TITLE:
Video-visit behavior therapy for anxiety and depression in youth: A randomized effectiveness-implementation study in low-resource primary care settings

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PROJECT SUMMARY AND AIMS:

This document summarizes the aims and analysis plan of an invited R56 project focused on adapting an efficacious brief behavioral therapy (STEP-UP) for youths with anxiety or depression to be delivered as a telehealth intervention by clinic staff in low-resource community health centers (CHCs). The R56 application was requested following the review of our R01 proposal, in which we proposed a randomized *hybrid 1 implementation-effectiveness study* of STEP-UP compared to referral to community treatment-as-usual. The R01 application (1R01MH125159-01) was viewed very favorably by reviewers and matches key NIMH priorities. However, our original design relied on the use of research staff as STEP-UP interventionists. ***Per review and program officer suggestions, we have obtained support of our community partners for a re-design of the R01 RCT using native clinic staff as interventionists. In preparation for this more ambitious R01 project, we are received 2 years of R56 support to:***

Aim 1. ***Assess degree of fit and need for adaptation***. We aim to systematically assess the degree of fit and needed adaptation of STEP-UP to be effective when delivered in CHC practice by CHC providers. Fit will be assessed at the clinic, provider, and patient level by leveraging secondary data available in the OCHIN network system, collecting original survey data, and seeking qualitative feedback from key stakeholders.

Aim 2. ***Complete adaptations of content and procedures***. Based on the results of Aim 1, we plan to adapt the STEP-UP intervention content, training, supervision, and implementation procedures to the CHC environment through iterative end-user feedback.

Aim 3. ***Conduct feasibility test of intervention implementation***. Finally, we aim to conduct a feasibility test of the intervention implementation process by conducting a case series of youth/parent participants (n=14) treated by two CHC providers.

NO STATISTICAL ANALYSIS PLAN:

Please note that this pilot R56 project focuses on calculating descriptive statistics and achieving feasibility benchmarks. There is no plan to conduct low power inferential statistical tests.

FEASIBILITY BENCHMARKS:

Thus, for each aim, we briefly describe benchmarks for successful completion and discuss how reaching these benchmarks will prepare us for submission of a follow-up R01 application.

Assess degree of fit and need for adaptation (Aim 1). In Aim 1, we systematically assess the fit between the STEP-UP intervention and the CHC setting and population. We will (a) leverage secondary data to assess features of OCHIN network CHCs that may influence implementation of the intervention, (b) conduct a brief survey with CHCs leaders to assess clinic readiness to implement STEP-UP, and (c) log communications (phone call, email) during clinic recruitment to identify barriers to implementation of STEP-UP and/or to participation in research related to STEP-UP. To assess fit to the population, we will meet with the OCHIN Patient Engagement Panel (PEP) prior to the R56 case series to review intervention dosing, content, and clarity and representativeness of materials; proposed outreach processes; and research activities. Our benchmarks for success at this stage include:

(a) Detailed analyses of EHR data on *characteristics of current TAU mental health* services for youths with target diagnoses, including use of telehealth. These data will allow us to understand the extent to which the STEP-UP model imposes more demands on CHCs than usual care. In analyses from the Kaiser system, the number of hours allocated for the STEP-UP intervention was comparable to usual care behavioral health services; however, this may not be true of lower resource CHC settings.

(b) *Successful recruitment of CHC clinics* and completion of leadership survey by at least one designated representative per clinic. Surveys will focus on issues of staffing and workflow and will form the basis of pilot clinical pathways that clinics may adopt when implementing STEP-UP.
(c) *Analysis of reasons for refusal* given by CHCs that chose not to participate in the R56 to identify barriers to larger scale implementation of STEP-UP in the OCHIN network. We anticipate that smaller clinics with less prior experience with integrated behavioral health will be more likely to refuse participation (i.e., related to concerns about staffing and workflow).
(d) *Identification of adaptation targets for the intervention* from clinic (see b) and patient perspectives (e.g., the PEP panel). We will be particularly alert to concerns about the length or number of intervention sessions.

