Developing an Optimized Conversational Agent or "Chatbot" to Facilitate Mental Health Services Use in Individuals with Eating Disorders

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NCT04806165

February 1, 2021

APPENDIX

PART I: PROTOCOL

Developing an Optimized Conversational Agent or "Chatbot" to Facilitate Mental Health Services Use in Individuals with Eating Disorders

Study 2

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VERSION 3
February 1, 2021

TABLE OF CONTENTS

A. List of Abbreviations

DSM-5	The Diagnostic and Statistical Manual of Mental Disorders
ED(s)	Eating Disorder(s)
EDE-Q	Eating Disorder Examination Questionnaire
MI	Motivational Interviewing
MOST	Multiphase Optimization Strategy
NEDA	National Eating Disorders Association
NIH NIMH	National Institutes of Health National Institute of Mental Health
PI	Principal Investigator
SUS	System Usability Scale
SWED	Stanford-Washington University Eating Disorder Screen
USE	Usefulness, Satisfaction, and Ease of Use Questionnaire

B. Introduction

B1. Study Abstract

Eating disorders (EDs) are serious mental illnesses associated with high morbidity and mortality, clinical impairment, and comorbid psychopathology. Although evidence-based treatments for EDs have been established, the treatment gap is wide. Indeed, <20% of individuals with EDs receive treatment. We need a novel solution not only to identify individuals with ED but also to encourage mental health services use and to address treatment barriers. We propose a research agenda to design a conversational agent or "chatbot" that is optimized to increase mental health services use among individuals with EDs through such features as: 1) providing a personalized recommendation for seeking intervention; 2) engaging the user in motivational interviewing to overcome barriers to care; 3) repeated check-ins with the user to encourage follow-up with care; and 4) education on the seriousness and consequences of EDs. Study 2 will utilize a randomized optimization trial with adults who have completed screening on the National Eating Disorders Association (NEDA) website and screen positive for an ED but are not in treatment to determine chatbot feasibility and to generate data on the effect of the chatbot on motivation for treatment and mental health services use at follow ups. This trial will employ the Multiphase Optimization Strategy framework, using a 2^4 full factorial design, to randomly assign participants to a combination of the three proposed intervention components (n=16 conditions) to isolate the active ingredients. Results from the proposed study will be used to optimize the chatbot, which will then be tested in a subsequent R01 randomized controlled trial.

B2. Primary Hypothesis

We will determine the feasibility of delivering the chatbot and generate data on the effect of the chatbot components on motivation for treatment and mental health services use.

C. Background

C1. Rationale for this Study

Clinical or subclinical EDs impact 10% of individuals in their lifetime, which translates to at least 30 million people in the U.S.[1] Although evidence-based treatments for EDs have been established,[2] <20% of individuals with EDs receive treatment,[3;4] which is problematic given that lack of or delays in treatment result in poorer prognosis and greater relapse.[5] While few individuals with an ED receive treatment specifically for their disorder, these individuals exhibit elevated health services use and costs compared to those without an ED.[6] The problem of access to care for EDs is even worse amongst racial/ethnic minority individuals.[7-9] Receiving services for a psychiatric disorder involves multiple steps, with identifying or learning one's symptoms are something in need of help being a crucial first step.[4] Yet even once symptoms are identified, individuals with EDs may experience numerous barriers to care, including stigma, denial of illness severity, lack of knowledge about resources, and practical barriers such as cost.[10] We need a novel solution to not only identify individuals with EDs but to also encourage mental health services use and address treatment barriers.

C2. Prior Literature and Studies

A conversational agent or "chatbot" has great potential for increasing mental health services use among those with EDs. People respond psychologically to chatbots as if they are people, even when they are aware they are conversing with a robot.[11;12] In one study, when people talked to an automated chatbot, they were less fearful of self-disclosure and displayed more intense sadness compared to those who thought the chatbot was human-controlled.[13] There is optimism regarding a role for chatbots in mental health;[11;14] the scalability, cost-effectiveness, and anonymity they provide make them ideal for delivering mental health interventions.

