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ABBREVIATIONS AND DEFINITIONS OF TERMS

ED	Emergency Department
AE	Adverse event
SAE	Serious adverse event
STAT-ED	Suicidal Teens Accessing Treatment
RCT	Randomized Controlled Trial
CBC	Congressional Black Caucus
EHR	Electronic Health Record
BHS	Behavioral Health Screen
ADAPT-ITT	Assessment, Decision, Administration, Production, Topical Experts and Integration, Training, and Testing
SACA	Briefest Service Assessment for Children and Adolescents
MYTS	Motivation for Youth's Treatment Scale
SIQ-Jr	Suicide Ideation Questionnaire-Junior
PANAS	Positive and Negative Affect Scale
ICD	International Classification of Diseases, Functioning and Disability
NDA	NIMH Data Archive
NIH	National Institutes of Health
DSMB	Data Safety and Monitoring Board

ABSTRACT

Context:

Recent research has shown significant increases in suicides among Black youth and suicide attempts among Black high school students.

Objectives:

Primary

- To conduct a systematic adaptation of STAT-ED for Black youth presenting in the ED who have suicidal risk.
- To examine preliminary efficacy of the intervention on primary (mental health treatment initiation and number of visits) and secondary (suicidal ideation) outcomes using a prospective RCT design.

Secondary

- To examine implementation outcomes of the adapted STAT-ED for Black youth and caregivers compared to the control condition (enhanced Treatment as Usual).

Study Design:

The study utilizes a mixed methods design which involves a qualitative phase (interviews and field testing) and RCT phase.

Setting/Participants:

The study will recruit from CHOP pediatric hospital ED with a total of 150 participants. Eligible youth will identify as Black, be between the ages of 10-18, have recent or past suicidal ideation or behaviors and are not currently receiving mental health treatment. Caregivers are parents or legal guardians of eligible youth. Study procedures may be conducted in-person, over the phone, or online.

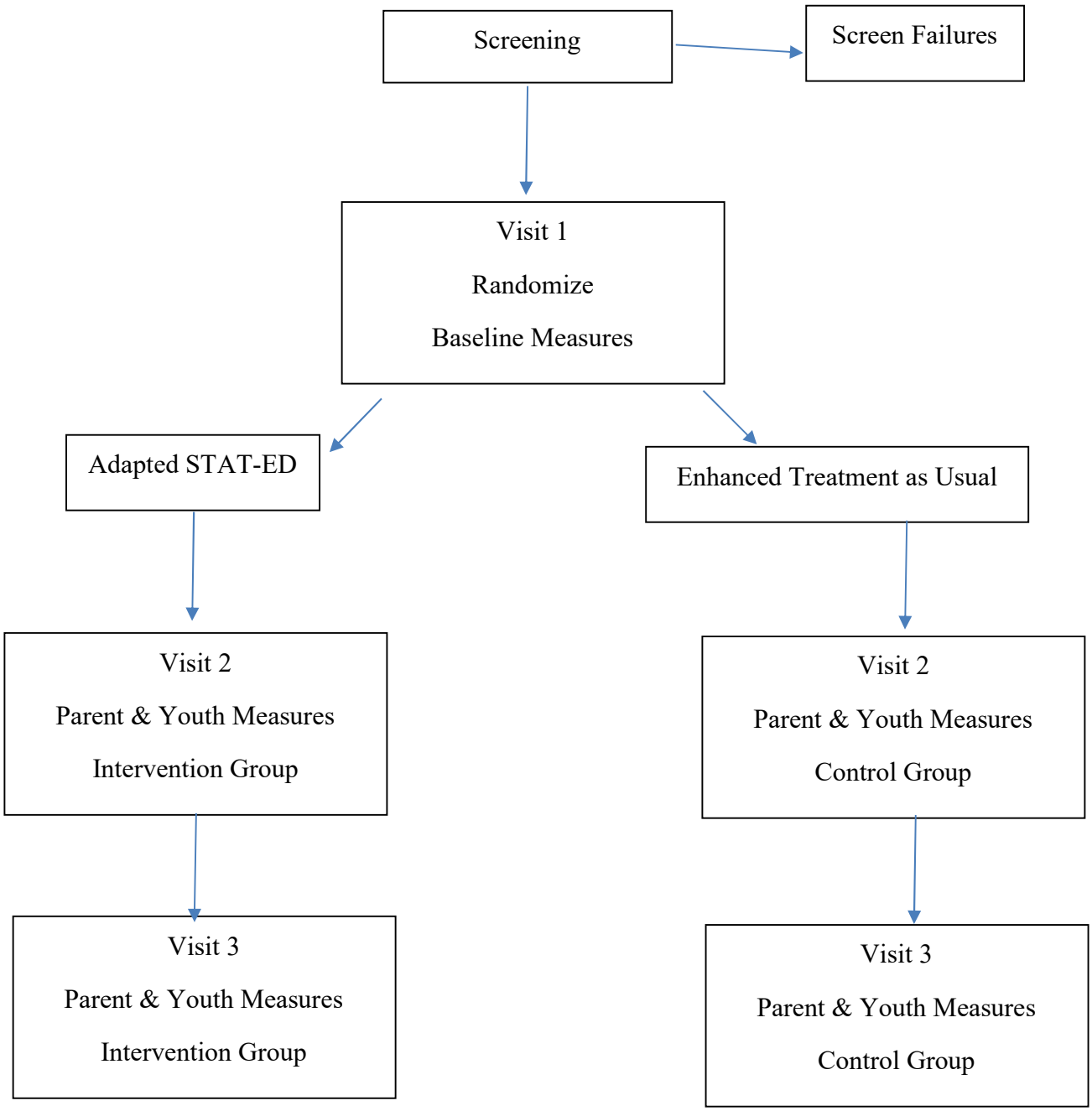
Study Interventions and Measures:

Participants will be randomized to the adapted STAT-ED or enhanced Treatment as Usual which will consist of follow up telephone contacts following discharge from the ED. Main RCT study outcomes are mental health treatment initiation and suicidal ideation.

