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Hybrid type 1 randomized controlled trial of a tablet-based application to improve quality of care in child mental health treatment

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Abstract

The quality of child mental health care is highly variable in community practice settings. Innovative technology-based solutions may be leveraged to improve quality of care and, in turn, treatment outcomes. This is a protocol paper that describes an innovative study design in which we rigorously evaluate the effectiveness of a tablet-assisted intervention, Supporting Providers and Reaching Kids (SPARK). SPARK consists of a collection of interactive games and activities that are designed to improve provider fidelity and child engagement in evidence-based psychotherapies. The methodology also allows us to explore the implementation and sustainability of a technology-enhanced intervention in more than two dozen community practice settings. This paper includes a description and justification for sample selection and recruitment procedures, selection of assessment measures and methods, design of the intervention, and statistical evaluation of critical outcomes. Novel features of the design include the tablet-based toolkit approach that has strong applicability to a range of child mental health interventions and the use of

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a hybrid type 1 effectiveness-implementation trial that allows for the simultaneous investigation of the effectiveness of the intervention and the implementation context. Challenges related to the implementation of a technology-enhanced intervention in existing mental health clinics are discussed, as well as implications for future research and practice.

Keywords

Technology; Mobile health; Child mental health; Hybrid type 1 trial; Traumatic stress

1. Introduction

Effectively treating youth mental health disorders is a public health imperative [36]. Approximately one in four children (15 million) in the United States currently has a mental health disorder [62,67]). The public health impact of existing efficacious interventions has not been realized [7,44]. Almost 80% of youth in need of services do not receive evidence-based mental health care [66]. Moreover, evidence-based interventions are often delivered with variable effectiveness in community settings due to factors like provider inexperience, caseload diversity, childrens lack of engagement, organizational culture, and inconsistent funding streams [63], which further compound and perpetuate the research-to-practice gap.

Implementation initiatives aim to directly address these concerns (see [60] for a review); however, gaps remain. Innovative solutions to address quality of care are needed. Rapid technological advances offer exciting opportunities to meet these goals in ways that are acceptable and desirable to providers (e.g., [37,42]). Technology-based, scalable tools can be used to target two primary quality of care indicators: 1) provider fidelity (i.e., degree to which providers adhere to a treatment protocol and deliver it competently) and 2) child engagement (i.e., general level of behavioral involvement in the treatment process) [34,45]. Regarding provider fidelity, technology may facilitate clear, consistent, on-protocol delivery of activities meant to teach skills or convey complex concepts that can be challenging for some providers to teach. Technology also can provide built-in, real-time tips and suggestions that may help providers remain adherent to treatment manuals. Regarding child engagement, technology may help to make treatment more interactive, enhance learning and skill acquisition, and prepare children for difficult therapeutic elements.

Although providers rate such technology-based resources as desirable and acceptable, little is known about how they will be used in practice. Several provider- and organization-level factors determine how technology is incorporated into practice ([30]); yet, few studies have empirically investigated how to promote uptake and sustained use [41,47].

The purpose of this project is to test the effectiveness of a tablet-based provider toolkit, Supporting Providers and Reaching Kids (SPARK), and to identify provider and organization factors that can be leveraged to promoted widespread implementation of technology-enhanced interventions. SPARK is composed of a collection of activities and games designed to increase the quality of child mental health treatment by enhancing provider fidelity and child engagement. This study leverages partnerships with community settings across 3 U.S. states. The potential impact is a scalable model that can be adapted to

numerous other well-established child mental health interventions to improve the quality of youth mental health care.

2. Methods and design

2.1. Study design

We proposed to use a hybrid type1 effectiveness-implementation trial [20] to evaluate an innovative, scalable, tablet-based resource designed to improve quality of care for children and families. Although the underlying structure and theoretical rationale for SPARK is not specific to a particular intervention, the current SPARK prototype was designed to complement Trauma-Focused Cognitive Behavioral Therapy (TF-CBT; [16,18]). Accordingly, in its current form, SPARK consists of nine interactive chapters – each consisting of videos, games, and/or activities – that correspond to the TF-CBT "PRACTICE" components: 1) Psychoeducation; 2) Parenting; 3) Relaxation; 4) Affective Regulation; 5) Cognitive Coping; 6) Trauma Narration; 7) In Vivo Exposure; 8) Conjoint Sessions; and 9) Enhancing Safety. The toolkit content was carefully designed and developed in collaboration with the treatment developers, with extensive input from certified national trainers ([31]), as well as feedback from mental health treatment providers and families involved in psychotherapy. SPARK was designed to be used with children and adolescents (i.e., children ages 5–16 years participated in our pilot study). Some elements of the SPARK toolkit have branching logic to accommodate children from different age groups, such as videos that show adolescents using different skills (e.g., different coping strategies that apply to both younger and older youth) and tailored parenting content that demonstrate the use of skills with different age groups. Optimized for use on tablets, SPARK was specifically designed for use by providers in session with children and caregivers throughout the treatment process to support high-fidelity delivery of treatment and child engagement. It was tested for feasibility and acceptability with 13 providers and 27 families. Pilot data indicated that SPARK was easy for providers to use and does not require significant preparation time outside of regular sessions Families found SPARK to be useful, engaging, and to aid skills-based learning.