Pilot work has demonstrated chatbots may be capable of instigating change in symptoms and behaviors related to health and mental health. College students with depression and anxiety who were assigned to a chatbot that delivered cognitive-behavioral therapy (CBT) self-help content reduced their depression over the course of 3 weeks, more so than the control.[15] Chatbots have also demonstrated success with promoting medication adherence for individuals with schizophrenia over 1 month.[16] Another study demonstrated sustained activity levels in overweight individuals when provided with a chatbot that set goals and gave personalized feedback, compared with a decline in activity in the control.[17] Overall, a 2017 scoping review identified 49 studies on conversational agents; none addressed EDs.[18] The review concluded that most studies show good usability and acceptability but that more research on clinical effectiveness is needed.[18]

In order to be successful, our novel chatbot would require the following features. First, we would need the capability to provide easily accessible ED screening that would allow for the identification of large numbers of individuals with EDs. Currently, many ED cases go undetected. A majority of individuals who ultimately receive treatment for an ED are first seen by their primary care physician, but 92% of these providers believe they have missed ED diagnoses.[19] This highlights the need for widely available online ED screening. Second, we would need the capability to provide personalized recommendations for seeking intervention while taking into account participant characteristics and addressing treatment barriers. Research has demonstrated that among college students at elevated risk for suicide, completion of an online mental health screen, accompanied by personalized feedback and the option to engage in brief online motivational interviewing (MI)-based counseling to address treatment barriers ("eBridge"), resulted in greater treatment readiness and linkage with treatment versus screen feedback only.[20] Relatedly, recent work with a number of patient populations (e.g., autism, severe mental illness) has demonstrated success with "navigator models" whereby a health care professional or paraprofessional assists patients in navigating health care systems and in overcoming gaps in service delivery.[21-24] A current NIMH initiative encourages research in this area (PAR-18-428) as a potential solution to the wide treatment gap for psychiatric disorders.[25] Third, the solution needs to be scalable to large user populations, for which mobile approaches hold great promise.[26] Although in-person navigator models have demonstrated some success in increasing services use, [21-24] high labor costs limit scalability.

There are very promising preliminary data on mental health chatbots built by X2AI, our chatbot design collaborator for this study. In one study, those with access to "Tess," X2AI's chatbot designed to target depression and anxiety using CBT, experienced reductions in depression and anxiety over 2-4 weeks with a d=.68 reported for depression.[27] One large health system in the U.S. customized X2AI's chatbot to deliver interventions based on MI and behavioral activation to

reinforce weight management goals in adolescents with pre-diabetes, with users rating the chatbot useful 96% of the time.[28] Third, our group has begun work with X2AI to develop a chatbot called "Tessa" to serve as an automated moderator for our well-established indicated ED prevention program, StudentBodies.[29-31] While still in development, preliminary user feedback has been very positive.

Research has shown support for the components proposed for inclusion in the chatbot: 1) meta-analytic findings have indicated that tailored messages have a greater impact on health behavior than control (r=.074)[32] and that text message based health promotion messages have an effect of d=.33, with greater efficacy for those using personalization (p=.001);[33] 2) a review of meta-analytic findings found that MI is significantly more effective than no treatment (ds up to .57) for a wide variety of problems and increasing treatment engagement;[34;35] 3) meta-analytic findings have indicated that reminder systems improve medication adherence in chronic disease (d=.41)[36] and other issues;[37] and 4) a meta-analytic study found psychoeducation to reduce symptoms of depression and psychological distress (d=.2)[38].

D. Study Objectives

D1. Study Aim

Aim 1) To determine chatbot feasibility and to generate preliminary data on the effects of the chatbot components on motivation for treatment and services use, employing the MOST framework. Aim 2) To test whether the chatbot components interact to predict outcomes.

Data will inform the development of an optimized chatbot, which I will test in an ensuing R01 randomized controlled trial.

D2. Rationale for the Selection of Outcome Measures

The goal is to determine the feasibility of delivering the chatbot and to generate data on the effect of the chatbot components on motivation for treatment and mental health services use. Motivation for treatment and mental health services use are the two main outcomes that will provide data for which chatbot components are most efficacious in promoting help seeking behaviors. We will also explore if the chatbot components interact to predict outcomes, which will also inform an optimized chatbot to be tested in a subsequent R01 trial.

E. Study Design

E1. Overview or Design Summary

We have used a user-centered design approach to create a single chatbot prototype, which includes four key features: 1) providing a personalized recommendation for seeking intervention; 2) engaging the user in motivational interviewing to overcome barriers to care; 3) education on the seriousness and health consequences of eating disorders; and 4) repeated check-ins with the user to encourage follow-up with care.

Study 2 will use a 2^4 full factorial trial design to test the four binary chatbot components. Thus, there are 16 experimental conditions, and participants will be randomized to 1 of those 16

conditions. Participants can be assigned to intervention (“yes”) or control (“no”) conditions for each chatbot component.