Table 1: Schedule of Study Procedures for Randomized Controlled Trial

Study Phase	Screening	Observation Study Visits		
Visit Number		Baseline	2 month follow up	6 month follow up
Informed Consent/Assent	X			
Review Inclusion/Exclusion Criteria	X	X		
MYST		X	X	X
SIQ-Jr		X	X	X
Demographics		X		
PANAS		X		
Intervention Acceptability			X	X
SACA			X	X
Adverse Event / Unanticipated Problems Assessment		X	X	X

Figure 1: Flow Diagram for RCT



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Suicide is the second leading cause of death among 10-24 year olds, and suicide rates are increasing (Curtin & Heron, 2020). Historically, Black youth have had lower suicide risk; however, recent research has shown disturbing and significant increases over the last 3 decades in suicides among Black youth and in self-reported suicide attempts among Black high school students (Sheftall et al, 2016; Bridge et al., 2015; Bridge et al., 2018; Ivey-Stephenson, 2020; Lindsey et al., 2018). Black youth are less likely than White youth to be treated for suicidal ideation or behaviors, and less likely to receive inpatient or outpatient care after a suicide attempt (Freedenthal, 2007; Marrast et al., 2016). Barriers to Black youth starting mental health treatment are myriad and include lack of perceived need, stigma, mistrust of providers and treatment, difficulties in physically accessing available services, and providers' lack of cultural competence (Fante-Coleman & Jackson-Best; Planey et al., 2019). Patient navigation offers a flexible model that can address many of these barriers and can be tailored to specific populations and needs. Although patient navigation models have been shown to improve outcomes such as screening and diagnostic appointment and referral completions in different patient populations (Ali-Faisal et al., 2017), there is paucity of such interventions and associated research to improve care and outcomes for suicidal youth. One of these patient navigation interventions, Suicidal Teens Accessing Treatment (STAT-ED) resulted in greater mental health care initiation and appointment at 6 months, however, adolescents of color were less likely to initiate mental health care than White adolescents (Grupp-Phelan et al., 2019). An intervention for Black youth requires adaptation, as many interventions do not address culturally relevant issues for Black patients. This proposed study will adapt and pilot test STAT-ED for Black youth presenting to emergency departments (EDs) with suicidal ideation or behaviors.

1.2 Name and Description of Investigational Product or Intervention

Patient navigation will generally be modeled after STAT-ED and can involve motivational interviewing, brief case management, and telephone contacts. While the complete intervention is contingent on our adaptations, we anticipate that the following strategies will be included: psychoeducation, problem-solving logistical barriers, and assistance with making and following up with mental health appointments (Godoy et al., 2019). As part of the cultural adaptation, we will directly address youth's and caregivers' negative perceptions and cultural stigma concerning mental health treatment. Psychoeducation will be provided on suicide risk, its negative effects, and treatment options. The intervention will assist the family in following up with mental health referral recommendations provided by ED staff and eliciting families' preferences in regards to race and gender of providers, convenience of provider, and type of treatment. This assistance could involve help with the initial telephone contact, getting to appointments, and preparing for the appointments. The patient navigator will communicate with the family in person, by telephone, and/or by text messaging as per family's preference. This once to twice a week communication will promote mental health care initiation and identify barriers and problem-solving solutions. The intervention group is expected to be administered the adapted STAT-ED until the first mental health appointment

date. A comparison intervention (enhanced Treatment as Usual) will consist of follow up contacts following discharge from the ED to confirm referral recommendations.

1.3 Relevant Literature and Data

A systematic review of interventions that attempted to increase initiation of mental health care for people of color found that most were culturally adapted. Adaptations included incorporating racially diverse perspectives in intervention design, training staff on cultural sensitivity issues, referencing racial/ethnic diversity in educational materials, and incorporating cultural conceptualizations of mental health (Lee-Tauler et al., 2018). A similar systematic review of psychosocial mental health interventions for youth of color found that all interventions shown to be efficacious were culturally adapted (Pina et al., 2019), and a third review supported cultural adaptations of interventions for mental health care engagement among adolescent and young adults of color (Moore, 2018). Although there are not substantial data indicating that culturally adapted interventions are more effective, in the mental health intervention field, the clear disparity in engaging Black individuals strongly suggests that current approaches may not be sufficient. The CBC Taskforce report on Black youth suicide and mental health (2019) further emphasizes this point, recommending that researchers develop and test interventions to mitigate suicide risk that are developmentally, culturally, and linguistically relevant for Black youth We will adapt a patient navigation intervention, the STAT-ED for Black youth with suicide risk, following the ADAPT-ITT framework steps of Assessment, Decision, Administration, Production, Topical Experts and Integration, Training, and Testing (Wingood et al., 2008). This will involve data from qualitative phases of study, as well as input for advisory group and consultants.

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to determine the efficacy of the adapted STAT-ED patient navigation intervention for Black youth initiation of mental health treatment.

2.1 Primary Objective (or Aim)

- To conduct a systematic adaptation of STAT-ED for Black youth presenting in the ED, who have suicidal risk.
- To examine preliminary efficacy of the adapted STAT-ED on primary (mental health treatment initiation and number of visits) and secondary (suicidal ideation) outcomes using a prospective RCT design.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- To examine implementation outcomes of the adapted STAT-ED intervention (acceptability, feasibility, fidelity) for Black youth and caregivers compared to the control condition (enhanced Treatment as Usual).

