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Clinical Trials Official Title: Adapting a Web-Based Professional Development for Mexican School Mental Health Providers Delivering Evidence-Based Intervention for ADHD and ODD
Protocol ID: CLSRFUERTE
NCT05425966

Principal Investigator: Dr. Lauren M Haack PhD
IRB Study Title: Remote School-Home Program to Improve Youth Attention and Behavior in Mexican Students
IRB #: 21-34748
Reference #: 321420
Committee of Record: San Francisco General Hospital Panel
Most Recent Approval Date: 08/22/2022

Pages 2-6 of the current document: Study Protocol
Page 6 of the current document: Statistical Analysis Plan

STUDY PROTOCOL: A total of N = 24 youth with inattention and disruptive behavior will participate in a 3-school open-trial evaluating the web-based CLS-R-FUERTE program in the Sinaloa Public School District (i.e., n = 8 youth/school). Youth with attention/behavior concerns will be recruited via school-wide meetings at each participating school and teacher/school clinician referral. Parents and teachers of youth will provide informed consent and baseline ratings of ADHD/ODD; youth will provide assent; and school clinicians will be tested on their evidence based practice skills. Next, our team will train school clinicians and monitor fidelity, satisfaction and adherence during the 6-week program. Then we will collect post ratings from parents/teachers and test school clinicians again. We will make iterative updates to the program as indicated after observation/ feedback from each school (totaling 3 iterations). School clinicians, parents, and teachers will be compensated $10 each time they complete ratings ($20 total). Our team will iteratively update the web-based program and research protocol based on observations and participant feedback.

CLS-R-FUERTE is a 6-week intervention aimed at reducing attention and behavior symptoms in students. The intervention is based on CLS and includes a comprehensive and integrated student, parent and teacher component. Students presenting with attention and behavior problems at school sites without the CLS-R-FUERTE intervention may be referred to the usual care protocol of that school which may include individual therapy, social skills groups or referrals to the community.

INCLUSION CRITERIA: The open-trial across 3 schools in the Sinaloa Public School District will include N = 3 School Clinicians (i.e., 1 per school); N = 24 youth with inattention and disruptive behavior (i.e., 8 youth/school); N = 24 parents (i.e., 1 per youth) and N = 24 teachers (i.e., 1 per youth). School Clinicians at the required N = 3 schools are recruited via annual conferences our team has held with the school district describing our preliminary results to-date. To qualify, school clinicians must speak Spanish, be employed as by a participating school, and be willing to engage in the training activities. Youth with attention/behavior concerns in grades 1-5 and their parents/teachers will be recruited via school-wide meetings at each participating school and teacher/school clinician referral. This is a procedure we've used successfully in our previous work in Sinaloa, Mexico. Specifically, we may invite all families and personnel at participating schools to a meet-and-greet. In this meet-and-greet, we introduce our study team and show a brief silent video depicting a youth with inattention and disruptive behavior. Families who identify with the families in the video can self-refer for a program screener with our team. Teachers or school clinicians also may refer families for a program screener with our team. We have used this recruitment strategy successfully in the CLS-FUERTE program pilot. To qualify, youth must demonstrate >6 symptoms of inattention and/or >6 symptoms of hyperactivity/

impulsivity rated by parents or teachers, and >1 domain of impaired functioning, on a screening with our study team). In addition, > 1 parent or caregiver (here-on referred to as "parent") and > 1 teacher of the youth must speak Spanish and be willing/available to participate in sessions.

EXCLUSION CRITERIA: Anyone who does not speak and read Spanish will be excluded, given that all informed consent, measurement, and activity procedures will be conducted in Spanish.

Child Participants

-Children taking medication will be eligible for screening after the child has been on a stable medication regimen for at least one month (to minimize chance that treatment effects are due to medication and not the proposed program).

-Presence of conditions that are incompatible with this study's treatment.

-severe visual or hearing impairment,

-severe language delay,

-psychosis,

-Child does not read or speak Spanish (inability to participate in group treatments).

-Child is in an all-day special education classroom. Children in these classrooms are frequently receiving intensive behavior modification programs and assistance such that the teacher consultation component would be expected to require modification for use in these settings.

Parent and Teacher Participants

-Student of parent/teacher does not meet child inclusion/exclusion criteria above

-Parent or Teacher does not read or speak Spanish (inability to complete assessment measures or participate in group treatments)

School Clinician Eligibility: Any school clinician working in the participating Sinaloa school district.

CHILD PARTICIPANT ELIGIBILITY: Screening and confirmation of eligibility for youth will follow a three-stage (multiple-gated) procedure.

Stage 1) Involves identification of children by parent self-referral or staff clinicians at each participating school; children must be having academic and social problems related to inattention and/or hyperactivity/impulsivity.

