Study Protocol

Official Title: BRITEPath-Phase 2

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Scientific Background

Previous BRITE study:

In a previous study, Dr. Brent and colleagues developed a brief, inpatient- based, novel intervention with an accompanying safety planning app (BRITE) for psychiatrically hospitalized, suicidal adolescents. In a pilot RCT with 66 adolescents, this app-supported intervention cut the incidence of recurrent suicide attempts by half (Incidence rate ration [IRR] for attempts=0.47, 95%CI 0.12-1.56, p=0.18), with a stronger effect in the 80% of adolescents with a previous history of a suicide attempt (IRR=0.23, 95% CI, 0.05-1.09). The app was accessed an average of 29 times over a 6-month period, 45.5% accessed the safety plan, and the more frequently the app was used, the greater the decline in suicidal ideation and increase in reasons for living (rho=0.36, p's=0.08). Participants rated BRITE high on usability using the Post-Study Satisfaction and Usability Questionnaire (lower score indicates greater satisfaction, range 10-70, mean scores 17.6-18.4). Moreover, clinicians who implanted the interventions wanted the app to guide them in formulating the safety plan and populating the app for use by the adolescent. These data provide preliminary support for the clinical utility of an app-supported intervention to reduce suicide risk in adolescents. While a multitude of apps are freely available on the Apple App store and Google Play Store, this is the only app available to promote self management of distress and suicidal ideation that has undergone a clinical trial with published results. We have made the app available for clinicians to use as part of their clinical care to aid their patients with self management of mood dysregulation and suicidality.

We are currently also disseminating the BRITEPath intervention for clinical use (STUDY20050047) and collecting anonymous usability feedback in real world clinical settings to further develop BRITE for future research and non-research projects, ultimately providing this in a much wider fashion for clinical use. In the currently approved BRITEPath related studies (STUDY18120080, STUDY20010135 & STUDY19050132) we developed a virtual treatment manual designed to guide clinicians in delivering the intervention and a clinician dashboard to monitor symptoms and treatment progress. It is this version that gained attention from clinicians which are providing for clinical use and would like to collect anonymized user data already collected through the clinician training process and on the app and clinician dashboard. We will not collect any clinical data from patients or clinicians as part of their clinical care.

Adolescent suicide is the second-leading cause of mortality in adolescents, and adolescent suicidal behavior is a common cause of morbidity associated with significant functional impairment. The rates of both adolescent suicide and suicidal behavior has been increasing. Currently, even with high quality treatment, there is a high incidence of early suicidal events in outpatient care.

Adolescent suicidal behavior is common, with more than 2,000,000 adolescents presenting to emergency departments (EDs) each year with suicidal behavior. Nearly 7% of adolescents in any one year make a suicide attempt, and an equal number have clinically significant suicidal ideation with a plan (Lewinsohn, Rohde, & Seeley, 1996). Suicide is the 2nd leading cause of death among 12-17 year olds, and suicidal behavior is associated with functional impairment and significant costs to the health care system, other service systems, and families (Centers for Disease Control and Prevention, 2010; Curtin et al., 2016; Florence, Haegerich, Simon, Zhou, & Luo, 2015; Shepard, Gurewich, Lwin, Reed, & Silverman, 2015). Short-term costs include costs of medical care for youth with suicide attempts, lost productivity for youth who die, and costs to families such as lost productivity for family members caring for youth in crisis. While Healthy People 2020 has as its objective to reduce suicide and suicide attempts in adolescents, trends for more than a decade have shown an increase in teen suicide (Curtin et al., 2016).

Focus early in treatment. In clinical populations, one of the times of greatest risk for recurrent suicidal behavior and completed suicide is during transition of care (transition between inpatient and outpatient care; prior to or at the onset of outpatient care), and quality improvements in this window of time have been shown to decrease the suicide rate in adults (Appleby, Dennehy, et al., 1999; Appleby, Shaw, et al., 1999; While, et al., 2012). The window of greatest risk is in the 1-4 weeks after the initial suicide attempt, with 25-50% of all suicidal events (defined as a suicide attempt or an increase in suicidal ideation)

occurred within the first 4 weeks of treatment (Brent, Greenhill, et al., 2009; Vitiello, Silva et al., 2009; Wilkinson, Kelvin, Roberts, Dubicka, & Goodyer, 2011). Thus, providing a brief, targeted intervention prior to discharge that protects against acting on suicidal urges in early outpatient treatment could make a substantial contribution towards reducing the incidence of youth suicidal behavior.

Early-onset of suicide event, even in high-quality treatment of suicidal ideation. In clinical studies of adolescents with treatment resistant depression, in which participants received close monitoring and either medication management alone, or in combination with CBT, the rate of suicidal events was 28% in the first 12 weeks of treatment, with a median time to event of 3 weeks (Brent, Emslie, et al., 2009). In an open trial of a CBT intervention especially designed to reduce suicide attempts in depressed adolescent suicide attempters, 40% of all suicidal events took place within the first 3 weeks of treatment (Brent, Greenhill, et al., 2009). Moreover, one of the most potent predictors of an eventual attempt or suicidal event is high baseline suicidal ideation (Brent, Emslie, et al., 2009; Brent, Greenhill, et al., 2009; Vitiello, Silva, et al., 2009; Wilkinson et al., 2011). In community samples, 56% and 29% of adolescents with suicidal ideation with or without a plan, respectively, will make a suicide attempt within a year of assessment (Nock et al., 2013).