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

The study utilizes a mixed methods design which involves a qualitative phase and randomized trial phase. The qualitative phase consists of two steps: 1) interviews with 15 youth and 15 caregivers and 2) field testing of the intervention with 10 youth and 10 caregivers. The qualitative phase and field testing will occur prior to the randomized trial. The randomized trial is a prospective design comparing adapted STAT-ED with comparison condition. We will test the adapted patient navigation intervention in a small RCT with 50 Black youth presenting in the ED with suicidal ideation or behaviors and their caregivers. The RCT will be conducted after an amendment to the study is approved by the IRB. Medical and mental health information will be collected from medical records.

Caregiver and youth interviews will be conducted separately and virtually either over the telephone or through Bluejeans. Interviews will be recorded. We will incorporate feedback from the youth and caregiver qualitative interviews as well as elicit feedback on which intervention components will be adapted and the types of cultural adaptations needed from the study Advisory Group (caregivers, youth, and clinicians) and a consultant.

During the field testing, we will gather feedback on intervention content and materials. This may involve participants watching a mock video of the patient navigator conducting the intervention with a family.[51] Participants also will be provided and asked to react to adapted content and materials.

3.1.1 Screening Phase

For both the qualitative interviews and the RCT, potential participants will be identified through three avenues in the ED: 1) clinicians; 2) a behavioral health screening conducted in the ED; and 3) diagnostic codes in the electronic health record (EHR). Co-I Esposito, ED attending physician and ED Behavioral Health Program Director and his team will identify and recruit potential participants via three avenues: (1) all ED patients aged >12 years

complete the Behavioral Health Screen (BHS), which includes a suicidal ideation item; the BHS is on a web-based platform, automatically scored, integrated with patients' EHR, generating automated notification to the ED clinician when the patient reports suicidal ideation. (2) We will peruse the EHR for an extensive list of diagnostic codes related to suicidal ideation, suicide attempt, and self-harm to identify potential participants. (3) ED clinicians can refer patients with suicidal ideation or attempt. Academic Associates, CHOP ED staff whose primary role is to approach potential participants for clinical research, will screen potential participants using protocol inclusion and exclusion criteria. They will be available in the ED to meet with youth and caregivers, discuss study procedures, enroll participatnes and gather consent/assent. For participants who meet the study eligibility criteria, we will either gather consent/assent from caregivers and youth in the ED or at a later time by study staff depending on what is convenient for family. Signed consent/assent forms and caregiver and/or youth contact information will be transferred from Academic Associates to study team in a secure manner. Study staff will contact enrolled participants to initiate study procedures for the RCT and within a week for the interviews.

For the field testing, potential participants will be identified from qualitative interview phase or clinicians in the DCPBS outpatient clinic. Research staff will contact potential participants and screen them using protocol inclusion and exclusion criteria. Consent and assent will be gathered at field testing session.

3.1.2 Study Treatment Phase (start of the study intervention)

Cargiver and Youth Interviews: We will develop an interview guide to identify barriers and facilitators to mental health treatment. We also will present STAT-ED content to obtain feedback on its usefulness and relevance and to identify what is missing. We will use prompts from our conceptual model to query about issues such as barriers to care that STAT-ED may address, the extent to which STAT-ED components address stigma, and the cultural relevance and appropriateness of STAT-ED components. Interviews will be conducted and the audio will be recorded by research staff separately for youth and caregivers. All audio files will be stored on a secure CHOP server for the study. All audio files will be sent to ADA Transcription services for transcription with deletion of any identifying information. The de-identified transcripts will be returned and maintained on CHOP's secure research server accessed only by members of the study team. The ADA Transcription services is a CHOP approved vendor that have been used before for other research studies at CHOP and will continue to be used in the future.
. Initial codes will be developed inductively through consensus of the investigative team. Themes pertaining to child and family factors and benefits and barriers to MH service use in a virtual environment will be identified. We will use NVIVO, a qualitative software program, to facilitate coding of transcripts and identification of themes. We will use the results to adapt STAT-ED content and materials in preparation for the RCT.

Field testing: We will gather feedback on adapted STAT-ED intervention content and materials via a survey of reactions This may involve participants watching a mock video of the patient navigator conducting the intervention with a family (Sullivan et al., 2014). Participants also will be provided and asked to react to adapted content and materials, such as

handouts for psychoedcation about mental health, mental health treatment and to address stigma.

Intervention adaptation: We will develop an intervention draft that will balance core elements of the STAT-ED intervention with information gathered from the qualitative interviews and field testing (Wingood et al., 2008). The intervention adaption will be informed by the caregiver and youth interviews, andthe current literature. We will also elicit feedback on which intervention components will be adapted and the types of cultural adaptations needed from the Advisory Group and consultantsThis will involve using relevant components, as well as writing adaptations to current components and potentially new content. The intervention will include patient navigator instructions, such as motivational interviewing questions, procedures for assisting with mental health appointments, and tips for problem solving barriers, and content for youth and caregivers. We will perform a readability test to assess reading level of intervention and corresponding materials and make necessary changes to increase how easy they are to understand. The intervention manual will also discuss potential intervention delivery strategies such as by telephone, in-person, and by texting. A written manual will be the end product.

RCT: Study staff will contact enrolled participants, complete baseline assessments, and randomize to the adapted STAT-ED or control condition (enhanced Treatment as Usual). The adapted STAT-ED will involve the following strategies: psychoeducation, motivational interviewing, problem solving logistical barriers, and assistance with making and following up with mental health appointments. This could involve identifying additional mental health resources and providers based on insurance type. Two social workers will be hired and trained to implement the adapted STAT-ED and the control condition (enhanced Treatment as Usual) for study. atient navigators will communicate with the family in person, by telephone, and/or by text messaging via family's preference. The control condition (enhanced Treatment as Usual) will receive telephone contacts to check in and remind families about mental health care initiation. Telephone contacts are consistent with current ED practice in which social work team members follow up by telephone with patients and their caregivers about referrals given at ED discharge. The proposed study is a small pilot to adapt a patient navigator intervention for suicidal Black youth and test the preliminary effectiveness of the intervention in preparation for a fully-powered RCT. We will perform initial analyses (chi-square and *t*-tests) to compare the intervention and control groups on proportion to initiate mental health treatment, mean number of days to treatment initiation, and mean number of treatment sessions at both 2 months and 6 months follow-up. A Cox proportional hazards model will examine group differences in mental health utilization, time to treatment initiation, suicidal ideation, and mental health motivation (Cox, 1972). Assessments may be conducted in-person, via telephone, or electronically/online. At the end of the study, we will also solicit and review feedback from the patient navigators who are research staff members about feasibility and acceptability. The patient navigators will also complete fidelity measures after each session of the adapted STAT-ED.