Complete adaptations of content and procedures (Aim 2). In Aim 2, we move from an assessment of fit to active adaptation of content and procedures to improve fit. We will seek to complete the majority of these adaptations before commencing the feasibility case series (see Aim 3); however, some of our adaptation targets, such as supervision processes, are intended to be refined iteratively during the pilot. Our benchmarks for success at the adaptation stage include:

(a) *Adaptation of STEP-UP dosing*, if indicated. We anticipate that clinics, providers, and patients may support moving to 30-minute versus 45-minute sessions. We also will evaluate feedback on the suggested total number of sessions, with the option of moving some content (e.g., relaxation) into an online only instructional format or allowing the total number of plan practice sessions to flex (from 4 to 8 visits), based on youth response to intervention. Given that the STEP-UP intervention has been successfully tested in a prior effectiveness RCT and telehealth case series, we do not anticipate *content* revisions at this stage of development.
(b) *Core materials refined for clarity and representation of diverse families*. Based on feedback, we will craft final versions of the web site, downloadable handouts, and instructions for accessing the intervention and moving through treatment.
(c) *Creation of provider-facing content and support tools*. Based on clinic leadership feedback and the experience of interventionists in the case series, we will create new provider support materials to aid in the delivery of the STEP-UP intervention. While STEP-UP has been previously delivered by Masters'-level mental health providers (MSW, MFT) and nursing staff, the program has not yet been implemented as part of the general workflow of a practice setting. To support the implementation of STEP-UP, we will create sample, standardized charting notes for sessions (based on our current adherence measures), after visit summaries, and workflow documents. In addition, we will include a provider-facing page on the STEP-UP website with these resources and with archived material from the STEP-UP provider training (e.g., videos of role play examples conducted during training).
(d) *Adaptation of training and supervision*. Based on clinic leadership input and initial interviews with the case series interventionists, we will finalize our model of training and supervision, prior to moving toward the second stage RCT. Our research staff-based model will be adapted to better fit the optimal duration and intensity of training within the constraints of the interventionists' settings, content and preferred style and mode of training, and preferred and sustainable levels of ongoing supervision and implementation supports.

Conduct feasibility test of intervention implementation (Aim 3). During the R56, we also will complete a STEP-UP case series with 14 youth/parent dyads treated by CHC interventionists. Our benchmarks for success at the pilot testing stage include:

(a) *Recruit a lead clinic* to pilot the intervention.
(b) *Train at least two interventionists* from the lead clinic in the STEP-UP intervention and have them deliver the intervention with adequate adherence (90% of content delivered in adherence ratings).
(c) *Identify and recruit eligible patients* as a pilot test of our EHR and provider-referred recruitment pathways.
(d) *Retain youths in the intervention.* We aim to retain 80% of enrolled youths in a minimum of 8 STEP-UP sessions (the minimum dose in the F2F RCT) and to have 80% youths and parents demonstrate at least adequate engagement with services (e.g., above the midpoint of TASC, above average for interventionists' ratings of session engagement).

(e) *Deliver the intervention with high satisfaction*. We will assess youth, interventionist, and clinic leadership satisfaction with the STEP-UP case series. We aim for 80% of families reporting satisfaction with the intervention and reporting no more than mild technical difficulties in accessing website content and connecting with telehealth video visit sessions.

(e) *Benchmark clinical and mechanism outcomes.* Finally, we will benchmark pre-post change in anxiety symptoms, depression symptoms, and behavioral avoidance (target mechanism) against the values observed in our F2F RCT. STEP-UP outcomes on anxiety symptoms have been particularly robust and stable; accordingly, we expect to observe at least a 7-point drop (approximately 1 standard deviation) in SCARED scores in 80% of the sample of youths enrolled in the case series.

Foundation for the R01 phase. Successfully achieving the benchmarks associated with the aims of the R56 will provide a solid foundation to move forward into an R01 RCT application. In the R01, we propose randomizing 200 youth/parent dyads to STEP-UP or community TAU. The R56 project will provide a critical opportunity for the OCHIN system and research team to pilot test and refine procedures for clinic-based implementation of the protocol. Of note, the R56 will also produce tangible products (e.g., revised intervention materials and dosing schedule, provider-facing tools and archived training resources, draft workflows) that will support scaling up the intervention not only for the R01 project but also for larger-scale dissemination and implementation projects in the future.