Interpretation Training to Reduce Anxiety: Evaluating Technology-based Delivery Models and Methods to Reduce Attrition

Informed Consent Form

NCT03498651

July 31, 2023

Note: Blue highlighted text is 'pop-up' text that appears when you hover your mouse pointer/press your finger on the section.

Informed Consent Agreement

['Print this Page' button]

Are you a current resident of the European Union? [Yes/No]
If a participant answers Yes to this question, they will see the regular consent form PLUS the European General Data Protection Regulation (GDPR) Informed Consent Addendum pasted at the end of this document. If a participant answers No to this question, they will only see the regular consent form.

What is the MindTrails Study?
The purpose of this study is to investigate a 5-week experimental anxiety reduction program called MindTrails. The program consists of the following parts:

- An initial set of questionnaires
- 5 weekly training sessions (with a set of questionnaires after sessions 3 and 5)
- A set of questionnaires 2 months after you finish the training

Each of the assessments and training sessions will take approximately 20 minutes to complete. Completion of the entire program and study will take approximately 140 minutes.

What will I be asked to do?

Assessments
You will be asked to complete questionnaires about your thoughts, mood, background, and personal mental health history.

Training
You will be presented with one of our training programs designed to shift how you think about situations. You may be asked to read brief stories about situations that often produce anxiety and fill in missing letters to complete words or read information about anxiety problems and their treatment.

If you get randomly assigned to a program that we do not think will be the strongest one, you will have the opportunity to complete the program that we expect to be most effective after you finish the study. In other words, EVERYBODY will eventually get the chance to try the program that we expect will be most effective.

At the end of the study, you will receive more details about the study's rationale and design. You will also receive feedback about the progress you made during the program!

In psychology research, a common way to compare programs is to randomly assign each participant to one of the training versions.

Are there any benefits or risks of participating?

For some people, completing the training program may help reduce symptoms of anxiety. However, there may be no direct benefits to you. For some people, being asked to answer questions about their thoughts and mood can be temporarily distressing, but most people experience minimal-to-no distress or do not feel distressed for long.

Please note that MindTrails does not provide specific diagnostic or medical advice on our website, and we are limited in how we can respond to your personal requests.

MindTrails is not able to offer financial compensation or to absorb the costs of treatment should you feel you have been injured as a result of participating in the MindTrails research study.

Can I stop at any time?
While we hope that you will complete the entire study, **participation in this study is voluntary**, and you may end your individual session participation at any time by closing the study window. Further, your participation in this study is not at all related to your standing with other ongoing therapy or employers.

Contact the team if you have any questions about the study or wish to be removed from the study.

What is the MindTrails Privacy Policy?
MindTrails uses the same secure hypertext transfer protocol (HTTPS) that banks and other commercial websites use to transfer credit card information in an encrypted format. This provides strong security for data transfer to and from our website, though privacy is necessarily limited by the security of the technology and Wi-Fi that is being used.

Please note that completing the study in a public place where others might view your screen, and use of open networks or free Wi-Fi can increase the chance for loss of privacy.

To view the entire privacy policy in a separate page, please click here. [INSERT LINK TO PRIVACY POLICY]

Google Analytics
MindTrails uses Google Analytics, a web analytics service by Google that tracks and reports website traffic. MindTrails uses this service to track device usage, navigation patterns, and referrals. While MindTrails can connect this data to other information you provide, **we will not share any of your personal information with Google.**

By participating in the MindTrails study, you consent to this information being collected by Google Analytics.

The information that Google collects is anonymous in nature, and will not be personally identifiable.

Publishing Data Online
Researchers like ourselves are encouraged to make data available to other researchers. This is becoming a common practice around the world because of the ways it helps make science more efficient and trustworthy. The publication of data online involves preparing a data file for other researchers that removes all identifying personal data before making it available over the internet (e.g., on the Open Science Framework). Your name and other personally identifying data will never be published online as the procedures in this laboratory involve assigning you a participant number such that your name is not connected to the data you provide.

National Institute of Mental Health Data Archive

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. You may not benefit directly from allowing your information to be shared with NDA, but the information provided to NDA may help researchers find better treatments.

You may decide now or later that you do not want to share your information using NDA. If so, contact us at studyteam@mindtrails.org, and we will tell NDA, which can stop sharing the research information. Please note that NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available online at https://data-archive.nimh.nih.gov/.

A data repository is a large database where information from many studies is stored and managed. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will review every request to minimize risks to your privacy.

NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

Contact Information

To obtain more information about the study, ask questions about the research procedures, express concerns about your participation, or report illness, injury or other problems, please contact:
Tonya Moon, Chair, Institutional Review Board for the Social and Behavioral Sciences, One Morton Dr. Suite 500, University of Virginia, P.O. Box 800392, Charlottesville, VA 22908-0392. Telephone: 1-434-9245999; irbsbshelp@virginia.edu; Website: www.virginia.edu/vprgs/irb.