Participants may be recontacted to update information or to see if they are interested in participating in other research.

3.2 Allocation to Treatment Groups and Blinding.

In the RCT, subjects will be randomized to either the adapted STAT-ED or to enhanced treatment as usual. Randomization will be accomplished in advance using computer-generated random numbers. Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Subject Study Participation

For the qualitative phase, the study duration will last one day. For the RCT, he study duration per subject will be up to 8 months, with up to 1 month screening, up to 6 months for baseline assessments and intervention delivery, and 2 months for study visits completion.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at approximately 1 investigative site at CHOP in the United States.

Recruitment for RCT will stop when approximately 100 participants (50 youth-caregiver dyads) are enrolled. It is expected that approximately 100 subjects will be enrolled to produce 85 evaluable subjects. Recruitment for interviews will stop when approximately 30 participants (15 youth-caregiver dyads) are enrolled and recruitment for field testing will stop when approximately 20 (10 youth-caregiver dyads) are enrolled.

3.4 Study Population

3.4.1 Inclusion Criteria

3.4.1.1 Youth Inclusion Criteria for qualitative interviews and RCT

1) Identify as Black
2) are between ages of 10-18 years
3) endorse suicidal ideation and/or behaviors within the last year at an ED visit
4) live within Philadelphia County or nearby Pennsylvania suburb
5) Must be able to read and understand English

3.4.1.2 Youth Inclusion Criteria for field testing

1) Identify as Black
2) Between ages of 10-18 years

3) Have history of suicidal ideation or behavior

4) Participated in Qualitative Interview study or is currently receiving services in outpatient clinic of the Department of Child and Adolescent Psychiatry and Behavioral Sciences

3.4.1.3 Caregiver Inclusion Criteria for interviews, field testing, and RCT

1) Parent or legal guardian of eligible youth

2) Must be able to read and understand English

3.4.1.4 Patient Navigator Inclusion Criteria for RCT

1) Employed by study to implement adapted STAT-ED

3.4.2 Exclusion Criteria

1) Does not identify Black as one of their races

2) Under 10 or over 18 years old

3) Does not speak English

4) No history of suicidal ideation or behavior

3.4.2.1 *Youth Exclusion Criteria for interviews and RCT*

1) Exclusion criteria listed in section 3.4.2

2) Requires acute or intensive treatment for safety or medical reasons

3) Currently engaged in mental health treatment

3.4.2.2 Youth Exclusion criteria for field testing

1) Exclusion criteria listed in section 3.4.2

2) Requires acute or intensive treatment for safety or medical reasons

Subjects with limited English proficiency will be excluded from this study because the interview materials and measures are not available in multiple languages. In addition, the adaptation and implementation of the intervention in multiple languages is not feasible for this pilot study. If this study shows efficacy, we will hope to be able to engage Black families who speak languages other than English in the next study.

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening Visit

Qualitative Interviews and RCT

- Informed Consent/assent/HIPAA authorization
- Medical Record Review
- Review of Inclusion/Exclusion Criteria
- Collection of demographics including contact information

4.2 Study Treatment Phase

This will include the qualitative interviews, field testing, and RCT.

4.2.1 Visit 1

Qualitative interviews

- Informed Consent/Assent
- Medical Record Review
- Review of Inclusion/Exclusion Criteria
- Recorded semi-structured interview
- Demographics questionnaire

Field Testing

- Review of Inclusion/Exclusion Criteria
- Informed consent/assent
- Demographics questionnaire
- Field testing procedures

RCT

- Medical records review
- Review of inclusion/exclusion criteria
- Youth and caregiver report measures (MYTS, SIQ-Jr, PANAS, demographics questionnaire)
- Randomization
- Intervention

4.2.2 Visit 2

RCT

- Youth and caregiver report measures (MYTS, SIQ-Jr, SACA, intervention acceptability survey)
- Assess possible adverse events
- Medical Health Record Review

4.2.3 Visit 6: End of Study

The end of the study visit for randomized trial is at 6 months after baseline assessment. Youth and caregiver report measures are administered (MYTS, SIQ-Jr, SACA, intervention acceptability survey). Adverse events will be assessed.

4.3 Unscheduled Visits

If a family needs additional intervention support to navigate mental health initiation, then this will be performed by the patient navigators.

4.4 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to the study visit schedule or any AEs. The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

4.4.1 Early Termination Study Visit

If early termination occurs, reasons for early termination will be documented.
Subjects who withdraw from the study or were withdrawn from study before or during the intervention will be asked to complete the post-intervention assessments. Subjects who withdraw prior to the baseline assessment will be considered lost and not be evaluable.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Medical Record Review

Medical record number
Date of birth
Demographics including county of residence

Race
Columbia Suicide Severity Rating Scale
Behavioral Health Screen
Problem list
ICD codes
Contact information
Languages spoken/read
Results of tests and procedures
Chart review for mental health treatment or hospitalizations (this will be gathered from medical records and will not access protected mental health records)

5.1.2 Other Evaluations, Measures

Qualitiative Interviews

- *Qualitative interview guide* will be developed. Questions concerning perceptions and preferences of mental health treatment and barriers and facilitators to accessing mental health services will be asked of participants.
- *Demographics survey* will gather information such as age, biological sex, gender, race/ethnicity, sexual orientation, and family income.

