STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

INCREASING PARENT DEMAND FOR EVIDENCE-BASED PRACTICES TO TREAT YOUTH ANXIETY: THE EFFECT OF PARENT KEY OPINION LEADERS

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STUDY DESIGN

Two-arm, cluster randomized controlled trial comparing two approaches for outreach presentations for caregivers about evidence-based practices for youth anxiety. One presentation will be facilitated by a researcher and a key opinion leader (KOL; KOL condition), and the other one facilitated by two researchers (researcher-only condition). Neither the researchers nor the participants are blinded to study condition.

STUDY AIMS AND HYPOTHESES

This study will use a mixed methods approach (integrating quantitative and qualitative methods) to test the effect of KOLs on increasing caregiver demand for CBT for youth anxiety through the following aims:

Primary Aims

Aim 1: Test the relative effects of researcher-only and KOL conditions on changing caregivers' intention to seek CBT for their youth, and actual CBT seeking at three-month follow up.

> ***Hypothesis 1a:*** Relative to the researcher-only condition, the KOL condition will result in a greater increase in intention to seek CBT with exposures.
>
> ***Hypothesis 1b:*** Relative to the researcher-only condition, the KOL condition will result in a greater seeking of CBT with exposures for their youth at the three-month follow-up.

Secondary Aims

Aim 2: Test the relative effects of researcher-only and KOL conditions on changing caregivers' (a) perceived subjective norms about seeking CBT, (b) attitudes about CBT, (c) stigma about mental illness, and (d) knowledge of how to seek EBPs.

> ***Hypothesis 2a:*** Relative to the researcher-only condition, the KOL condition will result in a greater (a) increase in subjective norms about seeking CBT, (b) attitudes about CBT, and (c) decrease in caregiver stigma about mental illness.
>
> ***Hypothesis 2b:*** Both presentation conditions will result in a similar increase in knowledge about how to seek EBPs.

Aim 3: Examine how KOLs affect participants' impression of the researcher presenter.

> ***Hypothesis 3:*** Participants will view the principal investigator (i.e., the first author) more favorably when she presents with the KOL, relative to when she presents with another researcher.

PARTICIPANTS

Criteria for inclusion:

- Be least 18 years of age
- Be fluent in English
- Be the primary caregiver of a youth aged 5 to 18 years
- Have a child at one of the schools offering a presentation

Criteria for exclusion:

- None

Sample size: For aim 1 and 3, a Monte Carlo-based power estimate was derived using Mplus with 10,000 replications. For the sample size of 180, assuming a Type I error rate of 5%, a two-tailed test, statistical power was .83 to detect a medium-sized effect (r = .30) of randomization group on longitudinal changes, given an expectation of a small (r = .15) effect for the control group. For aim 2, power was calculated using G*Power. Given the brevity of the three-month follow-up questionnaire, a 10% attrition rate was assumed. Assuming a Type I error rate of 5%,

a two-tailed test, and a 25% rate of seeking EBPs in the researcher-only condition, statistical power was .82 to detect a medium effect (odd ratio = 1.72).

Randomization: Participants will be cluster randomized by school using restricted randomization with Excel's random number generator.

INTERVENTIONS

Presentation: The outreach presentation will last 75 minutes with an additional 15 minutes for caregiver questions. The presentations will occur in the evening via Zoom. The presentation will include information about identifying anxiety disorders, strategies for caregivers to help their youth with anxiety, evidence-based practices to treat youth anxiety, and strategies for finding a therapist who uses cognitive behavior therapy with exposures. The text on the presentations is written at a 5.3 grade reading level. Presentations will incorporate stigma reduction strategies, such as education to dispel myths, and behavioral decision-making tools to elicit hope, empowerment, and motivation.

Researcher-Only condition: The researcher-facilitated presentation, led by two clinical psychology graduate students, will be the same for all schools.

Key opinion leader: The key opinion leader (KOL) co-facilitated presentations will include the same core principles as the researcher-facilitated presentation but may vary by school in terms of specific examples and content emphasized based on KOL feedback. A caregiver KOL from the local community will co-facilitate the presentation with a clinical psychology graduate researcher. To select the KOLs, the principal investigator will contact the school PTA (or a similar parent group), and PTAs will be asked, "please nominate a caregiver who is well-known and respected within your community, and who reflects the diversity of the school as a whole." The PI will meet with the KOLs to review the presentation and to engage them in championing cognitive behavior therapy for youth anxiety.

