

Self- Compassion for Children and Caregivers (SCCC)

Lead Researcher: Ryan Herringa, M.D., Ph.D. (608) 263-6068

Parent/Guardian Consent

**University of Wisconsin-Madison
Consent to Participate in Research and
Authorization to Use/Disclose Identifiable Information for Research**

TITLE OF THE STUDY: Self- Compassion for Children and Caregivers (SCCC)

LEAD RESEARCHER: Ryan Herringa, M.D., Ph.D.; (608) 263-6068

INVESTIGATORS: Ryan Herringa, M.D., Ph.D., Assistant Professor, Department of Psychiatry, UW-Madison; Christine Lathren, M.D., MSPH, Research Assistant Professor, Department of Physical Medicine & Rehabilitation. UNC-Chapel Hill

INVITATION

We invite you and your child to take part in a research study testing a self-compassion course designed for 8-11year-old children who have some depressive and/or anxiety symptoms and their caregiver. We are gathering feedback on the course to make it as helpful and interesting as possible for families from diverse backgrounds. We are also exploring if and how participation may impact caregiver and child well-being, relationships, and responses to social experiences. We are inviting you and your child because you may meet the eligibility requirements for this study.

The purpose of this consent and authorization form is to give you and your child the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future and requests your and your child's authorization (permission) to use your health information. Please ask questions about anything in this form that is not clear. If either of you want to talk to your family and friends before making your decision, you can. When we have answered all of your questions, you and your child can decide if you want to be in the study. This process is called "informed consent."

If you are the parent or legal guardian of a minor who is invited to take part in this study, your child can participate in the study only if you give your permission. We will also ask your child if he/she is willing to take part in the study.

IMPORTANT THINGS TO KNOW ABOUT ANY RESEARCH STUDY

Taking part in research is voluntary. You can choose not to be in this study or to stop at any time. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights.

STUDY SUMMARY

<p>What is this study about?</p>	<p>The purpose of this study is to gather feedback about a group-based online self-compassion course for children and their caregivers. We also want to understand how participation may impact child and caregiver well-being, relationships, and responses to social experiences.</p>
<p>What will happen during the study?</p>	<p>First, you and your child will come to the clinic, complete consent, and fill out questionnaires about feelings, relationships, puberty, and mental health.</p> <p>Then, your child will have stickers placed on their fingers, shoulder, and hip to record their sweat and heart rate. Your child will watch a short video and complete a short computer task while you watch. Afterwards, you and your child will be interviewed about the computer task. The computer task will be video recorded, and the interview will be audio recorded.</p> <p>You and your child will then participate in the self-compassion course. This course includes 6 weekly 1-hour online sessions with other caregiver-child pairs.</p> <p>After the course, you both will come back to the clinic to repeat the above steps (questionnaires and computer task).</p> <p>Finally, you and your child will be invited to provide feedback about your experiences in the self-compassion course via an online conversation with one of our study team members.</p>
<p>How much time will I spend on the study?</p>	<p>Total time in this study is approximately 10 hours over the course of 2-3 months. This includes 2 lab visits (1-1.5 hours each), (6 weekly) 1-hour online self-compassion course sessions, and a feedback conversation (30 minutes).</p> <p>The two in-person study visits may take place either at your school or at a local clinic in the community (Wisconsin Psychiatric Institute and Clinics, WisPIC; 6001 Research Park Blvd, Madison, WI 53719).</p>
<p>Could taking part in the study help me?</p>	<p>We hope that taking part in this study will help caregivers and children improve their well-being by learning how to cope with difficult emotions. However, we cannot guarantee that you or your child will receive any direct benefits.</p>

What are the main risks of taking part in the study?	All research is associated with possible risks. The risks of this study are low, and we will watch for any problems during the study procedures so that we can stop if necessary. The consent form explains the possible risks in more detail. For this study, there are some important risks for you to know. First, you and/or your child may feel emotional distress when answering questionnaires, participating in the course, or during the computer task. There may be risk of skin irritation or discomfort when putting on or taking off the sticker sensors during the lab visit. There is also a small risk to your confidentiality if someone outside the study team obtained the study data.
How is research different from health care?	When you take part in a study, you are helping to answer a research question. Test results will not be used for your health care.
Questions about the study?	Contact the research team: The BRAVE Research Center: 608-265-3610 brave@psychiatry.wisc.edu
Questions about your rights as a research participant?	Contact University of Wisconsin Hospital and Clinics Patient Relations Representatives at 608-263-8009

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MORE INFORMATION ABOUT THIS STUDY

Why are researchers doing this study?