Field Testing

- For the field testing, *a survey of reactions* will be developed for participants to complete.
- *Demographics survey* will gather information such as age, biological sex, gender, race/ethnicity, sexual orientation, and family income.

RCT

- *Briefest Service Assessment for Children and Adolescents (SACA*) is a 29-item interview that measures the types of mental health services children receive and the treatments they receive within service settings (Stiffman et al., 2000). Caregivers will complete the SACA. The parent version has good to excellent lifetime and satisfactory to good past-year test-retest reliability. There was satisfactory concordance ($\kappa = 0.76$) between parent report and medical records of youth inpatient, outpatient, and school service use (Horwitz et al., 2001).
- *Motivation for Youth's Treatment Scale (MYTS)* is an 8-item measure of intrinsic treatment motivation that has both youth and parent reports (Breda et al., 2012). It has two subscales: recognition that the youth has a problem and readiness to participate in the youth's treatment. It has good internal consistency and validity with support for the factors. MYTS has a 5-point Likert scale with

higher scores representing higher motivation. MTYS will be completed by youth and caregivers.

- *Suicide Ideation Questionnaire-Junior (SIQ-Jr)* is a youth report measure of frequency of suicidal thoughts over the last month (Reynolds, 1988). SIQ-Jr has high internal consistency, test-retest reliability, predictive validity for suicidal behavior, and is sensitive to change (Reynolds & Mazza, 1998).
- *Intervention acceptability* will be assessed by using a 5-point Likert scale. Both youth and a caregiver will rate the intervention helpfulness, satisfaction, and harm. Additionally, a semi-structured interviewed will be developed to assess patient navigators' views of intervention acceptability after the trial is completed.
- *Positive and Negative Affect Scale (PANAS)* is a widely used and validated measure (Watson et al., 1988). It has been used for adolescent samples with evidence of potentially three factors: Positive Affect, Negative affect with two factors of Distress and Fear (Villodas et al., 2011; Allan et al., 2015). The Positive Affect factor will be administered to youth.
- *Demographics survey* will gather information such as age, biological sex, gender, race/ethnicity, sexual orientation, family income, religion, and insurance type.
- A *fidelity checklist* will be developed to assess self-reported task completion by the patient navigators (0- not completed, 1- partially completed, 2- fully completed). This will be completed after each intervention contact. This will be completed after each intervention contact.

5.2 Efficacy Evaluations

In the RCT, these are the measures that will be used to assess efficacy (mental health utilization)- SACA. The three primary efficacy outcomes are 1) whether the patient initiated mental health treatment (yes/no), 2) time to treatment initiation, and 3) number of treatment sessions attended. Other outcomes are suicidal ideation and behavior measured by SIQ-Jr.

5.2.1 Diagnostic Tests, Scales, Measures, etc.

In the qualitative interviews, the research staff will conduct semi-structured interviews with questions concerning perceptions and preferences of mental health treatment and barriers and facilitators to accessing mental health services with youth and caregiver participants. In the field testing, a survey of reactions will be collected from caregivers and youth by research staff. In the RCT, SACA is an interview and will be administered by research staff to caregivers at 2 (Study visit 2) and 6 months (final visit) after baseline assessment. SIQ-Jr is a self-report measure that will be administered to youth at baseline and 2 and 6 months after baseline assessments.

5.3 Safety Evaluation

In the RCT, participant safety will be monitored by adverse events and the SIQ-Jr. It will also include responses on the intervention satisfaction.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

Primary endpoint for qualitative phase (interviews and field testing): themes of caregiver and youth mental health attitudes and engagement and an adapted STAT-ED manual
Primary endpoint for randomized trial: mental health treatment initiation. The three primary efficacy outcomes are: a) whether the patient initiated mental health treatment (yes/no), b) time to treatment initiation, and c) number of treatment sessions attended.

6.2 Secondary Endpoints

At the end of the RCT, we will also solicit and review feedback from the patient navigators about feasibility and acceptability and evaluate fidelity by calculating an overall adherence to intervention tasks score for each patient navigator by aggregating navigator ratings on the fidelity checklist. Both youth and caregiver will complete intervention acceptability survey that uses Likert ratings.

6.3 Statistical Methods

6.3.1 Baseline Data

For qualitative interviews, caregiver and youth interviews will be analyzed using NVivo qualitative analysis software. Initial codes will be developed inductively through investigative team consensus. Themes pertaining to child, family, clinician and systemic barriers and facilitators, motivation for treatment, receipt and perceptions of mental health services will be identified. After initial exploration, a comprehensive coding scheme will be developed and applied to all data to produce a fine-grained descriptive analysis.
For the RCT, descriptive statistics for demographic and behavioral characteristics measured at baseline will be examined across the two treatment groups to assess the success of the randomization.

6.3.2 Efficacy Analysis

These are the measures that will be used to assess efficacy (mental health utilization), SACA. The three primary efficacy outcomes are 1) whether the patient initiated mental health treatment (yes/no), 2) time to treatment initiation, and 3) number of treatment sessions attended. Other outcomes are suicidal ideation and behavior which will be examined by changed in total score over time from baseline to Visit 2 and final Visit.

6.3.3 Safety Analysis

In the RCT, Participant safety will be monitored by adverse events reporting. Participant safety will be monitored by adverse events and the SIQ-Jr. It will also include responses on the intervention satisfaction.

