

School-Home Program for Mexican Children with Attention and Behavioral Concerns

NCT number: NCT02888821

Document Date: 08/25/2021

Study Protocol

Participants

A total of $N = 58$ Mexican students in grades 1-5 across eight public elementary schools in Sinaloa, Mexico participated in the current study ($M = 7.25$ students/school, range = 6-8). For each student, one parent and one teacher were designated as “primary” (meaning they would participate in CLS-FUERTE and implement the strategies) and asked to complete all measures. All data was collected at the students’ respective schools. See Table 2 for demographic information and Figure 1 for participant flow.

Recruitment. Recruitment occurred between May and September each year and began with invitations to school principals suggested by the local SEP. As described in the introduction, as part of our augmented outreach/recruitment plan for Mexico, we invited all families and personnel in participating schools to an informational gathering in September in which we showed a silent video depicting a child with attention and impulse-control difficulties (i.e., the Behavioral Impairment Video; Haack, Gerdes, Lawton, & Schneider, 2014). We encouraged families to contact us if interested in a program to help children similar to the child in the video. School personnel also identified candidate children and contacted families about participating. See Figure 1 for recruitment flow and number of students deemed ineligible at each step of recruitment.

Screening. Interested parents scheduled an appointment to screen for eligibility. If parents attended the screening appointment, reported willingness/ability to participate in sessions, and described at least six youth symptoms of inattention and/or hyperactivity with at least one area of related impairment (i.e., school, family, or social impairment), we scheduled meetings for baseline assessments.

Baseline Assessment. After completing informed consent procedures approved by UCSF Committee on Human Research, parents and teachers of successfully screened students completed questionnaires, including the Child Symptom Inventory (CSI-4; Gadow & Sprafkin, 1997), Impairment Rating Scale (IRS; Fabiano et al., 2006), and demographic/history form. Students meeting the following criteria were eligible to participate: (a) at least six CSI-4 inattention symptoms and/or six

hyperactive/impulsive symptoms endorsed by parent or teacher as occurring often or very often, (b) at least one area of IRS functioning rated as ≥ 3 by both parent and teacher, thereby indicating cross-setting impairment, (c) a parent available to participate; and (d) a primary teacher agreeing to participate. The assessment and screening algorithm based on at least six symptoms per domain reported by parents or teachers has been used in previous school-based ADHD trials (Haack et al., 2018; Pfiffner et al., 2016) and is associated with strong predictive validity for ADHD (sensitivity = .80, specificity = .58; Gadow & Sprafkin, 2002) and ODD (sensitivity = .70, specificity = .90; Gadow & Sprafkin, 2002) diagnoses. Students taking medication were eligible as long as regimens were stable. Students with significant visual or hearing impairments, severe language delay, psychosis, or pervasive developmental disorder or who were in full-day special classrooms were excluded. Eligible students provided assent before participating.

Study Design

A 2-level (students, schools) cluster RCT design (Hayes & Moulton, 2009) accounted for treatment (CLS-FUERTE or BAU) within level 2 (schools). We randomized schools to CLS-FUERTE (school $n = 4$, student $n = 28$) or BAU (school $n = 4$, student $n = 31$). We determined our sample size based on practical considerations (i.e., previous CLS trial experience, years of funding). Each year, schools were divided into high or low Socioeconomic Status (SES) categories (determined by the Secretary of Public Education; SEP) after baseline assessments were completed in September. The first author coded schools to conceal their identity until treatment was assigned and a statistician randomized concealed ordered pairs to CLS-FUERTE or BAU using a random number generator. Those randomized to CLS-FUERTE received the intervention between October and December, followed by post assessments for all families in December each year.

Intervention: CLS-FUERTE

The CLS-FUERTE program is a comprehensive psychosocial treatment for school-aged youth (grades 1-5) delivered by Mexican School Mental Health Professionals (SMHPs) directly at the students' school site. The six-week program encompasses weekly parent management training groups led by the SMHP, weekly student skills groups led by the SMHP, and daily classroom management by the teacher

supported by the SMHP. The program is designed to teach parents, students, and teachers a common language encouraging skill use to address impairment related to ADHD and ODD. Thus, students in CLS-FUERTE receive around-the-clock prompting and reinforcement for goal behaviors related to school, family, and social functioning.

Parent component. Parents attended six 90-minute groups teaching strategies to manage attention/behavior challenges including positive consequences (e.g., rewards, praise), negative consequences (e.g., planned ignoring, removing privileges), and routines. Each group, SMHPs reviewed and troubleshooted strategies assigned and presented new strategies. Parents also reviewed skills covered in the student group and were taught methods to promote and reinforce skill generalization. Groups were held at school sites and scheduled to accommodate participating families, often after drop-off.

Child component. Students attended six 60-minute groups teaching strategies to compensate for attention/behavioral challenges, including organization (e.g., routines) and social skills (e.g., good sportsmanship, handling teasing). SMHPs targeted skill knowledge and implementation through didactic instruction, modeling, behavioral rehearsal via interactive games, corrective feedback, and in-vivo practice via role plays. Students received reinforcement (i.e., praise, tickets called “stars”, small prizes) for following rules, participating in activities, and practicing skills. Self-management of alertness was targeted with group-reinforced attention checks (Pelham Jr. & Hoza, 1996). To encourage skill generalization, students brought in “stars” they earned at home and class to exchange for praise and a group-based reward (i.e., celebratory party). Groups occurred during the school day at students’ respective schools; groups were scheduled by the SMHPs based on the collective input they received from participating teachers regarding the most suitable day and time for children to attend group, usually during a nonacademic period.

