Pilot Implementation of Depression Screening and Treatment for Adolescents in Mozambican Primary Care

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BACKGROUND

Study Purpose and Rationale

Mental disorders are the number one cause of disability in adolescents worldwide, accounting for 45% of years lived with disability (Gore, Bloem et al. 2011). It is estimated that 90% of adolescents live in lower middle-income countries (LMICs), (Organization 2008) and that 10-20% of these adolescents have one or more mental disorders (Erskine, Moffitt et al. 2015). Despite the substantial burden of mental illness in LMICs, adolescent mental health services are extremely limited in these regions.(Morris, Belfer et al. 2011) Because untreated mental illness hinders individual, social, and economic prosperity in the long term, (Chen, Cohen et al. 2006, Erskine, Moffitt et al. 2015) improving adolescent mental health services has become a focus of global development efforts (Collins, Insel et al. 2013, Votruba, Thornicroft et al. 2016). In high-income countries, mental healthcare integrated into primary care settings is effective for treating adolescent mental illness (Asarnow, Rozenman et al. 2015). Mental health services delivered by non-specialists (task-shifting) within primary care of LMICs has been proposed as an efficient and sustainable way to close the adolescent mental health treatment gap (Patel, Kieling et al. 2013, Juengsiragulwit 2015). However, research is needed to determine how to effectively integrate interventions for managing adolescent mental disorders within LMIC primary care settings (Patel, Kieling et al. 2013, Juengsiragulwit 2015).

Mozambique is the fourth poorest country in the world (The World Bank. World Bank Open Data. Washington) and has just 15 psychiatrists and 180 psychologists to serve its population of 29 million (Santos, Wainberg et al. 2016). Given this scarcity of human resources, the Mozambican Ministry of Health (MoH) has focused on integrating psychiatric treatment into primary care, utilizing a task-shifting approach. In 1996, the MoH began training PsyTechs to deliver psychiatric services at primary care clinics through a 30-month theoretical and practical course, and PsyTechs now practice in all 135 districts of Mozambique (Santos, Wainberg et al. 2016). However, even with the introduction of PsyTechs, there are still just 1.48 mental health specialists for every 100,000 Mozambicans (Santos, Wainberg et al. 2016). Since 2017, the MoH has begun further expanding access to adult mental health services by training nonspecialists (nurses, medical technicians, and community health workers) to screen for mental disorders and provide treatment for common mental illnesses or referrals to specialized care for serious mental

illnesses. Despite this progress toward increasing services for adults, Mozambique continues to have very little infrastructure for treatment of adolescent mental disorders. The results of this study will contribute an understanding of how to integrate mental health treatment for children and adolescents in primary care clinics of lowresource settings, and its impact on patient outcomes. It will also produce data on the challenges and facilitators to implementation of mental healthcare for adolescents in these settings. This knowledge will be applied to scale-up of services in Mozambique and may be used to inform scale-up of interventions for youth globally, helping to reduce the global mental health treatment gap.

Research Aims & Abstracts

We aim to examine patient and implementation outcomes of task-shifted depression screening and group IPT-A compared to treatment as usual in a pilot cluster-randomized trial at four PCCs. Guided by Proctor's Taxonomy of Implementation Outcomes (Proctor, Silmere et al. 2011), we will assess patient and implementation outcomes through quantitative measures and post-treatment qualitative interviews with adolescents and providers in the IPT-A and TAU study arms. We hypothesize that the IPT-A arm will have better patient and implementation and patient outcomes than TAU.

Globally, mental disorders are the largest contributor to burden of disease in adolescents (Gore Bloem et al. 2011). However, the majority of adolescents with mental illness in low- and middle-income countries (LMICs) do not have access to treatment (Kieling, Baker-Henningham et al. 2011, Patel, Kieling et al. 2013) and contextually appropriate strategies for delivering evidence-based practices for managing mental disorders are needed to expand services to these areas. To broaden engagement in care, new settings for adolescent mental health services must be identified. Evidence-based interventions for managing adolescent mental disorders integrated within primary care have been effective in high-income countries (Asarnow, Rozenman et al. 2015) but very limited data exist on how to adapt and implement these EBP in LMIC primary care (Patel, Kieling et al. 2013, Mertens, Ward et al. 2014). We previously conducted a qualitative assessment of barriers and facilitators to implementation from the perspective of adolescents, caregivers, providers, and policymakers. We then developed our plan to implement integrated adolescent depression services by holding a series of workshops with local stakeholders—including Ministry of Health and Education staff involved in adolescent, mental health, and

