Study Protocol

Official Title: Screening Wizard-Phase 2

ClinicalTrials.gov ID (NCT number): NCT04646369

Protocol Date: 7/21/21

Scientific Background

Background LEADING TO Phase 1b of Screening Wizard

In preliminary work, we examined EHR data of adolescents who screened positive on PHQ-9 for depression, and found that of 263 screen positive adolescents, only 23.6% accessed onsite mental health care. Study investigators interviewed PCPs to understand the low rate of treatment uptake, and found PCPs found it difficult to address barriers to treatment in patients and parents, and expressed a need for an intervention to help them address barriers and thus improve treatment adherence. PCPs identified certain barriers as both central and difficult to address, namely, skepticism about depression and need for treatment, perceived stigma of having a depression diagnosis, and difficulty differentiating patient and parental barriers. These findings shaped Screening Wizard, which will assess and integrate parental and patient barriers and focus on perception, motivation, stigma, and patient preferences. Since the initial submission, study investigators conducted focus groups with PCPs (n=14) from two CCP practices and asked for feedback regarding what additional information to PHQ-9 screens would help PCPs make treatment decisions. PCPs remarked that adding a parental assessment of the adolescents' functioning would be helpful when the adolescent does not want to be forthcoming about symptoms, and that awareness of potential barriers and treatment preferences would improve visit efficiency to allow them to narrow down discussion points when recommending treatment. They preferred receiving a printout to EHR alerts due to computer fatigue and were agreeable to receiving handouts printed at the time of the visit to easily use for talking points and to distribute to parents and adolescents as well as having this information integrated into the EHR.

Preliminary data FROM Phase 1b Screening Wizard Version 1.0

Initially the proposed study was to conduct an stepped wedge randomized trial where the participating practices would have a Treatment As Usual period and then randomized as to when they switch to the intervention (which would be when providers start to receive the decision support report with recommendations for referrals/action). During the course of 4 months, we worked with a research network collaborating with pediatric practices to administer the SW tool, however we had limited success in testing the intervention phase of SW 1.0 because of limitations imposed by practice work flow. In gathering qualitative data, we focused on teen and parent reactions and work flows when developing the intervention, however, provider reactions need additional considerations. As a result, study investigators found practices that had a more flexible work flow that work out bugs and flow issues that children's pediatric practices were unable to commit to at the time. As a result, little comparison data is available to reflect a difference between TAU vs. intervention groups in children's pediatric practices sites who were later added to this protocol as an open trial.

Below outlines qualitative reactions to SW 1.0

Initial reaction to SW was positive on the part of both parents and teens. Both parents and teens thought that teens would be comfortable with being screened on a tablet because they enjoy interacting with technology. Participants described a variety of positive health benefits that could result from Screening Wizard, including:

-Decreased stress or anxiety from disclosing mental health symptoms.
-Increased likelihood that teens will get treatment for mental health conditions.
-Mental health symptoms might be brought to light that would have been ignored before, particularly

by parents.
-Limited negative responses were reported, and mostly focused on a teen not wanting to be honest during screening because they wanted to avoid treatment, but this would be the case with any screening.

In addition to depression screening, participants thought that Screening Wizard should address:
-Teens' social lives (or social isolation, peer pressure, and bullying
-Teens' relationships with their parents, and abuse in the home
-Recent death of a friend or loved one
-Sleep

Even more so than issues surrounding mental health in general, teens were not comfortable with being asked or their parents knowing about substance abuse, or their suicidality.

