

Children's ADHD Telemental Health Treatment Study (CATTS)

**TELEMENTAL HEALTH (TMH) TO IMPROVE CARE AND
OUTCOMES FOR CHILDREN LIVING IN UNDERSERVED AREAS
(NIMH-Funded Study: 1-R01-081997-01A1)**

A Study for Kids with ADHD Who Live in Underserved Communities

SUMMARY OF THE STUDY DESIGN AND METHODS

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Children's ADHD Telemental Health Treatment Study (CATTs)

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Goals: To determine whether telemental health (TMH) with expert psychiatric and behavioral health interventions can improve outcomes for children struggling with mental health problems in underserved areas. In this study, we focus on whether TMH is “value added” for children with Attention-deficit Hyperactivity Disorder (ADHD) or Attention-deficit Disorder (ADD). ADHD, or ADD, is a very common mental health problem of childhood. Most children with ADHD are treated in primary care. So, it is a good model for examining whether providing expert evidence-based services through TMH is helpful to children and their doctors. If we can show that TMH is “value added”, we will make a major step to bringing TMH into the mainstream health care and expand treatment opportunities for underserved youth.

Subjects: boys and girls 5.5 to 12 years old diagnosed with or suspected of having Attention-deficit Hyperactivity Disorder (ADHD), ranging from mild to moderately severe. We are particularly interested in children who are newly suspected of having ADHD so that we may intervene before they experience major difficulties in their development.

We are also enrolling a large percentage of Hispanic families as research has shown that Hispanic children are under-diagnosed and under-treated for ADHD. The National Institute of Mental Health has mandated that investigators include more Hispanic children in research to provide them access to new treatments and to ensure that study results represent all of the nation's children. Caregivers and children must have basic conversational English.

All treatment occurs at a local clinic, e.g., Seattle Children's regional clinics in Olympia, Richland, Everett, or Bellevue, or the Family Health Services Clinic of Central Washington Hospital in Wenatchee, or the Child and Adolescent Clinic in Longview. In Oregon families go to the Community Counseling Solutions in Boardman.

Referral to the Study: All children must be referred to the study by their primary care physician (PCP), although teachers and families may initiate discussion with the PCP and request referral to the study. There is a referral form included with the family handouts provided here. Please visit our website: www.TV4ADHD.org, or call us at (800) 997-4017.

Initial Assessment: First, caregivers complete a rating scale, the Child Behavior Checklist (CBCL), and the Patient Intake Packet (PIP). These are standard tools that our outpatient clinic uses in admitting children to treatment. If these two tools indicate that the child appears to meet criteria for ADHD, the child then receives a structured diagnostic interview by the local therapist to confirm a diagnosis of ADHD, any relevant comorbidities that may be allowed in the study (eg, Oppositional Defiant Disorder (ODD), anxiety or depression) or that may comprise exclusion criteria (eg bipolar disorder or psychotic disorders).

Caregivers of eligible subjects then complete rating scales regarding their child's ADHD (the Vanderbilt Rating Scales: VADPRS), comorbidities (such as anxiety), and scales assessing the child's functioning. Caregivers also complete questionnaires that assess their own functioning and challenges in parenting a child with ADHD. Children complete short questionnaires on anxiety, depression, and overall functioning. Teachers are also involved. We ask them to complete the Vanderbilt ADHD Teachers' Rating Scale (VADTRS) at several points to determine how ADHD affects children's performance in school as the study progresses.

Subjects are then randomized to one of two study groups: 1) Treatment Stabilization Group (aka Group A) with 6 sessions of evidence-based medication and behavioral training, and 2) Consultation Group (aka Group B) with a telepsychiatry consultation and recommendations to the PCP to implement at his/her discretion. *All enrolled subjects receive some treatment. Treatment sessions are free to families. However, the study cannot cover the costs of medications.*

Following are details of the two groups.

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Study Groups.

Group A. Stabilization Group

Treatment Paradigm

Description:

Stabilization is achieved by a combination of two evidence-based treatment components: medication management and caregiver behavioral training. The active intervention runs 22 weeks, with formal assessments a five times throughout the study. Both the telepsychiatry sessions and the caregiver behavioral training occur at a local regional clinic, e.g., Seattle Children's regional clinics in Olympia, Richland, Everett, or Bellevue, or the Family Health Service of Central Washington Hospital in Wenatchee, or the Child and Adolescent Clinic in Longview. In Oregon families go the Community Counseling Solutions in Boardman.