6.4 Sample Size and Power

For the RCT, we followed established rules of thumb for pilot trial size estimation for two-armed studies to determine our total sample size of 100 (Whitehead et al., 2016). Even accounting for greater than 15% attrition, power analyses (Faul et al., 2009) indicate that this sample size will produce 80% power to detect a large effect for group differences between conditions over time ($f = .72$). This pilot trial is not intended to detect statistically significant differences in outcomes; rather, the primary aim of this pilot is to establish the feasibility of research procedures in preparation for a fully-powered RCT. The effect sizes obtained in this pilot study will be used to estimate parameters for a subsequent R01 to inform sample size considerations.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that do not meet prompt reporting requirements will be summarized in narrative or other format and submitted to the IRB at the time of continuing review (if continuing reviews are required), or will be tracked and documented internally by the study team but not submitted to the IRB (if continuing reviews are not required).

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

Randomization will be accomplished in advance using computer-generated random numbers. Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes.

8.1.2 Blinding

Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes to prevent staff and participants from manipulating the randomization.

8.2 Data Collection and Management

All records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. All data for these study procedures will be maintained on CHOP/Penn/NIH secure servers, and all analyses will be performed on de-identified data only. All collected study measures will be entered directly into a REDCap database maintained and protected on this secure research server. Any paper copies of research instruments will be kept in locked file cabinets at CHOP. Recordings of interviews will be stored on a password protected secured servers at CHOP/Penn to be coded and analyzed. All audio files will be sent to ADA Transcription services for transcription with deletion of any identifying information. The de-identified transcripts will be returned and maintained on CHOP's secure research server with regular backup. The ADA Transcription services is a CHOP approved vendor that have been used before for other research studies at CHOP and will continue to be used in the future. A master list, linking the study data with subject PHI will be stored separately from the data in a password-protected file on a secure CHOP drive accessible only to the study team. Participants' information will be stored in the REDCap database and configured to export data without PHI. The coded data may be shared with the study sponsor, University of Pennsylvania, other other research staff at CHOP/Penn for current or future research purposes. Every 6 months, the study sponsor NIMH requires a data transfer to the NIMH Data Archive (NDA). During the course of the study and after its completion, the research team will send coded data to the NDA repository where it will be stored and managed. Additionally, any necessary study data will be transmitted accordingly to Clinicaltrials.gov. Identifiable and non-identifiable information may be stored for future research purposes indefinitely.

8.3 Confidentiality

All data and records generated during this study will be kept confidential and in accordance with institutional policies and HIPAA on subject privacy. Participation in all aspects of the proposed study is completely voluntary. The research team will institute strict procedures to maintain confidentiality. Subjects will be assigned a unique identification code that will be used as the sole identifier whenever possible. Any results obtained cannot be related to the original source, so no results would be provided to the patient, healthcare provider, or insurance provider. Per standard NIH guidelines, a Certificate of Confidentiality will be automatically generated for this NIH-funded study. No identifiable data will be used for future study without first obtaining IRB approval or determination of exemption. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers before sharing a limited dataset.

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

The CHOP PI will monitor and review the study progress, subject safety, and the accuracy and security of the emerging data.In accordance with the NIH requirements, we will adopt a Data and Safety Monitoring Plan. All SAEs will be reported to the IRBs in accordance with CHOP and Penn IRB policies. AEs that are not serious will be summarized in narrative or other format and submitted to the CHOP and Penn IRBs the University of Pennsylvania, to

the OHRP and to the NIMH Project Officer at the time of continuing review. We will use the centralized Data Safety Monitoring Board (DSMB) that was developed for the Center. The DSMB will meet regularly to review the study progress, review modifications, and monitor compliance with IRB rules, human subjects' procedures, OHRP regulations, and plan for rules for stopping clinical trial. This project will be under the Penn Inspire DSMB. Its members and their credentials will be submitted to the University of Pennsylvania IRB and to NIMH prior to any Project accruing human research participants. The DSMB will comprise at least four members with expertise in clinical psychiatry, mental health services research, biostatistics, and bioethics. The DSMB will hold scheduled annual meetings in person or virtually to review any INSPIRE Project or Pilot Study involving a clinical trial by NIH criteria. These will be supplemented by *ad hoc* interim meetings on a particular project(s) during the year, as needed. The DSMB will review and approve the research protocol and examine progress annually.

8.4.2 Risk Assessment

The study procedure risks are not greater than minimal. The research involves the collection of sensitive and protected health information from participants. The risk of participation is considered minimal. There is a potential risk of breach of confidentiality of information and study results about individuals. This risk is minimized by measures taken by the study team to ensure confidentiality: use of secure files, storing data on secure computers, using unique study identifiers, using only coded data for analysis, and obtaining a Certificate of Confidentiality through NIH. A second risk is that participants may become uncomfortable in completing study measures. The risks to participants of the measures and intervention are similar to those associated with receiving care coordinating services for mental health treatment referral. The discussion of personal and sensitive material (e.g., mental health) may make participants uncomfortable. The participants' right to refuse to answer questions or discontinue a procedure will be communicated to them and respected and considered to be an essential component of maintaining a positive study experience for the participant. Some further potential risks to participants include disclosing child abuse/neglect, suicidal ideation and behaviors, and homicidal ideation. Additionally, the family's routine activities may be disrupted slightly because of participation in the study. Participants will not be deceived in any way about the nature of the study or reimbursement. Suicidal ideation and behavior are risk factors for suicide attempt or death. Therefore, there is increased risk of suicide among the participants regardless of their participation in the study.

Should suicidal ideation or behaviors or functioning worsen, we will implement a suicide prevention plan to assess immediate risk for harm. Participant will be assessed for suicidal risk and determine next steps, such as contacting provider, revising safety plan and/or referral to Emergency Department at a nearby hospital for evaluation for psychiatric hospitalization. Should child maltreatment be suspected, study staff will comply with all mandated reporting laws.

8.4.3 Potential Benefits of Trial Participation

There are direct benefits to the individuals for study participation for the randomized trial but not for the interviews or field testing. Youth assigned to the intervention arm will receive patient navigation services to potentially reduce barriers to receiving mental health treatment. Additionally, the youth in the control condition (enhanced Treatment as Usual) will receive telephone contacts which may benefit their receipt of mental health treatment. There are benefits to society for increasing the understanding of motivation for obtaining mental health treatment and providing more culturally informed care, which may help to increase service utilization among the underserved population of Black youth at risk for suicide.