Background & preliminary work on SOVA Intervention

SOVA Feasibility Study

The social media website for adolescents (SOVA: Supporting Our Valued Adolescents) and for parents (wiseSOVA) target these intermediate outcomes of 1) negative attitudes toward treatment, 2) mental health literacy, 3) perceptions of mental health providers, and 4) social support. In my initial work with intensive feedback from patient and clinician stakeholders, study investigators developed the SOVA and wiseSOVA social media websites which include daily blogposts and online interaction with peers and therapist moderators. The SOVA and wiseSOVA social media websites include daily blogposts and online interaction with peers and therapist moderators. The goal of these websites is to educate about depression, anxiety, and negative attitudes toward treatment, provide social support through peer interaction, and positive interactions with therapist moderators. It is thought this intervention will lead to increased uptake of treatment for depression and anxiety. The first phase protocol studied feasibility and acceptability of this technology. It focused on if the technology can build an active user community and is or is not feasible or acceptable to participants, in order to further test whether it can increase depression and anxiety treatment uptake.

SOVA Results

SOVA pilot efficacy study findings show support for the underlying conceptual model, study feasibility, and improved uptake of treatment at 3 months. We conducted a pilot efficacy randomized controlled trial to compare SOVA to Enhanced Usual Care (EUC) in a single high-resource adolescent medicine clinic that provides primary and specialty care and has multiple behavioral health providers who work alongside medical providers in a team based approach. Out of 167 adolescents screened, 35 were randomized, and 24 completed follow-up measures. At baseline, adolescents with a lower perceived need for mental health treatment also had higher stigma scores (20.9±10.7 vs. 18.6±7.5, p=.48), lower depression knowledge (10.9±3.4 vs. 12.7±3.2, p=.16) and anxiety knowledge76 (6.9±2.0 vs. 9.5±2.9, p=.02), higher barriers to seeking therapy (3.2±0.8 vs. 2.6±0.8, p=.07) and lower social support (75.3±29.2 vs. 88.5±22.8, p=.18). We found that at 3 months, 11/13 (85%) adolescents randomized to SOVA received mental health treatment as compared to 6/11 (55%) adolescents randomized to EUC (p=.18), where receipt of treatment was measured by a combination of either adolescent or parent self-report and a blinded manual electronic health record extraction. We found limited engagement in the treatment arm with only 50% of adolescents randomized to SOVA accessing the intervention, several

citing they would forget about looking at it. When using a per protocol analysis comparing those who accessed SOVA (n=5) at least once to those who were in the EUC arm or did not access SOVA (n=17), we found a signal for some targets including a decrease in stigma76 (-3.6±5.5 vs. -2.6±8.1, p=.67), an increase in social support (2.5±23.6 vs -0.2±28.4, p=.64), a decrease in attitudinal barriers toward therapy-seeking (-0.4±2.4 vs. -0.2±1.7, p=.97) and an increase in general functioning (2.8±4.7 vs. -0.8±5.8, p=.22). During the trial, recruitment rate increased after passing a waiver for parental permission and not requiring adolescents to enter the study as a dyad with a parent. This change is conceptually consistent as adolescents who have poor communication with their parent are a SOVA target population but may be more difficult to recruit if parental permission is required. We began to use text messages to send out links to online surveys due to low adolescent use of email. We determined that our safety protocols were adequate and experienced no adverse events.

The next step in further developing SOVA and wiseSOVA is to test it with a screening tool and follow up on a conversation where a provider makes a recommendation based on a youth or young adults mental health screening results.

Study Objectives

We propose a pilot randomized controlled trial of 100 youth who present to primary care settings or other specialty medical settings. Consenting participants will be randomized to one of three conditions in a 2:2:1 randomization scheme to either receive “Treatment as usual” which is a basic report listing mental health symptom scores (n=20), Screening Wizard 2.0, which includes symptom score report plus the enhanced screening questions and treatment guidelines (n=40), or Screening Wizard 2.0 + SOVA, a website encouraging patients to use referred mental health services (n=40). All participants will then complete a brief battery of self-report assessments at baseline and again after 12 weeks.