Participants will be recruited from those who complete the NEDA online screen and who meet eligibility criteria of screening positive for a clinical/subclinical ED, at least 18 years old, and not currently in treatment for an ED. For a period of time on the NEDA site, eligible users will be offered the chatbot. Interested individuals will be taken to a Qualtrics screen wherein those who endorse owning a smartphone and being a U.S. resident will be given access to participate in our study. Data from the NEDA eligibility screen will be collected. The consent form will be shown via Qualtrics and will encourage interested individuals to call a member of our research team to discuss the study. Once a participant completes the baseline measures, they will be randomized using Qualtrics. Once the baseline measures are completed, participants will be given information on how to access the chatbot and their unique chatbot start code.

Participants will engage with the chatbot for between 5-20 minutes, dependent on condition. Participants who are randomized to the repeated administration module will complete approximately 3 new conversations over the course of 2 weeks. The chatbot will automatically reach out to a participant if they do not complete a conversation within 1 day.

Assessments will occur online and may include data from the initial ED screen completed on the NEDA website. Assessments will take place at baseline (i.e., prior to chatbot use), and at approximately 2, 6, and 14 weeks after baseline completion via Qualtrics (see *F.2 Schedule of Measurements*).

We will document recruitment rates (i.e., percent of those offered participation in the study who sign up), as well as study retention rates, to assess appropriateness of follow-up procedures. Demand for the chatbot will be measured as: 1) number of texts to the chatbot; and 2) engagement at repeated administrations (if randomly assigned to this condition).

To validate receipt of treatment, a study team member will contact a random subset of participants (i.e., approximately 10%) who reported engaging in some kind of treatment to solicit additional details on their service use and experience through phone/Zoom call or online questionnaire, which will provide additional validation, and when possible, participants will also be asked to provide some kind of documentation for the services they reported using (e.g., send receipt of therapy session or provide email indicating they signed up for a recommended online program).

Participants will receive invitation and reminders via email, phone, and/or text message for each assessment, and if they have not completed the conversation with the chatbot. Participants may receive thank you messages for completing assessments.

PHI discussions via email will use WashU guidelines: 1) a test email will be sent to the participant to verify their identify (confirm correct recipient) and that this email will be sent in a secure manner (i.e., [secure] in subject line); 2) The body of the email will instruct the participant to send all information as a response to this thread and to not remove the "[secure]" from the subject line; 3) document in our research records the participant's agreement to provide information over email.

E2. Subject Selection and Withdrawal

E2.A. Inclusion Criteria

U.S. resident; English-speaking; age 18 years or older; own a smartphone; screen positive for a DSM-5 clinical or subclinical eating disorder; not receiving treatment for an eating disorder

E2.B. Exclusion Criteria

We will exclude participants who are currently receiving treatment for an eating disorder given the goal to increase access to services for those not receiving help. In addition, we do not plan on enrolling individuals who screen for Avoidant Restrictive Food Intake Disorder.

E2.C. Ethical Considerations

All key personnel involved in the design or conduct of research involving human subjects will receive the required education on the protection of human research participants prior to the start of the study. Participants will be informed that they do not have to answer any questions that make them uncomfortable. There are minimal risks for participating in testing.

Participants will be provided with the contact information of the research staff. As a clinical psychologist, the PI is trained in how to address safety issues. If any participant appears to be in crisis, they will be given information to call emergency services and will be notified that the chatbot is not designed to provide crisis support. Any adverse event will be reported promptly to the mentorship team, the NIH, and the IRB.

Confidentiality: Participant confidentiality will be maintained in compliance with HIPAA privacy protected servers. Study IDs will be linked with participant names, email addresses, and phone numbers in a separate password-protected file stored on a secure, password-protected server that only key study personnel have access to. All employees of the study with access to protected health information (PHI) are required to complete HIPAA training and comply with the privacy procedures in place at Washington University.

X2AI (x2ai.com), our chatbot collaborator, is a HIPAA-compliant mental health chatbot company with a dedicated and talented team of software engineers who are experienced in building chatbots that support mental health. X2AI will host the proposed chatbot and all data collected within the chatbot. X2AI will comply with the rules regarding handling of PHI under HIPAA.

Adverse Events: For the purpose of this study, adverse events will be defined as unanticipated problems involving risks to the study participants. A serious adverse event will be defined as any untoward occurrence that results in death, is life-threatening, or creates persistent and significant disability. The PI will consult with mentors to identify serious adverse events. Any potentially adverse events will be evaluated by the PI within 72 hours. All serious adverse events will be immediately reported to the IRB. All adverse events and study withdrawals, together with a detailed explanation of the event and withdrawal, will be provided to the mentorship team.