8.4.4 Risk-Benefit Assessment

The potential risks associated with study procedures are minimal. Results gathered from this study will provide preliminary information on the effects of the patient navigation intervention on use of mental health services and suicidal ideation and behavior. This information can be used in subsequent studies to test the effectiveness and implementation of this intervention. Given the minimal risk nature of the study, the risks are considered reasonable in relation to the generalizable knowledge to be gained.

8.5 Recruitment Strategy

For qualitative interviews, potential participants identified through any of the three avenues by clinicians, behavioral health screening and by diagnostic codes in CHOP ED. Academic Associates who work in the CHOP ED will confirm eligibility for the study, describe the study procedures, enroll interested participants, and notify study staff of the enrollment. Study staff will contact participants and schedule interviews.

For field testing, youth will be recruited from the qualitative interviews and from outpatient clinic in the Department of Child and Adolescent Psychiatry and Behavioral Sciences at CHOP. Study staff will recruit, discuss study procedures, and gather consent/assent from participants for field testing.

For RCT, potential participants will be identified through any of the three avenues by clinicians, behavioral health screening and by diagnostic codes in CHOP ED. Academic Associates who work in the CHOP ED will confirm eligibility for the study, describe the study procedures, enroll interested participants, and notify study staff of the enrollment. Study staff will contact participants and schedule study visit 1 (baseline assessment).
All recruitment materials will be IRB approved.

8.6 Informed Consent/Assent and HIPAA Authorization

Parent/legal guardian consent and child assent will be obtained for study participation. Consent will may be collected in-person or remotely and may be documented on paper or electronically. A waiver of screening consent is being requested to screen medical records

for inclusion/exclusion. For youth age 18 years, consent will be attained. If a youth turns 18 during the course of the study, consent will be gathered by the currently approved consent form for continued participation at the next study visit or contact after the youth reaches the age of majority. For youth between 10-17 years of age, youth assent and parental/ legal guardian consent will be attained. Participation in the study will be completely voluntary, and participants will have the study rationale and goals explained to them, as well as the requirements for participation, the risks and benefits of participation, and alternatives to participation. This is done by reviewing verbally and participants will be allowed to ask questions and state concerns. Should any participant become intolerant of any aspect of the study or an exclusionary condition be identified, their participation will be discontinued. If potential participants want additional time to consider study participation, they can be contacted at a later time by study staff to consent. There is no time limit for consent and participation as long as that phase of the study is still active. Parent consent and child assent also will be gathered for the qualitative interview consent form for their willingness to participate in the field testing study procedures. If consent is gathered in person, research staff will be given a hard copy of the signed consent form. In the event that the participants are not seen in person, an alternative method of obtaining informed consent will be used. Eligible participants will be sent the informed consent document electronically through REDCap. The study team will then go over the document in detail with the eligible parents/legal guardians and youth. The e-consent function in REDCap will be used to obtain the parent/legal guardian's signature. The signed e-consent will then be stored within REDCap, and a copy of the form will be available to download and emailed securely to the family.

Verbal Consent from patient navigators

Informed Consent of patient navigators will be obtained verbally. The aforementioned are employed at CHOP and will not be paid for their participation as a secondary research participant. A waiver of documentation of consent is being requested for these participants. Verbal consent will be documented internally by the study team using a Consent Affirmation Note. Informed consent will be conducted by a study team member (other than a principal investigator) so that the patient navigators does not feel pressure to be a secondary research participant. The provider will have no direct reporting relationship to the study team member that obtains informed consent from them. Those noted are research study team members as well as secondary research subjects. They will be provided with an information sheet outlining what their participation as a research subject will entail (use of feasibility, acceptability, and fidelity "data"). Given that these participants are research study team members providing a service as a part of this study, the completion of fidelity checklists will not be voluntary. Completion of fidelity checklists is a widely accepted, standard practice in the delivery of a behavioral intervention to monitor adherence to an intervention manual. These checklists will be used in the clinical supervision of the Community Health Partners. The use of the fidelity checklist "data" for research purposes (beyond use in clinical supervision) and feasibility and acceptability data by patient navigators will be voluntary. Participants will be given time to ask questions and make an informed decision regarding their completion of the feasibility and satisfaction surveys and use of the "data" from the fidelity checklists for research purposes. No HIPAA related information will be gathered from the patient navigators.

8.7 Payment to Subjects/Families

8.7.1 Reimbursement for travel, parking and meals

We will provide transportation services for each family to complete study visits if conducted in person.

8.7.2 Payments to subject for time, effort and inconvenience (i.e. compensation)

For qualitative interviews, $30 for each participant which includes both youth and cargiver. For field testing, $25 for each subject. For randomized trial: $25 for baseline, $25 for 2 month follow up and $50 for 6-month follow up for each subject.

9 PUBLICATION

The study protocol for this application will be registered with Clinicaltrials.gov. Results will be submitted to Clinicaltrials.gov after completion and analysis of data. Informed consent documents will include a specific statement regarding the dissemination of aggregate study results in Clinicaltrials.gov, peer-reviewed publications, and other policy-relevant summaries. The study team plans to work closely with the Penn INSPIRE center to disseminate and implement the findings of the research study into accessible and usable formats in research, clinical, and community-based settings. Using social media, policy briefs, mass emails and newsletters, we will target findings to city, state and national policymakers, county behavioral health departments across the state of Pennsylvania, and pediatric emergency departments. We will also work with PolicyLab at CHOP to develop dissemination plans. PolicyLab has extensive experience distilling research findings into policy-relevant summaries and disseminating research findings to end-users. We will also utilize traditional approaches such as peer-reviewed publications and presentations at national meetings to disseminate findings to other researchers.