Medication treatment: Children and caregivers receive 6 sessions of telepsychiatry, 3-5 weeks apart, for medication treatment. Treatment is delivered according to published algorithms from the Texas Children's Medication Algorithm Project (TCMAP). In addition, the telepsychiatrist conducts psychoeducation sessions with the family. This psychoeducation relates to the neurobiological model of ADHD. Families have greatly appreciated this educational component as it helps them to understand that their child is not being "bad" but is struggling with deficits in brain development. The family is assigned "homework" to further learn about ADHD and the brain and how medications work in the brain of ADHD children.

The telepsychiatrist then prepares a report and an ADHD Management Plan that summarizes the child's status/progress, medications, and "homework." The ADHD Management Plan is mailed to the PCP to apprise him/her about treatment. At the end of treatment, the PCP receives a final ADHD Management Plan that includes three new pieces of information: 1) dates for the child to receive the first follow-up appointment with his/her PCP; 2) range of dates for a second follow-up appointment; 3) three follow-up steps for the PCP to complete over the next 2 months. We later assess whether these three steps were helpful to the PCP's management and ADHD and to the child's outcome.

Caregiver behavioral training: Right after the telepsychiatry session, the local therapist works with the caregiver and child on-site at the clinic. The parent-behavioral training is a manualized evidence-based model of care for ADHD children. The therapist is trained and supervised by a telepsychologist, Carolyn McCarty PhD, who is a national expert in research on psychotherapy with youth. The parent behavioral training includes advocacy activities to help the parents to intervene for their children in school or other areas. The Therapist also provides "homework" to families.

At each clinic visit, caregivers take brief simple "quizzes" to determine their comprehension of basic educational materials and their adherence to the assigned "homework". ***Caregivers call 1-800-997-4017 at SCH if there are any problems or questions.***

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Group B: Consultation Group

Treatment Paradigm:

Most telepsychiatry across the country is consultative i.e., the telepsychiatrist acts as consultant to the referring PCP who then renders ongoing care. The consultation in this study consists of two sessions: a diagnostic session in person at the clinic to confirm the diagnosis of ADHD and establish any comorbidities and a telepsychiatry session to formulate a treatment plan including a review of other issues that may affect treatment.

Description:

After receiving a diagnostic interview by the therapist at the local clinic, subjects receive an evaluation by a telepsychiatrist who works at SCH. The telepsychiatrist then makes treatment recommendations to the PCP. The PCP resumes care up to week 30 after randomization into the study. During this time the PCP may follow the telepsychiatrist's recommendations or treat per his/her discretion. These children may receive whatever other services the PCP recommends, e.g., counseling, referral to school for an IEP. We later assess what treatments they received and whether the telepsychiatrist's recommendations were helpful to the PCP and the child's care.

Assessments:

Measuring Outcomes for Symptoms and Functioning. Caregivers and children complete outcome assessments at several points during the study. Caregivers are paid \$25 for each assessment with a \$25 bonus payment at the end if they have completed each assessment. Children are paid \$10 at each of these times with a \$10 bonus if they complete all assessments. There is a total possible payment of \$245.

Adherence Assessment: All sessions are recorded so that we can determine whether the telepsychiatrists and the therapists adhere to their treatment protocols. This will help us to determine whether evidence-based interventions can be faithfully implemented through telemental health. This component is critical to later convincing payers and policy makers that telemental health can deliver a high standard of care.

PCPs' Involvement: The value of the telemental health intervention to PCPs is assessed for each group at week 30 of the study (i.e., 8 weeks after completion of the 22 week intervention for Group A subjects and 30 weeks after completion of the consultation for Group B). These assessments help us to determine whether a consultation or collaborative model is best for children treated through telemental health.

- Group A (Stabilization Group): Whether the telepsychiatrist's 3 follow-up recommendations that are made at the end of the study intervention are implemented by the PCP and whether they were helpful to the PCP and patient.
- Group B (Consultation Group): How the patient progressed during the 30 weeks following the telepsychiatrists' consultation.