College Student Stress: Transitions Over Time

HUM00257547

Date of IRB Approval: July 23, 2024

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: College Student Stress: Transitions over Time (CSS-ToT), HUM00257547

Company or agency sponsoring the study: National Institute of Mental Health

Principal Investigator: Adam G. Horwitz, Ph.D., Department of Psychiatry, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

The purpose of this research study is to investigate how first-year college students develop and cope with stress during the transition to college and identify opportunities for improving outcomes. In Phase I of the study, participants will complete a brief 8-minute survey assessing social and emotional functioning, and stress management strategies. Participants who complete this survey will be entered into a drawing for one of ten $50 digital Visa cards. A subset of participants will be invited to Phase II of the study, which includes completing additional baseline surveys (with compensation), and weekly surveys (with compensation) during the next six weeks. Some participants will receive daily 1-minute surveys, text messages offering tips/strategies for managing stress, and personalized feedback reports regarding their surveys. Study participation will be complete at the conclusion of the final follow-up survey administered 6-weeks after study enrollment.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may feelings of discomfort answering personal questions on sensitive topics, and loss of confidentiality. More detailed information will be provided later in this document.

This study involves a process called randomization. This means that the intervention and surveys you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

This study may not offer any benefit to you now but may benefit others in the future by allowing us to develop mobile health interventions that can help prevent the negative progression of distress symptoms into depressive episodes or other negative mental health consequences. More information will be provided later in this document. You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: This research study is being conducted to better understand how college students develop and cope with stress in their lives, and to identify opportunities to help students notice and respond to stress early before they contribute to significant negative consequences.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

First-year adult (age 17+) college students (full- or part-time) enrolled at UM-Ann Arbor and UM-Flint are eligible to participate in this study.

3.2 How many people are expected to take part in this study?

We expect 425 participants in Phase I of the study and 100 participants in Phase II.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to participate in this study, we will ask you to complete a brief (~8 minutes) survey about symptoms of stress, coping, help-seeking, social relationships, and emotions. If eligible for Phase II, you will be asked to complete a subsequent baseline survey (~15 minutes) asking more in-depth questions about the previously mentioned topics. Phase II participants will receive brief (~10 minute) weekly surveys on the aforementioned topics and a final 6-week follow-up survey (~25 minutes). Some participants in phase II will be asked to complete daily 1-minute surveys, some phase II participants will receive brief text messages offering tips/strategies for managing stress, and some phase II participants will receive feedback reports concerning their surveys. Survey links and communications during Phase II will be delivered via SMS-texts through Twilio.

As a participant engaging in this research study, you have certain responsibilities that may apply to this study, such as completing surveys to the best of your abilities and reporting any difficulties that interfere with participation.

4.2 How much of my time will be needed to take part in this study?

Participation in the initial survey will take approximately **8 minutes**. Those invited to Phase II will complete a **15-minute** baseline survey, receive brief weekly **(10 minutes per week)** surveys, and complete a **25-minute** follow-up survey at six weeks. Some participants will be asked to complete 1-minute daily surveys **(7 minutes per week),** some may receive brief text messages offering tips/strategies for managing stress (<**1 minute to read)**, and some may receive feedback reports concerning surveys, which take ~**2 minutes** to review.

4.3 When will my participation in the study be over?

Your participation in the study will be over following completion of the brief initial survey, unless you are invited to Phase II. For those participating in Phase II, participation is complete following the **6-week** follow-up survey.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are less common (1-10% of participants may experience):

- There is a risk of psychological discomfort or stress resulting from answering study survey questions and/or being presented with feedback about your responses. Some of the questions will ask you about sensitive or personal information such as your emotional health. These questions might make you feel uncomfortable or anxious. To minimize this risk, we provide a link to resources that can provide help and support if ever needed. If responding to any questions or reviewing feedback makes you feel distressed, we urge you to call any of the resources listed.

The researchers will try to minimize these risks by allowing participants to end their participation at any point and skip survey questions they do not feel comfortable answering.

The rare risks (approximate incidence <1%) include:

- Loss of confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable genetic or health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers.

The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study that allow researchers to develop mobile health interventions that can help prevent the negative progression of distress symptoms into depressive episodes or other negative mental health consequences.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Your participation is completely voluntary. Your alternative is not to participate in the study, in which case there will be no penalty.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

We do not expect that you would experience any harm for leaving the study.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researchers believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

In Phase I, participants who complete the screening survey will be entered into a drawing for one of ten $50 digital Visa cards.

In Phase II, participants completing the baseline survey will receive $20. Participants will receive $10 per each completed weekly survey, and $1 for each completed daily survey. Finally, participants will receive $25 for completing the final 6-week follow-up survey. Digital Visa cards will be used to compensate participants and will be delivered electronically. After the initial $20 payment from the baseline survey, digital Visa cards will be reloaded on a weekly basis with the earned compensation from daily and/or weekly surveys.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., e-mail address, phone number).

Your survey data will be provided with a unique non-decodable identifier so that all information provided by you will remain confidential. Identifying information will be stored and secured in HIPAA-compliant environment and will only be accessible to essential study personnel. All personal, identifiable information (e.g., names, e-mail addresses) will be destroyed once final study payments have been processed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm

If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

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

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner and for quality improvement purposes.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting

purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you leave the study before it is finished or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

If your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Adam Horwitz, Ph.D.
Mailing Address: 4250 Plymouth Rd. Ann Arbor, MI 48105
Telephone: 734-232-0519

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)

Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You may download this electronic consent form or receive one via e-mail, upon request.

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information and leftover samples such as blood, tissue, saliva, and cells to use in future research. These future research uses take different basic forms, which are described below. The medical information and leftover samples may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information and leftover samples is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information and leftover samples; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information and samples would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

For purposes of this research study, your collected private information and any biospecimens will be shared with the study sponsor, the National Institutes of Health, its collaborators, and associated research partners.

With appropriate institutional and regulatory permissions, your collected private information and identifiable biospecimens could be used for future research with other researchers and companies, including those in other countries, with or without your consent.

In addition, after identifiers are removed from your private information and any biospecimens, the information and biospecimens could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

Keep in mind, too, that in cases where giving us your permission to store, use, or share your information is necessary in order for you to participate in this study, changing your mind later and withdrawing your consent to that storage, use, or sharing will also mean that you can no longer take part in the study, and we will remove you unless your participation has already ended.

NIH data management and sharing (DMS) policy

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information. We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you. Researchers who wish to access your information must obtain permission to access your information. You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future. Permitting us to store and share your information is a condition of participating in this study. If you do not want us to share your information with other researchers, you should not take part in this study.