10 REFERENCES

Ali-Faisal SF, Colella TJ, Medina-Jaudes N, Scott LB. The effectiveness of patient navigation to improve healthcare utilization outcomes: A meta-analysis of randomized controlled trials. *Patient Education and Counseling*. 2017;100(3):436-448.

Allan NP, Lonigan CJ, Phillips BM. Examining the factor structure and structural invariance of the PANAS across children, adolescents, and young adults. *Journal of Personality Assessment.* 2015;97(6):616-25.

Breda CS, Riemer M. Motivation for Youth's Treatment Scale (MYTS): A new tool for measuring motivation among youths and their caregivers. *Administration and Policy in Mental Health and Mental Health Services Research*. 2012;39(1-2):118-132.

Bridge JA, Asti L, Horowitz LM, et al. Suicide trends among elementary school–aged children in the United States from 1993 to 2012. *JAMA Pediatrics*. 2015;169(7):673-677.

Bridge JA, Horowitz LM, Fontanella CA, et al. Age-Related Racial Disparity in Suicide Rates Among US Youths From 2001 Through 2015. *JAMA Pediatrics*. 2018;172(7):697-699.

Congressional Black Caucus. *Ring the Alarm: The Crisis of Black Youth Suicide in America*.; 2019. https://watsoncoleman.house.gov/uploadedfiles/full_taskforce_report.pdf

Cox D. Regression Models and Life-Tables. *Journal of the Royal Statistical Society Series B (Methodological)*. 1972;34(2):87-22.

Curtin SC, Heron M. *Death Rates Due to Suicide and Homicide among Persons Aged 10–24: United States, 2000–2017*. National Center for Health Statistics; 2019. Accessed October 26, 2020. https://www.cdc.gov/nchs/data/databriefs/db352-h.pdf

Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods*. 2009;41(4):1149-1160.

Freedenthal S. Racial disparities in mental health service use by adolescents who thought about or attempted suicide. *Suicide and Life-Threatening Behavior*. 2007;37(1):22-34.

Godoy L, Hodgkinson S, Robertson HA, et al. Increasing Mental Health Engagement from Primary Care: the potential role of family navigation. *Pediatrics*. 2019;143(4).

Grupp-Phelan J, Stevens J, Boyd S, et al. Effect of a Motivational Interviewing–Based Intervention on Initiation of Mental Health Treatment and Mental Health After an Emergency Department Visit Among Suicidal Adolescents: A Randomized Clinical Trial. *JAMA Network Open*. 2019;2(12):e1917941-e1917941.

Horwitz SM, Hoagwood K, Stiffman AR, et al. Reliability of the services assessment for children and adolescents. *Psychiatric Services*. 2001;52(8):1088-1094.

Ivey-Stephenson AZ, Demissie Z, Crosby AE, et al. Suicidal Ideation and Behaviors Among High School Students - Youth Risk Behavior Survey, United States, 2019. *MMWR Suppl*. 2020;69(1):47-55.

Lee-Tauler SY, Eun J, Corbett D, Collins PY. A systematic review of interventions to improve initiation of mental health care among racial-ethnic minority groups. *Psychiatric services*. 2018;69(6):628-647.

Lindsey MA, Sheftall AH, Xiao Y, Joe S. Trends of Suicidal Behaviors Among High School Students in the United States: 1991–2017. *Pediatrics*. 2019;144(5):e20191187.

Marrast L, Himmelstein DU, Woolhandler S. Racial and ethnic disparities in mental health care for children and young adults: A national study. *International Journal of Health Services*. 2016;46(4):810-824.

Moore KL. Mental health service engagement among underserved minority adolescents and young adults: a systematic review. *Journal of racial and ethnic health disparities*. 2018;5(5):1063-1076.

Pina AA, Polo AJ, Huey SJ. Evidence-based psychosocial interventions for ethnic minority youth: the 10-year update. *Journal of Clinical Child & Adolescent Psychology*. 2019;48(2):179-202.

Planey AM, Smith SM, Moore S, Walker TD. Barriers and facilitators to mental health help-seeking among African American youth and their families: A systematic review study. *Children and Youth Services Review*. 2019;101:190-200.

Reynolds WM. *SIQ, Suicidal Ideation Questionnaire: Professional Manual*. Psychological Assessment Resources; 1988.

Reynolds WM, Mazza JJ. Reliability and validity of the Reynolds Adolescent Depression Scale with young adolescents. *Journal of School Psychology*. 1998;36(3):295-312.

Sheftall AH, Asti L, Horowitz LM, et al. Suicide in elementary school-aged children and early adolescents. *Pediatrics*. 2016;138(4):e20160436.

Stiffman AR, Horwitz SM, Hoagwood K, et al. The Service Assessment for Children and Adolescents (SACA): Adult and Child Reports. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2000;39(8):1032-1039.

Sullivan PS, Stephenson R, Grazter B, et al. Adaptation of the African couples HIV testing and counseling model for men who have sex with men in the United States: an application of the ADAPT-ITT framework. *SpringerPlus*. 2014;3(1):249.

Villodas F, Villodas MT, Roesch S. Examining the factor structure of the positive and negative affect schedule (PANAS) in a multiethnic sample of adolescents. *Measurement and Evaluation in Counseling and Development*. 2011;44(4):193-203.

Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *Journal of Personality and Social Psychology*. 1988;54(6):1063-70.

Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res*. 2016;25(3):1057-1073.

Wingood GM, DiClemente RJ. The ADAPT-ITT Model: A Novel Method of Adapting Evidence-Based HIV Interventions. *JAIDS Journal of Acquired Immune Deficiency Syndromes*. 2008;47.
https://journals.lww.com/jaids/Fulltext/2008/03011/The_ADAPT_ITT_Model__A_Novel_Method_of_Adapting.8.aspx

APPENDIX

See attached.