

Study title: Randomized Controlled Trial (RCT) of StriveWeekly for Anxiety and Depression Prevention
for College Students During COVID-19

NCT #:NCT04927845

Document date: 09/09/2021

Consent form version approved by Harvard Institutional Review Board on 09/09/2021

Study Title: Randomized Controlled Trial of StriveWeekly for Anxiety and Depression Prevention in University Students during COVID-19

Researcher: Leslie Rith-Najarian, PhD

Faculty Advisor: Katie McLaughlin, PhD

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study? We invite you to take part in a research study because you are (a) currently enrolled as an undergraduate student at Harvard College and (b) interested in participating in the StriveWeekly programming that was advertised in the recruitment materials.

What should I know about a research study?

- This electronic consent form survey will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide. To do so, please email [Kevin Shani](mailto:KevinShani@hks.harvard.edu): kevinshani@g.harvard.edu.

Why is this research being done? StriveWeekly is an online mental health program designed for teaching university students stress management skills. A prior research study found that students who were assigned to have access to StriveWeekly experienced psychological improvements. Given the unprecedented remote learning environment due to COVID-19, the Dean of Students Office is sponsoring StriveWeekly as a support for all Harvard College students. The StriveWeekly content has also been recently updated to have more inclusive and accessible content. This research study with Harvard college students will help evaluate StriveWeekly's acceptability and effectiveness in supporting diverse students during a global health pandemic and remote learning.

How long will the research last and what will I need to do? We expect that you will be in this study until the final survey is administered in April 2022. During this time, you will be invited to:

- **Survey #1 in September 2021** (online, ~10 mins)
- **StriveWeekly access by the third week of Fall or Spring semester**, set up a user account (online, ~10 mins)
- **7 weeks of StriveWeekly during Fall or Spring Semester:** participate in the online program as much or as little as you want
- **Surveys #2, #3, and #4 in November, January, and March:** (online, ~3-5 mins each)

Compensation: \$5 per survey guaranteed, \$20 total guaranteed for all four surveys, and entries for bonus \$50 gift card raffles (elaborated in Detailed Information).

You will be assigned to StriveWeekly either in the first half or second half of this semester:

| Fall StriveWeekly Access | Spring StriveWeekly Access |
|--|--|
| Houses: Adams, Cabot, Currier, Dudley, Mather, Quincy, Winthrop | Houses: Dunster, Eliot, Kirkland, Leverett, Lowell, Pforzheimer |
| Freshmen: Ivy Yard, Elm Yard | Freshmen: Crimson Yard, Oak Yard |

Is there any way being in this study could be bad for me?

We do not expect any significant risks from participating in this research. You may experience mild discomforts such as boredom, annoyance, or mild psychological discomfort related to study surveys and email communications. Loss of confidentiality is always a risk in studies using human subjects, though efforts will be made to protect your confidentiality. More detailed information about the study procedures can be found under ***“What can I expect if I take part in this research”***

Will being in this study help me in any way?

By participating in this research study, you will be offered free access to the StriveWeekly program, specifically to a course offered only to Harvard College students. We cannot promise any benefits to you or others from your taking part in this research. However, based on prior research, students who complete StriveWeekly may experience the possible benefits of learning skills that they find helpful for stress management and/or experiencing improvements in symptoms related to anxiety, mood, and stress. You will retain access to your StriveWeekly account even after the study is over. In terms of benefits to society, the results of this research study may advance our knowledge about effective prevention programming for mental health promotion on university campuses. The results of this project are intended to contribute to generalizable, and publishable knowledge in the field.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

What is the purpose of this research?

StriveWeekly is an online mental health program design to teach stress management skills to university students in order to prevent symptoms related to anxiety, depression, and stress. In prior research trials, StriveWeekly has demonstrated broadscale reach and effectiveness in reducing symptoms of anxiety and depression. In earlier implementation studies at the University of California – Los Angeles and at Yale University, StriveWeekly was found to reach hundreds of students with no prior mental health service use (e.g., therapy, psychiatric medication meditation groups, peer counseling; Rith-Najarian, Sun, et al., 2019)). In a randomized controlled trial of StriveWeekly (ClinicalTrials.gov: NCT04361045), results showed that students assigned to the online intervention experienced small but significant improvements in total symptoms of depression, anxiety, and stress.

With the COVID-19 pandemic completely altering the landscape of higher education, students are experiencing more stress than ever. StriveWeekly's effectiveness has not been tested in the midst of a global health pandemic or within a remote learning setting. Therefore, the current research trial is being conducted in order to evaluate the program's effectiveness in addressing anxiety and depression symptoms within this broader unprecedented context. The results of this trial will support evidence of the effectiveness of offering such online mental health interventions to university students, even when a campus is experiencing unique stressors and/or is using remote learning.