primary care programming; staff from local NGOs that have experience implementing adolescent health programs in primary care; and primary care providers. Now we aim to pilot test the implementation strategy developed in these workshops. We will examine patient and implementation outcomes of depression screening and group IPT-A compared to treatment as usual in a pilot cluster-randomized trial at four primary PCCs with two PCC as the IPT-A arm and two PCC as the TAU arm.

STUDY DESIGN

We will examine patient and implementation outcomes of depression screening and group interpersonal therapy for adolescents (IPT-A) compared to treatment as usual in a pilot cluster randomized trial at four primary care clinics (PCC). Two PCC will be randomized to routine screening and IPT-A (intervention) and the other two PCC with be randomized to treatment as usual (TAU). In the IPT-A arm, providers (nurses and/or medical technicians) at PCCs will be trained to conduct paper-based depression screening as part of routine clinical care. Two providers (nurses and/or medical technicians) per clinic will be trained to facilitate group IPT-A. In the TAU arm, primary care providers will continue referring adolescents to specialized mental health services per existing protocol (when they believe the adolescent is struggling with a mental health problem or when the adolescent/their caregiver requests a referral to mental health services). Treatment providers in the TAU arm are the Psychiatric Technicians and psychologists at primary care clinics to whom adolescents are currently referred.

Study procedures

In the treatment study arm, we are evaluating the impact of IPT-A on depression symptoms in adolescents as well as the feasibility and acceptability of its introduction in primary care clinics. Therefore, adolescents identified as having depression, via screening on the PHQ-A, will be referred to IPT-A treatment groups instead of being referred to Psychiatric Technicians and psychologists in Mental Health Services at the PCC who provide unstructured psychotherapy (TAU).

IPT-A (Treatment) Study Arm: Prior to initiation of the pilot study, we will train providers at the PCC in the IPT-A arm to screen for depression using the Patient Health Questionnaire for

Adolescents (PHQ-A). Training will include didactics and role-plays to practice administration of the PHQ-A with corrective feedback and evaluations. Two providers per PCC will be selected to be trained on delivery of group IPT-A. Training will occur via an apprenticeship model which includes trainers (i.e., non-local experts in the mental health intervention), supervisors (i.e., local individuals chosen for an advanced role), and counselors (i.e., local individuals who provide the interventions). A group IPT-A training expert will train two psychologists from the MoH. Following this, the MoH psychologists will train the two staff members at the IPT-A arm PCC to facilitate group IPT-A. The MoH psychologists will supervise PCC providers for an additional 3 months to achieve competency prior to pilot trial initiation.

Every adolescent who attends PCCs will be screened for depression as part of their routine clinical care. Providers will use the PHQ-A for screening. Using a script, trained research assistants will introduce the study to adolescents who screen positive for depression and their caregivers. If interested, research assistants will collect patient demographic data (age in years, gender) on a questionnaire to verify eligibility.

Group IPT-A begins with one individual session, followed by ten group sessions, and ends with one individual session. As part of each Group IPT-A session, providers will collect data from adolescents on depression symptoms using the PHQ-A at treatment initiation, 6 weeks after treatment initiation (treatment midpoint), 12 weeks after treatment initiation (end of treatment), and 24 weeks after treatment initiation (3-month follow-up). The Project Coordinator will call adolescents who do not enter or who discontinue treatment to arrange data collection at these time points. For adolescents who do not enter treatment, the first scheduled session will be considered the “treatment initiation” timepoint.

Data on treatment fidelity will be collected via the Group IPT-A Fidelity Checklist, completed by the local IPT-A trainers at 10 randomly-selected sessions for each provider. On the Fidelity Checklist, providers are scored for low (1), moderate (2), or high (3) adherence to each essential element of treatment, and fidelity is measured by the total score.