IRB-SBS Protocol #: 2220

Principal Investigator:
Prof. Bethany Teachman, Department of Psychology, Millmont Building, 1023 Millmont St, Rm 234, University of Virginia, Charlottesville, VA 22903. Telephone: 1-434-924-0676; Email: bteachman@virginia.edu

Create an account

First name / Nickname [fill-in field]

Email [fill-in field]

☐ I would like to receive email reminders when it is time to take the next session.

Please note that even if you do not want reminders for each session, you will still receive a few messages from us as you enter new phases in the study or if you are inactive for an extended period.

Cell phone [fill-in field]

☐ I would like to receive text reminders to this number when it is time to take the next session.

Password [fill-in field]

Confirm password [fill-in field]

☐ I am over 18

By providing your name and e-signature, and clicking the button below, you are indicating that you have read the informed consent statement above and agree to participate.

Type your first and last name [fill-in field]

E-signature [e-signature field]

European General Data Protection Regulation (GDPR) Informed Consent Addendum Study: IRB-SBS 2220

In the Consent Form for this study you are told about how personal information about you will be collected and handled as part of your participation in the study. We would like to give you additional information due to the European General Data Protection Regulation (GDPR). This affects the handling and control of your personal information in this study.

1. Information about the Institution carrying out this study:

The institution carrying out the study and collecting your personal information is University of Virginia, PO BOX 400400, Charlottesville, VA, 22904-4400.

We will not share your identifiable personal data with any third party (all servers hosting data are part of IRB-approved institutions). We will only disclose the identifiable personal data to authorities for those situations where we will receive a lawful order to do so. See public data sharing agreement above (this does not include identifiable data).

2. Personal data use
We will only use your identifiable personal data for the purposes of this research project.

3. Special categories of personal information:

Please be aware that the personal information about you that will be collected in the study includes special categories of personal data, namely information about:

- Demographics: Age (birth year)
- Contact Information: email, phone, zip code, IP address (stored separate from other data)
- Health Information
- Racial or Ethnic Origin
- Criminal Activity (varies by region and age: primarily, illegal use of alcohol)

As a safeguard to protect your privacy, we will link your personal data with a code and store your identifying information separately.

4. Your privacy rights
For your personal information collected by the study you have the following data privacy rights:

- To request information about the handling of your data. However, to protect the scientific integrity of the study, you may not be able to receive access to some of the data before the study ends.
- To request correction of data about you if it is incorrect or incomplete. During the assessment of this request, you have the right to restrict the processing of data about you.
- To request transfer of data about you to you or someone else in a commonly used format.
- To file a complaint with a data protection authority.
- To withdraw your consent at any time without giving a reason. You can withdraw your consent for study treatment and/or further follow up, without withdrawing consent for handling your data. You may also withdraw consent to the handling of your data, as described in the Consent Form. Then you will no longer be in the study, but the researchers will still use the data about you that was collected before you withdrew. After you withdraw, no further data will be collected from you.
- Along with your withdrawal, you have the right to request the deletion of data about you if your data are no longer needed or there is no other legal requirement for their use.

5. Transfer of data to other countries
Your information may be transferred to or handled in countries other than the country where it was originally collected. Those countries may not have the same data protection laws as the country in which you initially provided the information. When we transfer your personal information to countries whose data protection level has not been confirmed as adequate by the European Commission, we will provide appropriate safeguards for the transfer of personal information as required by law. Your personal data will be transferred to the United States, which has not sought nor obtained an adequacy decision from the European Commission. This means that there may be risks to your personal data under this jurisdiction. However, we adopt and implement sufficient safeguards to

protect your personal data, as described in this form. We transfer your data on the basis of your explicit consent, under Article 49 GDPR.
If you have any concerns about how your personal data is being handled, use the address below to contact us. If you are not satisfied with our reply and how we protect your personal data, you can contact the data protection authority in your home country or in another relevant jurisdiction for this processing activity, pursuant to the conditions of Article 77 GDPR.

If you wish to pursue any of your data privacy rights, please contact:
Prof. Bethany Teachman, Department of Psychology, 102 Gilmer Hall, rm. 207, University of Virginia, Charlottesville, VA 22903. Telephone: 1-434-924-0676. E-mail: bteachman@virginia.edu or IRB-SBS, Telephone: 1-434-924-5999, Email: irbsbshelp@virginia.edu, Website: https://research.virginia.edu/irb-sbs, Website for Research Participants: https://research.virginia.edu/research-participants, UVA IRB-SBS # 2304

6. Retention of personal information
Your information may be stored indefinitely after the end of the study.

Click to [Accept]