The aims of this study will be accomplished in two phases. First, the SPARK toolkit will be refined based on provider and family feedback from the pilot feasibility trial. These refinements include increased content (e.g., video demonstrations, activities) for adolescents, new parenting videos to demonstrate a wider range of skills, and updated graphics. Second, the hybrid type 1 trial will be conducted to test the effectiveness of the toolkit using a randomized controlled design, while also systematically collecting data related to the potential for implementation. Effectiveness of the intervention will be tested by examining differences in child engagement and provider fidelity across the standard vs. SPARK-enhanced treatment group. Implementation evaluation will follow the Consolidated Framework for Implementation Research (CFIR; [21]) and will include: (1) field note observations collected during practice orientations to the study that describe organizational climate, access to resources, and providers' reactions to SPARK; (2) quantitative data on organizational climate and attitudes and knowledge of evidence-based practice, as well as attitudes toward incorporating technology into practice; and (3) semi-structured qualitative

interviews with providers, organization leadership, and families to assess determinants (i.e., barriers and facilitators) of SPARK toolkit adoption and use.

2.2. Rationale for TF-CBT

Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) was selected as the model intervention for this project because it addresses a wide range of symptoms using techniques that are shared by several other youth mental health interventions. TF-CBT is a well-established, evidence-based intervention with approximately 15 randomized controlled trials and numerous studies providing empirical support for this intervention (e.g., [17,19,22,24,25]). TF-CBT has been implemented internationally, with a number of cultural adaptations to enhance its reach. It incorporates treatment techniques (e.g., relaxation, parenting skills, affective regulation, exposure) that are effective in treatment of trauma- and stressor-related disorders, disruptive behavior disorders, depression, and anxiety disorders, thereby underscoring the applicability of the toolkit content to a range of child treatments. TF-CBT also includes caregiver involvement throughout the treatment, which allows preliminary exploration of tablet-based approaches with caregivers.

2.3. Rationale for settings

This project builds on our pilot infrastructure to finalize and test the SPARK toolkit based on recommendations by providers and families. Our research team has a long history of developing, evaluating, and facilitating access to evidence-based treatments for children, including regional and national dissemination of TF-CBT ([25,54]). TF-CBT *Web*, for instance, is a TF-CBT provider training course developed by our team that has been used by more than 400,000 providers in all 50 states and over 100 countries since its launch in 2005 ([61,68]). Further, our team has strong relationships with community-based agencies through two dissemination initiatives, Project BEST (Bringing Evidence-Supported Treatment to South Carolina) and the Program on Adolescent Traumatic Stress (PATS). We will leverage existing relationships with over 70 agencies across three states, resulting in a diverse sample with respect to recency of training, provider experience and skill level, and race/ethnicity of both providers and patients.

2.4. Participants and recruitment

At least 120 providers will be recruited from partnering mental health service settings across three states in southeastern United States. These sites collectively have significant geographic (i.e., rural and urban) and racial/ethnic diversity. Providers must have completed some training in TF-CBT (e.g., completed TF-CBT *Web*, intensive in-person training, telephone or in-person consultation), be full- or parttime employees of the partnering clinic, and must have obtained at least a Master's degree in social work, counseling, clinical psychology, or related field. Each provider will be asked to refer five families to the study to maximize the likelihood that treatment is completed with at least three study cases. South Carolina State regulations for state-employed providers prohibit incentivizing individual providers. Therefore, all partnering clinics will receive one iPad for each participating provider for use by their providers upon study completion.

We will recruit 360 8–16-year-old youth and their caregivers. Participating children must have been the victim of a potentially traumatic event (e.g., sexual assault, physical assault, disaster, serious accident) and must be deemed appropriate for TF-CBT by the participating clinician. Although TF-CBT can be used with children as young as three years, we have restricted the age range to 8–16 years due to lack of compelling evidence for the feasibility of conducting telephone-based assessments with youth younger than eight years. Youth will be excluded when the child or caregiver exhibits psychotic symptoms (e.g., active hallucinations, delusions) or the child has significant cognitive disability or developmental delays. Additionally, children will be excluded if there is not a reliable caregiver informant available to participate. To ensure that interviews are completed with the target child, providers provide us specific demographic information, including age and trauma type when making the referral. This information is then verified with both the child and caregiver. All interviews and therapy sessions with the target child also are audio recorded and reviewed.

