OFFICIAL TITLE OF STUDY: Targeting Burdensomeness Among Clinic Referred Youth

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PROTOCOL

Suicidal ideation is prevalent in youth: 17.7% of high school students seriously considered a suicide attempt and 14.6% made a specific plan for suicide in the past 12 months[1]. Suicidal ideation also is a strong predictor of future suicide attempts and suicide[2-3]. Despite decades of research and intervention, the rates of suicidal ideation and suicide in youth continue to rise in recent years[1]. There is critical need for novel intervention targets to prevent and reduce suicidal ideation in youth. To address this critical need, the Sponsor (Dr. Pettit) is developing and evaluating a novel, brief psychosocial treatment module targeting perceived burdensomeness towards others that can be embedded within existing psychosocial treatments for youth. This F31 project leverages the sponsor's clinical trial to allow the applicant to collect additional qualitative and quantitative data on the module (described below) and gain clinically relevant research experience by assisting the sponsor in the development of the module, implementation of the trial, and analysis of additional data.

Substantial research documents perceived burdensomeness towards others as a risk factor for suicidal ideation[4], including in youth[5-6], highlighting the potential promise of perceived burdensomeness as an intervention target to prevent or reduce suicidal ideation. Only one study, conducted by the Sponsor, has examined an intervention targeting perceived burdensomeness in youth[7]. In 80 youth ages 13 to 19 years, subjects who completed two brief online modules targeting perceived burdensomeness showed significantly lower levels of perceived burdensomeness at POST compared with subjects who received online psychoeducation. This initial finding is exciting because it demonstrates a brief psychosocial intervention can successfully target and reduce perceived burdensomeness when administered online. However, tempering this excitement is the finding that approximately 50% of subjects did not complete the online modules. Thus, there is need to enhance engagement with treatment, as well as expand intervention approaches to clinic-referred populations at higher risk of suicidal behaviors than community-based populations.

One strategy for enhancing engagement and completion of a brief intervention targeting perceived burdensomeness is to embed it within existing psychosocial treatments for youth psychopathology (e.g., cognitive-behavioral therapy [CBT] for youth anxiety disorders). Consistent with a modular CBT approach[8], this strategy would enable clinicians to select and employ a brief intervention module when youth clients demonstrate thoughts of being a burden on others, with minimal disruption to the ongoing intervention protocol.

The purposes of this project are to (1) develop a novel, brief psychosocial intervention module (the GIVE module) targeting perceived burdensomeness towards others that can be embedded within existing CBT protocols for youth internalizing problems, and then (2) collect data relevant to the timing of reductions in perceived burdensomeness. The following aims will be pursued with N=30 clinic referred youths ages 10 to 17 who are receiving outpatient CBT for anxiety or depression.

Aim 1: Develop a manualized module targeting perceived burdensomeness to be used as an adjunct to existing psychosocial treatments. The GIVE module will consist of one core intervention session involving the youth and a parent (approx. 50 minutes) and one follow-up discussion of homework completion (approx. 10 minutes).

Aim 2: In an open trial, examine adherence and satisfaction with the GIVE module. Adherence, operationalized as provider fidelity and integrity, will be assessed by coding recorded session content. Youth and parent satisfaction will be assessed using the Client Satisfaction Questionnaire.

Aim 3: In an open trial, demonstrate reductions in youth levels of perceived burdensomeness. Perceived burdensomeness will be assessed at pretreatment (PRE), midtreatment (MID; i.e., CBT session 6), every treatment session, and posttreatment (POST). We expect that perceived burdensomeness will be significantly lower at POST relative to MID (i.e., CBT session 6, immediately before beginning the GIVE module).

APPROACH

General overview. Following parental consent and youth assent, parents and youths will be administered interviews and questionnaires as part of PRE assessment to determine eligibility for this study (see Inclusion/Exclusion criteria). Eligible youths will be allocated to a 12-session CBT protocol with an additional module targeting perceived burdensomeness to be administered during CBT session 6. Youth participants' levels of perceived burdensomeness will be assessed weekly at the beginning of each session of the CBT protocol and again at a POST assessment one week after the final CBT session.

Participants. N=30 youths ages 10 to 17 years will be recruited upon entry into clinical services for anxiety and/or depression.