Aim 1. To examine the efficacy of Screening Wizard 2.0 at improving the process of screening and referral for youth with depression and/or suicidality:
Hypothesis 1: Screening Wizard 2.0 will result in more referrals to a mental health provider for symptoms of depression and/or suicidality compared to “Treatment as usual” (increase >30% compared to “Treatment as usual”)
Hypothesis 2: Screening Wizard 2.0 will result in higher rates of follow-through with mental health services (defined as attendance at an initial appointment) compared to “Treatment as usual” (increase >30% compared to “Treatment as usual”)
Hypothesis 3: Screening Wizard 2.0 will have higher adolescent and parent perception of being involved in a shared decision-making process compared to “Treatment as usual” (SW involvement > “screening as usual” involvement)

Aim 2. To examine the added efficacy of SOVA in combination with Screening Wizard 2.0:
Hypothesis 1: Adolescent and parents in Screening Wizard 2.0 + SOVA will have less negative attitudes about psychotherapy, higher depression literacy, and a higher readiness for treatment as compared to Screening Wizard 2.0 alone or “screening as usual.”

Hypothesis 2: Adolescent and parents in Screening Wizard 2.0 + SOVA will result in higher rates of follow-through with mental health services (defined as attendance at an initial appointment) compared to Screening Wizard 2.0 alone (increase >10%) and "screening as usual" (increase >40%)

Study Design & Method

We will conduct a 3-arm randomized trial of Screening Wizard 2.0 in 100 youth (age 12-26) presenting to clinical care in primary care and community mental health settings onboarded to the study.

Arm 1 will include 20 participants randomized to receive "Treatment As Usual." This will include the practice's standard practice for the presenting patient which may include universal screening for depression and/or suicidality with the practice-preferred screening instrument/modality, targeted screening (decision to screen based on symptoms or complaint), and/or no screening. Due to practice heterogeneity and our pilot findings that attempting to standardize the control arm disrupted clinical workflows and recruitment rates, we will not standardize the practices' screening instrument or practice. We will ask that the participant complete SW (via email link or over the phone) and study staff will provide a list of symptom scores to provider in this arm, regardless of type of screening processes are in place.

Arm 2 will include 40 participants who will be given the Screening Wizard 2.0 tool and the provider will be given a detailed output report of symptom scores highlighting any acute concerns such as suicidality, patient treatment preferences, and potential patient barriers to treatment.

Arm 3 will include 40 participants who will be given the Screening Wizard 2.0 and the provider will be given the detailed output report as well as participant and parent given access to the SOVA intervention (regardless of results).

Youth randomized to receive SOVA will be asked to provide their desired usernames and will be provided with log-ins to the website intervention. Youth and parents will then be contacted for an onboarding phone call explaining use of the site, and receive weekly text messages reminding them to view articles which may be relevant to addressing specific barriers they identified using Screening Wizard as well as new articles written by other youth with lived mental health experiences (i.e. SOVA Peer Ambassadors).

<u>Screening Wizard 2.0 Questions</u>

The screening wizard will administer the standard of care measures (i.e. PHQ-9 depression screener and SBIRT-CRAFFT substance use questions) in addition to the supplemental questions (i.e. preferences for treatment, readiness, co-morbid dx, etc.) to complete the intervention.

If the family chooses to take the screening wizard questionnaire at a different time than before their scheduled appointment (telehealth or in person), the research staff/ARC assessors will provide the primary care provider with the Screening Wizard results, so that s/he can follow up on positive screens for depression and/or suicidality. Imminent risk will be managed through the ETUDES study safety management protocol.

Screening Wizard 2.0 Basic Report vs. Intervention Report

The Basic report is a report of symptom scores that populates from Screening Wizard 2.0 will be provided to ARM 1 participant providers and this follows current standard of care. The conditions screened include: depression, anxiety, mania, suicidality, and substance use. The overall scores and each individual response to the symptom questions are contained on this report. Based on qualitative feedback and interaction with providers in Phase 1b trial of, providing item level details as well as overall scores was necessary and preferred and process was developed to match current standard of care so it could be adopted by the practice.