It is important to note that in previous similar clinical trials of digital health interventions, the procedures outlined above have been used to protect against and minimize potential risks to

participants, and they have proved effective in preventing emotional and physical complaints as well as adverse events.

E2.D. Participant Recruitment Plans and Consent Process

We plan to enroll approximately 200 English-speaking adults ≥18 years with a DSM-5 clinical or subclinical eating disorder who own a smartphone and are not in treatment for an eating disorder.

Participants will be recruited from the NEDA online screen. Once an individual screens positive for a clinical/subclinical ED, is not currently in treatment, and is ≥18 years old, they will be given a link to the Qualtrics eligibility screen. If an individual endorses owning a smartphone and being a U.S. resident, they will be shown the consent form in Qualtrics and will be asked to either agree to or decline participation in the study. Individuals will be encouraged to call a member of our research team to discuss the study.

E2.E. Randomization Method

Study 2 will use a 2^4 full factorial trial design to test the four binary chatbot components: psychoeducation, motivational interviewing, personalized recommendations, and repeated administration. Thus, there are 16 experimental conditions, and participants will be randomized to 1 of those 16 conditions. Participants can be assigned to intervention ("yes") or control ("no") conditions for each chatbot component.

Risks

There are minimal risks for participants.

Physical Risks: N/A

Psychological Risks: Our proposed chatbot designed to facilitate mental health problems may promote increased focus on mental health symptoms in some individuals**.** It is also possible that participants may feel uncomfortable disclosing information about certain behaviors such as disordered eating. However, we have asked questions of a similar nature in several studies in the past and have not had participants report discomfort.

Social Risks: There may be some embarrassment related to completing questions related to disordered eating symptoms.

Financial Risks: N/A

Legal Risks: N/A

Risks to Privacy: We will go to great lengths to keep participant information private and confidential. Participant confidentiality will be maintained in compliance with HIPAA regulations.

Other Risks: N/A

*Alternative Treatment*s: N/A -- Participants in the current study will be participating in usability testing to inform the development of a chatbot for facilitating mental health services use in individuals with eating disorders not currently in treatment. The proposed chatbot is designed to increase the likelihood that individuals will seek mental health care. There are no other widely available digital tools designed for this purpose. All participants who participate in the usability testing will be offered referral information for in-person/ telehealth treatment.

Benefits

The benefits to participants in this study and to society are expected to be great. In terms of possible benefits to participants, they include potential improved uptake of services. In addition, if successful, this study could demonstrate the potential of utilizing a chatbot to bridge the treatment gap for individuals with eating disorders by connecting them to treatment. Therefore, the potential risks that are associated with this study are reasonable when considering the many benefits that participants and society may gain.

Importance of the Knowledge to be Gained: Eating disorders are serious mental illnesses associated with high morbidity and mortality, clinical impairment, and comorbid psychopathology. Although evidence-based treatments for eating disorders have been established, the treatment gap is wide. Indeed, <20% of individuals with eating disorders receive treatment, which is problematic given that lack of or delays in treatment result in prolonged illness, poorer prognosis, and greater likelihood of relapse. Thus, developing a scalable, digital intervention to address this wide treatment gap is crucial. Furthermore, applying user-centered design and usability testing will result in a chatbot that aligns with users' needs, which may increase engagement and improve outcomes. Once established, the proposed chatbot has the potential to be a scalable tool that can facilitate mental health services use for individuals with eating disorders and also has great potential to be applied for use with other psychiatric disorders as well.

E2.G. Early Withdrawal of Subjects

Informed consent will make clear that participants may withdraw at any time with no penalty.

E2.H. When and How to Withdraw Participants

Taking part in this research study is voluntary. Participants may choose not to take part in this research study or may withdraw their consent at any time. They may withdraw by telling the research team they are no longer interested in participating in the study or they may send in a withdrawal letter. There will be no penalty or loss of benefits to which they were otherwise entitled.

E2.I. Data Collection and Follow-up for Withdrawn Subjects

When a participant withdraws from the study, the research team will stop collecting data from them.

F. Study Procedures

F1. Screening for Eligibility

Eligibility will be assessed using the NEDA eating disorder screen and eligibility questions in Qualtrics.

F2. Schedule of Measurements

Measure	NEDA Screen	Baseline Assessment	Chatbot Use	2 Week	6 Week	14 Week	Explanation/ Primary Purpose
SWED	X						To determine if the individual has a clinical/subclinical ED and to determine if they are in treatment.
Demographic Questions	X	X					To determine if individuals are 18 years or older. To obtain demographic information for analyses.
Recruitment Rates	X	X					To obtain the percentage of those offered participation who enroll.
Retention Rates				X	X	X	To obtain the percentage of follow-up completion.
Demand for Chatbot			X				Number of texts sent to the chatbot and engagement with repeated administration, if applicable.
SUS and USE				X	X		To examine usability of the chatbot.