Inclusion criteria. To be included in this study, youth must: 1) be between ages 10 to 17 years old; 2) meet for a primary DSM-V diagnosis of an anxiety disorder, persistent depressive disorder, or major depressive disorder; 3) score $\geq$ 4 on the youth self-report Interpersonal Needs Questionnaire- Perceived Burdensomeness

Scale at PRE and again at CBT session 5; and 4) if youth have ADHD, tics, or impulse control problems, those disorders must receive an impairment rating no greater than 4 ('Moderate') on the 0–8 point scale on the Anxiety Disorders Interview Schedule Child/Parent versions (ADIS-C/P).

Exclusion criteria. Youth will be excluded from this study if they: 1) meet diagnostic criteria for Psychotic Disorders, Autism Spectrum Disorder or Intellectual Disability, 2) show high risk of imminent self-injurious behaviors, 3) are involved currently in another psychosocial treatment; 4) are not living with a primary caregiver who is legally able to give consent for the youth's participation, or 5) are a victim of previously undisclosed abuse requiring investigation or ongoing supervision by the Department of Social Services.

GIVE module. The GIVE module will include three components: (1) in-session cognitive restructuring, introduced by a brief rationale and psychoeducation; (2) a home assignment to be completed by youth; (3) a parent component providing psychoeducation on burdensomeness that sets up a brief parent-child relationship task. Table 1 provides an outline of the core session of the module, and the follow-up session. The module will be briefly introduced to youth with a rationale outlining the importance of addressing specific negative beliefs that may appear as secondary to the presenting problem but which are nonetheless critical to address, particularly perceived burdensomeness; this brief rationale will be followed by psychoeducation on what fosters this negative belief and outcomes related to this belief (overall introduction is approximately 5 minutes). The first major component of the GIVE module (during the subsequent 15 minutes of session 6), in-session cognitive restructuring with the youth only, consists of identifying negative thoughts (i.e., burdensomeness) using real-life examples and then collaboratively evaluating cognitions of burdensomeness using techniques such as reality testing and cost-benefit analysis[18], with the aim of developing and shaping more adaptive cognitions. Cognitive restructuring will be conducted in a developmentally appropriate manner based on empirically-supported CBT protocols for youth. Consistent with the priority of minimal disruption to ongoing treatment, session 6 is an ideal session to introduce the module because it will leverage existing CBT skills covered earlier in treatment (i.e., cognitive restructuring).

Table 1. Module Outline

Core Session (session 6 of CBT protocol)	• 5 minutes: Rationale for module and psychoeducation on burdensomeness • 15 minutes: Cognitive restructuring of burdensomeness • 15 minutes: Planning home behavioral assignment • 5 minutes: Psychoeducation on parental acceptance • 10 minutes: Parental acceptance activity (positive qualities and ways to show acceptance lists)
Follow-up Session (session 7 of CBT protocol)	• 5 minutes: Discussion of home behavioral assignment • 5 minutes: Wrap-up • Resume ongoing CBT

The second component of the GIVE module is a home behavioral assignment to be planned in the subsequent 15 minutes of session 6. This home assignment is based on a brief online intervention developed by the sponsor[7]. In this brief at-home assignment, youths will identify one family member on whom they believe themselves to be a burden, and will design an activity to contribute to the well-being of that family member[7] (usually the mother). This home assignment will be collaboratively planned during the session, including identification of barriers to completing the assignment and problem-solving aimed at improving completion of the assignment. Youths will already have been completing home assignments during previous CBT sessions and so the current home assignment should not impose new burden in terms of planning or execution. There will also be a brief discussion of this task in the beginning of the following session for approximately 5 minutes.

The third component of the GIVE module is a brief in-session parent-child relationship component. Unlike the first two components, the entirety of this component is done with both the youth and the parents present in the subsequent 15 minutes of session 6. This component begins with brief psychoeducation for the parent explaining parental acceptance and its implications in the context of perceived burdensomeness. Then, the parent will devise two lists: one that highlights the positive qualities of the child, and a second that includes ways that the parent can show acceptance and warmth. The inclusion of the third component is driven by research indicating that low parental acceptance fosters negative cognitive styles, and forthcoming research from our team indicating that low parental acceptance is significantly associated with youth perceptions of burdensomeness towards others[18]. There will also be a brief 5 minute wrap-up which encompasses review of the module and prevention (i.e., discussing the use of the module tools in forthcoming situations and experiences).

