

Official Title: “Supplement: Long-term effects of the Family Check-Up on Depression and Suicide Across Trials and Development” AKA “The Family Check-Up to Prevent Mental Health Problems in Response to the Covid-19 Pandemic”

Brief Title: Middle School Success Over Stress

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Consent for Research Participation

Title: Middle School Success Over Stress

Sponsor: National Institutes of Health, NIDA

Researcher(s): Beth Stormshak, Ph.D, University of Oregon
Arin Connell, Ph.D, Case Western University

Researcher Contact Info: Project Coordinator: Allison Caruthers phone: 503-412-3770
ascaru@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this research is to test the effectiveness of a web-based parenting curriculum (the Family Check-Up Online) to strengthen family functioning and improve caregivers' and children's response to the stresses of the Covid-19 pandemic. This curriculum provides parents/ caregivers of middle school-aged youth with information and support to reduce stress, enhance parenting skills, and improve children's school-related behaviors.
- **Duration.** It is expected that your participation will last approximately 7 hours across 6 months. Your child's participation will last approximately 1 hour across 6 months.
- **Procedures and Activities.** You will be invited to participate in the following activities:
 - Surveys and Interviews:
 - Parent/ Caregiver Surveys: Four private surveys, one at the beginning of the study, and follow-up surveys 2 months, 4 months, and 6 months later. You may complete these surveys on a computer or, if you prefer, as an interview with research staff via phone or Zoom. Each one should take about 45 minutes to complete. The surveys ask questions about your feelings, your health, your family, your child's abilities and behavior, parenting your child, and life stressors.
 - Youth surveys: Two private surveys, one at the beginning of the study and a follow-up survey 6 months later. Your child may complete these surveys on a computer or as an interview with research staff via phone or Zoom. Each one should take about 30 minutes to complete. The surveys ask about his/ her personality, health, mental health, family life, and school life. We will not



share your child's answers to these questions with you unless we believe your child is in danger of seriously hurting himself/ herself or others. In that case, we would immediately share this information with you and work with your family to develop a safety plan and to get immediate support for your child.

- You will be paid \$75 at each of the 4 time points, which will be paid by check or Amazon gift card. Your child will be paid \$25 after completing their baseline survey, and again after completing the 6-month follow-up survey. This payment will be made via check or Amazon gift card.
- FCU Online: You will be asked to use the FCU Online app on your smartphone to think about parenting and practice new skills. The topics covered include healthy behavior for stressful times, positive parenting, rules and consequences, supporting school success, and positive communication.
- Telehealth Support from a Family Consultant: A Family Consultant will support you in setting goals and using the FCU Online through phone calls, text, or Zoom check-ins. You will complete check-in appointments with your Family Consultant for each of the 5 topics in the FCU Online. Each check-in will take approximately 20 minutes and will be recorded in order to evaluate how well the Family Consultant follows the Family Check-Up model during their work with you.
- FCU Online Feedback Survey: After you have used the FCU Online app and completed check-in appointments with your Family Consultant, you will be asked to complete an additional survey regarding your feelings about the web-based application and the support you received from your family consultant. This survey will take approximately 10 minutes.

Over the course of the study, your family may earn up to \$350 for participation in using the FCU Online, doing surveys and interviews, and receiving check-ins from Family Consultants. You'll be paid \$75 after completing the first parent/ caregiver survey. You'll be paid an additional \$75 after each of the three follow-up surveys/ interviews. Your child will be paid \$25 after completing their baseline survey, and another \$25 after completing the 6-month follow-up survey. This payment will also be made via check or Amazon gift card.

- **Risks.** Some of the foreseeable risks or discomforts of your participation include feeling uncomfortable answering some questions in the surveys or talking with your Family Consultant. You can choose not to respond to questions in the surveys. There is also a risk that your private information could be revealed. However, we take precautions to guard against this.
- **Benefits.** Some of the benefits that may be expected include enjoying thinking about parenting and practicing new skills. You may enjoy talking to your Family Consultant about your goals and getting support on parenting.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The researchers, Dr. Beth Stormshak from University of Oregon and Dr. Arin Connell from Case Western University, are asking for your consent to this research. The study is funded by the National Institutes of Health.



The PI, Beth Stormshak, is founder of Northwest Prevention Science, Inc., a for-profit entity that provides consultation and training services on the Family Check-Up. Research on the Family Check-Up may contribute to and inform the services Dr. Stormshak provides through Northwest Prevention Science, Inc. As a result, Dr. Stormshak and Northwest Prevention Science, Inc. may financially benefit from this research. Questions about this may be directed to Dr. Stormshak.

Why is this research being done?

The purpose of this research is to test the effectiveness of a web-based parenting curriculum (the Family Check-Up Online) to strengthen family functioning and improve caregivers' and children's response to the stresses of the Covid-19 pandemic. This curriculum provides parents/ caregivers of middle school-aged youth with information and support to reduce stress, enhance parenting skills, and improve children's school-related behaviors. You are being asked to participate because you are the parent/ legal guardian of a child between the ages of 10 and 14. About 150 families will take part in this research.

How long will I be in this research?