Target measure: motivation for treatment and mental health services use questions		X		X	X	X	To determine motivation for treatment and mental health services use.
Target measure: SE-KNOW		X		X	X	X	To determine self-efficacy in help seeking.
Target measure: personal relevance question		X		X	X	X	To determine efficacy of personalized recommendation component.
Target measure: Dissonance Thermometer		X		X	X	X	To determine efficacy of motivational interviewing component.
Target measure: opportunity question		X		X	X	X	To determine efficacy of repeated administration component.
Target measure: EDs Literacy Scale		X		X	X	X	To determine efficacy of psychoeducation component.
EDE-Q		X			X	X	To examine ED symptoms.
EDs Quality of Life Scale		X			X	X	To examine quality of life.
Patient Health Questionnaire 9		X			X	X	To examine depression.
Generalized Anxiety Disorder 7		X			X	X	To examine anxiety.
Treatment and Barriers to Care Questions		X			X (if no to receiving treatment)	X (if no to receiving treatme	To determine any barriers to treatment utilization.

						nt)	

F3. Data Collection and Reporting Procedures for Adverse Events

For the purpose of this study, adverse events will be defined as unanticipated problems involving risks to the study participants. A serious adverse event will be defined as any untoward occurrence that results in death, is life-threatening, or creates persistent and significant disability. The PI will consult with mentors to identify serious adverse events. Any potentially adverse events will be evaluated by the PI within 72 hours. All serious adverse events will be immediately reported to the IRB. All adverse events and study withdrawals, together with a detailed explanation of the event and withdrawal, will be provided to the mentorship team.

F4. Study Outcome Measurements and Ascertainment

The goal is to determine the feasibility of delivering the chatbot and to generate data on the effect of the chatbot components on motivation for treatment and mental health services use. We will also explore if the chatbot components interact to predict outcomes. Data will inform developing an optimized chatbot, which we will test in a subsequent R01 trial.

The goal of this optimization trial is to inform an R01 randomized controlled trial of an optimized chatbot vs. a control condition. We will achieve that goal by evaluating feasibility and generating effect sizes of each component on outcomes, which will inform which components to retain in the optimized chatbot and be used to power a subsequent R01 trial.

G. Data Handling and Record Keeping

G1. Confidentiality and Security

Participant confidentiality will be maintained in compliance with HIPAA privacy protected servers. Study IDs will be linked with participant names and email addresses in a separate password-protected file stored on a secure, password-protected server that only key study personnel have access to. All employees of the study with access to protected health information (PHI) are required to complete HIPAA training and comply with the privacy procedures in place at Washington University.

X2AI (x2ai.com) is a HIPAA-compliant mental health chatbot company with a dedicated and talented team of software engineers who are experienced with building chatbots focused on supporting mental health. X2AI will host the proposed chatbot and all data collected within the chatbot. X2AI and Washington University are in a Business Associate agreement. X2AI will comply with the rules on handling of PHI under HIPAA.

Training: All staff personnel are trained and comply with HIPAA regulations. All study team members will complete the CITI training and Good Clinical Practice training.

Performance Monitoring: The Data and Safety Monitoring Plan for this trial includes close monitoring by the PI and her mentoring team. Any adverse event will be reported promptly to the NIH and to the IRB.

H. Study Administration

H.1. Funding Source and Conflicts of Interest

This study is funded by NIH. Any potential financial conflicts of interest for individual research team members are reported according to the IRB requirements and procedures.

H.2. Participant Payment

Participants will receive a $5 electronic gift card for completion of the baseline assessment, a $10 electronic gift card for completion of the 2 week assessment, a $10 electronic gift card for completion of the 6 week assessment, and a $20 electronic gift card for completion of the 14 week assessment.

H.3. Study Timeline

As detailed in the table below, recruitment and enrollment for the randomized pilot trial (Study 2) will begin in the middle of Year 2. It is anticipated that enrollment will continue for one year, into the middle of Year 3. All enrolled participants will receive access to chatbot designed to facilitate health care utilization. Engagement with the chatbot will occur for up to approximately 2 weeks. Participants will complete a baseline assessment, and follow up assessments about 2 weeks, 6 weeks, and 14 weeks after baseline completion.