How long will I take part in this research?

We expect that you will be in this research study until the final survey is administered in March-April 2022. It is possible that the researcher will add opportunities for additional research participation during the study. You may get contacted with such invitations. Any additional research opportunities will also be voluntary, and will have their own consent forms at that time.

What can I expect if I take part in this research?

All research study activities will be completed online. Your research participation will follow one of two timelines, depending on your assignment.

[Based on residential affiliation] You are assigned to receive the StriveWeekly program as Group A.

- **Survey #1 in September.** You will complete a baseline survey online by 11:59pm ET on 9/17/2021. This survey will ask you about your demographics, psychological symptoms, history of mental health service use, motivation for signing up, and recent experiences. It will take approximately 10 minutes to complete.
- **Account set-up in September.** A StriveWeekly access code will be included in the email you receive after completing survey #1. You will need to open this email to follow the instructions to create your StriveWeekly account. It will take approximately 10 minutes to create, verify, and finish setting up your StriveWeekly user account.
- **Your StriveWeekly program is live, September 20 – November 7.** You will log into your StriveWeekly user account any time you would like to engage with the materials or log skills practice. The activities and check-ins that you log on your online account will be included as part of our data collection. You can spend as little or as much time as you want using the StriveWeekly program.
- **Survey #2 in November.** You will be invited via email to complete this survey on 11/8/2021 and will have until 11/19/2021 to provide your responses. This survey will ask you again about psychological symptoms, other mental health service use, and recent experiences. In addition, you will be asked questions about your StriveWeekly experience and be invited to provide feedback. It will take approximately 5 minutes to complete.
- ***Note:** If you change residential affiliation mid-year, you will stay assigned to whichever group you were told in September.
- **Survey #3 in January.** You will be invited via email to complete this survey in late January and must provide your responses within ~2 weeks. This survey will ask you again about psychological symptoms, other mental health service use, and recent experiences. It will take approximately 3-5 minutes to complete.
- **Survey #4 in March.** You will be invited via email to complete this survey in late March and must provide your responses within ~2 weeks. This survey will ask you again about psychological symptoms, other mental health service use, and recent experiences. It will take approximately 3-5 minutes to complete.

[Based on residential affiliation] You are assigned to receive the StriveWeekly program as Group B.

- **Survey #1 in September.** You will complete a baseline survey online by 11:59pm ET on 9/17/2021. This survey will ask you about your demographics, psychological symptoms, history of mental health service use, motivation for signing up, and recent experiences. It will take approximately 10 minutes to complete.
- **Survey #2 in November.** You will be invited via email to complete this survey on 11/8/2021 and will have until 11/19/2021 to provide your responses. This survey will ask you again about psychological symptoms, other mental health service use, and recent experiences. In addition, you will be asked questions about your StriveWeekly experience and be invited to provide feedback. It will take approximately 5 minutes to complete.
- ***Note:** If you change residential affiliation mid-year, you will stay assigned to whichever group you were told in September.
- **Survey #3 in January.** You will be invited via email to complete this survey in late January and must provide your responses within ~2 weeks. This survey will ask you again about psychological symptoms, other mental health service use, and recent experiences. It will take approximately 3-5 minutes to complete.
- **Account set-up in January.** A StriveWeekly access code will be included in the email you receive after completing survey #1. You will need to open this email to follow the instructions to create your StriveWeekly account. It will take approximately 10 minutes to create, verify, and finish setting up your StriveWeekly user account.
- **Your StriveWeekly program is live, January to March.** You will log into your StriveWeekly user account any time you would like to engage with the materials or log skills practice. The activities and check-ins that you log on your online account will be included as part of our data collection. You can spend as little or as much time as you want using the StriveWeekly program.
- **Survey #4 in March.** You will be invited via email to complete this survey in late March and must provide your responses within ~2 weeks. This survey will ask you again about psychological symptoms, other mental health service use, and recent experiences. It will take approximately 3-5 minutes to complete.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. To formally withdraw and stop receiving study survey invitation emails, email kevinshani@g.harvard.edu and simply state that you would like to withdraw from the study. It is up to you if you would like to provide an explanation or reason for your withdrawal. If you decide to withdraw from the study, data collection up to the point of withdrawal will be retained, unless you ask us to destroy it. If you withdraw from the study after you have received a StriveWeekly access code, you will still be allowed to continue accessing your StriveWeekly course. If you withdraw from the study before completing the respective survey that provides your StriveWeekly access code, you will not automatically be provided with access. If you would like to be manually granted StriveWeekly access after withdrawing, you can email kevinshani@g.harvard.edu to request it. Regardless of formally withdrawing, you can stop completing surveys and/or activity on the StriveWeekly platform at any time, but you may continue to receive study and program email communications.

Can I be removed from the research without my OK?