2.5. Randomization

Providers will be randomly assigned to the SPARK + TF-CBT or the standard TF-CBT condition. Providers will be blind to condition until their initial study-eligible family has been enrolled in the study. To decrease risk for contamination within clinics (i.e., providers in the control group using the toolkit), providers randomized to the SPARK condition will be assigned a unique access code to enable tracking of the frequency and usage of each component of the toolkit. We carefully weighed the pros and cons of randomization at the level of provider vs. family vs. clinic. In principle, randomization at the family level is optimal for studies in which the primary goal is effectiveness evaluation, but in practice, the contamination threat of this approach for this study is too great – providers' use of the SPARK toolkit with some of their families would have had the potential to influence how they interact with and engage with standard care patients. For example, SPARK use with some patients might improve provider competence and fidelity to the intervention with standard care patients. For these reasons, randomization will occur at the level of the provider.

2.6. Assessments

Consistent with other studies with similar RCT designs (e.g., [15,39]), baseline and 3-, 6-, 9-, and 12-month post-baseline assessments will be administered by trained independent evaluators blind to study condition and trained in the administration of all measures. Due to the number of partnering clinics and wide geographic area covered by the study, in-person interviews are cost prohibitive. It is also impractical, costly, and burdensome to patients to complete all assessments via clinic-based televideo, which would necessitate significant travel to clinics after completion of treatment for many families. All assessments will therefore be conducted via telephone. Consent and assent will be obtained via an IRB-approved online platform (i.e., REDCap) during the baseline assessment. All assessments will be scheduled directly with caregivers to reduce provider and clinic burden. As part of the consent process, caregivers can consent for their data to be shared with participating providers. These data, however, will only be shared to facilitate risk assessment for suicidality of abuse/neglect. Measures were selected based on high relevance to constructs

targeted by the intervention, sound psychometric proprieties, and brevity and simplicity for phone administration.

Providers will also be asked to complete baseline and post-study assessments via an online platform. Once providers have consented, they will be sent a link to a battery of questionnaires to assess preliminary knowledge, attitudes, and organizational climate. The measures were selected to assess a number of inner and outer characteristics from CFIR (Damschroder et al., 2009) hypothesized to impact the implementation of the toolkit. Providers will be asked to complete a similar set of questionnaires upon study completion. Providers will also be asked to audio-record all sessions with participating families to allow coding of child engagement and treatment fidelity.

Qualitative telephone-based interviews will also be conducted with a subset of providers, organizational leaders, and families upon study completion. The goal of these interviews is to assess barriers and facilitators to SPARK toolkit implementation and use. For each group of informants, we will use a purposive sampling approach drawing from participants and community partners to ensure recruitment of diverse samples of families, providers, and organization leaders. Semi-structured interview guides will be designed to identify implementation challenges and successes. Interviews will be audio-recorded and transcribed for coding and analyses.

2.7. Intervention

TF-CBT is a conjoint treatment approach for youth with significant emotional and behavioral difficulties related to traumatic events [16,18]. TF-CBT consists of 12–16 sessions addressing the major ‘PRACTICE’ components (**P**sychoeducation and **P**arenting; **R**elaxation; **A**ffective Regulation; **C**ognitive Coping; **T**rauma Narrative and Processing; **I**n vivo exposure; **C**onjoint Sessions; **E**nhancing Safety). All of the chapters in SPARK correspond to these PRACTICE components. Components include psychoeducation; teaching of relaxation skills; affective coping skills; and cognitive coping skills. Others feature gradual exposure, including development of a narrative about the child’s experiences and affective and cognitive processing of the event; in vivo mastery of trauma reminders; joint sessions during which the trauma narrative is shared; and enhancing safety. TF-CBT is a well-established evidence-based intervention that has received the highest ranking for empirical support from several professional organizations and federal agencies (National Child Traumatic Stress Network; SAMHSA; California Evidence-Based Clearinghouse for Child Welfare; [15,24]).

2.8. Measures

2.8.1. Observational measures—

Two of our primary outcomes, treatment fidelity and child engagement, will be measured by coding audio recorded sessions using a well-established observational coding schemes. The TF-CBT *Therapy Process Observational Coding System for Child Psychotherapy* (TPOCS; [23] will be used to assess provider fidelity. The TPOCS manual includes detailed instructions to code the specific content and technique items of TF-CBT as well as the therapeutic strategies typically used by providers implementing TF-CBT. Coders record clinicians’ use of 25 different item codes that

correspond to the TFCBT PRACTICE acronym, other content items, and therapeutic techniques (e.g., establishing an agenda, Socratic questioning, teaching, reflective listening) during each session. The TPOCS will facilitate a components-based assessment of the thoroughness with which each component is administered. Use of iPad activities is recorded on the integrated coding form, and iPad activity use also is recorded in the tablet TF-CBT system for each study case. After the full session is coded, coders provide a rating of "extensiveness" (a 6-point rating to reflect the thoroughness or intensity of the intervention) for each item coded (by session type). Each trained coder will complete an estimated 65–70 h training process consisting of reading the manual, in-person training, independent coding, group coding review, and certification.

