

Feasibility of Conducting a Randomized Controlled Trial of Telemental Health with Children Diagnosed with Attention-Deficit/Hyperactivity Disorder in Underserved Communities

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Abstract

Objective: Telemental health (TMH), the use of videoteleconferencing to provide care that is usually delivered in person, is increasingly used to rectify disparities in access to care. Few studies, however, have been conducted to demonstrate the effectiveness of TMH as a service delivery model. The Children's Attention-Deficit/Hyperactivity Disorder (ADHD) Telemental Health Treatment Study (CATTS) is a randomized clinical trial (RCT) of TMH conducted in multiple underserved communities. This article reports on the feasibility of conducting an effectiveness trial of TMH with children.

Methods: The CATTS trial used videoteleconferencing to provide guideline-based care and secure web sites to coordinate key aspects of trial implementation, such as participant recruitment and retention, intervention fidelity, and completion of assessments.

Results: The CATTS trial engaged seven communities and 150 primary care providers as partners in the study, and enrolled 223 children 5.5–12.9 years old. The intervention group completed an average of 5.3 of 6.0 planned sessions and 96% of controls completed a TMH consultation. Both groups completed an average of 4.8 of the 5.0 assessments. Clinicians demonstrated high fidelity to their treatment protocols. Minor technical difficulties did not interfere with providing care.

Conclusions: The CATTS trial demonstrated the feasibility of conducting an RCT of TMH with children living in multiple underserved communities. Telecommunications technologies can facilitate the coordination of research activities across sites and clinicians. Future trials should work closely with study partners to ensure referral of a representative study sample. Further trials are needed to help establish the effectiveness of TMH as a service delivery model.

Trial Registration: <http://clinicaltrials.gov/show/NCT00830700>.

Introduction

TELEMENTAL HEALTH (TMH) REFERS TO THE USE of video-teleconferencing (VTC) to provide psychiatric and other mental health services that are usually provided in person. TMH is increasingly used as a strategy to help to redistribute the workforce and to correct disparities in children's access to needed mental health care. An evidence base is now needed to establish TMH as an effective mental health service delivery model for children and adolescents.

Research in TMH

Multiple investigations have demonstrated that TMH is a feasible and acceptable service delivery model for the evaluation and treatment of adults diagnosed with psychiatric disorders. An evi-

dence base establishing the efficacy of TMH is evolving. Comparability trials have shown that psychiatric treatment provided through VTC yields lengths of hospitalization (Graham 1996; De Las Cuevas et al. 2006; O'Reilly et al. 2007), medication use (Fortney et al. 2007; O'Reilly et al. 2007), symptom reduction (Graham 1996; De Las Cuevas et al. 2006; Fortney et al. 2007; O'Reilly et al. 2007; Saeed et al. 2011) and patient satisfaction (Bishop et al. 2002) that are comparable to care rendered in person. A foundation has been laid for teletherapy. Morland and colleagues found that a manualized, evidence-based psychotherapy for post-traumatic stress disorder (PTSD) was reliably implemented through VTC (Morland et al. 2011) and randomized, noninferiority trials have shown significant reductions in PTSD symptoms from treatment delivered through TMH that were comparable with treatment provided in person (Frueh et al. 2007; Morland et al. 2010).

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A small body of research on the use of TMH with children and adolescents has been published. Descriptive studies have shown that parents (Elford et al. 2001; Greenberg et al. 2006; Myers et al. 2008), referring physicians (Elford et al. 2001; Greenberg et al. 2006; Myers et al. 2007) and teens (Myers et al. 2006; Boydell et al. 2010) are highly satisfied with mental health care provided to children through TMH. Elford and colleagues demonstrated the reliability of diagnoses made through TMH (Elford et al. 2000). In a comparability trial, Nelson and colleagues randomized 28 children diagnosed with depression to receive cognitive behavioral therapy either in person or through TMH. The two groups showed similar significant symptom reductions over the 8 week intervention (Nelson et al. 2003). Finally, Yellowlees and colleagues (2008) used a pre-post design to evaluate behavior change in a convenience sample of 41 children who received a psychiatric consultation through TMH. Parents rated girls as significantly improved in the Affect Domain and boys as significantly improved in the Oppositional Domain on the Child Behavior Checklist (CBCL) (Achenbach and Rescorla 2001) 3 months following the teleconsultation.