The staff of the research study can remove you from the research study without your approval. Possible reasons for removal include providing responses to surveys that are deemed invalid data. Examples of invalid data responses include:

- If you straight-line survey responses, e.g., answer “1” on all Likert-scale questions, despite questions assessing different and sometimes opposite things
- If you report highly inconsistent information within a survey (e.g., saying “every day” to experiencing a specific psychological symptom assessed in one survey item, then saying “never” to experiencing the same symptom in a different survey item)
- If you report highly inconsistent information across surveys (e.g., reporting past/current use of multiple mental health services in the baseline survey, but then reporting never having used any type of mental health service in a subsequent survey)

If it is determined that you have provided invalid data within the surveys, you will not necessarily be contacted, but may not receive invitations to complete remaining research surveys from that point on. If you are removed from the study after you have received a StriveWeekly access code, you will still be allowed to continue accessing your StriveWeekly course. If you are removed from the study before receiving a StriveWeekly access code, you will not be provided with access. If you do not receive a survey invitation email around the time you expect one per the study timeline outlined above, you can email kevinshani@g.harvard.edu to confirm if you have been removed. If you have been removed and yet would like to be manually granted StriveWeekly access, you can email kevinshani@g.harvard.edu again to request it.

Is there any way being in this study could be bad for me? (Detailed Risks)

We do not expect any significant risks from participating in this research. You may experience **mild discomforts** such as mild boredom when completing surveys, mild annoyance for receiving reminder emails, or mild discomfort upon self-reflection about emotional experiences as prompted by surveys and the prevention program content. **Loss of confidentiality** is always a risk in studies using human subjects. See details below on the efforts we will take protect your privacy and the confidentiality of your survey responses. **We will also resource and referral information for anyone experiencing discomfort** due to survey questions related to mental health and stressful experiences. _____

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your Personal Information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. We will maintain the following safeguards to protect the information that we obtain from you and keep it confidential.

During the Study

1. **Qualtrics.** All consent forms and survey responses will be kept electronically within the Harvard Qualtrics, which is encrypted and accessible only by the PI through HarvardKey dual authentication. The surveys for this study are configured on the Harvard Qualtrics site to require all participants to login via HarvardKey dual authentication before completing surveys.
2. **Consent forms.** Documentation of identifying information (name, email address, signature) within the electronic consent forms will be stored on Harvard Qualtrics separately from your survey responses. This electronic consent form is configured to automatically capture your name, email address, and signature from your HarvardKey, in order to confirm your identity. It is also configured to auto-generate a participant ID, which is matched to your email addresses in the separate ID key.
3. **Research surveys.** You will again be required to login to your HarvardKey for each survey. The surveys are configured to record your participant ID along with your responses, rather than associating your responses directly with any identifying information.
4. **StriveWeekly database.** The StriveWeekly Platform User Database for Harvard students is stored on a HUIT-managed AWS EC2 instance. Every time you visit StriveWeekly you will need to sign in via your HarvardKey. This database can be accessed by designated HUIT staff and Leslie Rith-Najarian in her role as the StriveWeekly owner. Both HUIT and Leslie Rith-Najarian are bound to terms of confidentiality in signed agreements with the Dean of Students Office on behalf of Harvard University.

After the Study

1. **Master dataset.** Leslie Rith-Najarian in her role as the Harvard-affiliated study PI will download all the survey datasets and the separate participant ID key file from Qualtrics; Leslie Rith-Najarian in her role as the StriveWeekly owner will download the StriveWeekly user database. Note that Dr. Rith-Najarian will not be reviewing any individual student's data when it is still identifiable. All separate files will be downloaded over a secure wifi connection onto a password-protected personal work while logged into Harvard's network via Cisco VPN. Once all files are downloaded, the participant ID key will be used to link all datasets and merge them into a password-protected master dataset. The only information collected through StriveWeekly user database that will be saved in the research dataset are: email timing preferences, personal program goals, weekly check-ins, virtual medals earned, practice activity logs, and self-reported stress/mood ratings. This master file will contain no identifying data and will be saved on the PI's Harvard O365 OneDrive. All local research data files will then be permanently deleted. The de-identified master dataset can may be stored locally by the PI or future authorized researchers for the purpose of data analysis.

- **Published results.** The results of this project are intended to contribute to generalizable, and publishable knowledge in the field. All summaries of results that are either published in an academic journal or provided to the Dean of Students Office or other administrative representatives will be presented in an aggregated and de-identified manner. Any qualitative findings will be presented in an aggregated and de-identified way, with selected quotes accordingly redacted.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

What else do I need to know?

This research is being funded by a few sources:

- The costs related to delivering the StriveWeekly service are funded by the Harvard College Dean of Students Office.
- The costs associated with the research study and research participant compensation are funded by grants from the Harvard Foundation of Human Behaviors Initiative and the Harvard FAS Dean's Competitive Fund for Promising Scholarship.

