Duke University Health System

Consent to Participate in a Research Study
ADULT (multiple baseline study)
FlexED: A digital, gamified intervention

CONCISE SUMMARY

The purpose of this study is to test a digital intervention for individuals with body image distress. Eligible persons are adolescents and adults (between the ages 15-25) who have weight and shape concerns and are engaging in behaviors to try to change their body weight or shape.

Participants in the study are randomly assigned (like a coin toss) to a waiting period of 2 or more weeks. Participants complete eight 20-30 minute sessions of a game-like digital intervention using their mobile phone over about 8 weeks. The digital intervention presents a storyline with a main character that encounters challenging thoughts and feelings about their body. The player follows the character through the storyline and completes interactive exercises that teach skills to cope.

Participants also complete a clinical interview and questionnaires and other measurements, including heart rate and reaction time in response to body-related words and/or images every 2 weeks and one month after they complete the intervention.

Participants are in the study for up to 18 weeks (exact time in the study depends on the waiting period). During this time, participants are asked to not start any new treatment.

If you participate, you may benefit from the digital intervention, however, this cannot be guaranteed. There is some indirect benefit if this study leads to a new intervention to reduce the prevalence or impact of eating disorders. Risks of participation include psychological discomfort in considering your body image concerns, answering questions about your eating and weight concerns and encountering body image words and images. There is also the possibility of physical discomfort in wearing a heart rate monitor or the potential for loss of confidentiality or privacy, although all efforts will be made to prevent this.

You are being asked to take part in this research study because you are experiencing body image distress. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

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

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Rhonda M. Merwin, PhD will conduct the study and it is funded by the ***National Institute of Mental Health (NIMH)***. The sponsor of this study, ***NIMH***, will pay Duke University to perform this research, and these funds may reimburse part of ***Dr. Merwin's*** and her research team's salaries.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, ***Rhonda M. Merwin, PhD*** will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of the study is to test a new digital intervention for individuals with early signs of an eating disorder.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 24 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

- Clinical interview of eating disorder symptoms to determine eligibility for the study.
- Assessments including questionnaires about demographics (age, race etc.), psychological symptoms (anxiety, depression), body image, and eating and weight control behaviors, and measurement of heart rate and reaction time to body-related words and images.
- Eight 20-30 minute digital intervention sessions in which participants follow a character through a storyline and complete interactive exercises.

If you agree to be in this study, you will be asked to electronically sign and date this consent form. You will then complete some questionnaires and a clinical interview to confirm your eligibility for the intervention sessions. Because this is an early intervention study, individuals who meet full diagnostic criteria for anorexia or bulimia nervosa are not eligible. If based on the clinical interview, you meet full diagnostic criteria for one of these disorders, you will be provided with treatment resources and your participation in the study will end at that time.

If you continue in the study, you will first enter a waiting period during which time you will complete assessments, but not yet start the intervention. The duration of your waiting period will be randomly determined by a computer program (similar to a coin toss) but will be no longer than 6 weeks. Every other week, you will complete an assessment that includes questionnaires and computer-administered tasks that measure things like reaction time in response to body-related words or images. The assessment will take no longer than 45 minutes to complete. During some of these assessments, you will wear a heart rate monitor. You will come to Duke North Pavilion to complete the study assessments.

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At the end of your waiting period, you will start the intervention. The intervention is accessed through a website that you will visit on your digital device (e.g., smartphone) and complete at home. The intervention consists of 8 sessions and is self-paced (you complete them on your own timeline) but sessions are designed to be completed weekly and must be completed within approximately 8 weeks (at which time you will be scheduled for your final assessments). The sessions are game-like and use avatars, visual and audio effects to create a storyline of a main character encountering situations that generate difficult thoughts and feelings about their body. You follow the character through the storyline and complete interactive exercises to learn skills to manage these experiences. Sessions are approximately 20-30 minutes long.

After Sessions 2, 4, 6 and 8, you will be invited back to Duke North Pavilion to complete the questionnaires and computer-based tasks that you completed during your waiting period. You will do these same assessments one more time, approximately one month later.

An overview of the study timeline is provided in Table 1.

Waiting period (Up to 6 weeks)	Sessions 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8	1 month
	8 Weeks								
Bi-Weekly Assessments		Assessment		Assessment		Assessment		Assessment	Assessment

Table 1. Assessment and intervention schedule.