Classroom component. Teachers attended a 60-minute orientation, during which SMHPs provided an overview of attention/behavior concerns and the use of a school–home daily report card (DRC). Teachers selected two or three behavior goals tailored for each student, which were discussed with the parent and student during a 15 to 30-minute meeting. Behavior goals could include academic

targets (e.g., gets started on work right away, completes work accurately) or social-emotional targets (e.g., keeps hands/feet to self, asks for help when needed). Teachers rated each behavior up to three times per school day on a 3-point scale (0= goal not met, 1=needs improvement, 2=goal met). Students were prompted to bring their DRC home daily to exchange points for rewards. Skills taught in the student groups were shared with teachers to promote cross-setting reinforcement and generalization.

SMHP Training, consultation, and fidelity monitoring. SMHPs in the Sinaloa school district have bachelor's or master's degrees in education but are not consistently required to receive training or observation in EBTs (Sanchez-Sosa, 2007; Stark et al., 2010). Typically, they are assigned caseloads of students with mental health disorders (approximately 20 students per caseload with a maximum of 25 students). SMHPs are provided a manual which contains information for educating youth with mental health disorders but lacks presentation of any specific strategies (*The New Mexican School*, 2019). We recruited SMHPs in the current study via their school principals. Each SMHP was assigned a member of our team as their primary trainer. To enhance consistency in training and feedback, each SMHP's primary trainer led (or co-led) their initial training and consultation meetings, as well as attended each session.

Each participating SMHP attended an initial 8-hour training with their trainer to learn psychoeducation about attention/behavior challenges and the principles supporting psychosocial ADHD/ODD intervention (such as structuring antecedents and providing reinforcement to encourage goal behaviors), learn and practice behavior management strategies to employ during meetings and groups (e.g., attention checks, differential reinforcement), as well as learn and practice the first meetings of each component (i.e., the first parent group, the first student group, the teacher orientation and the teacher-family-student DRC meeting). Each week during the program, SMHPs attended 60-90 minute consultation meetings with their trainer to review upcoming manual content, role-play key content, and troubleshoot problems. SMHPs were provided a detailed, scripted manual for each component. In the initial training and weekly consultation meetings, trainers modeled intervention delivery, presented video clips of previous SMHPs delivering the intervention, and guided SMHPs in role-playing the intervention delivery.

Each parent, child, and classroom component session was led by SMHPs with in-vivo observation from their trainer to rate fidelity/engagement and answer questions or provide modeling of the curriculum as needed. Specifically, trainers monitored how much of the scripted manual content SMHPs delivered in each session, as well as the quality of SMHP delivery, including clarity in presenting each skill, effectiveness in responding to questions, use of group management strategies to maintain balance of participant involvement and enhance engagement, and use of time management strategies. Trainers also rated each participant's attendance and engagement in the session. Trainers provided prompting or modeling as needed to ensure accurate delivery of content, improve group implementation quality, and/or enhance participant engagement. Fidelity ratings were reviewed in weekly consultation meetings and strategies were discussed and practiced as needed to improve SMHP fidelity and participant engagement in future meetings.

BAU Condition. Those assigned to BAU received school services as usual. These services typically included tutoring with SMHPs. Of note, those in CLS-FUERTE also continued to receive school services as usual throughout the intervention period. After post assessments were completed (which occurred at the same time in both treatment conditions), BAU families were invited to receive CLS-FUERTE and BAU SMHPs were trained to implement the program.

Data Analytic Approach

We performed all statistical analyses using SPSS (Version 26; IBM Corp, 2019). We analyzed outcomes in three domains (i.e., ADHD and ODD symptoms, and overall impairment) separately for each rater (i.e., parent and teacher). Primary analyses involved generalized estimating equations (GEE) using the SPSS GENLIN procedure with unstructured correlation matrices to examine within (baseline; post-treatment) and between (CLS-FUERTE vs BAU) group comparisons, adjusting for school clustering. GEE was chosen over alternative methods due to relaxed distribution requirements. Analyses were completed initially without covariates. We then performed follow-up analyses adjusting for parental level of education and child age, gender, and ADHD medication status; however, inclusion did not change the pattern or interpretation of results. Therefore, simple analyses without covariates are presented. To control

for Type 1 Error, a Benjamini-Hochberg false discovery rate (FDR; Benjamini & Hochberg, 1995) was applied within domain. The FDR exerts a more powerful control over wrongly rejecting the null compared to other procedures that control for family-wise error (e.g., Bonferroni correction). For all pairwise comparisons, Hedges' *g* effect size metrics are provided. Hedges' *g* estimates are Cohen's *d* estimates corrected for the upward bias associated with smaller sample sizes. Interpretation of Hedges' *g* estimates are consistent with traditional effect size conventions (i.e., 0.2 = small; 0.5 = moderate; 0.8 = large).