Compensation - If you agree to take part in this research study, you will earn Amazon.com gift cards (or CrimsonCash, if mentioned in the survey invitation email) for your time and effort. Total amount of compensation per participant will vary based on number of Qualtrics surveys completed, with a minimum of \$5 and a maximum of \$70.

- Only one survey = \$5
- two surveys = \$10
- three surveys = \$15
- four surveys = \$20
- one survey + one raffle win = \$55
- two surveys + one raffle win = \$60
- three surveys + one raffle win = \$65
- four surveys + one raffle win = \$70

You will receive each gift card within two weeks of submitting the respective survey. You will receive instructions to redeem each gift card via email from either the principal investigator's Harvard Qualtrics survey account or an Amazon.com account that belongs to the faculty sponsor's lab.

Raffle/Lottery – For every survey that you complete, you will also be entered into a drawing for an additional **bonus \$50 Amazon.com gift card**. You are eligible to win only one of these bonus gift cards across the course of the study. We will use a random number generator to select 10 research participants as the winners for each survey. If a participant is drawn but has already received a bonus gift card, a replacement participant will be randomly drawn. Odds of winning will depend on how many total participants complete each survey, and are expected to improve over time at each survey assessment. We estimate that odds of winning a bonus \$50 gift cards over the course of the study as less than 1:30. Winners will be notified and receive this gift card electronically within two weeks of submitting the respective survey.

In addition, you will have opportunities to earn prizes through StriveWeekly program participation. These prize drawings are not connected with your research participation, but are additional opportunities to earn prizes by those students who are actively participating in the StriveWeekly program. A random number generator will be used to select winners from the pool of eligible participants, according to these requirements:

- **Weekly Prizes** are items worth ~\$20 and will be randomly given out weekly to 1-5 students. Who is entered into prize drawing: everyone who logs at least one activity on their StriveWeekly user account that week and completes the Weekly Check-In (see the “Progress” tab on your dashboard) by Sunday at midnight of the respective week. Winners will be notified by an email sent via the StriveWeekly platform within seven days of the drawing.
- **Finalist Prizes** are worth <\$100 and will be randomly given to 3-10 students at the end of the 7 weeks of StriveWeekly programming each semester. Who is entered into prize drawing: everyone who logs at least one activity every week on their StriveWeekly user account. Winner will be notified by an email sent via the StriveWeekly platform within seven days of the drawing. Of these 3-10 winners, they will get priority of prize choice based on total number of logged activities.

Clinically-Relevant Results. Most tests done in research studies are only for research and have no clear meaning for health care. The self-report measures related to symptoms of anxiety and depression in this study’s surveys are not valid diagnostic indicators, and therefore the researchers will not contact you regarding your survey responses. Moreover, any open-ended responses with health-related information that you provide either via your StriveWeekly user account or one of the online surveys will not be reviewed or monitored during the study. If you are feeling distressed during the study, then you may want to consult your own doctor or get professional counseling. You may have to pay for those additional services yourself. For your convenience, referral information to mental health services will be provided at the end of every survey and within the “campus” section of the StriveWeekly platform.

Researcher Financial Interests in this Study

Leslie Rith-Najarian, the study PI, is the creator of Strive Weekly and owns the copyrights to StriveWeekly.com, the online intervention being studied. Accordingly, while she does not currently receive any income from Strive Weekly in addition to her salary from Harvard University, she may benefit financially if the intervention is marketed in the future. This disclosure is made so that you may determine whether this relationship affects your willingness to participate in this study. If you have questions, please contact research collaborator Prof. Katie McLaughlin at kmclaughlin@fas.harvard.edu and she will put you in touch with someone to talk to.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research study PI at rithnajarian@fas.harvard.edu or the faculty sponsor Prof. Katie McLaughlin at kmclaughlin@fas.harvard.edu. If you are student who is affiliated with Kirkland House or enrolled in a course taught by Dr. Rith-Najarian, and have concerns about data privacy please contact research collaborator Prof. Katie McLaughlin at kmclaughlin@fas.harvard.edu and she will put you in touch with someone to talk to.

This research has been reviewed and approved by the Harvard University Area Institutional Review Board (“IRB”). You may talk to them at (617) 496-2847 or cuhs@harvard.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Signature Block for Adult subject

Your signature documents your permission to take part in this research.

Note: This electronic consent form is configured to automatically capture your name, email address, and signature from your HarvardKey info, in order to confirm your identity. If you do not complete this consent form, all information you have entered will automatically be deleted within 7 days. If you do complete this consent form you will be assigned an automatically associated participant ID that will be linked to future surveys for this study when you login via HarvardKey.

(electronic signature field on Qualtrics)

Signature of Subject

Printed Name of Subject

Date