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**Signature of Person Obtaining Consent**

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**Date**

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**Time**

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**Printed Name of Person Obtaining Consent**

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**Date**

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**Time**