Study	Activity	Year 1		Year 2		Year 3		Year 4	
		1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48
Study 2: Randomized Optimization Trial	Recruit and enroll participants				X	X			
	Deliver the chatbot				X	X			
	Conduct follow-up assessments				X	X	X		
	Analyze data and write-up						X	X	
	Write and submit NIH R01 grant					X	X	X	X

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PART II: STATISTICAL ANALYSIS PLAN

Statistical Analysis Plan

Data will be analyzed using R version 4.2.1.

Primary Outcome: Chabot Component Effects on Self-Reported Receipt of Treatment and/or Services Utilization

Analyses will be executed using discrete time survival analysis and will reflect the proportional increase in odds of treatment and/or services utilization corresponding to receiving each chatbot component (motivational interviewing, psychoeducation, personalized recommendations, repeated administration). This approach estimates the effect of independent variables (i.e., chatbot components) on the occurrence of an event (i.e., treatment utilization). Models will be fit with treatment use regressed on follow-up time (2-week, 6-week, or 14-week) and each chatbot component. Models will not incorporate an intercept; this allows for estimation of treatment utilization odds among participants who have yet to report seeking treatment. The model will be estimated using a logit link, and for all coefficients, odds ratios and 95% confidence intervals will be computed. Parameters of primary interest include the time effects, which reflect odds of treatment seeking at each time point, as well as the main effects of each chatbot component. Censoring and missing data were accommodated using maximum likelihood estimation.

Primary Outcome: Time Effect on Help-Seeking Attitudes (Motivation and Willingness to Change and Seek Help)

Data on help-seeking attitudes will be collected via items in each of the baseline, 2, 6, and 14-week follow-up assessments) on change in motivation (comprised of importance and readiness items) and change in willingness to seek psychotherapy for eating, shape, or weight concerns. These variables reflect putative psychological antecedents of treatment seeking and are not relevant for participants who have already sought treatment; therefore, data will be analyzed only among the subset of participants who do not report seeking treatment at any of the 2, 6 and 14-week follow-up assessments. Analyses will be conducted using multilevel models, which will estimate the effect of each chatbot component and all interactions among chatbot components on changes from baseline on each outcome at each timepoint.. Models will be fit with a given outcome regressed on follow-up time (baseline to 2-week, baseline to 6-week, or baseline to 14-week) and each chatbot component. The effects of primary interest are the interactions between the chatbot components and time, which indicate whether a component is associated with change from baseline in the outcome variable. Models will include fixed and random intercepts to accommodate nesting of repeated measurements within participants, and missing data will be accommodated using maximum likelihood estimation.

As a standardized effect size metric for these models, Cohen's *d* will be calculated as

$$2(ZN\surd)1-(ZN\surd)2\overline{\qquad\qquad}\surd2(\quad)1-(\quad)2$$

, where Z = *b / SE*. Cohen's *d* values of 0.2, 0.5, and 0.8 represent benchmarks for small, medium, and large effects, respectively. We will define sufficiently large main effects as those with *p* values ≤ .05 or with 95% confidence intervals that do not include 0.

Of note, all models will include estimates of interaction effects in addition to main effects of each chatbot component. To guide the interpretation of interaction effects, we will follow the guidelines of Collins et al. (2014). These guidelines suggest that significant interaction effects in factorial experiments have a bearing on decision-making regarding the best overall treatment package if at least one of the components involved in the interaction has a sufficiently large main effect. We define sufficiently large main effects as those with p values ≤ .05 or with 95% confidence intervals that do not include 0. Thus, interaction effects will be probed and interpreted if at least one component involved in the interaction has a significant effect alone.

References

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PART III: INFORMED CONSENT FORM

INFORMED CONSENT FORM

Project Title: Developing an Optimized Conversational Agent or "Chatbot" to Facilitate Mental Health Services Use in Individuals with Disordered Eating

Principal Investigator: Dr. Ellen Fitzsimmons-Craft

Research Team Contact: Bianca DePietro (Phone Number: 1-(314)-399-9218)

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

You should read and understand the information in this document including the procedures, risks and potential benefits.

If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.

- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

This is a research study conducted by Dr. Ellen Fitzsimmons-Craft which aims to test if a "chatbot" (a computer program that simulates conversation) can increase mental health service use among individuals with eating disorders. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree, you will be volunteering to participate in the research study. As a voluntary participant, you will complete an online baseline assessment and will be asked to use our chatbot for up to approximately two weeks. You will complete online assessments 2 weeks, 6 weeks, and 14 weeks after you complete the baseline assessment. These assessments will ask questions related to your experience using the chatbot and your eating behaviors. You will complete all research activities on your own time and anywhere you have access to your smartphone. The main risk to you if you participate is emotional discomfort in using and providing feedback on a chatbot that talks about eating disorders.

