Study Protocol Official Title: BRITEPath-Phase 2

ClinicalTrials.gov ID (NCT number): NCT04672798

ICF Date: 1/19/2021

UPMC | University of Pittsburgh Medical Center

Western Psychiatric Institute and Clinic
Division of Child and Adolescent Psychiatry

Consent to Participate in a Research Study

BRITEPath Research Study-ETUDES Center Phase 2
MINOR & PARENT

Principal Investigator: Stephanie Stepp, PhD (faculty, Psychiatry, University of Pittsburgh)
Co-Investigators: David Brent, MD (faculty, Psychiatry, University of Pittsburgh)

Description of this research study
This research is being conducted to test if BRITEPath, an app-supported intervention to guide mental health clinicians, is effective in supporting your child's treatment with their mental health clinician or provider. Our goal is to enroll 100 youth and their parents from primary care offices or mental health care offices who have been referred to or engage in mental health treatment to use the BRITEPath intervention. This study is sponsored by a Grant from the National Institute of Mental Health.

What will the study involve?
If you and your child choose to participate, your child will either be randomly assigned (like the flip of a coin) to the "Intervention" group or the "Treatment as Usual" group. You will not be able to choose which group your child receives. Those assigned to the intervention group will receive BRITE, which is a safety planning smartphone application, to use in place of the "Treatment As Usual" paper-based safety plan that is used as part of standard clinical care.

In the treatment as usual group, mental health therapists will work to develop a safety plan of which you may also receive a copy. Your child's care experience could be approached differently depending on what he/she discusses with the therapist at the time. Please note that the research team will not act as your child's treatment team and will not know the content of the discussions between your child and the therapist.

In the intervention group, through the use of a web-based platform we call Guide2BRITE, therapists will receive step by step instructions for how to assist adolescents in loading personalized content (like photos, videos, or favorite websites) onto the BRITE app that is used in conjunction with clinician-recommended content. BRITE lists steps in your child's safety plan, techniques for lessening distress, and ways to reach out to friends, family, and other social supports (such as professionals who can assist in a crisis). For those assigned to receive BRITE, information on use of the app will be sent to an online portal, called BRITEBoard, that will be

reviewed by therapists. In the "Treatment as Usual" group, your child's mental health therapist will not use the Guide2BRITE and clinician portal, BRITEBoard.

For youth using the BRITE app safety plan, youth will be able to log into the BRITE app at any time with a pin code. If a pin code is lost, a text will be sent with the pin. The content of the safety plan will be available, even when the phone or device does not have access to wifi/data. We ask that you consult with your child's therapist before removing access to their phone to assure they maintain access to their safety plan.

While staff do not monitor the app 24 hours a day, your child could use the app to connect with a crisis line in your county in an emergency. The crisis information will be populated with your child's mental health therapist and I can also give you the contact information today, if you're interested. Additionally, the therapist is trained to be available to meet with parents and children to introduce the app and answer questions. The child will discuss his/her use of the app with their therapist on an ongoing basis. The ETUDES research assessor who calls you and your child will be "blinded" or not know if your child is using the BRITE app or a paper safety plan. This is to ensure as unbiased a phone assessment as possible for our research. We ask that you try to remember not to tell the researcher assessor who calls you which safety plan mode your child is using.

In both the treatment as usual group and intervention group, your son or daughter will be asked to participate in 3 one-hour phone calls with our research team. The first phone assessment will occur after you have agreed to participate in this study. The next call will take place 4 weeks later, and the third call will be made 12 weeks after to initial call. During the three phone calls, we will ask him or her about physical, emotional, social, behavioral and academic functioning. The phone calls will be recorded.

The data collected about your child's use of health services during the phone call study visits will be shared with the Kaiser Permanente Center for Health Research for analysis. Dates of your child's use of health services will be shared. Names of providers or other identifiable information will not be shared.

Will your adolescent benefit from participating in this study?

Your child will not directly benefit from participating in this study. The information we get from your child and other adolescents or teens who participate, may help researchers find better ways to help young people who are going through hard times in their lives.

What are the risks associated with this study?