Clearly, stronger research evidence is needed to establish TMH as an effective service delivery model for youth. With demonstrated effectiveness, TMH has great potential to address the current workforce shortage of child and adolescent psychiatrists, and the geographic disparities in access to child mental health services that are projected to continue into the foreseeable future (Thomas and Holzer 2006). There are, however, many deterrents to conducting a randomized clinical trial (RCT) of TMH. The current study examines the feasibility of conducting a trial designed to test the “superiority” of clinical outcomes of children given expert care provided through TMH compared with outcomes of children given treatment as usual in primary care. As Leon and colleagues (2011) have noted, the feasibility of conducting a “superiority trial” focuses on a number of critical aspects of the research process, including recruiting children and families from distant sites into an RCT, retaining an active intervention group treated through TMH, retaining a control group, and obtaining outcome assessments from participants living in remote communities. Additionally, the VTC equipment must be technically adequate for clinical care, acceptable to families as a service delivery venue, and reliably utilized by TMH providers to render guideline-based intervention protocols. To ensure successful implementation of a RCT for TMH, communication among research and clinical staff dispersed over multiple settings must be rapid, convenient, and accurate. Strategies must be developed to ensure adherence to guidelines for engaging and protecting human subjects in research. Here, we describe how we addressed these challenges using a variety of telecommunications technologies. By sharing our experiences in conducting an RCT of TMH delivered to children in multiple non-metropolitan communities, we hope to strengthen the foundation for future TMH trials that will continue to build an evidence base for TMH as an effective service delivery model.

Methods

The Children’s Attention-Deficit/Hyperactivity Disorder (ADHD) Telemental Health Treatment Study (CATTs) is an RCT funded by the National Institutes of Mental Health (<http://clinicaltrials.gov/show/NCT00830700>) to determine whether an evidence-based intervention for children’s mental health needs can be faithfully implemented using VTC, and can improve child outcomes over treatment as usual by primary care providers (PCPs) practicing in underserved non-metropolitan areas.

Trial implementation

The CATTs trial was conducted using a “hub-and-spoke” organizational model. All research activities and the child and adolescent telepsychiatrists were located at Seattle Children’s Hospital and Research Institute (SCRI), the “hub.” Seven communities in western and central Washington and Oregon participated. Participants, their referring PCPs, and study therapists were located in and surrounding the spoke communities. Referral was open to all PCPs practicing in these sites. Referring PCPs agreed to resume care of children after treatment provided by the CATTs trial was completed. A description of the seven sites is shown in Table 1 and a description of participants is shown in Table 2.

Subjects and eligibility

Subjects. Boys and girls 5.5–12.9 years old with suspected ADHD were referred to the CATTs trial by their PCPs. Selected common psychiatric disorders comorbid with ADHD were allowed. Ineligibility criteria included not living with a legal guardian, being homeschooled, being non-English-speaking, or being diagnosed with a comorbid medical or psychiatric disorder that required treatments not included in the study protocol.

Eligibility determination. Eligibility for participation was determined in a two-step process. After referral of suspected cases of ADHD by PCPs, caregivers completed the CBCL (Achenbach and Rescorla 2001) to screen for the presence of ADHD symptoms in their children. If the CBCL revealed ADHD symptoms, the caregiver then completed the fully structured Computerized Diagnostic Interview Schedule for Children (CDISC) (Shaffer et al. 1996) administered in person by a study therapist to confirm an ADHD diagnosis. The principal investigator reviewed intake information regarding comorbidities to make the final eligibility determination.