The purpose of this study is to help improve the emotional well-being of youth and their families by offering a course teaching self-compassion to children who have some symptoms of depression and/or anxiety and their caregiver. We will ask participants' feedback in order to modify and improve the course. We are also interested in how participation may impact caregiver and child well-being, the caregiver-child relationship, and responses to social experiences.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about approximately 24 youth between the ages of 8-11 and their caregivers will participate in this study. Funding for this study is provided by the Mind & Life Institute.

What will happen in this study?

If you decide to participate in this research study, you and your child will participate in 2 study visits and 6 course sessions over 2-3 months. The in-person study visits will last between 60-90 minutes each and take place either at Glenn Stephens Elementary School or the Wisconsin Psychiatric Institute and Clinics (WisPIC). The course sessions will take place after school or over the weekend using an online video call. Each session will be 60 minutes in length. After the course is over, we will gather your feedback about the course during a 30-minute online conversation.

The self-compassion course sessions will be led by a certified instructor and will include about 9 other caregiver-child pairs. Each session includes activities designed to keep kids interested and to help caregivers and children learn together about self-compassion. These activities include mindful movement and games, teaching components using of props (e.g., stuffed animals, blankets, short videos), guided visualizations, group discussions, and opportunities for you and your child to practice skills one-on-one together by muting yourselves and engaging in discussion. Home practices will be suggested after each session, and you will be emailed a "picture review" of practices and ideas each week that you can incorporate together at home.

Before and after the course, you and your child will be asked to complete *an in-person study visit*. At these visits, you and your child will separately complete online questionnaires about feelings, relationships, puberty, and psychological health. Then, your child will complete a computer task. Before the task, we will place two small sensor stickers on your child's index and middle fingers and two small stickers on their collar bone and hip to record their heart rate and sweat levels. You and your child will watch a short video, then your child will complete a computer task (10 minutes) while you watch. Then, you and your child will be separately interviewed (10 minutes) about the task. Both you and your child will be video recorded throughout the computer task and audio-recorded during the interview. We will end with a final, fun activity.

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Finally, you and your child will have a chance to provide feedback about the course during a 30-minute online session with a study team member. With your permission, we will audio-record this conversation.

What protected health information (PHI) will be used in this study?

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will collect and use the following kinds of PHI from both you and your child:

- From You:
 - Information about you and your child, such as your names, phone numbers, e-mail addresses, and birth dates.
 - A video recording of you and your child completing the computer task
 - An audio recording of your interview after the computer task and youth feedback about the course
- From medical tests or other procedures done for this study:
 - Body responses from your child, including sweat and heart rate.
 - Questionnaire and interview information provided by you and your child about your thoughts and experiences.
 - Results of tests or procedures done as part of the study.
 - Things you tell the researchers about your health.

We are requesting your email address so we can schedule appointments, send reminders, or answer any general questions you may have. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the study team at 608-265-3610. You do not have to provide your email address to participate in this study.

How long will I be in this study?

Your participation will include up to 2 in-person study visits, 6 online course sessions, and an online feedback session. You will be a part of this study for approximately two to three months, as scheduling allows.

How is being in this study different from my regular health care?

If you take part in this study, the main difference between you and your child's regular care and the study is that in this study, we are testing a new course. We do not know if this course will be helpful in caregivers and youth with depression and anxiety symptoms. We also do not provide any follow-up care. This study is not part of your health care.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you and your child do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization allows researchers to use your protected health information (PHI) indefinitely. However:

- You can choose to take back your authorization for researchers to use your health information at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to continue to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Ryan Herringa, MD, PhD, at brave@psychiatry.wisc.edu.

Will being in this study help me in any way?

It is possible that taking part in this study will lead to decreased levels of depression and anxiety and increased well-being in your child. You and your child may gain skills that help you to cope with difficult emotions. As a caregiver, you may learn ways to support your child when they are struggling with difficult emotions. However, the specifics of what (if any) potential benefits that you may experience are unknown and there is no guarantee that you or your child will receive any direct benefits from participating.