The interviews and self-reported questions may potentially cause psychological distress. There is a risk of feeling embarrassed by providing responses about mental health questions. There is a risk of feeling tired or inconvenienced. Trained and experienced research clinicians will conduct the interviews. If your son or daughter becomes upset, the interviewer can assist.

Because the study is enrolling individuals with suicidal ideation, there is always a risk of worsening suicidal ideation. Should this occur, the research team will refer you to your mental health therapist for evaluation and treatment.

There is potential for a breach in confidentiality if your answers were somehow to become available to non-study personnel. As such, transmissions like texting a crisis line or calling a crisis line on your personal device may be unknowingly and/or unintentionally intercepted by third parties. Someone not associated with the research study may see the messages on your phone. We ask that you minimize this risk by (1) setting up a password protection on your cellular phone and (2) immediately erasing messages after responding to our queries.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

How will my child's information be protected?

The information we receive from your child and you will be labeled with a code number that we assign and not with anything that directly identifies either of you. All recordings will be coded by participant identification number, date, study name, and initials of interviewer. Digital records will be kept on secure servers behind UPMC's firewall. Any hard copy notes will be kept in locked research offices in locked storage cabinets to which only research study staff has access. Your child will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to your participation in this research study:

- Authorized representatives of the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study.
- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information to provide services and addressing billing and operational issues.
- Information collected from this study may be shared with sites participating in this multi-site study and other investigators; however, this information will be shared in a de-identified manner (i.e., without identifiers).

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 or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including

for your medical treatment; 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 NIMH. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about your child's 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.

Research records will be maintained for at least 7 years following final reporting or publication of a project. For projects involving children, records will be maintained for 5 years past the age of majority (age 23 per PA State Law) after study participation ends.

Are there costs associated with participation? Will my adolescent be paid?
Neither you nor your insurance provider will be charged for participation in this research study. To thank you and your child for your time and efforts you will be paid $20 for the first phone assessment, $30 for the second phone assessment, and $50 for the third phone assessment. Payment will be mailed to your address to be shared with your child for your joint participation.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for 'backup withholding'; thus you would only receive 72% of the expected payment.

Who will pay if I am injured as a result of participating in this research study?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

Is my participation in this study voluntary?
Yes, your participation in this research study is completely voluntary. Also, you can, at any time, choose to withdraw from this research study. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh, your current or future care at UPMC or affiliated care provider, or your current or future relationship with a health care insurance provider.

Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will remain. To formally withdraw your consent for your participation in this research study, you should provide a written and dated letter of this decision to the principal investigator of this research study Dr. Stephanie Stepp, at the following address: 3811 O'Hara St Pittsburgh, PA 15213.

HIPAA Authorization for Disclosure of Protected Health Information (PHI)

As part of this research study, we are requesting your authorization or permission to review your child's medical records to [determine whether you meet the conditions for participation in this study, to compare your earlier test results to the findings from this study, and if possible, to use your previous exam results in place of, or in addition to, some of the exams needed for this study.] This authorization is valid for an indefinite period of time. We will obtain the following information: your child's diagnosis, age, past medical history, mental health symptom scores and service utilization.

As part of this research study, some information that we obtain from your child will be placed into your medical records held at UPMC, including mandated reporting results of child abuse or neglect report, and notes that enhance communication between research staff and treatment providers related to managing suicidality.

This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Your child's medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

We will protect your privacy and the confidentiality of your child's records, as described in this document, but cannot guarantee the confidentiality of your child's research records, including information obtained from your child's medical records, once your child's personal information is disclosed to others outside UPMC or the University.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office, 1.866.212.2668.

If you have any questions for the research staff, please reach out to Brandie George-Milford at 412-246-5629 or georgeba2@upmc.edu or Amy Anderson at 412-586-9851 or amy.anderson2@chp.edu.

The above information has been explained to me and all of my current questions have been answered. To indicate my agreement to participate in this research study, and to allow the use and disclosure of my child's medical record information for the purposes described above, I consent to participate in the study by clicking the 'I agree' box and by completing the fields below

Click here to print a copy of the consent form to keep for your records.

Full Name: _____ ___ _____(first, middle initial, last name)

Birthdate: ____ / _____ / _____ (mm/dd/year)

Answer to ONE of 3 questions from drop-down box:
What is your mother's maiden name?
In what city were you born?
What high school did you attend?