

MESSAGE-BASED PSYCHOTHERAPY AND DIGITAL TREATMENT SEQUENCES FOR
DEPRESSION

STUDY00010391

09/11/2023

NCT04513080

ADAPT Study Consent Form

Before we move forward to asking whether you would like to participate in the study, we want to make sure you have a better understanding of the study and what it means to participate. Please read the details of the study outline below.

Since this is a research study, it is important for us to know that you understand what you are agreeing to. After you read about the study, we will ask some questions to make sure you understand crucial details about the study.

Please read the details of the study outline below to decide if you consent to participating.

Thank you!

UNIVERSITY OF WASHINGTON & TALKSPACE

Message-based Psychotherapy and Digital Treatment Sequences for Depression

Overview

Talkspace and University of Washington are conducting a research study. The purpose is to determine the effectiveness of different types of message-based and/or video-based care. Participation in the study lasts for 12 weeks. Participants do not pay for treatment while they are in the study. You will be compensated up to \$125 for completing assessments throughout your time in the study.

Treatment

During the twelve weeks that you are in the study, you will receive therapy from Talkspace. You will be randomly assigned to receive either unlimited message-based care or weekly video-chats with a therapist. You will be assigned a therapist based on your location. Because this is a research study, **you will not be able to choose which treatment you will receive.** You will receive this treatment for at least five full weeks. At six weeks, you will continue in this treatment if it appears that your depression symptoms are improving. If it does not seem like your depression symptoms are improving, you will be randomly assigned to receive additional care. All treatment is provided within Talkspace's platform.

If you are in the messaging treatment plan to start, you can expect your provider to respond **5 days a week, twice a day, typically within 4-6 business hours.** If you are in the video-based treatment plan to start, your provider will only use the chat feature for scheduling and logistics. Because of this, we might not be able to respond to you immediately if you have thoughts of harming yourself. If you are ever experiencing thoughts that life is not worth living, self-harm, or suicide and need to speak with someone immediately, please call 1-833-929-1721 to speak to someone 24/7, go to www.imalive.org/online to message someone online 24/7, or call 9-1-1.

Assessments

Talkspace regularly checks in on how their clients are doing by asking them to complete questionnaires about the symptoms they are experiencing every 3 weeks within the app, and these are for use by your therapist. For the 12 weeks that you are in the study, your answers to those questionnaires will be

shared with the study team. Neither your name nor any other identifiable information will be stored along with your answers though.

In addition to these questionnaires, the research team administers separate questionnaires, and you are paid for completing the weekly questionnaires throughout the study. You will receive links to these questionnaires via SMS text message and will complete them on a web browser. We will ask you to complete an initial baseline assessment, which we think should take about 15 minutes; quick daily questions, which should take 2-3 minutes to complete; and weekly questionnaires, which should take about 10 minutes to complete.

Compensation

All participants in the study will be compensated up to \$125 for completing assessments. **You'll receive \$7 for completing the baseline questionnaire, and \$7 for each weekly questionnaire completed in weeks 1-4. You'll receive \$10 for each weekly questionnaire completed in weeks 5-8. You'll receive \$12.50 for each weekly questionnaire assessment completed in weeks 9-12. If all weekly questionnaires are completed, you will earn a total sum of \$125. Should you choose to withdraw from the study early, you will be asked to complete a short exit survey and be paid \$3 for completing this survey.** You will not be paid for completing daily quick questions. Gift codes are distributed monthly, and it may take up to five weeks for your first payment to process.

Payment is distributed to participants who engage in the study by providing complete and consistently accurate data. If we later find that you have not engaged to this standard, we will let you know via email and your participation in the study will end. If you are not compensated, please contact the study team at adapt-study@uw.edu to receive a detailed explanation of why your data did not reach study standards.

Participation is voluntary and you may refuse or discontinue without penalty. However, if you choose not to participate in the study, you will no longer be eligible to receive free care from Talkspace. You will be able to purchase available care through Talkspace.

Will information about me be kept private?

Your privacy is very important to us. We will use strong precautions to protect the data collected through the surveys, but there is a small risk of a break of confidentiality as with data from all digital surveys. The data collected within Talkspace and through the study is stored in compliance with HIPAA privacy standards. This means that your data is protected. Instead of using your name or information that identifies you, we will create a Global Unique Identifier (GUID) which we will use instead of your name alongside your data. The study team maintains a link between your name and the GUID that is kept separate from any data provided. The GUID on its own cannot be used to identify you.

It is possible that the information we obtain from you for this study might be used for future studies. If we remove anything that might identify you, that information may then be used for future research studies or given to another investigator without getting additional permission from you. If we want to use or share study information that might identify you, a review board will decide whether we need to get additional permission from you.

Are there any risks or costs to taking part in the study?

We do not anticipate significant risks or significant benefits to you due to participating in this study. Some questions asked in the questionnaires may make you feel uncomfortable. You can choose to skip any question and remain in the study. There are no costs to you for participating in the study. However, taking surveys with your mobile phone may count against your mobile data plan. You may change your settings to only use Wi-Fi connections to manage how this data collection will affect your plan. Alternatively, you may take the surveys with a computer.

Can I choose not to participate, or stop participating in the study at any time?

Participation is voluntary. You may refuse or discontinue without penalty. and you would not lose access to any available care through Talkspace.

Other Information

This study is funded by the National Institute of Mental Health. A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We have a Certificate of Confidentiality from the federal National Institute of Mental Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to: a member of the federal government who needs it in order to audit or evaluate the research; individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly; the federal Food and Drug Administration (FDA), if required by the FDA; individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form; authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others. The Certificate expires when the NIMH funding for this study ends. Currently this is June 30, 2024. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

If you have questions while you are in the study, or feel you have been harmed by participating, please ask your study therapist or contact Dr. Patrick Raue, the University of Washington professor in charge of the study, at 206-616-2129. If you have questions about your rights as a research subject, you may call the University of Washington's Human Subjects Division at 206-543-0098 or call collect at 206-221-5940.

Since this is a research study, it is important for us to know that you understand what you are agreeing to. Before we move forward to asking whether you would like to participate in the study, please answer the following TRUE/FALSE questions.

Q: T/F: I get to choose the type of treatment I receive as a participant in this study.

A: False. Correct! You will not be able to choose your treatment plan, and if you feel that only one type of treatment will work for you, the study is not a good fit for you. An important part of the study is randomly assigning participants their treatment plan. You will be notified by email of your treatment assignment before starting treatment with your provider.

True: Sorry, that is incorrect – please try again!

Q: T/F: I will be randomly assigned my treatment plan at the start of the study.

A: True. Correct! You will be randomly assigned to either a message-based treatment plan or video-based treatment plan.

False: Sorry, that is incorrect – please try again!

Q: I will be completing questionnaires throughout the study and will receive Amazon gift codes for answering those questions. T/F

A: True – Correct! We offer gift codes as compensation for the completion of weekly study questionnaires.

False: Sorry, this is incorrect – please try again!

Q: I am a volunteer and can drop out of the study at any time, without risk of losing access to available care.

A: True – Correct! Participation in the study is voluntary and choosing to drop out at any point will not impact your ability to access available care through Talkspace.

Thank you! Would you like to participate in the research study?

Yes: Great! Soon after the submission of this form, please expect to receive a text message via SMS linking your baseline assessment. Please complete the assessment within 48 hours and reach out to the study team with any questions by email (adapt-study@uw.edu).

No: Thanks for your interest and for taking the time to learn more about the study! Feel free to reach out to the Talkspace team if you would like to pursue other treatment options, and if you have any questions about the study, please send us an email at adapt-study@uw.edu. Thank you!