University of Wisconsin-Madison
Consent to Participate in Research and
Authorization to Use and/or Disclose Protected Health Information for Research

TITLE OF THE STUDY: Self-Compassion in Dialectical Behavior Therapy

INVESTIGATORS: Ryan Herringa, M.D., Ph.D., Assistant Professor Department of Psychiatry; BRAVE Research Center (BRC); Department of Psychiatry, UW-Madison

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 they are willing to take part in the study. In this consent form, “you” means the child who takes part in the study. “Your caregiver” means you as the parent/guardian. As the parent/guardian, you are also asked to participate in the study. Your involvement is described in this document as well.

INVITATION
You are invited to be in a research study that looks at how you manage your emotions using different methods, or strategies, and how your ability to use these methods change over time as you participate in therapy. We are inviting you because you are already engaged in therapy, and are between 13 and 18 years of age.

The purpose of this consent and authorization form is to give you 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 authorization (permission) to use your health information. Ask questions if anything in this form is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent”.

IMPORTANT THINGS TO KNOW ABOUT ANY RESEARCH STUDY
Taking part in research is voluntary. You can choose not to be in this study, or 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.

WHY ARE RESEARCHERS DOING THIS STUDY?
The purpose of this research is to look at how you manage your emotions using different methods, and how your ability to use these methods change over time as you participate in therapy. We are doing this research because we want to see if your ability to use specific methods changes due to your work in therapy. We want to look at how the ability to use these methods is impacted by your mental health and other past experiences. We want to look at how these change in adolescents, because there hasn’t been a lot of work done in how adolescents use these methods. We will also look at what your body is doing while you use these methods, to see how hard you are working.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 50 adolescents will participate in this study.
MORE INFORMATION ABOUT THIS STUDY

WHAT WILL MY PARTICIPATION INVOLVE?
If you decide to participate, you will be asked to complete two study visits over the course of approximately 6 weeks. Each visit will be around one and a half hours long. If you choose to participate, activities that you will complete include the following: answering questions about your mood and health and completing a task on the computer where you will practice different methods for managing your emotions. While completing the computer task, you will have stickers on your body that allow us to see what your body is doing as you manage your emotions using these different methods. While completing surveys about your moods and health and experiences, you may skip any questions you do not wish to answer.

Both study visits will be the same. The second one will be approximately 6 weeks after the first. You will begin each visit by having some stickers placed on your hands and on your torso, which will measure your heart and sweat levels. You will have a band placed around your chest to measure your breathing. After that, you will complete a task on the computer where you will look at groups of emotional images while following a specific instruction about how to manage your emotions. These images are made to cause a variety of emotions, some of which may be distressing, and some may be happy. After you see an image and follow the instructions, you will be asked to say how you are feeling. After several images, you will be asked a few questions about how well the strategy worked for you. You will view several groups of images. We will give you a chance to practice following these instructions before you begin. We expect the practice and task to take about 45 minutes.

After you complete the task, you will complete several surveys asking about your mood, health, and other past experiences. Again, you may skip any questions you do not wish to answer. We expect the surveys to take about 45 minutes to finish. You may also finish early.

PROTECTED HEALTH INFORMATION (PHI) 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 use the following kinds of PHI:

- Information about you and your parent/guardian, such as your names, phone numbers, email addresses, and birth dates
- Things you or your parent/guardian tell the researchers about your health about your thoughts and experiences, and if you have any mental health diagnoses
- Body responses including muscle tension, perspiration, heart rate, and respiration

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 608-263-3610. You do not have to provide your email address to participate in this study.

HOW IS BEING IN THIS STUDY DIFFERENT FROM MY REGULAR CARE?
This study is not part of your health care. While some of the surveys you complete may be similar to those use by a doctor, psychologist, or counselor, these are separate from your health care. Your decision to participate should not impact your visits with your doctor, psychologist, or counselor in any way.
DO I HAVE TO BE IN THE STUDY? WHAT IF I SAY “YES” NOW AND CHANGE MY MIND LATER?
No, you do not have to be in this study. Taking part in research is voluntary. This means you decide if you want to be in the study. If you decide now to take part in the study, 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.

Let the researchers know if you choose to leave 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 for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this 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 take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher:
  Dr. Ryan Herringa  
  Department of Psychiatry  
  University of Wisconsin  
  6001 Research Park Blvd  
  Madison, WI 53719

WILL BEING IN THIS STUDY HELP ME IN ANY WAY?
Being in this study may help you learn more about how you manage your emotions, or may teach you different ways to manage your emotions. You may also help you learn more about your health. We may also be able to direct you to appropriate resources. There will be no other direct benefit to you. There is a potential benefit to society of better understanding the effects of affective disorders, traumatic stress, and PTSD during adolescence. This could someday lead to better detection and treatment.