Safety Planning. The safety plan, a structured set of coping strategies that a suicidal individual can deploy to de-escalate suicidal risk in the face of suicidal urges or identified precursors thereof (e.g., anger, sadness) is considered best practice for the management of high risk patients. The plan, developed with a mental health clinician, consists of: (1) activities the suicidal individual can do independently or alone (e.g. distraction, deep breathing); (2) reaching out to supportive individuals; and (3) finally, seeking clinical attention (Samra & Bilsker, 2007; Stanley et al., 2009). A safety plan is developed in the context of treatment, in which a chain analysis of the events leading up to the suicidal episode is conducted, a more comprehensive treatment plan to reduce suicidal risk is developed, and motivational techniques are deployed to enhance use of the safety plan and follow-up with treatment.

While safety plans have become a mainstay of clinical care, methods to facilitate their implementation have not yet been critically evaluated, nor has the efficacy of safety plans in preventing future suicidal acts been carefully evaluated (Knox et al., 2012). In order for a youth in crisis to deploy his or her safety plan, the plan has to be accessible. Youth at high risk for suicide who are being treated for suicidality may have a written safety plan as part of their treatment; however, this plan may not always be accessible when they experience suicidal urges. Therefore, identifying an alternative mechanism to increase accessibility and utility of safety plans could be quite helpful.

A precursor of the modern safety plan was developed by Rotheram-Borus and Bradley (1991), in which youth in a shelter for homeless runaways were taught a 5-step program for coping with suicidal ideation: 1. Identify 3 positive compliments about self; 2. Identify 3 people to go to for support; 3. Learn how to monitor and regulate emotion using an “emotion thermometer” in order to cope with suicidal urges; 4. Develop a concrete alternative to acting on suicidal impulses; and 5. Make a commitment to refrain from engaging in suicidal behavior. The number of suicide attempts in these shelters prior to implementation of the program was 9 in the previous 3 months, compared to 2 in the subsequent 18 months, which, when corrected for the period of observation, is a 27-fold decrease in the incidence of suicide attempts (assuming a similar number of youth in both conditions). This suggests that a brief intervention using emotion regulation techniques and mobilization of social support to cope with suicidal urges can be effective in reducing the probability that an adolescent will act on his or her suicidal ideation. However, to our knowledge, other than this study, the efficacy of safety planning has never been critically evaluated, particularly in adolescents.

Utilizing technology for improving distress tolerance and safety planning. Approximately 73% of American youth have or have access to smart phones (Lenhart, 2015). Close to 80% of homes have internet access, and for 21% of teens (up to 44% of minority teens), a cell phone is the teen’s sole means of access to the

Internet (Lenhart, 2010). Consequently, use of technology in this population to extend treatment is logical and timely. There are no empirically tested phone apps for safety planning, especially for teens, but there is a randomized trial to evaluate a safety planning app in adults currently underway (Andreasson et al., 2017). While there are cell phone applications related to safety planning in adults with suicidal behavior (Emory News, 2013; De la Torre, Castillo, Arambarri, Lopez-Coronado, & Franco, 2017; Larsen, Nicholas, & Christensen, 2016; Stanley & Brown, 2012;). We propose to supplement standard care by evaluating a safety plan smartphone application (which has been developed with promising outcomes; Kennard et al., 2015) that teens can easily access to provide tools to cope with suicidal urges and preserve safety.

Study Objectives

The purpose of the study is to test the efficacy of BRITEPath intervention components developed in the open feasibility trial in STUDY18120080. This Phase 2 BRITEPath study will test 100 participant dyads (age 12-26; adolescent & parent or just young adult) in a 2:1 allocation toward intervention compared to Treatment As Usual (TAU) randomized controlled trial.

Aim 2 (Phase 2, Deployment)
RE-AIM Framework. We will evaluate uptake of BRITEPath by clinical sites utilizing the RE-AIM framework and determine implementation outcomes as follows: Reach: Compare demographic and clinical characteristics of those patients who do versus do not (opt-out) get BRITEPath in practice for sample representativeness. Efficacy: Measure the percentage of patients for whom clinically significant reductions in depressive symptoms and suicidality as well marked improvements in functioning are obtained. Adoption: The percentage and characteristics of clinicians who participate in the BRITEPath study. Implementation: The percentage and characteristics of clinicians who follow through with BRITEPath use procedures (examining different components of app use). Maintenance: Extent BRITEPath is utilized and predictors of utilization after research support has been withdrawn. Please see Methods Core for full list of measures that will be collected and mapping of assessment measures onto RE-AIM framework.

Method: We will test efficacy of BRITEPath (Study 3) using 2:1 allocation randomized controlled trial of intervention compared to Treatment As Usual (n = 100). Qualitative study findings by Dr. Hamm and within the Methods Core will inform iterative updates to BRITEPath platform to optimize practice implementation. The Methods Core details additional information regarding this design approach.