MEASURES

Primary outcome measure:

1. Change From Pre-Presentation to Post-Presentation in Treatment Seeking Evaluation - Intention to Seek Cognitive Behavioral Therapy [Time Frame: pre-presentation; post-presentation (within 1 week after the presentation)]

   Participants rate how likely they are to seek a therapist who uses exposure therapy for their child in the next three months on a scale ranging from 1 (*very unlikely*) to 5 (*very likely*).

2. Number of Participants Who Sought Cognitive Behavioral Therapy as Assessed by Treatment Seeking Evaluation - Actual Cognitive Behavioral Therapy Seeking [Time Frame: 3-month follow-up]

   Participants indicate whether they sought exposure therapy for their child since the presentation (yes/no).

Secondary outcome measures:

3. Change From Pre-Presentation to Post-Presentation in Parent Engagement in Evidence-Based Services Questionnaire, Knowledge Subscale [Time Frame: pre-presentation; post-presentation (within 1 week after the presentation)]

   The Parent Engagement in Evidence-Based Services Questionnaire, Knowledge subscale (PEEBS-K) assesses caregiver perceived understanding of how to seek evidence-based practice (Chang et al., 2019). Participants rate five items on a ranging

from 1 (*strongly disagree*) to 5 (*strongly agree*). Items are summed; higher scores indicate higher levels of perceived knowledge about seeking evidence-based practice.

4. Change From Pre-Presentation to Post-Presentation in Therapy Subjective Norms Questionnaire [Time Frame: pre-presentation; post-presentation (within 1 week after the presentation)]

   The Therapy Subjective Norms Questionnaire is a six-item measure of caregiver perception of subjective norms for seeking therapy. It was modeled from previously used measures of subjective norms (Glanz et al., 2008; Park & Smith, 2007). Items are rated on a scale ranging from 1 (*strongly disagree*) to 7 (*strongly agree*). Items are summed; higher scores indicate more positive subjective norms about seeking therapy.

5. Change From Pre-Presentation to Post-Presentation in Caregiver Attitudes About Cognitive Behavioral Therapy [Time Frame: pre-presentation; post-presentation (within 1 week after the presentation)]

   The Caregiver Attitudes about Cognitive Behavioral Therapy includes 18 strategies used in cognitive behavioral therapy for youth anxiety. Participants rate how helpful they believe each strategy would be for treating their child on a five-point scale ranging from 1 (*very unhelpful*) to 5 (*very helpful*). Items are summed; higher scores indicate more favorable attitudes.

6. Change From Pre-Presentation to Post-Presentation in Parents' Internalized Stigma of Mental Illness Scale [Time Frame: pre-presentation; post-presentation (within 1 week after the presentation)]

   The Parents' Internalized Stigma of Mental Illness Scale (PISMIS) assesses caregiver perception of internalized stigma for having a youth with a mental illness (Zisman-Ilani et al., 2013). Participants rate each statement on a scale ranging from 1 (*strongly disagree*) to 4 (*strongly agree*); some items are reverse scored. Items are summed; higher scores indicate higher levels of family stigma.

Exploratory outcome measures:

7. Change From Pre-Presentation to Post-Presentation in Barriers to Seeking Treatment [Time Frame: pre-presentation; post-presentation (within 1 week after the presentation)]

   The Barriers to Seeking Treatment questionnaire asks participants to indicate whether they agree with 21 potential barriers to treatment (Heeringa et al., 2004). A count of the total number of barriers will be used in analyses.

8. Change From Pre-Presentation to 3-Month Follow-Up in Barriers to Seeking Treatment [Time Frame: pre-presentation; 3-month follow-up]

   The Barriers to Seeking Treatment questionnaire asks participants to indicate whether they agree with 21 potential barriers to treatment (yes/no; Heeringa et al., 2004). A count of the total number of barriers will be used in analyses.

9. Client Satisfaction Questionnaire [Time Frame: post-presentation (within 1 week after the presentation)]

   The Client Satisfaction Questionnaire assesses participants' satisfaction with the presentation. Items are rated on scale ranging from 1 to 4. Items are summed; higher composite scores indicate greater program satisfaction.

10. Relatability Evaluation [Time Frame: post-presentation (within 1 week after the presentation)]

The Relatability Evaluation will be used to evaluate participants' impression of the presenter. Participants will rate each presenter (scale ranging from 1 to 5) on 10 items associated with aspects of key opinion leaders: relatable, likeable, similar, think similarly, similar beliefs, credible, trustworthy, understanding of the local community, familiar, and friendship. Items are summed; higher composite scores indicate that the presenter is more relatable.

