

Title of research study: *Stress and Coping in College Youth (SCCY): A Multi-Site Longitudinal Study*

IRB Protocol Number: 21-0605

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Sponsor: National Institute of Mental Health

Key Information

- This study has the goal of understanding what factors help or make it more difficult for students to cope with stress and thrive in college.
- This study lasts three semesters:
 - At the beginning of the study and in your third semester, you will complete a 4-6 hour lab visit.
 - In your second semester you will complete two sets of online questionnaires (<1 hour)
 - Each semester you will complete a short (1-3 min.) survey every day for three weeks.
- Participation in this study may involve some minor risks or discomforts from answering personal questions, boredom, and exposure to an annoying stimulus (mild electric current calibrated to be annoying but not painful to you).
- You will be asked to abstain from using stimulant medications or other medications that affect cardiac or autonomic responses or neurocognitive functions for two days before each of your two lab visits, recreational drugs, nicotine, and alcohol for one day before your lab visits, and caffeine, antihistamines, or related medications for 4 hours before your lab visit
- You will be compensated for your time in this study. There are no costs to you.
- We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include insights that this research may provide into stress, coping, and wellness among college students.

Purpose of the Study

This study has the goal of identifying the factors that help young adults cope with stress and thrive in the transition to college, and the factors that make stress coping difficult and contribute to mental health challenges including anxiety and mood problems.

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The transition to college is a time in which young adults navigate many new responsibilities and daily activities. Meanwhile, in late adolescence into our early twenties, we also go through important changes in how we think, pay attention, and respond to rewards or threats in our world. This combination of life transitions and cognitive development is a time of opportunity for us to become independent and move into the next step of adulthood. But, life transitions are also stressful, and deploying new strategies for coping with stress also makes this a time of risk: it is during the transition to college and independence that some of us start to have mood problems, like feeling depressed, unusually keyed up, irritable, or anxious.

The purpose of the study is to discover the factors that contribute to risk or resilience during the college years, and use data-driven tools like machine learning to forecast student mental health over time. We hope to use what we learn from this research to inform the development of clinical strategies for predicting and supporting wellness in students.

We invite you to take part in this research study because you are a full-time undergraduate student at the University of Colorado Boulder or Brandeis University between the ages of 18-23. Your participation in this research study is voluntary.

We expect that you will be in this research study for a total of three consecutive semesters (about fifteen months). We expect about 249 people will be in this research study at the University of Colorado, and about 249 people will be in this study at Brandeis University. We expect about 498 people in the entire study nationally.

Explanation of Procedures

You can expect the following during your research experience:

At the beginning of this three-semester study, you will have an in-person study visit, lasting about four to six hours. You will be asked to abstain from using stimulant medications or other medications that affect cardiac or autonomic responses or neurocognitive functions for two days before your lab visit, recreational drugs, nicotine or alcohol for one day before your lab visit, and caffeine, antihistamines, or related medications for four hours before your lab visit. During this study visit you will be interviewed about your life experiences; you will answer some electronic questionnaires on a computer; and you will complete some computer games that involve paying attention and learning while we measure your physiological functioning (for example, heart rate and breathing). For the computer games, part of the game includes exposure to an annoying stimulus (a mild electric current). The stimulus will be calibrated to make sure that it is annoying but not painful for you. At the end of the study visit, you will also install an app (Catalyst) on your phone or preferred mobile device. The Catalyst app will allow us to send you a brief (1-3 minute) microsurvey every day for three weeks for you to tell us about your mood and stress in your daily life.

At the beginning and end of the second semester in the study, you will complete a series of electronic surveys (taking about one hour total to complete), which will be delivered online. For each survey, you will get an email message with a link, saying that the survey is ready for you to complete. You can complete the survey anywhere, using your preferred electronic device.

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After you complete the first series of surveys, we will send you another series of microsurveys for three weeks to complete on our app.

Figure. Research Schedule and Procedures

In your third and final semester in the study, you will complete another in-person study visit lasting about four to six hours. This study visit will include the same procedures as the first. Again, we will send you the three-week microsurveys after your in-person visit.

