Implementing a Pragmatic, Multi-Site Effectiveness Trial Examining Pediatric Anxiety Treatments During COVID-19

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INTRO

- Anxiety is the most prevalent pediatric mental health problem.
- Up to 80% of youth with a diagnosable anxiety disorder do not seek or receive treatment.
- Kids FACE FEARS (KFF) is a multi-site pragmatic RCT designed to compare two evidence-based CBT delivery methods in the treatment of youth anxiety
- Modalities of interest: (1) therapist-led, telehealth or office-based vs. (2) self-administered, online intervention.
- Planned recruitment of 300 patients across four US regions: Boston, Miami, Baltimore, and Seattle.
- Eligible youth (ages 7-18 years) are identified via universal screening and/or anxiety referral in large pediatric health care networks serving primarily racial/ethnic minority children.
- Study includes both English and Spanish speaking families.
- Recruitment began in November 2020, 5 months prior to the start of the COVID-19 pandemic.

OBJECTIVE

Describe collaborations between study team and stakeholders to:

- **Assess barriers** to continued implementation of RCT
- **Identify strategies** to safely continue recruitment
- **Execute solutions** for implementation, uptake and sustainability of treatment delivery in both arms

Engaged Partners	Members
Study Team	Principal Investigators, Site Investigators, Clinic Champions, Project Manager, and Site Research Assistants/Coordinators
Patient and Family Advisory Council (PFAC)	English and Bilingual Parent Group Parents of children with anxiety disorders
	Monolingual Spanish Speaking Parent Group Parents of children with anxiety disorders
	Bilingual Youth Group Children and adolescents with lived experience of anxiety
Study Advisory Committee (SAC)	Community stakeholders including: · Pediatric Health Care Providers · Mental Health Policy Makers · Pediatric Health Care Researchers
Scientific Steering Committee (SSC)	Experienced researchers in the fields of Psychology, Psychiatry, and Pediatrics

METHODS OF COMMUNICATION

- Study Team:
  - Bi-weekly 1-hour research staff meeting via teleconference with project manager and site research coordinators
  - Bi-weekly 1-hour site investigator meeting with principal investigators, project manager, study investigators, and clinic champions
- PFAC: 1-hour semi-structured group interviews every 3 months with each sub-group
- SAC: 2-hour semi-structured group interviews every 6 months
- SSC: 2-hour semi-structured group interviews every 6 months
- Meetings held via teleconference
- Findings shared across study teams and stakeholder groups

Collaboration with all study team members, stakeholder groups, and other researchers was necessary to overcome **barriers to implementation** of multi-site pragmatic RCT during COVID-19, and maintain **patient-centeredness** of the study.

Figure 1: Collaboration and Execution

Assess barriers to continued implementation of RCT during COVID-19

Research Staff Meeting
Report on:
1) Local COVID-related IRB regulations
2) Barriers to recruitment
3) COVID-related changes in policies and clinical care at recruitment sites

Site Investigator Meeting
Report on:
1) Local COVID-related IRB regulations
2) Barriers to recruitment
3) COVID-related changes in policies and clinical care at recruitment sites
4) State legislation related to insurance coverage for telehealth delivery of behavioral healthcare

Barriers shared with stakeholders to determine strategies for recruitment and implementation

Patient and Family Advisory Council Meeting
Provide feedback and insight on:
1) Strategies to keep families engaged in treatment during a pandemic
3) Use and familiarity with telehealth platforms
4) Attitudes towards anxiety treatments and preferences for in-person vs. telehealth care

Study Advisory Council Meeting
Provide information regarding:
1) Successful strategies to keep therapists engaged in study
2) Strategies used to recruit families to participate in studies remotely
3) Current status of clinical care and changes implemented in response to COVID-19

Scientific Steering Committee Meeting
Provide feedback and suggestions on:
1) Strategies to increase retention rates
2) Strategies to assess the use of online treatments during pandemic
3) Data collection tools to capture COVID-19 exposure and healthcare utilization during pandemic

Identification and execution of solutions for implementation, uptake, sustainability of treatment delivery

Executive Team
The Principal Investigators, Project Manager, and Data Manager weigh feedback to identify potential solutions.

Site Investigators
Potential solutions shared with Site Investigators to assess feasability for their site. New procedures are finalized with flexibility to account for site differences in:
1) Clinical care practices during pandemic
2) IRB regulations on research during pandemic

Research Staff
Project manager, data manager, and research assistants/coordinators:
1) Update assessments on REDCap
2) Update protocols and procedures to reflect changes
3) Submit amendments to institutional IRB for approval

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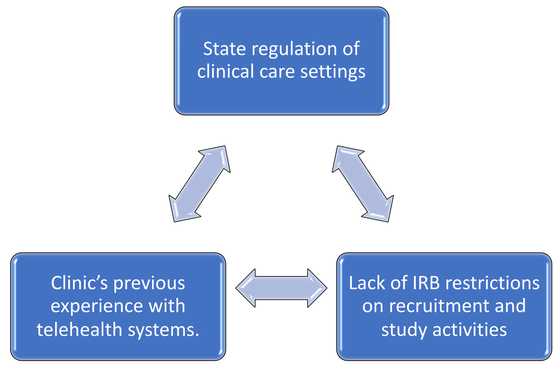
RESULTS

Barriers to Implementation	Solution	Study Action
Clinics were no longer allowed to have in-person visits. The therapist-led arm at the outset of study only included office-based therapy.	Allow therapist-led study arm to include telehealth.	The study design, analysis plan, and recruitment procedures were changed to expand therapist-led arm to include telehealth. Active participants were provided with the option to continue treatment via telehealth.
Within clinics with permission to resume office-based services, participants and therapists had varied preferences for treatment format; some preferred to continue with telehealth due to fear of infection while others opted to resume in person due to privacy concerns, or "Zoom fatigue."	Include a hybrid model of office-based and telehealth for therapist-led delivery to account for participant and therapist preferences.	The study design, analysis plan, and recruitment procedures were changed to allow for both office-based and telehealth CBT. Study measures were also updated to capture treatment preferences if assigned to the therapist-led condition and treatment delivery formats (e.g., videoconference, in-person, telephone).
Sites and clinics can only complete study and treatment tasks with participants over videoconferencing software(s) approved by their institution.	Flexibility to use secure videoconferencing software that may differ across sites for recruitment and study visits.	The study design and recruitment procedures were updated to allow sites to use platforms approved by their institution. Each site submitted an IRB amendment indicating the secure, HIPAA-approved videoconferencing software(s) they could use.
Not enough information is being collected about participant COVID-19-related experiences. These experiences can affect treatment effectiveness and the interpretation of data.	Addition of assessment questions regarding exposure to COVID-19.	The study design was updated to include questionnaires about: (1) Child exposure to COVID-19; (2) Family proximity to COVID-19; (3) COVID-19-related financial difficulties, (4) COVID-19-related life and role disruptions, and (5) COVID-19-related schooling experiences.

Figure 2: Key Factors for Recruitment Success



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