ISRCTN61214172 https://doi.org/10.1186/ISRCTN61214172

Using a mental health chatbot, Tess, to relieve symptoms of depression and anxiety

Submission date
31/10/2018

Recruitment status
No longer recruiting

Registration date
19/11/2018

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Students in need of mental health care face many barriers including cost, location, availability, and stigma. Studies show that digital mental health solutions offer a less intensive and more cost-effective alternative for reducing symptoms of depression and anxiety. Artificial intelligence (AI) offers a scalable solution as the demand for affordable, convenient, lasting, and secure support grows. The aim of this study is to assess the feasibility of using an AI chatbot called Tess to deliver emotional support and reduce self-identified symptoms of depression and anxiety in college students.

Who can participate?
University students enrolled in the USA are invited to participate regardless of gender, race, or socioeconomic status. As healthy volunteers, students are expected to speak English, be over the age of 18, and to sign the informed consent in order to participate.

What does the study involve?
Participants are randomly allocated to one of three groups. The control group receive an e-book with no access to the AI, Tess, until after the study has ended. Test group 1 receive unlimited access to Tess with daily check-ins for two weeks. Test group 2 receive unlimited access to Tess with bi-weekly check-ins for four weeks.

What are the possible benefits and risks of participating?
By participating in this study, students gained free access to a unique and on-demand emotional support service that usually costs $5.00 month. Students are also offered an incentive for participating in the form of a $20 Amazon e-gift card upon completion of the study. Students are offered a secure and confidential space to talk about sensitive issues they may otherwise have a hard time sharing with others. While there were no clinical risks observed in the results of this study, one potential risk may have been that interacting with the AI system, Tess, may lead a student to desire more support in a clinical setting which may require financial and other resources to achieve.

Where is the study run from?
The study was conducted by primary investigator, Russell Fulmer, PhD from Northwestern

University in Illinois, USA. Dr. Fulmer collaborated with the vendor called X2 AI Inc., which funded and provided the AI service called Tess to deliver support to participants during the study.

When is the study starting and how long is it expected to run for?
July 2017 to October 2017

Who is funding the study?
X2 AI Inc. (USA)

Who is the main contact?
Dr Russell Fulmer
russell.fulmer@northwestern.edu

Study website
https://www.facebook.com/ChatWithTess/

Contact information

Type(s)
Scientific

Contact name
Ms Angela Joerin

ORCID ID
http://orcid.org/0000-0003-3667-9636

Contact details
995 Market St. Suite 209
San Francisco
United States of America
94103

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10.2196/mental.9782

Study information

Scientific Title
Using psychological artificial intelligence (Tess) to relieve symptoms of depression and anxiety: randomized controlled trial

Acronym
Tess RCT

Study objectives
This study aimed to assess the feasibility and efficacy of using an integrative psychological AI, Tess, to reduce self-identified symptoms of depression and anxiety in college students.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was considered exempt from ethics approval and registration in a public trials registry, since it involved a nonclinical population of college students. The support delivered by the artificial intelligence service called Tess does not qualify as a clinical intervention. Participants in the control group received only a brief self-help e-book written by the National Institute of Mental Health (NIMH). Program evaluation outcomes from this study will support content enhancements for future IRB approved studies.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Providing on-demand support for students with self-identified, and non-clinical range, symptoms of depression and anxiety

Interventions
Confirmed participants were randomized via a computer algorithm that automatically generated a number between 0 and 2, and then placed into one of three groups.
No Intervention: Control Group participants were sent a link to NIMH's self-help eBook.
Test Group 1 participants were granted unlimited access to the Tess chatbot through Facebook messenger for 2 weeks.
Test Group 2 participants were granted unlimited access to the Tess chatbot through Facebook messenger for 4 weeks.

Intervention Type

Behavioural

Primary outcome measure
1. Depression severity assessed using the Patient Health Questionnaire-9 (PHQ9) at baseline, 2 weeks, and 4 weeks for the control group, at baseline and 2 weeks for Test Group 1 and at baseline and 4 weeks for Test Group 2
2. Generalized anxiety disorder severity assessed using Generalized Anxiety Disorder-7 (GAD7) questionnaire at baseline, 2 weeks, and 4 weeks for the control group, at baseline and 2 weeks for Test Group 1 and at baseline and 4 weeks for Test Group 2
3. Positive and negative mood assessed using the Positive and Negative Affect Schedule (PANAS) questionnaire at baseline, 2 weeks, and 4 weeks for the control group, at baseline and 2 weeks for Test Group 1 and at baseline and 4 weeks for Test Group 2

Secondary outcome measures
User satisfaction assessed using a survey at week 4 for the control group, week 2 for Test Group 1 and at week 4 for Test Group 2

Overall study start date
01/07/2017

Completion date
16/10/2017

Eligibility

Key inclusion criteria
1. Current enrollment at a university in the United States
2. Aged 18 years and older (screened at the first level via checkbox confirmation)
3. Able to read English (implied)
4. Informed consent signed
5. To guard against compromise, for example, from malicious bots, all potential participants were sent an email requesting that they respond using their university email denoting their confirmation

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
115

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
01/08/2017

Date of final enrolment
29/08/2017

Locations

Countries of recruitment
United States of America

Study participating centre
Northwestern University
Evanston
United States of America
60201

Study participating centre
X2 AI Inc.
995 Market St. Unit 209
San Francisco
United States of America
94103

Sponsor information

Organisation
X2 AI Inc.

Sponsor details
995 Market St. Suite 209
San Francisco
United States of America
94103
+1 (0)2489356366
angie@x2ai.com

Sponsor type
Industry

Website

https://www.x2ai.com/

Organisation
Northwestern University

Sponsor details
633 Clark Street
Evanston
United States of America
60208

Sponsor type
University/education

Website
https://www.northwestern.edu/

Funder(s)

Funder type
Industry

Funder Name
X2 AI Inc

Results and Publications

Publication and dissemination plan
This study has been accepted for publication through JMIR and is available for download here: https://preprints.jmir.org/preprint/9782/accepted

Intention to publish date
29/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Angie Joerin (angie@x2ai.com). Type of data: SPSS output. Data requests may take up to 90 days to process and may be shared only to those who meet the criteria defined below. Data may be shared only through secure, password protected platforms and only to researchers or organizations who submit a written request with aim to further evaluate the feasibility, generalizability, efficacy or other of using the artificial intelligence system called Tess to deliver emotional support. The X2 ethical board and Northwestern University primary investigator maintain the right to refuse access to data. Participants signed an electronic

consent form and agreed to the services privacy policy (https://www.x2ai.com/privacy) before participating in the study. Participants were randomly selected into three groups and automatically assigned a unique user ID. The system automatically de-identified transcripts, which were stored on a HIPAA compliant server in which only a select few individuals from the core research team were granted security level access during the duration of the study. The terms of use for the system used to deliver support during this study are described in this link: https://www.x2ai.com/terms.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/12/2018		Yes	No
Participant information sheet			09/01/2024	No	Yes