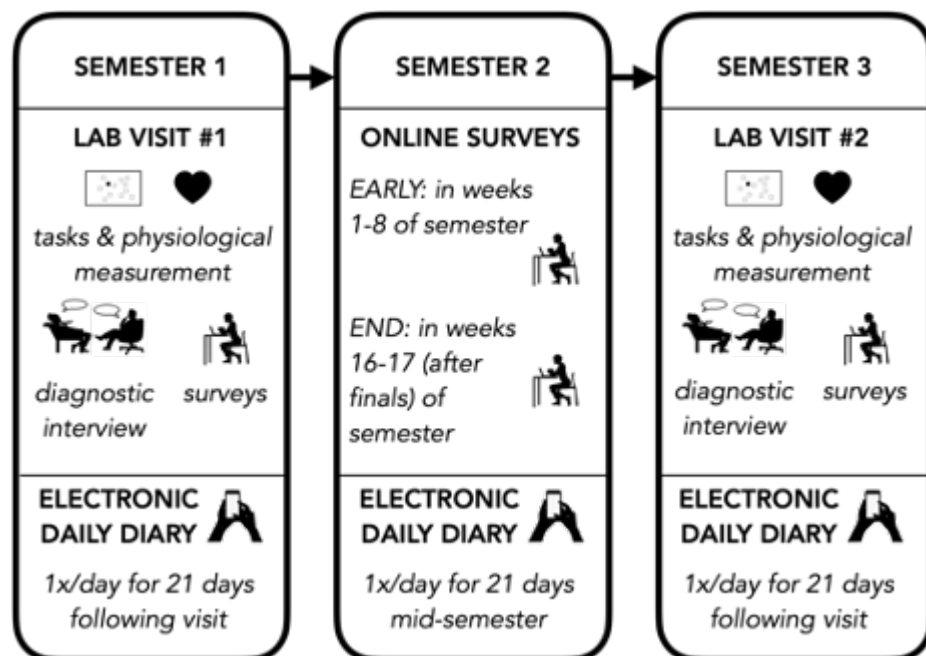


Figure. Research Schedule and Procedures

Here are some more details about what you will do in this study:

Semester 1

In-Person Lab Visit:

- At this research session, a member of the staff will interview you on your life experiences, including things like feeling sad, feeling keyed up and excited, or feeling anxious. We will also ask about thoughts about death or hurting yourself. Please know that all this information is kept confidential, except when we are mandated to report information, such as plans to hurt yourself or someone else (see the Confidentiality section below for details). We do not report other information about life experiences to anyone.
- You will also complete a set of computer games or “tasks”. In some of the games, you will have to pay attention to different types of symbols or pictures. In other games, you will learn which button to push when you see a certain picture, in order to get a reward (win bonus money) or avoid an annoying stimulation (mild electric current). Before you

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start the task, we will work with you one-on-one to make sure that the strength of the stimulation feels annoying but not painful.

- During the computer games, we will measure your physiological functioning (for example, breathing, heart rate) using special equipment. In order to measure physiological functioning, a trained research staff member will place small sensors on the skin of your neck and torso, and a flexible band around your chest.
- Finally, you will answer a set of surveys that ask about life events, stress, mood, and behaviors.
- If you are a CU student, the research session will take place at RADD Lab facility located in the Center for Innovation and Creativity building (at 1777 Exposition Drive, Boulder, CO). If you are a Brandeis University student, the research session will take place at the CoPE Lab in the Brown Social Sciences building or 51 Sawyer Road.

Daily Diary Microsurveys

- Immediately following your research session, you will begin a three-week series of daily diary microsurveys that will be sent to you through an app. We will help you install the Catalyst app on your phone or preferred mobile device.
- At the time of this introductory meeting, you will receive information about the mobile phone application, “Catalyst” (see *Mobile App Information Sheet*). The researcher will help you download the Catalyst application to your mobile device. The researcher will confirm activation of the app and teach you how to navigate the app. In addition, the researcher will answer questions about data privacy and encryption (see *Mobile App Information Sheet* for these details).