Will I receive the results of research tests?

All of the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your doctors the results of these research tests. The exception to this may be if your child has severe anxiety or depression symptoms at any point during the study, we will notify you via phone or email and provide additional support and local mental health resources.

What are the risks?

There is a risk that you or your child’s information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

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Some questions that we ask in questionnaires or activities that you complete during the course may make you or your child feel uncomfortable. These questions are similar to what would be asked in a clinic or by a mental health professional. You and your child may choose not to answer such questions or complete any activities. Some people may also feel uncomfortable answering questions about their thoughts and feelings and physical development.

You or your child may experience brief emotional distress during the computer task or interview; however, we will make every effort to minimize any distress you or your child may experience. One aspect of the study involves applying and removing sensors with stickers from your child's skin. Our research assistants are trained to apply and remove the stickers carefully, to minimize any skin irritation or discomfort. We will explain all procedures thoroughly, will frequently ask you and your child how you are feeling, and answer any questions you might have.

Will being in the study cost me anything?

There will be no cost to you for any of the study activities or procedures. You may need to pay for basic expenses such as childcare or transportation to our facility. We will offer a taxi service to and from study visits and childcare during visits, if needed. In addition, if you do not have reliable access to internet for the duration of the intervention, we may be able to offer you a hotspot to use.

Will I be paid or receive anything for being in this study?

We will be compensated a total of \$125 for completing study assessments. This includes \$50 after completion of the pre-intervention study visit, \$50 provided after completion of the post-intervention study visit, and \$25 after completion of a post-course interview. If, for some reason, you are asked to repeat a full visit, you will be compensated at the rate of that visit.

If you choose to leave or we take you off the study for any reason, you will only receive the payment for completed visits. If you choose to withdraw from the study at any time during a visit, you will receive payment for that entire visit.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, phone number, and other information that can identify you. We will also store this information securely. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or

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health care providers, if we learn during the study that you or others are at risk of harm (for example, if we learn about child or elder abuse).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Accounting and billing personnel, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- Collaborating researchers outside UW-Madison

Certificate of Confidentiality

The study will be protected by a Certificate of Confidentiality from the National Institutes of Health. This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study. Once issued, the Certificate will retroactively cover information collected since the beginning of the study.

What will happen to my data after my participation ends?

We will keep all of your data, including recruitment information and study activity data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers.

This is what will happen with your banked data and biospecimens:

- We will use the data in future research projects research on mental health. We may also use them for other types of research.
- The data may be shared with other researchers at University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data will be labeled with a code instead of your name.

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- When we give your data to other investigators for research projects, they will not be able to use the code to figure out which data are yours.
- The research team will maintain a link between your data and your identifiable information kept by the study team.
- You can request to have your data removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data and biospecimens:

- Banked data will not be shared with your healthcare providers or used in your treatment outside this study.

Will information from this study go in my medical record?

A medical record may be created for you if you do not already have one. None of the information we collect for this study will go in your medical record.

What if I have questions?

Study team members are the primary point of contact if you have questions during a study visit. In addition, please contact the study team at 608-265-3610 or email brave@psychiatry.wisc.edu with any questions or comments you may have about the study.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Contact for future studies?

We would like to keep your contact information so that we can reach you for possible future studies, furthering our efforts to better understand how parent-child relationships and experience affect child development. Your contact information will be kept in a secure location. This is completely voluntary and optional. You can choose to have the study team destroy your contact information after this study is completed, and you will not be contacted for any follow-up studies.

Caregiver initials:

_____ **Yes**, the research team **may** keep my contact information for possible future studies conducted in the BRAVE Research Center.

_____ **No, I do not want** the research team to keep my contact information after this study is completed, and I do not want to be part of any future studies conducted in the BRAVE Research Center.

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**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY
AND
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION**

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study and your child's participation, and the researchers have answered your questions.
- You and your child agree to participate in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

You will receive a signed and dated copy of this form for your records.

Parent/Guardian Consent for the Participation of a Minor

Printed Name of Parent/Guardian

Signature of Parent/Guardian

Date

Parent/Guardian Consent for the Participation of Self

Printed Name of Parent/Guardian

Signature of Parent/Guardian

Date

Signature of Person Obtaining Parental/Guardian
Permission and Authorization and Child Assent

Date