Child engagement will be observationally rated by independent, trained coders via review of audio-recorded sessions. The *Child Involvement Ratings Scale* (CIRS; [13,14]) will be used to code child engagement. Ten "child involvement" items – 6 positive, 4 negative – are rated for each session on a 6-point scale (i.e., "not at all" to "a great deal present"). The positive-involvement items emphasize the extent to which children initiate discussions, demonstrate enthusiasm, self-disclose, and demonstrate understanding. Items for negative involvement address withdrawal or avoidance in treatment. Coders will provide separate ratings for the first and second halves of each session, permitting observation of shifts in engagement within and across sessions. CIRS child engagement ratings have been associated with clinical outcomes and provider flexibility in delivery of EBTs [13,14]. Initial reliability training will consist of a 2-day in-person didactic that reviews the CIRS manual and illustrates the individual items and scoring using "gold standard" recordings of TF-CBT. Coders will be considered reliable when they have achieved an ICC ≥ 0.60 on all 10 CIRS items compared to gold standard ratings.

Caregiver engagement will be assessed using the *Parent Involvement Rating Scale* (PIRS). The PIRS was adapted from the CIRS to observationally code parallel forms of caregiver involvement, including interest in session activities, demonstration of knowledge of lessons, behavioral participation, and self-disclosure. "Negative involvement" (e.g., opposing therapy activities, withdrawal from session activities) also will be assessed. The PIRS will be used to assess parent involvement in all sessions where a caregiver is present.

2.8.2. Quantitative measures

2.8.2.1. Child self-report measures: *The Child and Adolescent Trauma Screen- Child Version* (CATS; [53]) serves as a screening tool to identify children with trauma histories and posttraumatic stress disorder (PTSD) symptoms in youth ages 7–17 years. The CATS will be completed at all timepoints. The measure provides a list of 14 commonly experienced traumatic events (e.g., child sexual abuse, physical abuse, neglect), and has 20 items assessing the severity of PTSD symptoms across all four symptom clusters over the past two weeks. Youth rate their symptoms on a four-point scale ranging from 0 (*Never*) to 3 (*Almost Always*). A score of 12 or higher is considered clinically significant.

Center for Epidemiological Studies Depression Scale for Children (CESDC; [27,65]) will be administered at all time points and assesses the severity of depressive symptomatology in children. It is a 20-item self-report measure with possible scores ranging from 0 to 60. Youth

rate their symptoms on a four-point scale ranging from 0 (*Not at All*) to 3 (*A Lot*). Scores over 15 are indicative of significant levels of depressive symptoms.

Abuse-related shame will be assessed at each time point using four items: (1) "I feel ashamed because I think that people can tell from looking at me what happened"; (2) "When I think about what happened I want to go away by myself and hide"; (3) "I am ashamed because I feel I am the only one in my school/work who this has happened to"; and (4) "What happened to me makes me feel dirty." The items will be rated on a 3-point scale ranging from 1 (*Not True*) to 3 (*Very True*). Items will be summed, with a higher score indicating greater abuse-related shame [28].

The *Therapeutic Alliance Scale for Children* (TASC; [56,57]) will be given at the three-month assessment to assess child-therapist alliance. It is an 8-item measure using a 4-pt scale. It has good internal consistency and interrater reliability [26].

The *Child/Adolescent Satisfaction Questionnaire* (CASQ; [40]) will also be administered at the three-month follow-up. The CASQ is a 15-item instrument that assesses child satisfaction with mental health treatment on a 5-point Likert scale to rate the extent to which children agree with the statements about their treatment from 1 (*Very Much False*) to 5 (*Very Much True*).

2.8.2.2. Caregiver measures: *The Child and Adolescent Trauma Screen-Caregiver Version* (CATS; [53]) will be given at each time point to assess caregiver's perceptions of their child's PTSD symptomatology. Caregivers will complete a trauma-history screen and then be asked to answer 20 items to assess the severity of their child's PTSD symptomatology. Caregivers will rate their child's symptoms on a four-point scale ranging from 0 (*Never*) to 3 (*Almost Always*). A score of 12 or higher is considered clinically significant.