Researchers may develop products from the samples and information you provide for this study. Some of these products may have commercial value. If the research team or others use your samples or information to develop products of commercial value, you will not receive any profits from products created.

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.

ARE THERE ANY RISKS?
Some questions may make you or your caregiver feel uncomfortable. These questions are similar to what would be asked in a clinic. You and your caregiver may choose not to answer such questions. Some people may also
feel uncomfortable answering questions about their thoughts and feelings. This may be especially true for participants when asked about their traumatic experiences. It may be painful or upsetting to recall details of the event.

While your data are kept in very secure locations, there is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

We might find out during the study if you may be in danger of being hurt by someone, are contemplating harming others, or considering self-harm or suicide. If signs of child and/or elder abuse and/or neglect are observed/disclosed during any of the study visits, members of the study team may be required by state law to report this to the appropriate authorities or protective services. This includes responses to questions on any study surveys. If your parent/guardian is suspected of mistreating you, another legal guardian would need to be willing to agree to let you participate. The study team would also need to clarify that any maltreatment has been properly reported.

**WILL BEING IN THE STUDY COST ME ANYTHING?**
There will be no cost to you for any visits that are part of this research study.

**WILL I BE PAID FOR PARTICIPATION?**
You will get up to $125 for participating in the study. You will get $50 if you complete the first visit, and $75 for completing the second visit. You will receive a separate cash payment at the end of each visit.

**HOW WILL MY DATA BE USED, CONFIDENTIALITY PROTECTED, & WHO WILL USE MY HEALTH INFORMATION?**
We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely. 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 and/or government officials responsible for monitoring study procedures and/or data (e.g., monitors, auditors, Institutional Review Boards). This can include accessing medical records so that regulatory authorities can verify study protocol and data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records.

Others at UW-Madison and UW Health who may need to use your health information during the course of this research can include:
- Researchers in the University of Wisconsin Department of Psychiatry
- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison, University of Wisconsin Medical Foundation, and University of Wisconsin Hospital and Clinics
- Research support services staff at the UW-Madison and its affiliates

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 and physiological data 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.

We will keep information provided as part of this study indefinitely, a process called data banking. If you would not like us to maintain your information indefinitely, you may contact the study team, and we will remove your data from our servers after we have finished all study activities.

**WILL INFORMATION FROM THIS STUDY GO INTO MY MEDICAL RECORD?**

None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

**WHAT IF I HAVE QUESTIONS?**

The experimenter at your session will answer any questions you may have about the study. In addition, you may call the study team at 608-263-3610 or email emotionstudy@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 subject, or have complaints about the research study or study team, contact Confidential Research Compliance line at 1-833-652-2506. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

**IF I START THE STUDY, CAN I CHANGE MY MIND?**

Your participation is completely voluntary; you may stop participating at any time during the study. Stopping the study will not affect present or future medical care at this institution in any way. Furthermore, participation in the research study or refusal to do so will not affect a caregiver participant’s employment or status as a student (e.g., grades or class standing) at the university.

**OPTIONAL STUDY ACTIVITIES**

This part of the consent form is about additional related activities that you can choose to take part in. These activities are optional. You can still take part in the main study even if you say “no” to any or all of these. These activities will not help you directly. We will not tell you the results of these optional components, and we will not put any of these study results in your medical records. Taking part in the optional activities will not cost you anything.

**Contact for Future Studies (Parent/Guardian):**

We would like to keep your contact information so that we can reach you for possible future studies. 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 the study is completed, and you will not be contacted for any follow-up studies. Please state your preference by initialing the appropriate line:

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

_____ No, I do not want the research team to keep my contact information after this study is completed.

**Agreement to participate in the research study**

You are making a decision whether or not to have your child participate in this study. You do not have to sign this form. If you refuse to sign, however, your child cannot take part in this research study.
If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your child’s participation, and received answers to your questions
- decided to allow your child to participate in this study
- given authorization for the person’s 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.

__________________________
Printed Name of Parent/Guardian or Youth Participant Age 18+

__________________________  _______________________
Signature of Parent/Guardian or Youth Participant Age 18+          Date

__________________________
Printed Name of Subject (age 15 – 17)

__________________________  _______________________
Signature of Subject (age 15 – 17)          Date

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