Measures.

Primary Outcome.

Interpersonal Needs Questionnaire- Burdensomeness Scale (INQ10-PB). The INQ10 is a widely used self-rated measure of perceived burdensomeness and thwarted belongingness. The burdensomeness subscale (INQ10-PB) consists of 6 Likert-type items. Prior research supports the convergent validity and internal consistency of the subscales in youth[5, 20].

Secondary Outcomes.

The Child and Parent's Report of Parental Behavior Inventory (CRPBI/PRPBI- warmth/acceptance subscale). The CRPBI/PRPBI are 30-item youth-rated and parent-rated measures of perceived parental behavior[21]. The warmth and acceptance subscale consists of 10 items of the CRPBI/PRPBI, with subscale scores ranging from 10 to 30, and higher scores representing higher levels of parental warmth and acceptance.

The Screen for Child Anxiety Related Emotional Disorders (Child Version and Parent Versions; SCARED-C/P). The SCARED-C/P is a 41-item youth-rated and parent-rated measure of youth anxiety symptoms[22]. Items are rated on a 3-point likert scale ranging from "not true or hardly ever true" to "very true or often true".

The Children's Depression Inventory 2- Child and Parent Version (CDI 2-C/P) The CDI 2-C/P is a widely used measure of youth depressive symptoms, with a 28-item child-rating version and a 17-item parent-rating version[24].

The Client Satisfaction Questionnaire-8 (CSQ-8) The CSQ-8 is an 8-item rating scale of client satisfaction with treatment administered[26].

Anxiety Disorders Interview Schedule – Child/Parent-V (ADIS-C/P-V). The ADIS-C/P is a widely used semi-structured diagnostic interview for youth and parents. It will be used to determine inclusion/exclusion criteria.

STATISTICAL ANALYSIS PLAN

Data management protocols will be used to ensure data integrity. Missing values will be estimated using full information maximum likelihood where applicable. A Holm modified Bonferroni correction will be used to control experiment wise error rate. We will examine variables measured at PRE, including demographics, symptom severity, parental warmth, and diagnostic status (presence of an anxiety or depressive disorder) for possible inclusion as covariates in the analyses.

Aim 1: Develop a manualized module targeting perceived burdensomeness to be used as an adjunct to existing psychosocial treatments. No statistical analyses will be needed to address this aim.

Aim 2: In an open trial, examine adherence and satisfaction with the GIVE module. Adherence will be examined through descriptive statistics of therapist adherence to the GIVE module protocol. Youth patient and parent satisfaction will be examined using total mean scores and frequencies of item responses on the CSQ-8.

Aim 3: Demonstrate reductions in youth levels of perceived burdensomeness. Reductions in levels of perceived burdensomeness will be examined using two approaches. In the first, a paired samples t-test will be conducted to examine changes in mean scores from MID (i.e., session 6 INQ10-PB score) to POST. A priori power analysis for the paired-samples t-test indicated that N=27 would provide sufficient power to detect a medium effect size, thus the current study would have adequate power. In the second, segmented regression analysis will be conducted by the applicant to preliminarily gain insight into the timing and maintenance of changes in levels of perceived burdensomeness. The segmented regression method is a powerful analysis for a quasi-experimental, interrupted time-series designs[28-29], recommended for small samples[28]. In segmented regression analysis, session to session assessments of perceived burdensomeness will be used to examine the slopes in perceived burdensomeness before and after intervention in CBT session 6. The intervention effect is examined by statistically comparing the PRE and POST intervention slopes. In an interrupted time-series design, it is recommended that observations be equally balanced between pre intervention and post intervention (e.g., 6 observations before and after), and for the PRE assessment variability to be reduced (e.g., only selecting youth with higher PB for the study) to maximize power[28]. For this reason, there are six assessment points (administrations of INQ10-PB) planned prior to and after the administration of the module for a total of 12 observations, and only youth with elevated PB will be recruited (i.e., variability reduction). The segmented regression analysis is intended to be preliminary to gain insight into the timing of changes, and as such, may be underpowered by design.