The *Center for Epidemiological Studies Depression Scale* (CES-D; [51]) will be administered at each time point to assess caregivers' depression symptomatology. The CES-D assessing depressive symptoms across four dimensions: negative affect; positive affect; somatic; and interpersonal. It consists of 20 items, each rated on a 4-point scale ranging from 0 (*rarely/none of the time*) to 3 (*most/all of the time*). Scores range from 0 to 60 with higher scores indicating more depressive symptoms.

The *Kessler-6 Distress Scale* (K-6; [38]) will be administered to caregivers at each time point to assess overall levels of caregiver distress. The K-6 consists of 6 items that measure global distress in the past week and includes both symptoms of depression and anxiety. Items are rated on a 5-point Likert scale ranging from 0 (*All of the Time*) to 5 (*None of the Time*).

Caregivers will also complete the *Brief Problem Monitor* (BPM; [4]) Parent Form at each time point. The BPM is a brief measure of overall child functioning and can be used to assess treatment response. It assesses three broad domains: internalizing behaviors, externalizing behaviors, and attention, and a total score can be derived. The BPM consists of 19 items that are rated on a 3-point Likert scale ranging from 0 (*Not True*) to 3 (*Very True*).

Two scales of the *Alabama Parenting Questionnaire* (APQ; [29]), the Discipline and Positive Parenting scales, will be administered at each time point. The APQ consists of 42 items assessing different parenting dimensions. This study will include 13 items, six items assessing positive parenting (e.g., "You praise your child for behaving well.") and 7 items assessing other discipline strategies (e.g., "You send your child to his/her room as a punishment."). Items are rated on a 5-point scale ranging from 1 (*never*) to 5 (*always*) and are summed to produce each scale total.

Working Alliance Inventory-Caregiver (WAI-; [33,35]) is a 12-item measure of caregiver–therapist alliance with subscales that assess the extent to which caregivers and their child's clinicians agree about the goals of therapy (goal), agree about the tasks of therapy (task), and acknowledge a bond between the patient and clinician (bond) using a 7-point Likert scale from 1 (*never*) to 7 (*always*). Scores for each subscale are calculated as the mean rating for the four items that make up each subscale, and scores ≥5 indicate agreement between the caregiver and provider from *often* to *always*. Caregivers will be asked to report on their alliance with the clinician at the three-month assessment.

Caregivers will also complete the Caregiver Satisfaction Questionnaire (CSQ; [40]) at the three-month assessment. The CSQ is a 12-item measure to assess caregiver satisfaction with mental health treatment that uses the same 5-point Likert scale.

2.8.2.3. Provider measures: Providers will complete the *Evidence-Based Practice Attitudes Scale* (EBPAS; [2]). The EBPAS has 15 items that assess four different attitudes toward adopting new evidence-based practices. These domains include: 1) the intuitive appeal of evidence-based practice, 2) the likelihood of adopting, 3) openness to new practices, and 4) the perceived divergence of the evidence-based practice from current practice. In past research, scores on the EBPAS were related to provider demographics, organizational climate, and adoption and use of evidence-based practices [1–3].

Additionally, providers will complete the *Computer-Assisted Therapy Attitudes Scale* (CATAS, [6]) to assess attitudes toward incorporating technology into practice. The CATAS has eight items that are rated on a 5-point Likert scale and includes two subscales: 1) comfort with technology and 2) efficacy. Higher scores indicate more positive attitudes.

The *Knowledge of Behavioral Principles Applied to Children* (KBPAC; [49]) is a multiple-choice measure designed to assess knowledge of behavioral concepts to be used with children. The modified version has two 22-item forms that allow for pre-test and post-test comparisons and providers will be randomly assigned to the initial form to minimize practice effects [5]. Items are scored as either being correct (one point) or incorrect (zero points). This measure will be used to assess changes in provider's knowledge over the course of their study engagement.

The *Organizational Readiness for Implementation Change* (ORIC; [55]) is based on theories of organizational change that posit that organizational readiness for change is related to high change initiation, greater effort and commitment to change, and more cooperative behavior to change. The ORIC will be administered at pre and post-assessment. It contains 24-items

that yield five subscales. Items include: “People who work here feel confident that the organization can get people invested in implementing this change.” Items are rated on a scale from 1 (*disagree*) to 5 (*agree*). Higher scores indicate greater beliefs related to readiness to change.

The *Trauma-Focused Cognitive Behavioral Therapy Organizational Support Measure* [32] also is administered to providers. This measure includes 18-items that assess organizational support for TF-CBT delivery, such as “In our organization, clinical supervisors provide regular supervision specifically on using TF-CBT.” Items are rated on a 5-point Likert scale ranging from 1 (*Strongly Disagree*) to 5 (*Strongly Agree*).