We expect that your participation will last approximately 7 hours across 6 months. This includes times spent to complete four surveys, using a web-based application (FCU Online), and participating in five check-ins with a family consultant. Your child's participation will last approximately 1 hour, split into two sessions of roughly 30 minutes. This includes time spent completing 2 surveys, six months apart.

What happens if I agree to participate in this research?

If you agree to participate in this research, your participation will include:

- **Baseline surveys:** You will be asked to complete a survey that takes about 45 minutes to an hour to complete. You will have a choice to complete this survey on your own via computer or as an interview via phone or Zoom. Your survey asks questions about your feelings, your health, your family, your child's abilities and behavior, parenting your child, and life stressors. Your child will also be asked to complete a survey and will also have a choice of completing this survey on their own via computer or as an interview via phone or Zoom. This survey takes about 30 minutes to complete. Your child's survey asks questions about his/ her personality, health, family life, and school life. Given the stress of the pandemic, and the things children have gone through over the past few years, we are concerned about children's mental health and take it very seriously. Therefore, during the youth survey we will also be asking children some sensitive questions about their current emotional functioning, anxiety, and symptoms of depression, which can include suicide risk. If your child were to indicate that they are in danger of seriously hurting him/herself or someone else, we would immediately share this information with you and work with your family to develop a safety plan and to get immediate support for your child.

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- **Group selection:** After completing surveys, your family will be put into one of two study groups by chance (like tossing a coin). You have a 50% chance of being placed in each group. You cannot choose your study group. The two study groups are:
 - **App + coach:** Parents/ Caregivers in this group will be asked to log-in and explore an app that offers an online parenting program. This website includes 5 modules. Each one consists of a brief survey (roughly 10 questions each), feedback, and parenting resources such as videos and interactive tools. Parents/ caregivers will be given the opportunity to discuss parenting with a family consultant after completing each module. These check-ins can occur via text, phone, or Zoom, and give you the opportunity to get personalized support. Sessions completed over phone or Zoom will be recorded via Zoom in order to evaluate how well your Family Consultant followed the elements of the Family Check-Up model during their appointments with you. If you choose to complete these sessions by phone, the family consultant will put you on speaker phone and start a Zoom “meeting” with themselves, recording the meeting. The only image that would appear in this recording is the family consultant’s black screen. After the meeting is over, the video portion of the recording would be deleted while retaining the audio file. If you choose to complete the meeting via Zoom, the meeting will be recorded. Your image and the family consultant’s image would be recorded (assuming you both choose to share your video), but, again, the video portion would be deleted after the meeting is over and only the audio file would be retained for analysis.
 - **Waitlist control:** Parents/ Caregivers in this group will be given the same opportunities and resources as the App + Coach group starting 4 months after completion of the baseline survey.
- **Follow up surveys:** To help researchers understand how children and families may change after using the FCU Online program, you and your child will each be asked to complete follow-up surveys/ interviews identical to the baseline surveys. You will be asked to complete these surveys 2 months, 4 months, and 6 months from now. Each parent/ caregiver survey will take about 45 minutes to an hour to complete. Your child will be asked to complete their survey now at baseline and again in 6 months. Each child survey will take about 30 minutes to complete.
- **FCU Online Feedback Survey:** After you have used the FCU Online app and completed check-in appointments with your Family Consultant, you will be asked to complete an additional survey regarding your feelings about the web-based application and the support you received from your family consultant. This survey will take approximately 10 minutes.

The research project is being conducted remotely, meaning that all research activities will be conducted online or over the phone.

When completing surveys and interviews, you and your child may skip any question that makes either of you uncomfortable and you may stop your participation at any time.

What happens to the information collected for this research?

Information collected for this research will be used to test the effects of the FCU Online program on parenting skills, parental depression, parent and child self-regulation, child adjustment, and family functioning. Your name will not be used in any published reports or conference presentations about this study. 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.

In addition, de-identified study data will be deposited with the NIMH National Data Archive to increase its utility to qualified individuals within the scientific community. This means that variables that could be used to identify you and other participants will be removed from the data set. The remaining data could then be distributed to another investigator for future research studies without



your additional informed consent. In order to access these data, the NIMH Data Archive will require that investigators (1) use the data for research purposes only; (2) not to identify any individual participant; (3) secure the data using appropriate computer technology; and (4) destroy or return the data after analyses are complete.

In addition, identifiers will be removed from the identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Measures we will take include:

- Using a HIPAA-compliant Zoom account issued through the University of Oregon to conduct interviews and check-ins.

We will take measures to protect the security of all your personal information, but we can never fully guarantee confidentiality of all study information. Measures we will take include:

- Training staff conducting phone/ Zoom interviews and check-ins to protect participant privacy;
- Storing consent forms, surveys collected via Qualtrics, and video recordings of sessions with Family Consultants on our secure server;
- Strictly limiting access to our secure server to authorized research staff involved in the project;
- Not including participants' identifying information on surveys or recordings, instead assigning a unique family ID number;
- Recording directly to a University-owned computer (not the cloud) and storing them in a password protected file on a secure server; and
- Using audio/ video recordings for research purposes only. We will not use recordings for other purposes without your written consent.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include: the Institutional Review Board that reviewed this research and the study sponsor, the National Institute for Drug Abuse.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. You should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state,



or local law that requires disclosure (such as to report child abuse, but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute for Drug Abuse which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

What are the risks if I participate in this research?