Students who meet first stage entry criteria (e.g., age, grade, mainstream class placement, absence of significant visual or hearing impairment, severe language delay, psychosis, global intellectual impairment, or serious emotional disturbance requiring special education services, per school clinicians and school records, and living with a caretaker who is available to participate in treatment) will be invited to participate in screening.

Stage 2) Next, our program staff will initiate contact with families who self-referred or are referred by the school or referred families can contact our program staff themselves. Families will complete a screening (remote or in-person, depending on their preference) with our program staff about academic, social, and behavioral functioning at school and at home. Questions from the Developmental Family History Form and items from the Child Sympto Inventory-CSI are used to determine sufficient impairment. Parents of children who meet these criteria will be invited to the third stage of screening.

Stage 3) During the final stage, parents complete the CSI, IRS, and Developmental History Form. Teachers also complete the CSI and IRS. After parents and teachers complete rating forms, judgements about eligibility at stage 3 will be made by UCSF program staff based on the interview and ratings provided by teachers and parents. To document ADHD symptom presence, we require six or more inattention symptoms and/or six or more hyperactive-impulsive symptoms endorsed by either the parent or teacher as occurring ‘often’ or ‘very often’. To document cross-situational impairment (and need for home and school treatment), we require impairment in at least one domain on the Impairment Rating Scale by both parent and teacher (score of 3 or greater). Committee on Human Research (CHR)-approved study descriptions are reviewed and families complete consent and assent forms. Those who consent will complete remaining baseline measures. we will then review all available data, including symptom counts and impairment, following DSM-V guidelines. Final determination of eligibility will be based on the child meeting all study criteria as determined by the PI.

Parent Participant Eligibility: Must have a child whom meets the above eligibility requirements. The parent must participate in the intervention.

Teacher Participant Eligibility: Must have a student whom is participating in the program. The teacher must be willing to participate in the intervention.

We have used these eligibility criteria successfully in the CLS-FUERTE program pilot.

CONSENT AND ASSENT PROCESS

School clinicians are informed about the study through the school district SEP liaison. When school clinicians express interest, school site meetings are conducted with the school principal, school clinician and other school staff (if requested) to describe the project and obtain principal approval for participation. If approval is obtained, consent forms will be administered to the school clinicians by our staff.

School clinicians approach referred families to explain the project. At this time, students who meet first stage entry criteria will be invited to participate in the screening process to determine eligibility and will provide verbal consent for exchange of information between the school and our program staff.

Families will have the option to complete the consent process over the phone or Zoom video conferencing (using Docusign to electronically sign the form), at the child's school, or at UAS. Our staff will explain the study and review the consent/assent forms with the family, ensure that the family understands the major points of informed consent, and address any questions. Families will be given as much time as they need to consider participation, and if they prefer to reschedule their appointment to allow for more time to consider, that will be arranged. If more than one parent/guardian has legal custody, reasonable effort will be made to contact the second parent/guardian and gain consent (and such efforts will be documented on the consent form). Minors will complete a simplified assent form. If, after carefully reviewing the study requirements including risks and benefits, the parent wishes to participate but the child does not, the family will not be eligible. Parents will be referred back to the school for assistance with alternative services, if desired.

Once the family has consented our staff will obtain written consent from teachers at their school site or electronically using Docusign. Teachers will have the option to complete the consent process in-person, over the phone or Zoom video conferencing (using Docusign to electronically sign the form), at their school, or at UAS.

ESTIMATED TIME COMMITMENT FOR PARTICIPANTS:

Youth: 6 60-minute sessions and 1-2 30-minute meetings (Total up to 7 hours)

Teachers: 1 1-hour session, 1-2 30-minute meetings, and up to 2-hours to fill out measures (Total up to 4 hours)

Parents: 6 90-minute sessions, 1-2 30-minute meetings, and up to 2-hours to fill out measures (Total up to 12 hours)

School clinicians: 6 60-minute child sessions, 6 90-minute parent sessions, 1 1-hour teacher sessions, up to 16 30-minute meetings, 9 hours of consultation, and up to 2-hours to fill out measures (Total up to 35 hours)

STATISTICAL METHODS: We will initially test the web-based CLS-R-FUERTE program in a 3-school open trial by examining if: 1) school clinician fidelity to intervention on the CORS reaches >80% of content delivered and >4 out of 5 quality rating; school clinicians' ratings on the satisfaction questionnaire reach >4 out of 5; school clinicians' ratings on the SUS reach >80%; and school clinicians' evidence based practice skills, knowledge, and attitudes on the KAB improve from pre to post using repeated-measures T-tests; 2) participant session attendance and engagement/adherence ratings reach >4 out of 5 on the CORS with a benchmark of at least 80%; DRC use reaches >3 out of 5 days; and SUS ratings reach >80%; as well as if improvements on youth outcomes improve from pre to post using repeated-measures T-tests. We will conduct analyses in SPSS. 3) Themes from observation and feedback from the open-trial will be incorporated with results above to inform iterative changes to the web-based program after each school.