11. Brief Revised Child Anxiety and Depression Scale-Parent Version [Time Frame: pre-presentation]
    The total anxiety scale (15 items) from the Brief Revised Child Anxiety and Depression Scale-Parent Version will be used to assess youth anxiety (Ebesutani et al., 2017). Participants rate items on a scale from 0 (*never*) to 3 (*always*). Items are summed; higher scores indicate higher levels of anxiety.

12. Demographics [Time Frame: pre-presentation]
    A demographics questionnaire will assess caregiver and youth age, gender, race, ethnicity, and nativity; caregiver level of education, income, and religion; and youth health insurance status.

13. Content Checklist [Time Frame: during the 1.5 hour presentation]
    A content checklist will assess the core components of the presentation, as well as presenter and audience member self-disclosure about experiencing receiving therapy for themselves or their child (yes/no). Self-disclosure will be considered to have been made if either the presenter or an audience member self-discloses about their experiences.

14. Qualitative Interview [Time Frame: 3-month follow-up]
    A qualitative interview will ask participants about the following topics: (1) their perception of presenters; (2) ways in which the presenters affected their decision to seek treatment; (3) factors they considered when seeking treatment; (4) strategies they have used from the presentation; (5) their perception of exposure therapy; and (6) general ways that the mental health system could be improved to improve access to therapy.

STATISTICAL ANALYSIS PLAN:
Missing Data: Potential sampling biases will be identified by multiple logistic regression analyses examining whether key predictors at baseline (primary and secondary outcome measures; demographics) are associated with study retention. Should analyses reveal that dropout is differentially associated with outcomes, multiple imputation will be used.

Planned Analyses
Quantitative Analyses: All analyses will use multilevel modeling to account for the nesting of repeated measures within caregivers. Preliminary analyses will examine the effect of clustering of caregivers within schools. If schools account for more than 10% of variance in the outcomes after controlling for condition, a three-level multilevel model will be used to account for nesting of repeated measures within caregivers within schools.

Analyses will consider intention to seek CBT with exposures (Treatment Seeking Evaluation - Intention to seek CBT), subjective norms about seeking CBT (Therapy Subjective Norms Questionnaire–CBT), attitudes about CBT (Caregiver Attitudes about CBT), caregiver stigma about mental illness (Parents' Internalized Stigma of Mental Illness Scale), and knowledge about how to seek EBPs for youth anxiety (Parent Engagement in Evidence-Based Services Questionnaire–Knowledge Subscale) as person-level dependent factors; condition (caregiver or

researcher co-facilitator) as a person-level predictor; and time (pre- and post-presentation) as an observation-level predictor. In separate multilevel models, (a) intention to seek CBT, (b) Therapy Subjective Norms Questionnaire–CBT, (c) Caregiver Attitudes about CBT, (d) Parents' Internalized Stigma of Mental Illness Scale, and (e) Parent Engagement in Evidence-Based Services Questionnaire–Knowledge subscale will be regressed on time, condition, and the interaction between time and condition; a random intercept will be included in all five multilevel models. A binary logistic regression will be conducted with CBT service seeking at the three-month follow-up (Treatment Seeking Evaluation - Actual CBT seeking) entered as the dependent variable, condition entered as the independent variable, and youth anxiety (Brief Revised Child Anxiety and Depression Scale–Total Anxiety) entered as a control variable. T-tests will be used to compare difference between conditions for each item on the Relatability Evaluation of the principal investigator. This study will examine caregiver demographic factors, youth anxiety (Brief Revised Child Anxiety and Depression Scale–Total Anxiety), racial similarity to the presenter (Demographics, same race), and self-disclosure (Content Checklist, self-disclosure), as potential moderators of the effect of presentation condition on intention to seek CBT. In separate multilevel models, intention to seek CBT will be regressed on time, condition, each potential moderators, and their three-way interaction.

Qualitative Analyses: The transcribed qualitative interviews will be entered into NVivo software for analysis. Qualitative analyses will use a direct content analysis approach (Hsieh & Shannon, 2016). The coding team will create an initial codebook using the primary topics asked in the qualitative interviews. Additional codes will be added to code text that does not fit into the initial categories, either to split the initial codes into two, or to create new codes. Coding will occur through a consensus process in which each transcript will be coded independently by two raters, who will arrive at consensus through discussion (Hill et al., 2005). Thematic responses will be examined by both condition and by whether the caregiver has sought treatment for their youth (4 groups total).

Integration Procedures: Mixed methods integration will follow a QUAN → qual structure with an expansion approach (Palinkas et al., 2010); quantitative methods being used to test hypotheses about the intervention and qualitative methods being used to contextual the results.

Data collection at the time of the SAP: As of 8/11/21, pre/post presentation data has been collected from 17 participants. Three-month follow-up data has not yet been collected. No data has been analyzed.

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