Semester 2

Early Semester Online Surveys

- Early in semester 2 of your participation (before week 8) we will send you a set of online electronic surveys that will ask about your mood, stress, and behaviors. The link for the online survey will be sent to your email to fill out on your own computer or preferred device. This set of surveys will take up to one hour.

Daily Diary Microsurveys

- After you complete your online surveys in semester 2, you will begin a three-week series of daily diary microsurveys that will be sent to you through an app.

End of Semester Online Surveys

- At the end of semester 2 of your participation (after finals), we will send you a second set of electronic surveys. Again, this set of surveys will take up to one hour.

Semester 3

In-Person Lab Visit:

- In your third semester of participation, you will complete a second research session that includes the same procedures as the first session.

Daily Diary Microsurveys

- After you complete your in-person lab visit in semester 3, you will begin a final three-week series of daily diary microsurveys that will be sent to you through an app.
- At the end of your daily diary, we will help you to securely uninstall the Catalyst app from your device.

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Voluntary Participation and Withdrawal

Whether or not you take part in this research is your choice. You can leave the research at any time and it will not be held against you.

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal from the study include no longer meeting eligibility requirements or failing to complete scheduled research procedures or respond to research staff after multiple attempts to contact you. If possible, we will still invite you to participate in all the parts of the study that you are still eligible to complete. If you withdraw from the study or are withdrawn because you no longer are eligible, we will maintain your data in our records, unless we hear from you that you would like us to destroy your data. Our ability to destroy your data will depend on whether it has already been distributed for approved research use. In the event that you request your data be destroyed, research staff will provide additional information about the removal of your data.

You should know that as a CU Boulder or Brandeis student or employee, taking part in this research is not part of your class work or duties. You can refuse to enroll, or withdraw after enrolling at any time, with no effect on your class standing, grades, or job at CU Boulder/Brandeis University. You will not be offered or receive any special consideration if you take part in this research.

Risks and Discomforts

Participation in this study may involve some minor risks or discomforts. During the study, you will be asked some personal questions which may cause you to feel different emotions. You are free to skip any questions or to stop the experiment if the questions are upsetting.

You may experience some minor boredom during the psychological testing. We take breaks between each part of the study session, for example, between the computer games. You are free to stop your participation at any time.

As noted above, in some of the computer games you will play, you will be exposed to an annoying stimulus (mild electric current). The stimulus is designed to be annoying but not painful. You may experience some discomfort during this procedure. Again, you are free to stop your participation at any time.

As part of the computer games, you may experience changes in breathing, heart rate and blood pressure. While rare, these changes may lead to decreased or increased lightheadedness or dizziness. You can take breaks as needed during the computer games, and again, you are free to stop your participation at any time.

Potential Benefits

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include insights that this research may provide into stress, coping, and wellness among college students.

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Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the University of Colorado Boulder Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Office for Human Research Protections. The information from this research may be published for scientific purposes; however, your identity will not be given out.

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. This certification means that the researchers cannot be forced to tell people who are not connected with the study, such as the court system, about your participation in this study. But, if you request that we do so, we will release information that is unique to you.

There are three exceptions to this promise of confidentiality:

1. If we see or are told information that makes us reasonably suspect that a child or at-risk adult is being or has been abused, mistreated, or neglected, we will immediately report that information to the county department of social services or a local law enforcement agency.
2. If we learn of a serious threat of imminent physical violence against a person, we will report that information to the appropriate legal authorities and make reasonable and timely efforts to notify the potential victim.
3. This promise of confidentiality does not include information we may learn about future criminal conduct.

If you tell us about harm that may come to you or others, for example a plan to hurt or kill yourself, we are mandated to report it to emergency services (calling 911 and/or campus emergency services) and we will help connect you with clinical services.

