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MEMORANDUM
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TO: Kathryn Tuchscherer Franklin and Mark Schure

FROM: Mark Quinn *Mark Quinn CJ*
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: July 24, 2020

SUBJECT: *"A Feasibility Study for Implementing and Evaluating an Internet-based Cognitive Behavior Therapy Intervention in School Settings and Its Impact on Adolescent Mental and Behavioral Health" [KF072420]*

The above proposal was reviewed by **expedited review** by the Institutional Review Board. This proposal is now approved for a period of one-year.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. ***If there are any adverse consequences, please report them to the committee within 3 calendar days.*** If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research require submission of the **"Request for Modification/Amendment"** form in order for those changes to be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. If the research is still in progress in **5 years**, a complete new application will be required.

INFORMED ASSENT – YOUTH PARTICIPANT
TO BE READ ALOUD TO YOUTH PARTICIPANTS

Project Title: *A feasibility study for implementing and evaluating an Internet-based cognitive behavior therapy intervention in school settings and its impact on adolescent mental and behavioral health*

Principal Investigator: Dr. Katey T. Franklin, PhD, LCPC

Scientific Advisor: Dr. Mark Schure, PhD
Montana State University, Bozeman

Partner Organization: Miles City and Park County Public School Systems

Sponsor: Center for American Indian and Rural Health Equity (CAIRHE) and
National Institute of Health (NIH)

Version Date: July 21, 2020

Purpose:

You are being asked to take part in a research study. The purpose of this study is to understand the impact of an online program called Youth Thrive (Y-T) for adolescents' emotional wellbeing. The goal of the Y-T program is to help understand normal challenges and learn how to cope with stress in a healthy way. You may learn about yourself- for instance, how do you handle stress in your life? You may learn new coping skills to help in tricky social situations with friends and family. You may learn about how you think about challenges and learn healthy ways to think about stressful situations.

Activities:

The activities include your participation in online sessions with the Y-T program in your Health Enhancement class- this is the educational part of the project. You will be asked to take 3-5 periodic assessments over the course several weeks- this is the research part of the project. All of these assessments are online and will take about 15 minutes to complete. Given the research design, there is a chance that you might take these assessments before you begin the Y- T program. You may also be asked to participate in a focus group where we ask you questions about your experience with the Y-T program. You can participate in the study but choose not to participate in a focus group.

Time: Your participation in this study will last about 8-16 weeks. The assessments will occur approximately every two weeks. The focus groups are online through Zoom or Webex and will last about 30 minutes to an hour. Participation in the focus group is one-time only, and may happen after you finish the Y-T program.

Benefit: The Y-T program is not counseling, it is a program which teaches skills for improving your mental and behavioral health, and coping strategies for normal teenage stress. You may learn about yourself and new ways to rethink challenging situations and deal with stress.

Compensation: Upon completing all of the assessments you will be awarded a \$50 Amazon gift card. If you are selected to participate in the focus group, you have the option to not participate and still be eligible for the \$50 Amazon gift card.

Data: If you participate in the research portion of the study, we will collect information about your experience of anxiety and depression symptoms, attitudes or experience of substance use, and experience of the Youth Thrive program.

APPROVED
MSU IRB
07/24/2020
Date approved

Risk: The nature of the assessments used in the study examine depressive, anxiety, and addictive behaviors, and may cause emotional discomfort with some of the youth participants. You may discover that you do experience symptoms of depression or anxiety. You will be asked about your attitudes about substance use, and your own alcohol and drug use. School staff are prepped and trained in talking with youth in distress. Your Health Teacher and School Counselor work with the MSU research team and will help support you if you experience discomfort or have questions about the assessments.

Confidentiality: Your answers to the assessments and focus group questions will remain private and your name will never be attached to your personal answers. However, in the event that you score yourself as high risk on any assessment, the research team will contact the school, who will then ensure your safety and notify your parent/guardians. If you are selected to participate in the focus groups, we cannot guarantee confidentiality of your answers as you will be in a group setting with your peers.

Voluntary: Participation in the research aspect of this study (taking the assessments and participating in the focus group) is voluntary. You may choose not to answer any question on the assessment that makes you uncomfortable or that you don't want to answer. It is important to know that you can choose to withdraw from the research part of the study (that means that you have the ability to choose not to complete the assessments). You can quit at any time. If you choose not to participate in the assessments, you will not be eligible for the \$50 Amazon gift card. If you choose not to participate in the research part of study, an alternative activity will be provided to you at school during the brief assessment periods.

Research Study contacts:

If you have any questions about this research project, please contact: Dr. Katey Franklin at Kathryn.franklin1@montana.edu.

If you have questions about your rights as a participant, please contact the Montana State University Institutional Review Board (IRB) Office, at (406) 994-4706.

I agree to participate in this research study.