Providers will also complete three brief measures to assess implementation outcomes. The *Acceptability of Intervention Measure* (AIM), *Intervention Appropriateness Measure* (IAM), and *Feasibility of Intervention Measure* (FIM) are each 4-items long and will be used to assess the acceptability, feasibility, appropriateness of the SPARK toolkit [64]. Providers will rate their perceptions of the toolkit on a 5-point Likert scale ranging from 1 (*Completely Disagree*) to 5 (*Completely Agree*).

2.8.3. Qualitative measures—Each interested site will receive an hour-long on-site orientation to study procedures. During this time, study team members will introduce the SPARK toolkit, discuss provider and family roles in the study, and obtain consent of interested providers. A trained study team member will collect field notes during these site visits. Field notes are considered to be essential to rigorous qualitative research and add valuable context to other quantitative and qualitative data [48,50]. A semi-structured field note template was developed in collaboration with an experienced implementation scientist and qualitative researcher. During visits to sites, notes will be taken by a trained observer who will document information relevant to the potential implementation of the tablet-assisted intervention, including access to technology, size of the practice, observed receptiveness to the intervention, and relationship among providers and leadership. Additionally, providers will be asked a set of questions to assess their preliminary reactions to the SPARK toolkit. For example, they will be asked about perceived barriers to using SPARK, how they believe their patients will respond to SPARK, and how they anticipate they would use the toolkit.

Additionally, qualitative telephone interviews will be scheduled directly with informants in the experimental (i.e., SPARK) arm of the trial to examine reactions to using the toolkit as well as barriers and facilitators associated with implementing and sustaining tablet-based resources in child mental health facilities. This will occur at the completion of treatment for families; and at the completion of study requirements for providers, supervisors, and senior leaders. For each group of informants, we will use a purposive sampling approach drawing from trial participants and partners to ensure recruitment of diverse samples of families (e.g., age of child, race/ethnicity, rural/urban), providers (e.g., years of experience, level of tablet use, rural/urban setting), and senior leaders (e.g., agency directors, program managers). Each of these 30–60-min qualitative interviews will be guided by a semi-structured interview guide designed to identify the implementation challenges and successes, processes

developed, problems overcome, and adaptations required. All interviews will be audio-recorded and transcribed verbatim for later analysis.

Patients will be asked about their reactions to different types of activities (e.g., video-based, game-based, writing/drawing), recommendations for improving these activities, and general reactions to the use of the SPARK toolkit in treatment. Providers will be asked about their overall experiences with the SPARK toolkit, barriers and facilitators associated with use of various chapters in the toolkit, reasons for non-use or low use of the toolkit, and perceptions around types of patients and providers to whom a tablet-based approach is best suited. Supervisors will be asked about strengths and weaknesses of the tablet-facilitated delivery model, barriers and facilitators associated with providers' use and non-use of the tablet toolkit, and perceptions around benefit to families. Senior leaders will address barriers and facilitators associated with planning, engaging, executing, reflecting, and evaluating implementation, integrating into dissemination initiatives, and sustaining tablet-based toolkits; strengths, weaknesses, opportunities, and threats associated with a tablet-based delivery model.

2.9. Data analysis plan

2.9.1. Quantitative analyses—The RCT will enroll at least 120 providers who are expected to complete treatment with at least 3 child TF-CBT cases over the course of the project. This strategy results in a nested data structure in which cases (*i*) are nested within providers (*j*), which are nested within sites (*k*). Hypotheses will be tested within a multilevel modeling framework (MLM) that accounts for several issues including: (1) dependency in outcomes due to the nesting; (2) multiple outcome distributions; (3) linear, non-linear, and/or piece-specific change patterns; (4) variable measurement points; and (5) missing observations [52]. First, site-level variation will be evaluated to determine if there is systematic variability attributed to provider location. If there is evidence for significant between-site variability, then site will be added as additional level of analysis. However, if the amount of between-site variability is negligible, then the effects of site can be ignored. The benefit of removing site as an additional level is the increased power it affords to detect the primary effects of interest. The aims of the study do not include hypotheses for effects at the level of site. Separate models will be used for each variable described below. All subsequent models will be constructed according to the guidelines of Singer and Willett [58] with respect to including fixed and random effects. Statistical significance will be determined with false discovery rate based on the number of tests conducted to account for multiple testing [8].

To determine if provider fidelity is affected by overall SPARK use, a 2-level MLM (level-1 child; level-2 provider) will be used. Fidelity will be measured by the TF-CBT TPOCS-S. Providers' overall use of the toolkit will be calculated per child participant and averaged across toolkit content. Fidelity scores will be calculated per child participant such that each provider will have three ratings. An aggregate fidelity score will determine if there are differences across conditions (SPARK + TF-CBT vs. standard TF-CBT) while accounting for the nesting of providers. A similar approach will be used to evaluate the effect of SPARK use on child engagement.