For Brandeis Participants: Brandeis staff are considered “Responsible Reporters” who have a duty to report any incidents of discrimination, harassment, or sexual violence related to Brandeis University students, employees, and participants in on or off-campus events to the OEO (Office of Equal Opportunity).

This study is sponsored by the National Institute of Health (NIH). As a participant in this study, you are agreeing to participate in NIH data sharing. In order to create a de-identified confidential code that is unique to your data, we ask you please provide us with your location of birth (city/municipality, state/province, and country). This information is only used for creating the confidential code and will not be included in any data sharing or analyses. See section titled Location of Birth on page 8.

Data we collect during this study will be protected using the following methods.

- Information about your name and how to contact you (address, phone number) will be maintained for the duration of the research study but will be kept separate from any research data.

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- If you agree to be contacted for future research studies, your contact information will be maintained beyond the end of the research study, kept separate from any research data (see Contact for Future Studies section of this form).
- Identifiable information required for data coding (see above) will be retained only to generate data codes, and then destroyed.
- Alphanumeric codes will be used to label your research data. Coded research data are kept separate from any information about your identity. We maintain an encrypted electronic database that links your name to your alphanumeric codes, and this is stored in a separate location from your personal information.

After the study is completed, we will de-identify the data by removing the identifiers that link it to you. The deidentified data may be used for future research purposes by the Principal Investigator of this study. The deidentified data may also be shared with other investigators for future research.

We are pleased to share results of the research study with you at the end of the study. If you would like to receive a summary of the research results, we will include you on our research newsletter that reports on study findings.

Payment for Participation

If you agree to take part in this research study, we will pay you according to the table below for your time and effort. Payments will be made in the form of electronic gift card or cash/check, based on your preference. If you choose cash payment, we will schedule a time for you to come to our lab facility for payment. If you choose check payment, we will mail a check to you. Payments will be made each semester for the research procedures you completed in that semester. It is important to know that payment for participation is taxable income.

Semester	Procedure	Time	Payment Details	Payment
1	Lab Visit	4-6 hours	\$12/hour plus up to \$45 bonus winnings from computer games	\$105-117
1	Daily Diary Microsurveys	~1-3 minutes/day for 21 days	\$2 per microsurvey plus \$5 bonus for completing at least 75% (16 out of 21) of microsurveys	\$47
2	Online Survey	1 hour	\$25 for completing	\$25
2	Daily Diary Microsurveys	~1-3 minutes/day for 21 days	\$2 per microsurvey plus \$10 bonus for completing at least 75% (16 out of 21) of microsurveys	\$52
2	Online Survey	1 hour	\$30 for completing	\$30
3	Lab Visit	4-6 hours	\$12/hour plus up to \$45 bonus winnings from computer games	\$105-117

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3	Daily Diary Microsurveys	~1-3 minutes/day for 21 days	\$2 per microsurvey plus \$15 bonus for completing at least 75% (16 out of 21) of microsurveys	\$57
3	Study Completion Bonus	-	Bonus for completing all of the study procedures listed above	\$25
TOTAL				\$446-470

Contact for Future Studies

We would like to keep your contact information on file so we can notify you if we have future research studies we think you may be interested in. This information will be used by only the principal investigator of this study and only for this purpose.

Please initial your choice below:

____ Yes, you may contact me for future research studies. The best way to contact me is: (enter preferred telephone number and/or email address)

____ No, you may not contact me for future research studies.

Location of Birth:

This study is sponsored by the National Institute of Health (NIH). As a participant in this study, you can choose to participate in NIH data sharing.

In order to create a de-identified confidential code that is unique to your data, we require your location of birth (city/municipality, state/province, and country). Please note that you can decline to provide this information and still remain in the study. Please check yes if you consent to sharing your location of birth.

☐

Yes

☐

No

Questions

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team: CU Boulder 303-735-8306 (phone) or raddlab@colorado.edu (email); Brandeis University 781-736-3376 (phone) or copelab@brandeis.edu (email).

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This research has been reviewed and approved by an IRB. You may talk to them at (303) 735-3702 or irbadmin@colorado.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.

Signatures

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

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

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