Feasibility: All sites will have a trained mental health specialist on site. Assessments: In both treatment conditions, patients will rate depressive symptoms and functioning as well as the extent of distress and intensity of suicidal and self-harm urges using an emotional thermometer on a 0-10 Likert scale prior to and after each MH visit in both BRITEPath and TAU. Follow-up assessments will be Call Center supported by our Methods Core blind to intervention. Primary outcomes are changes in suicide ideation and NSSI; secondary outcomes include changes in impairment and service use. Assessments will occur at 4 & 12 weeks post intake, and will cover self-reported depression (PHQ-9), suicidal ideation and behavior and NSSI (C-SSRS), imminent suicide attempt risk (adaptive suicide risk screen), impairment (parent report on 5- item scale from SDQ), firearms access and storage, and service use (CASA and EHR).

Study Design & Method

This study is a randomized controlled trial with a 2:1 allocation of the BRITEPath intervention to Treatment As Usual comparator

Overview of the BRITEPath intervention
There are three components of the BRITEPath intervention, each of which will be described: 1) BRITE, 2) GUIDE2BRITE and 3) BRITEBoard. All participants assigned to the intervention components will receive each of these 3 components.

BRITE
BRITE is a tool for self-monitoring and self-management that is not targeting any specific diagnosis or medical condition. BRITE includes monitoring of distress on a daily basis paired with content targeting skill targeting emotion regulation, distress tolerance, social support, and reasons for living. Content will take the form of clinician-recommended videos, photos, and websites, as well as personalized content that has salience to the adolescent that they may add onto their app. In this way, the app is customizable to uniquely meet the adolescents' needs and preferences. Adolescents will be encouraged to use the skills on the app on a daily basis. Additionally, the BRITE app will include an electronic version of a safety plan that will be developed in collaboration with the youth's therapist. Safety plans, which contain coping strategies, social supports, and crisis contacts are used as a standard of care in the treatment of suicidal youth. Finally, on each screen of the app, there is a link to crisis contacts that will be programmed onto the app with the assistance of their therapist.

GUIDE2BRITE
Embedded mental health providers, who will treat youth who have access to the BRITE app, will use GUIDE2BRITE to facilitate the process of orienting youth to the app. GUIDE2BRITE will be an interactive website that leads the clinician through the process of developing a safety plan and identifying appropriate content for the BRITE app with their adolescent patient. During this process, providers will orient patients on the purpose and function of the app, demonstrating and practicing skills they will use as part of the app-based intervention. Guide2BRITE supports clinicians in the delivery of an intervention designed to: (a) identify likely triggers of suicidal and self-harm urges; assess lethality and restricting access to means; (b) teach skills via modeling and role-play to cope with suicidal and self-harm urges and (c) identify professional resources to access in a crisis should others means of coping fail. A mock-up that shows the integration between BRITE and GUIDE2BRITE is provided within question 2.

BRITEBOARD
BRITEBOARD is a web-based portal that tracks participants use of the app, e.g. tracking distress ratings and times in which they added/removed content, as well as changes in patient outcomes over time, e.g. depression ratings collected as part of the study. In order to facilitate effective communication within the participant's clinical team, information on this portal will be shared among the adolescents' providers within their CCP practice, including the embedded therapist, their primary care provider, and other providers within the office that are designated as part of the adolescents' care team.

Treatment As Usual
Those who are assigned to the treatment as usual group will receive standard care within study practices. Among MH clinicians in primary care and mental health organizations, standard care involves developing a paper-based safety plan with depressed youth and youth who are at suicidal risk.

Eligibility Criteria

Inclusion Criteria:

-Youth aged 12-26 yo
-Own a device (e.g. smartphone, ipod, ipad, tablet) with capability to download BRITE app
-Biological or adoptive parent is willing to provide informed consent for teen to participate
-Youth speaks and understands English
-Patient is seeing mental health clinician for a mood or behavior problem at a study recruitment site

Exclusion Criteria:

Non English speaking
No parent willing to provide informed consent
No cell phone capability of downloading BRITE app

For the following symptoms-youth has to be prohibited by the diagnosis or symptoms to the point they would not understand or be able to participate in the study:
Current or past history of mania or psychosis symptoms
Evidence of an intellectual or developmental disorder (IDD)
Life threatening medical condition that requires immediate treatment (included emergent suicidality, homicidality, abuse/neglect, or other mental or physical condition)
Other cognitive or medical condition preventing youth from understanding study and/or participating.

Statistical Considerations

Due to the pilot nature of the Center's research studies, sample size and power considerations center around the precision of confidence interval (CI) width estimation for feasibility outcomes. In Phase 1 in previous ETUDES studies (Development), a sample size of 50 afforded 95% CI width of no more than 0.28.

In the Deployment (phase of this current protocol-Phase 2) and future phases, a sample size of 100 (assuming 80% retention) affords us a 95% CI width of 0.09 0.13 for BRITEPath study (study 3).