_____	_____	_____
Youth Participant Name	Youth Participant Signature	Date
_____	_____	_____
Principal Investigator	Principal Investigator Signature	Date

APPROVED
MSU IRB
07/24/2020
Date approved

INFORMED CONSENT – PARENT/GUARDIAN

Project Title: *A feasibility study for implementing and evaluating an Internet-based cognitive behavior therapy intervention in school settings and its impact on adolescent mental and behavioral health*

Principal Investigator: Dr. Katey T. Franklin, PhD, LCPC

Scientific Advisor: Dr. Mark Schure
Montana State University, Bozeman

Partner Organization: Miles City and Park County Public School Systems

Sponsor: Center for American Indian and Rural Health Equity (CAIRHE)
and National Institute of Health (NIH)

Version Date: July 21, 2020

Purpose:

You are being asked for permission for your child to take part in a research study. The purpose of this research study is to examine an internet based Cognitive Behavioral Therapy (iCBT) program called Youth Thrive (Y-T) in a school setting and evaluate its potential impact on participants experience of symptoms of depression and anxiety, and attitudes toward addiction. Y-T uses best practices from CBT and delivers information through an online, structured and guided curriculum. CBT aims to replace dysfunctional thought patterns and behaviors with healthier ones. It does so by identifying and challenging negative thinking patterns and identifying areas for improving behaviors.

The purpose of this study is to understand the impact of Youth Thrive (Y-T) on adolescents' emotional wellbeing. The goal of the Y-T program is to help youth understand normal challenges and learn how to cope with stress in a healthy way. Your child may learn about themselves- for instance, how do they handle stress in their lives? Your child may learn new coping skills to help them in tricky social situations with friends and family. Your child may learn about how they think about challenges and learn healthy ways to think about stressful situations.

Access to the online Y-T program is available for your review upon request.

Activities:

The study activities include your child's participation in online sessions with the Y-T program in their Health Enhancement class- this is the educational part of the project. Your child will be asked to take 3-5 periodic assessments over the course several weeks- this is the research part of the project. All of these assessments are online and will take about 15 minutes to complete. Given the research design, there is a chance that they might take these assessments before they begin the Youth Thrive program. Your child may also be asked to participate in a focus group where we ask them questions about their experience with the Y-T program. Youth participants can participate in the study but choose not to participate in a focus group.

Time: Your child's participation in this study will last about 8-16 weeks. The assessments will occur approximately every two weeks. The focus groups are online through Zoom or Webex, and will last about 30 minutes to an hour. Participation in the focus group is one-time only, and may happen after they finish the Y-T program.

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Benefit: The Y-T program is not counseling, it is a program which teaches skills for improving mental and behavioral health, and coping strategies for normal teenage stress. Your child may learn about themselves and new ways to rethink challenging situations and deal with stress. Also, the researchers intend to use the feasibility research results to inform best practice in the creation and delivery of curriculum aimed at increasing adaptive coping strategies in mental and behavioral health, decreasing symptoms of anxiety and depression, and decreasing permissive attitudes toward addictive behaviors and substance use.

Compensation: Your child will receive a \$50 Amazon gift card for completing the entire study. If your child is selected to participate in the focus group, they have the option to not participate and still be eligible for the \$50 Amazon gift card.

Data: If your child participates in the research portion of the study, we will collect information about their experience of anxiety and depression symptoms, attitudes or experience of substance use, and experience of the Youth Thrive program.

Risk: The nature of the behavioral health assessments which assess specifically for depressive, anxiety, and addictive symptomology may cause emotional discomfort with some of the youth participants. Youth participants may discover they experience symptoms of anxiety or depression. Youth participants will be asked about their attitudes about substance use, and their own drug and/or alcohol use. School community staff are prepped and trained as part of their education training programs in how to encounter and talk with youth in distress. Moreover, school staff will understand the nature of the assessments and be prepared to discuss with and support youth participants.

Additionally, assessment results will be promptly scored by the MSU research team (within 24 hours of administration). Safety protocols and reporting procedures are established at each research site prior to the delivery of Y-T program and assessment tools. If any youth participants' score in the "severe" category for anxiety, depression and/or addiction symptomology, parents/guardians will be notified. The researchers will notify the corresponding school authority, who will then implement existing student safety policies towards parental notification and referrals. Appropriate referrals will be made to low/no-cost behavioral health clinicians in the community.

Confidentiality: Your minor child's participation in this study is confidential. Your child's answers to the assessments and focus group questions will remain private and their name will never be attached to their personal answers. However, in the event that they score themselves as high risk on any assessment, the research team will contact the school, who will then ensure your child's safety and notify parents/guardians. If your child is selected to participate in the focus groups, we cannot guarantee confidentiality of their answers as they will be in a group setting with their peers. As fore-mentioned, confidentiality will be broken if participants' assessment results are in the 'severe' range for depression, anxiety and/or addictive behaviors.

Voluntary: Participation in the research aspect of this study (taking the assessments and participating in the focus group) is voluntary. Your child may choose not to answer any question on the assessment that makes them uncomfortable or that they don't want to answer. It is important to know that they can choose to withdraw from the research part of the study (that means that they have the ability to choose not to complete the assessments). Your child can quit at any time. If they choose not to participate in the assessments, they will not be eligible for the \$50 Amazon gift card. If your child chooses not to participate in the research part of study, an alternative activity will be provided to them at school during the brief assessment periods.

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07/24/2020
Date approved

Research Study contacts:

If you have any questions about this research project, please contact: Dr. Katey Franklin at Kathryn.franklin1@montana.edu. If you have questions about your rights or welfare as a participant, please contact the Montana State University Institutional Review Board (IRB) Office, at (406) 994-4706. If you would like to direct questions or concerns to your school district, please contact your school administrator.

As legal guardian of identified youth participant, I consent to their participation in this research study.

Youth Participant Name

Date

Parent/Guardian Signature

Date

Principal Investigator

Principal Investigator Signature

Date

APPROVED
MSU IRB
07/24/2020
Date approved