Protocol Number R44MH116751

Online System for Identifying and Addressing Teen Depression in Primary Care

Date June 22, 2020

Phase II Summary for finalizing and testing the CHADIS Teen Depression Module (TDM)

These aims are unchanged except that health screening visits may be in-person or conducted via telehealth.

II-1. Revise programming and training materials: TDM- an addition for primary care screening and care for teen depression as part of the CHADIS online questionnaire delivery system with decision support including "motivational interviewing teleprompters", care coordination functionality for referrals, and text chats- will be revised and programmed as needed to adjust for Phase 1 feedback and training materials created.

II-2 Recruit 20 study PCP's, set up care coordination with MH specialists and assess: We will recruit 20 primary care providers (PCPs), assuring representative Medicaid-insured teens, and randomize to intervention or control. Intervention PCPs will identify their local Mental Health (MH) resources to recruit for referrals and use of care coordination functionality. 2 Therapists, 2 PCPs, and 2 Psychiatrists (Psy) using the care coordination will give feedback on functionality, acceptability and likelihood of continued use as well as use of chatbot messaging about referrals after the baseline. We will document current PCP access to MH services.

II-3 Baseline (3 mo.), refine implementation strategies using CFIR and QI MOC-4 sessions:

All 20 PCPs will use the Patient Health Questionnaire-9 (PHQ-9) for depression (without follow-up questions) for a baseline, and have implementation issues addressed using Consolidated Framework Implementation Research Quality Improvement (QI) methods. Data will be collected from teens and parents before in person or telehealth Health Supervision Visits (HSV) using CHADIS. Data on rates of depression screening using CHADIS and billing data will be shared with PCPs as part of Maintenance of Certification Part 4 (MOC-4) sessions for intervention and controls. Teens (<=480) will be sent a text survey post visit of any strength- or emotion-supporting care received.

II-4 Create child psychiatry version of TDM: Denver team will modify TDM for Psy including care plans.

II-5 Obtain MOC-4 approval for child psychiatry by ABMS (covering ABPN) for Child Psychiatrists for use of the TDM created in II-4 and MOC-4 will be offered to participating Child Psychiatrists.

II-6 Intervention trial: Primary Question 1 (PQ1). For teens PHQ positive, does TDM use result in lower Short Mood & Feelings Questionnaire (SMFQ) scores at 3-, 6-and 11.5-months vs at start of intervention? PQ2. For teens PHQ positive, does TDM use result in lower teen and parent SMFQ scores at 3-, 6-and 11.5-months vs controls? Secondary Q1 (SQ1): Of teens PHQ positive, does TDM use result in higher rates of accessing treatment at 3-, 6-and 11.5 months vs controls? SQ2. Does QI method increase rates of teens screened? SQ3. Does QI method increase rates of Ask Suicide Questions (ASQ) screening?

Design: A cluster randomized trial with a 2-group pretest-posttest design clustered at the PCP level will determine pre-post differences within patients and intervention vs control group differences. Sample size estimates consider the design effect and use an Intent to Treat model.

Sample sizes of 107/PCP in both intervention and control will achieve 89.5% power to detect a difference between group means of >=2; also sufficient power for SQ1-3.

Procedure: Both groups: **All teens** before HSV will do: Visit Priorities, Teen Health & Goals comprehensive of standard guidelines, and PHQ-9 with follow up to SMFQ, if positive and get health information chats with links to education/advice in their CHADIS Care Portal. **All parents** will do Visit Priorities and Pediatric Symptom Checklist-17 (PSC) for behavior/mood with follow-up parent SMFQ if the internalizing subscale is positive and can access "handouts" in the parent Care Portal. **All PCPs** see questionnaire results and earn MOC-4.

Intervention group: **Teens**: will do: goals/strengths/values and ASQ. If PHQ-9 is >=8 they will get follow-up questions and SMFQ. Teens will get follow-up chatbot dialogues with topic based on if a referral was accepted and other priorities. Chats may encourage strengths and provide resources, goals, mindfulness apps, journaling or depression-CBT dialogues for PHQ positive teens. **Parents:** get resources. **PCPs**: will use TDM results and decision support to detect, educate on depression, and motivate for intervention. They earn MOC.

Follow Up Measures: All teens and parents: get email/text reminders to do questionnaires 3, 6 and 11.5 months (pre next HSV) after initial HSV. Teens positive on initial PHQ-9 in both groups will be paid (and called) to do a repeat PHQ-9 with follow-up about interval treatment (TIQ) and parents will do SMFQ and provide impressions of PCP management and success of any referrals (PIQ). Rates for ASQ will be in the intervention group only, as it is not usual care, but any PCP may use it. Evaluation will include: depression screening rates, decision support use, proportions of positive teens referred via care coordination and teen use of resources.

II.7 Analysis of Results of Intervention: Initial: Descriptive analyses. PQ1&2: t-tests adjusted for design effect, categorical statistical tests of inference appropriately matched to the underlying distributions of the measures used at T1 and T2, adjusted for design. SQ2: Chi-Squared Test of Independence on two cross-sectional samples tabulated at T0 and T1. Rates of ASQ use will be assessed for T2-T3. Tests will be applied to 2 cross-sectional samples regardless of treatment arm. Multi-Level Linear Regression models for PQ1-2 and Logistic Regression models for SQ1-3 will assess impact of patient characteristics and item responses, and control for design effect of a cluster-randomized design.