Response to the intervention will be evaluated with a piecewise longitudinal MLM that contains an additional level corresponding to time. Level-1 will correspond to time, level-2 to child, and level-3 to provider. The primary outcome will be scores on the CATS, CAT-Caregiver, CES-DC, and BPM. A piecewise model allows for separate change trajectories to be estimated for distinct periods of time. Patients are expected to show more rapid change during treatment than during follow-up (roughly corresponding to 9- and 12-month post-baseline period). Group comparisons will be made at level-3. Of interest is the cross-level interaction between rate of change during treatment and the condition to which the provider was assigned. Cross-level interactions between the rate of change during follow-up also will be examined.

An enhancement mediation design will be used to determine if provider fidelity and child engagement are the mechanisms by which SPARK reduces symptomatology. Enhancement designs evaluate mediation by experimentally manipulating a variable that enhances the effect of the mediator when direct experimental control of the mediator is not possible [43]. These mechanistic hypotheses will be tested with established guidelines for multilevel mediation [8]. Significance is determined by a product of coefficients test with asymmetric bootstrapped standard errors and 95% confidence intervals for the product. This requires estimation of two paths: the effect of SPARK on engagement and fidelity (a-paths); and the effect of engagement and fidelity on outcomes, controlling for the effect of SPARK (b-paths). A Monte Carlo method is used to create a 95% confidence interval to test for the mediated effect as this effect does not assume a normal distribution. Provider fidelity and child engagement will be evaluated in separate models. The mediation hypothesis will first be evaluated using all time points. If supported, follow-up analyses in which mechanism measures obtained from the first half of treatment will evaluate change in symptomatology in the second half of treatment. Combined, the proposed mediation model will provide important evidence to support, or reject, therapist fidelity and child engagement as potential mediators of the effect of SPARK on child outcomes.

2.9.2. Cost analyses—We will also evaluate the cost-effectiveness of SPARK + TF-CBT vs. standard TF-CBT. We will collect data on the incremental cost the intervention adds to standard TF-CBT. Costs include the cost of training providers in SPARK use and study personnel time needed to address providers' needs while using SPARK. Further, it will include technology-related costs associated with maintaining the app over time. We will note the cost of development of SPARK, as well as other exclusive research costs, but because these are one-time development and research costs that will not be replicated in other facilities, we will exclude them from cost-effectiveness and cost-benefit analyses. We will define benefits as the difference in cost of health services utilization in the event SPARK reduces the number of sessions a provider needs to achieve the desired clinical outcomes. We will estimate an incremental cost-effectiveness ratio as: [(cost of SPARK + TF-CBT − cost of TF-CBT) divided by (effectiveness of SPARK + TF-CBT − effectiveness of standard TFCBT)]. Effectiveness will be measured based on child mental health outcomes. In addition to calculation of cost-benefit and cost-effectiveness ratios, generalized linear models (GLM) adjusting for child and caregiver demographics and provider fixed effects,

will be estimated for sensitivity analyses. The GLM models will use the family and distribution links based on the distribution of the cost-benefit and cost-effectiveness ratios.

2.9.3. Qualitative analyses—Qualitative interviews with patients, providers, supervisors, and senior leaders will be audio-recorded and transcribed. The qualitative approach chosen for this analysis is derived from constructivist grounded theory [11]. The qualitative approach chosen for this project was thematic analysis [9], which was guided by constructivist grounded theory [12] for coding data since it is an approach that acknowledges the researchers' prior knowledge and influence in the process, and provides guidelines for building a conceptual framework to understand the interrelations (e.g., what and how) between constructs [10]. First, a content analysis of interview responses will be conducted through multiple close readings of the transcriptions by trained, master's and doctoral level, independent coders to identify common themes as they relate to specific toolkit chapters and features and to specific populations (e.g., boys, younger children, providers with greater experience). Initial and secondary coding passes will be conducted by coders to identify thick descriptors of informants' responses, refine theme classifications as they emerge, and impose a data-derived hierarchy to the nodes identified. Focused coding will be used to refine the coding, ensure that data are coded completely with minimal redundancy, and impose a data-derived hierarchy [46]. Interrelations between person node classifications (e.g., gender, ethnicity, age) and themes will also be examined for causal networks (i.e., data relations). Verification will be conducted following completion of focused coding to evaluate the reliability and validity of the conclusions. A coder will independently code a random selection of 20% of these cases and interclass correlation coefficients (ICCs) will be computed to assess reliability; member checks for validity of the findings will be conducted with key stakeholders. Results will guide integration of the tablet TF-CBT toolkit into existing statewide and regional dissemination initiatives for sustained national impact. We also hope to grow partnerships to broaden impact to other well-established child mental health treatments.