The SW 2.0 "intervention" report includes summary scores, some item level detail scores, responses to questions about barriers & facilitators to treatment, beliefs about mental health diagnoses and treatment, and treatment preferences in the case of positive screen for mental health symptoms. This is considered enhanced standard of care at the practices in this study. Based on how these questions and the symptoms questions are answered, best practice guidelines from American Academy of Pediatrics and Psychiatry, CDC, NIH, AHRQ, the UPSTF, among other institutions etc. on the intervention report to aid the provider in discussing the results of the report.

SOVA

Youth randomized to receive SOVA (ARM 3) will be asked to provide their desired usernames and will be provided with log-ins to the website intervention. Youth and parents will then be contacted for an onboarding phone call explaining use of the site, and receive weekly text messages reminding them to view articles which may be relevant to addressing specific barriers they identified using Screening Wizard as well as new articles written by other youth with lived mental health experiences (i.e. SOVA Peer Ambassadors).

SOVA Intervention.

The SOVA intervention uses a technology familiar to adolescents, an online blog with social media (SM)-like interactions with other users and specifically targets the proposed factors that influence perceived need for depression and anxiety treatment. SOVA Peer Ambassadors are adolescents and young adults who anonymously share their experiences with depression and anxiety through blog posts. These posts are reviewed by the research team and have featured ambassadors' own poems, mental health app reviews, advice about using SM in a responsible way, coping strategies they have used, and education about mental illness in their own words. The SOVA websites are mobile friendly and easily viewed on a smartphone mobile browser. Feedback from technology experts has been to avoid a mobile application due to higher risks of disengagement, while mobile websites can share many of the same features with less investment.

SOVA consists of two separate secure websites: SOVA (sova.pitt.edu) for adolescents and wiseSOVA (wisesova.pitt.edu) for parents. Every weekday, a new publicly viewable blog article is posted to each website. Articles feature topics around improving mental health literacy, normalizing negative health beliefs, positive content, or SM use. The interactive functionality of the sites involves creating an anonymous user profile, commenting on a blogpost, and a discussion board and these features are password-protected and only accessible to users. Users who log-in may access comment sections below posts where they can provide comments to the blogpost writer (research team website editor or SOVA

peer ambassador) and in response to each other. They can also participate in a discussion board where they can start or respond to threads and post questions and comments. Besides comments and discussion boards, users cannot interact with each other and are anonymous. New articles are posted every weekday covering topics from “How to Start a Conversation about Suicide” to “Why Do Plants Improve Our Mood” and “Instagram Invites.” Most are written with an intended youth voice by the research team graduate students in their early 20’s and about a third by SOVA Peer Ambassadors. All posts are reviewed by the research team using established tools for health literacy and readability with a goal of 8 or lower. All comments are reviewed and screened by a research team moderator (at least every 3 hours) and any comments that violate ground rules (e.g., include identifying information, bullying, imply suicidality) are removed (in prior studies, we have observed no bullying and only removed comments due to identifying information). Although no user has implied suicidality on the site in the past, moderators will follow a suicidality protocol as described in human subjects if a user posts such a comment to clarify its meaning, potential extent of suicidality, and provide support. Moderators will also encourage comments from users if no other user has responded in 24 hours by offering gratitude and encouragement, asking follow-up questions, and limiting their own opinion/experience. Parents who enroll for the site with their child will have access to the wiseSOVA site only and view blog posts there that are on parallel daily topics. Posts composed for the adolescent site are modified by the website editor for a parent audience (i.e., same topic written about with guidance for parents; SOVA ambassador’s articles featured with introduction for parents that reading an article from a young person’s perspective may help them consider their child’s viewpoint and can be used as a conversation starter). Parents will also have access to a discussion board and commenting, but there will not be parent ambassadors. Prior stakeholder feedback from parents found they lacked a desire to use the wiseSOVA site for peer blogging; they preferred to use it to access information when needed, but not longitudinally as they would then move on to prioritize other tasks. For adolescents whose parents do not enroll in the study, during the informational phone call , the RA will provide them with information about wiseSOVA that they can offer to their parent or guardian if they choose – as a goal of using SOVA is to encourage them to communicate about mental health with their parent or guardian.