You may benefit from volunteering because the chatbot may increase your motivation to seek care and/or provide you with resources for help for your eating, shape, or weight concerns. There is no cost to you and you will receive a $5 electronic gift card for completion of the baseline assessment, a $10 electronic gift card for completion of 2 week assessment, a $10 electronic gift card for completion of the 6 week assessment, and $20 electronic gift card for completion of the 14 week assessment. In addition, if you complete all four assessments, you will be entered into a sweepstakes to win one of three $100 electronic gift cards. All of this

information is listed in more detail in this consent document. The research team must give you a copy of this consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you screened positive for disordered eating symptoms, are currently not receiving treatment for your eating, shape, or weight concerns , are at least 18 years old, a U.S. resident, and own a smartphone.

The purpose of this research study is to test a chatbot with the goal of ultimately increasing mental health services use in individuals who have disordered eating symptoms. Individuals with eating disorders often do not receive any treatment and this study aims to find new ways to increase access to mental health care.

The chatbot is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be randomized (assigned by chance, like rolling dice) into one of sixteen conditions. Each condition will either include or exclude components of psychoeducation (education on health), motivational interviewing (help with ambivalence toward help), personalized recommendations (personalized resources for help), and follow ups to see if you received the help you want. You have an equally likely chance to be assigned to any of the 16 study conditions.

If you participate you will be testing how well our chatbot works.

1) After you agree to participate, you will complete a few short questionnaires. You are free to skip any questions you prefer not to answer.
2) Once you complete the questionnaires, you will send a text message to the chatbot.
3) You will complete the initial conversation with the chatbot. After the initial conversation, the chatbot may contact you approximately three times to start a new conversation over approximately two weeks.
4) Approximately two weeks after you have completed the first set of questionnaires, a member of our research team will send you the second set of questionnaires to complete. You are free to skip any questions you prefer not to answer.
5) A member of our research team will send you follow up questionnaires approximately 6 and 14 weeks after you have completed the first set of questionnaires. You are free to skip any questions you prefer not to answer.

You may be selected for an additional interview/questionnaire after you receive your final follow up set of questionnaires.

Research activities will all take place during your own personal time in any place of your choice that has internet or mobile phone service.

A member of our research team may call, text message, and/ or email you if you do not respond to a message from the chatbot or from our team within approximately one day of receipt. In addition, if you do not complete the first set of questionnaires/ start talking to the chatbot within approximately one day of agreeing to participate, you will be contacted by our research team. To protect your confidentiality, we suggest you prepare your phone and email with personal privacy settings in anticipation of contact from our research team.

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding how to help individuals with disordered eating or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

Your data will be stored without your name or any other kind of link that would enable us to identify what data is yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

If you use the application Recovery Record, we may obtain your data from this application for research purposes.

Audio/Video Recording or Photographs

You may be asked to participate in one aspect of this study which involves making audio/ video recordings of you. To verify receipt of help for your eating/ body image concerns, we will audio and/ or video record you during a phone or Zoom interview. Only the principal investigator and the designated research team will have access to the recordings, which will be stored on a secure server identified only by a study ID number. The study team does not plan to destroy the recordings and they will be kept indefinitely.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 200 people will take part in this study conducted by investigators at Washington University.

Approximately 20 of the 200 participants may be selected for an additional interview/questionnaire to verify receipt of help, if applicable.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately four months from completing the first assessment..

- You will complete the first online assessment and initiate conversation with the chatbot today and complete the first conversation. The chatbot may initiate contact with you approximately three separate times over approximately two weeks to start a new conversation. The chatbot will automatically reach out if you do not finish a conversation within one day.
- You will be contacted to complete online assessments approximately 2 weeks after you complete the first assessment, and approximately 6 and 14 weeks after you complete the first assessment.
- You may be contacted after you receive your final assessment to verify receipt of help via phone/ Zoom interview or online questionnaire. We may ask you to provide us with digital or scanned receipts, screenshots, emails, or verification of the like to verify the help you received.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- There are minimal psychological risks of participating. It is also possible that you may feel uncomfortable disclosing certain information about behaviors such as disordered eating.
- There may be some embarrassment related to completing questions about disordered eating symptoms.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we are determining what parts of the chatbot are most successful in increasing motivation to seek care and mental health services use. The ultimate goal of the chatbot is to increase mental health services use in individuals with disordered eating symptoms.