3. Results

At the time of manuscript submission, Phase 1 of the study was complete. Recruitment and data collection for the hybrid type 1 effectiveness trial are currently underway; however, no data have been analyzed. All aspects of this federally funded study have been approved by institutional review board (IRB) at the institution where the research is being conducted. As part of the iterative design and development process the investigative team updated components of the SPARK toolkit based on qualitative usability and feasibility data from providers collected in the pilot study. For example, tailoring features for certain activities have been enhanced, additional demonstration videos for caregivers were added, and graphics were refined. We are actively recruiting partnering sites, providers, and families to the study.

4. Discussion

This project aims to implement a highly novel, scalable tablet-based toolkit designed to address two key modifiable targets associated with child mental health outcomes: provider

fidelity and child engagement. Our hybrid type 1 effectiveness-implementation design will allow us to (1) examine the benefits of technology-based resources in mental health care and (2) inform integration and implementation of technology aids in community practice settings. With regard to the former aim, this study will assess the extent to which tablet-based resources designed to facilitate delivery of treatment may have additive benefits with regard to child engagement, provider fidelity, and child mental health outcomes. With regard to the latter, we will also identify clinic-, provider-, and patient-level barriers and facilitators associated with implementation of the SPARK toolkit and similar innovations in community-based practices. This represents an important first step in understanding how best to increase uptake of technology-enhanced interventions at the level of providers and organizations, and, in turn, improve the quality of child mental health care.

This project has a number of methodological strengths. First, this study assesses barriers and facilitators at three important levels: the patient, the provider, and the organization. This will be completed through interviews with key stakeholders including families, providers, supervisors, and senior leaders to inform future implementation initiatives in practice settings. Second, the hybrid type 1 effectiveness-implementation trial allows targeting of multiple aims including quantitative aims that will teach us about impact on provider fidelity, child engagement, and clinical outcomes while also addressing critical qualitative aims that relate to facilitators and barriers to implementing and sustaining use of technology-based innovations in community practice settings. Third, the costs associated with maintaining and nationally disseminating technology-based provider-assistance resources will be assessed. This allows for cost estimation (e.g., costs associated with training, purchasing tablets, providers' setup, app maintenance), assessments of cost-effectiveness, and identification of potential cost savings associated with treatment efficiency.

There are some potential limitations to note as well. Our research infrastructure will support implementation and maintenance throughout the course of the study, but less is known about sustainability over time and our efforts to estimate costs and cost effectiveness may not fully capture challenges to sustainability that may occur outside of a research context. Similarly, it is possible that adoption and use may be increased by the research infrastructure. However, our incentives to providers are very limited, and prior work without provider incentives has shown strong provider enthusiasm and use. A related limitation, perhaps more likely, is that friction created by the research methodology (e.g., time associated with referring families to the project, audio recording sessions, uploading audio recordings of sessions for observational coding) may dampen participation and use. This project will examine these challenges and facilitators, thereby serving as an initial step toward understanding factors associated with provider adoption and sustainability through interviews targeting barriers and facilitators toward widespread implementation. An additional important consideration is that providers in the current study have previous training and comfort using evidence-based practices. Less will be known about providers who are less open to using evidence-based practices, have less experience with these practices, or have limited experience with technology.

4.1. Future directions

While this project will be valuable toward understanding the impact of technology-based tools on children's care and outcomes, it will teach us little about provider adoption, use, and sustainability outside of a research context, particularly for providers with less training in evidence-based practice. One important next step is to conduct a more naturalistic trial with the goal to assess organizational factors and provider adoption more thoroughly, as well as implementation strategies to promote adoption, use, and sustainability. Upon completion of this project, if findings favor this approach, we plan to investigate factors associated with widespread implementation of this toolkit to enhance access to mental health care for children and families who need it most. Results from our interviews with key stakeholders will inform these future implementation initiatives.

If this tablet-based approach is found to improve quality of care, this will represent an important step toward making evidence-based treatments more effective for children. Data will have high relevance to other child treatments due to the emphasis in TF-CBT on several mental health symptom domains and use of treatment techniques that are shared across numerous treatments addressing emotional and behavioral disorders. We developed a wide range of tools (e.g., videos, interactive games, drawing activities) that providers actively used with children and caregivers in our pilot work. This will ensure collection of valuable data relevant to several populations. Had we taken a narrower focus on a specific population (e.g., adults with depression) or specific type of resource (e.g., videos only), or specific target (e.g., provider fidelity or engagement vs. both) our study would have had less potential to advance the field. If effectiveness is supported by this project, we will target wide scale dissemination and implementation of this toolkit for a variety of evidence-based protocols nationally to improve reach and impact. Additionally, we have already engaged developers of several child mental health treatments who have shown interest in adapting this model to their well-established interventions. Addressing the quality of care chasm in children's mental health is a major public health priority, and research that bridges these gaps and scales effective solutions will continue to be critical.

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