Participants who receive a log-in to SOVA sites will view a short video explaining the “ground rules” or expected use of the site. They will also receive emailed instructions and a text message reminder to log-in for the first time. About 24-72 hours later, a research assistant will contact adolescents (and parents if enrolled) to schedule an introductory phone call to discuss the websites. If adolescents would rather use a messaging app instead of a phone call, we will use Google Voice. Prior to this conversation, the research assistant will review the Screening Wizard results and make personalized article recommendations to the patient (e.g anxiety., if they have high stigma, they may suggest articles about talking to others about mental health difficulties) to individualize the participant’s experience and enhance engagement. During this conversation, RA’s explain:

(1) the expected use of the site (i.e., provide examples of blog content, explain role of blogging ambassadors, encourage commenting) in an effort to increase excitement about using the site;
(2) the “ground rules” of the site which ask subjects to not share identifying information, not meet with other participants outside of the study, avoid bullying, and take a break if they feel upset by using the site;
(3) that although the site is moderated, it is not considered a substitute for therapy or access to crisis

services;
(4) where crisis resources can be located on the site; and the RA will also
(5) provide any technical assistance to ensure the participant can log-on and access the site and walk them through this procedure during the phone call.

Eligibility Criteria

Youth Inclusion Criteria:

-Youth aged 12-26 yo
-Biological or adoptive parent is willing to provide informed consent for teen to participate
-Youth speaks and understands English
-Receives care at a participating SW practice

Youth Exclusion Criteria:

-Non English speaking
-No parent willing to provide informed consent for minor participants
-Is currently experiencing acute mania or psychosis, evidence of an intellectual or developmental disorder (IDD), life threatening medical condition that requires immediate treatment, or other cognitive or medical condition preventing youth from understanding study and/or participating.

Statistical Considerations

Aim 1. To examine the efficacy of Screening Wizard 2.0 at improving the process of screening and referral for youth with depression and/or suicidality:
-Hypothesis 1: Screening Wizard 2.0 will result in more referrals compared to "Treatment as usual" (increase >30% compared to "Treatment as usual"). We will calculate referral rates for each condition and compare them using chi-square tests.
-Hypothesis 2: Screening Wizard 2.0 will result in higher rates of follow-through with mental health services compared to "Treatment as usual" (increase >30% compared to "Treatment as usual") We will calculate follow-through rates for each condition and compare them using chi-square tests.
-Hypothesis 3: Screening Wizard 2.0 will have higher patient satisfaction compared to "Treatment as usual" (Screening Wizard 2.0 satisfaction > "Treatment as usual" satisfaction). We will calculate mean satisfaction scores (CSQ) scores for each condition and compare them using t-tests.

Aim 2. To examine the added efficacy of SOVA in combination with SW:
-Hypothesis 1: Adolescent and parents in Screening Wizard 2.0 + SOVA will have less negative attitudes about psychotherapy, higher depression literacy, and a higher readiness for treatment as compared to Screening Wizard 2.0 alone or "Treatment as usual." We will calculate mean psychotherapy attitudes using the BASH-B scale for adolescents, and Parent version BASH scale; and depression literacy using the D-LIT scales and compare them using t-tests. We will collapse readiness for treatment for parents and teens to ready vs. not ready and compare these using a Chi-square test.
-Hypothesis 2: Adolescent and parents in Screening Wizard 2.0 + SOVA will result in higher rates of follow-through with mental health services (defined as attendance at an initial appointment) compared to Screening Wizard 2.0 alone (increase >10%) and "Treatment as usual" (increase >40%). We will calculate follow-through rates for each condition and compare them using chi-square tests.

Power Analysis. The proposed study is a preliminary randomized pilot study. We expect that the small sample will provide sufficient comparison data to guide the design of a larger-scale controlled study that would be sufficiently powered to determine the efficacy of the intervention.