There may be risks of stress, emotional distress, inconvenience, and possible loss of privacy and confidentiality associated with participating in a research study.

What are the benefits of participating in this research?

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits to you include enjoying thinking about parenting and practicing new skills. You may also enjoy talking to your Family Consultant about your goals and getting support on parenting.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon. If you decide to leave this research, contact the research team so that the investigator can delete your survey/ interview data and any recordings of sessions with family consultants. Please note that if data has already been de-identified at the time of your request and no link between identifiers and family ID number remains, we will not be able to delete your data.

Will I be paid for participating in this research?

For taking part in this research your family may receive up to a total of \$350. You'll be paid \$75 after completing the first parent/ caregiver survey. You'll be paid an additional \$75 after each of the three follow-up surveys/ interviews. Your child will be paid \$25 after completing the first youth survey and again after their 6-month follow-up survey.

Payment will be made via check or Amazon gift card and will be mailed within one week of receiving completed surveys from you and your child. Please be aware that compensation for participation in research studies may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data. If you receive \$600 or



more in a calendar year, you may be contacted to provide additional information (e.g., social security number) for tax reporting purposes.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Dr. Allison Caruthers, Project Coordinator
503-412-3770
ascaru@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510
ResearchCompliance@uoregon.edu

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Please enter your full name below. This will serve as your signature indicating your consent to participate in this study.

Please enter today's date:

Name of child participating in study: _____

Relationship to child participating in study: _____

As described above, you will be video recorded while receiving parent/ caregiver coaching sessions with the family consultant. Recordings will only be used to monitor the family consultant's fidelity to the research model and will be destroyed at the end of the project.

Please enter your initials in the space below if you consent to the use of videorecording as described.



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Please click **NEXT** to complete the consent process.

Official Title: “Supplement: Long-term effects of the Family Check-Up on Depression and Suicide Across Trials and Development” AKA “The Family Check-Up to Prevent Mental Health Problems in Response to the Covid-19 Pandemic”

Brief Title: Middle School Success Over Stress

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Middle School Success Over Stress Student Assent Form

Purpose:

- The purpose of this research study is to test a web-based parenting program to see how useful it is to families.
- We have two goals:
 - to strengthen family relationships;
 - to help parents and children feel less stressed about the Covid-19 pandemic.
- You and your caregiver are asked to participate because you are between the ages of 10 and 14.
- About 150 families will take part in this study.
- If you want to participate, it will be take about 1hour of your time. This hour will be broken up into 2 sessions 6 months apart.

Surveys/ Interviews:

- We would like you to answer some questions about your personality, health, family, and school life.
- You have the choice of answering these questions by either completing a survey on a computer or by being interviewed by a member of our research team over Zoom.
- You will be asked to answer these questions two times, 6 months apart.
- Each survey or interview will take you about 30 minutes.
- We repeat this interview so that we can see how things have changed or stayed the same for you and your family over the 6 months.
- Your caregiver will also complete surveys or interviews. In addition, they will be asked to use an app on their phone.
- Once you complete your interview/ survey, you will be paid \$25 with either a check or an Amazon gift card.
- This will happen at each of the two points in time.

Procedure:

- If you choose to answer these questions by computer survey, we will send a link to the email address your parent provided. You will answer each question on your own, and submit the survey when you are done.
- If you choose to answer these questions by interview, research staff will have a survey on a computer in front of them. They will read you the questions and type in your answers.

Privacy:

- Your answers to the interview questions are kept private.
- Your name will not be stored in the same computer file as your answers.
- Your name will not be included in the data file. Instead we will use an ID number that is unique to you.
- Only a few people on our research team have the ability to link your name to your ID number.
- Your name will not be put on any papers or reports written about this project.



- We do not plan to share your answers with your caregiver. However, if we believe that you are in danger of hurting yourself or others, our family consultant will first talk with you about your safety and then talk with your parent so that, together, we can keep you safe.
- The only time we will share your name or your parent's name with anyone outside the family is if we think someone is being abused or plans to harm one's self. We are required by the State of Oregon to report that.

Risks:

- You may feel uncomfortable answering some questions in the interview.
- You can skip any questions you do not want to answer.
- It is possible that someone may accidentally see your private information.
- We take many steps to protect your privacy, but we cannot be positive an accident will not happen.

Voluntary:

- You can help with this project if you would like to.
- You do not have to help if you do not want to.
- You can also change your mind and stop participating at any time for any reason.

Questions:

- Do you have any questions about this project?
- If there is ever a time that you do not understand what we are asking you to do, please ask us questions or ask your parents to ask us questions.

☐

I agree to participate in the Middle School Success Over Stress Study.

☐

I understand that I will be mailed a copy of this assent form to keep for my records.

Student Name: _____

Today's Date: _____

Name of Staff member who explained the study to me: _____