The website used in this study is built by Silversky 3D VR Technologies Ltd, a digital development company located in Cyprus. The website is accessed via internet browser on your phone. You may also choose to come to Duke to complete the sessions and the assessments using Duke computers/phones. Responses to the interactive exercises that you complete on the website will be stored on the server maintained by Silversky during the testing phase. You are asked to not enter any personally identifying information into the text fields when completing the interactive exercises.

As with any website that you visit or software that you download, there may be potential security risks and Duke cannot guarantee that the website/software is free of risk. In general, it is recommended that you run a current operating system (OS) on your computer or other device, review the privacy/security settings on your web browsers, run antivirus software, make sure that your connection is encrypted (look for the lock icon when you connect), and log off of websites when you are done. With mobile apps, it is important that you read the terms and conditions and be aware of what the app is being allowed to access on your phone. You may also choose to delete or uninstall the application.

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Participation in this study is voluntary. Refusal to participate or early withdrawal will involve no penalty or loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you may continue to receive care, but not as a part of this study. If you are a student or employee of Duke University, your participation or a lack of participation will not positively or negatively impact your performance evaluation or advancement. If you decide to participate, you can discontinue participation at any time. If you wish to withdraw from the study, we ask that you do so in writing by sending a note to Dr. Merwin at rhonda.merwin@duke.edu.

HOW LONG WILL I BE IN THIS STUDY?

If you participate in this study, you will be enrolled in this study for up to 18 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

Risk of loss of confidentiality
As with any research, there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is an additional risk for loss of privacy associated with digital or online interventions.

Risks associated with psychological assessments
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. Some of the assessments may trigger upsetting thoughts and feelings about your body. You may stop your participation in this study at any time.

Risks associated with eye-tracking software/hardware
The Tobii eye tracker emits pulsated infrared light and contains magnets. Certain medical devices are susceptible to disturbance by IR light, radiation, and/or magnetic fields. As a result, Tobii Spark eye - tracking hardware and software may cause negative effects in people who have a history of epilepsy, seizures, or who have a pacemaker or other implanted medical device. If you have any medical conditions that may make it unsafe for you to complete tasks involving eye tracking, you will either complete the task minus eye-tracking or skip the task entirely.

Risks specific to mobile apps
Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow

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unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

There may be risks, discomforts or side effects of participating in this study that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are not any direct benefits to participation, although the digital intervention may be helpful in managing your body concerns or improve your relationship with your body, this cannot be guaranteed. Your participation may have indirect benefits by helping to develop a new intervention that may reduce eating disorder symptoms or prevent the development of an eating disorder.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you can seek treatment from a healthcare provider.
Please talk to your doctor about this and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related procedures may be reported to the National Institutes of Mental Health (NIMH) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of NIMH, the Duke University Health System Institutional

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Review Board and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

Studies funded by NIMH are subject to their data sharing policy. This policy requires that data are deposited in the National Institute of Mental Health Data Archive (NDA) for collaborative science and discovery. The NDA uses the GUID (Global Unique Identifier) software tool to de-identify you (separate your data from your personally identifying information) but also link your data to data from other research studies you may have participated in that also use the GUID system. To receive this number, a study staff member will go to a secure internet website on a computer at the research clinic and enter information about you: your first, middle and last names at birth, any suffixes (Jr., III, etc.), your date of birth, name of the city where you were born, and your country of birth. Once your GUID is created, your personal information is deleted.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be

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destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study (NIMH). If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There are no costs associated with participation; however, if you use a personal cell phone or other mobile device to run the digital program, this may impact your WiFi bandwidth or data usage. If you do not have an unlimited data usage plan with your cell phone provider you should take into consideration the data usage required to avoid incurring incidental charges through your cellular carrier.

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Merwin. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The study sponsor, NIMH, has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

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We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
You will receive $25 for completing the enrollment visit and clinical interview, and for each bi-weekly assessment during your waiting period. You will receive an additional $25 for each of the assessment visits that you complete during the intervention period and $25 for completing the one-month follow-up assessment, for a total possible compensation of $200-$250.

You will receive parking vouchers to cover your parking at Duke North Pavilion.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact ***Rhonda M. Merwin, PhD*** at ***(919) 681-7231*** during regular business hours and at ***(919) 244-8801*** after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Merwin in writing and let her know that you are withdrawing from the study. Her mailing address is Pratt Street, Durham NC 27705. You will be provided with a list of treatment resources (local providers who work with eating disorders).

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The

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sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include a pattern of participants' conditions worsening. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of the clinical trial associated with this study will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Merwin at (919) 681-7231 during regular business hours and at 919-244-8801 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time