WHAT OTHER OPTIONS ARE THERE?

The chatbot is designed to increase the likelihood that individuals will engage with mental health services. There are no other widely available digital tools designed for this purpose. You will be offered referral for in-person/ telehealth treatment at the end of this document.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. You will be required to use SMS text messaging to interact with the chatbot, message and data rates may apply.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will receive a $5 electronic gift card for completion of the baseline assessment, a $10 electronic gift card for completion of the 2 week assessment, a $10 electronic gift card for completion of the 6 week assessment, and $20 electronic gift card for completion of the 14 week assessment. In addition, if you complete all four assessments, you will be entered into a sweepstakes to win one of three $100 electronic gift cards.

If you are selected for the additional receipt of help interview, you will receive an additional $5 electronic gift card for your participation.

The maximum amount you could be paid for study participation is $150. If you do not complete all parts of the study you will be paid for those you do complete.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that the Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 1-(314)-286-2074 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could

contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The NIH
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will use Health Insurance Portability and Accountability Act (HIPAA) privacy protected servers to store study information. Study IDs will be linked with participant names and email addresses in a separate password-protected file stored on a secure, password-protected server that only key study personnel have access to. All employees of the study with access to protected health information (PHI, information that identifies you) are required to complete HIPAA training and comply with the privacy procedures in place at Washington University. Our chatbot collaborator, X2AI (x2ai.com) is a HIPAA-compliant mental health chatbot company. X2AI will host the chatbot and all data collected within the chatbot. This includes information such as your name, phone number, and any messages you send to the chatbot. X2AI will comply with the rules on handling of PHI under HIPAA. X2AI and Washington University are in a Business Associate Agreement. Qualtrics is the online survey platform that will be hosting some of your PHI. Qualtrics and Washington University are in a Business Associate Agreement.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"
Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide to decline participation in this study, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you decide to participate in this study:

- You authorize the use of your PHI for this research
- This authorization does not expire.

You may later change your mind and not let the research team use or share your information (you may revoke your authorization).

- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
  - If you revoke your authorization:
  - The research team may only use and share information already collected for the study.
  - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
  - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment, it would not be safe for you to continue, because the funding for the research study has ended, or if you have disengaged with the study.

REFERRAL TO IN-PERSON/ TELEHEALTH CARE

Please see resources below to find in-person or telehealth care.
1) National Eating Disorders Association Helpline
Phone number: +1 (800) 931-2237
Hours of operation: Mondays-Thursdays 11 AM - 9PM ET; Fridays 11 AM - 5PM ET

2) Please visit https://map.nationaleatingdisorders.org to find eating disorder treatment providers near you.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Bianca DePietro, 1-(314)-399-9218. If you feel that you have been harmed in any way by your participation in this study, please contact Dr. Ellen Fitzsimmons-Craft, 1-(314)-286-2074.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office website, http://hrpo.wustl.edu. To offer input about your experiences as a

research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before agreeing to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

QUALTRICS CONSENT FORM EXAMPLE

You are eligible for our study!

This study will investigate whether a chatbot (a computer program that simulates conversation) can assist individuals who have disordered eating with finding help. By participating, you will be providing valuable information on how to best make services accessible to individuals with disordered eating.

In this study:

1. You will send a text message to our chatbot, Alex, to have a conversation today.
    - This conversation will take between 5-20 minutes to complete. (After this conversation, you *may* receive a few more messages from the chatbot over the course of about 2 weeks.)
2. You will complete 20-minute online questionnaires at:
    - Baseline (now)
    - About 2 weeks from now
    - About 6 weeks from now
    - About 14 weeks from now

Payment schedule:

1. You will receive Amazon e-gift cards for completing questionnaires at:
    - Baseline **$5**
    - 2 weeks **$10**
    - 6 weeks **$10**
    - 14 weeks **$20**

2. In addition, if you complete all 4 questionnaires, you will be entered into a sweepstakes to **win one of three $100 Amazon e-gift cards!**

Please review the full consent form by clicking **HERE (upload final)**. You may also save and print a copy of the consent form via this document.

If you have any questions, we strongly encourage you to contact our study coordinator (insert information).

We highly recommend you complete the survey at one time. If you cannot complete the full 20-minute survey now, please come back at another time to start the survey. Please save this link. **Note, this url is tied to your information, please do not share it with anyone.**

Have you read the consent form, and do you agree to participate in the study as described in the consent form?

Yes, I have read the consent form and agree to participate in this study

No, I decline participation in this study

SIGN HERE

clear