TAU Study Arm: Following usual procedures, providers at the TAU arm PCC will refer adolescents who request mental health care or are suspected of mental illness to Psychiatric Technicians or psychologists at the primary care clinic. Trained research assistants will then inform these adolescents and their caregivers about the proposed study. If interested, research assistants

will administer the brief demographic questionnaire and the PHQ-A to determine eligibility. For eligible adolescents, For eligible adolescents, research assistants will conduct informed consent and assent procedures. Adolescents will be referred to treatment by mental health specialists at the PCC, per existing protocol. Research assistants will visit the PCC at the patients' treatment appointment times to collect data on depression symptoms and functioning. Similar to protocol for the IPT-A arm, data will be collected using the PHQ-A at treatment initiation, 6 weeks after treatment initiation, 12 weeks after treatment initiation, and 24 weeks after treatment initiation. While the treatment timeline in TAU will not necessarily be aligned with IPT-A (e.g. 12 weeks may not be the end of treatment that is provided), we will use these timepoints for both IPT-A and TAU adolescents to measure symptom improvement over time consistently across study arms. The Project Coordinator will call adolescents who do not enter or who discontinue treatment to arrange data collection at these time points. For adolescents who do not enter treatment, the first scheduled session will be considered the "treatment initiation" timepoint.

Post Treatment Data Collection: After the final treatment session (either full course of treatment or after the adolescent discontinues treatment), research assistants will conduct semi-structured exit interviews with participating adolescents and their caregivers (IPT-A arm only), which will be digitally audio-recorded, to collect feedback on acceptability and appropriateness of the depression care they received. Research assistants will also conduct exit interviews, which will be digitally-audio recorded, with PCC providers (IPT-A arm only) after the completion of the pilot trial period to collect feedback on acceptability and appropriateness of depression care they provided. Data on treatment penetration (number adolescents entering treatment/ number referred), feasibility (retention in treatment, measured as number of treatment sessions completed/number of planned treatment sessions), and sustainability (penetration and retention in the 6 months following trial end) will be collected by research assistants from clinic records (both study arms).

STATISTICAL PROCEDURES

Quantitative analysis: Power was calculated conservatively based on participation of 90 adolescents, anticipating possible loss-to-follow up of ~10% as seen in similar trials (Bolton, Bass et al. 2007, Murray, Skavenski et al. 2015). Assuming an intra-PCC correlation coefficient of 0.02-

0.10,(Hemming, Girling et al. 2011) we will have 80% power to detect a moderate 0.6 to large >1.0 effect size of continuous outcomes using a two-sided z-test with an alpha level of 0.05. All analyses between arms will be based on intention to treat. Symptom change between baseline and treatment midpoint, treatment end, and 3- month follow-up will be compared in the IPT-A versus TAU study arms through mixedmodels linear regression analysis, treating PCC as a random effect and baseline symptoms and treatment arm as fixed effects. Subsequently, patient age and gender will be introduced into the model as independent fixed effects to adjust for their potential effect on symptom change. Similar analyses will be used to compare penetration, retention, and sustainability across arms. Within each arm, I will conduct exploratory analyses of the effect of adolescent age and gender on symptom change as well as provider age, gender, and years working in PCCs on fidelity to treatment using linear regression.

Qualitative analysis: Patient and provider perspectives on acceptability and appropriateness of IPT-A or TAU will be evaluated using the Framework Method (Spencer and Ritchie 2002, Gale, Heath et al. 2013). All interviews will be digitally recorded, professionally transcribed, and loaded into Dedoose software for qualitative data management and analysis. We will independently read all transcripts and develop an open coding schema based on a priori and emergent themes. We will use Dedoose to code all data consistent with the Analytic Framework. To establish coding reliability, two research team members will independently code up to 10% of the transcripts. We will meet weekly during this process to review definitions and assignments of codes and to resolve differences until interrater reliability Kappa coefficient is higher than 0.7.(Landis and Koch 1977) If additional codes emerge during this process, they will be added to the codebook. Once all data are coded, they will be charted and assessed with a framework matrix.