Obtaining consent for participation. The study therapists in the participating communities obtained written consent and assent for participation in the study. According to the study protocol approved by the SCRI Institutional Review Board, informed consent was administered to parents prior to administration of the CDISC. Oral and written assent were administered to children prior to the commencement of the first treatment session.

Research design and intervention groups

The study was designed as an RCT. The study intervention was developed on the basis of findings from the Multimodal Treatment for ADHD (MTA) study showing that combined medication and behavior interventions were more beneficial for children with ADHD and comorbid conditions of oppositional defiant disorder (ODD) and anxiety disorders than either usual treatment provided by PCPs in the community or medication management alone (MTA Cooperative Group 1999).

Based on the MTA study findings, assuming attrition of 20% during the trial, and setting the detection of group differences at the 0.05 level of statistical significance, we estimated a sample size of 250 participants. Subsequently, based on low attrition during the trial, we recalculated a sample size of 210 participants.

Children who met all eligibility criteria were randomized within site and age groups (5.5–9.9 and 10.0–12.9 years) to one of two interventions. Participants assigned to the active intervention, Group A, received six sessions spaced 4 weeks apart with two components. The first component consisted of an algorithm-driven pharmacological treatment for ADHD (Pliszka et al. 2006)

TABLE 1. CHARACTERISTICS OF SITES PARTICIPATING IN THE CATTs STUDY

Site	Date joined study	Distance from Seattle	Population Size ^a	Racial/Ethnic composition ^b	Economic base
Boardman and Hermiston, Oregon	January 2009	268 miles	20,245 both towns Morrow and Umatilla Counties:	74.2% White 0.8% Black 34.9% Hispanic	Agriculture, livestock, food processing, and forest products
Longview	January 2009	126 miles	36,648 city (102,498 Cowlitz County)	86% White 0.9% Black 9.7% Hispanic	Medical, marine, timber, and recreational
Olympia ^c	September 2009	60 miles	46,478 city (256,591 Thurston County)	83.7% White 2.0% Black 6.3% Hispanic	Government, real estate, insurance, and college
Wenatchee ^d	September 2009	138 miles	31,925 city (72,453 Chelan County)	76.7% White 0.4% Black 29.4% Hispanic	Agriculture, forestry, and ranching
Tri Cities ^{c,e}	October 2009	216 miles	182,000 three cities (262,000 Franklin and Benton counties)	56.0% to 87.0% White 1.4% to 1.9% Black 8.0% to 56.0% Hispanic	Agriculture, technology, biotechnology, manufacturing, service industry and government.
Everett ^c	February 2011	30 miles	103,019 city (722,400 Snohomish County)	74.6% White 4.1% Black 14.2% Hispanic	Marine, naval, manufacturing and retail, and technology
Bellevue ^c	February 2011	11 miles	122,363 city (1,969,722 King County)	62.63% White 2.3% Black 7.0% Hispanic	Services, retail, commerce technology, biotechnology

^aAll information from the United States Census Quick Facts: (<http://quickfacts.census.gov/qfd/states/53/5335275.html>).

^bPercentages may exceed 100%, as individuals could have more than racial and/or ethnic heritage.

^cSatellite clinics of Seattle Children's Hospital.

^dRegional partner of Seattle Children's Hospital.

^eIncludes the three cities of Richland, Kennewick, and Pasco, which have widely varying ethnic compositions.

TABLE 2. DESCRIPTION OF REFERRED AND ENROLLED SAMPLE

Characteristic	Total sample
Total referred subjects	530
Total referring PCPs	150
Total enrolled subjects	223
Referring PCPs for enrolled sample	88
Age mean (\pm SD)	9.25 (\pm 1.99)
Age groups <i>n</i> (%)	
5.5–9.9 years	136 (61.0%)
10.0–12.9 years	87 (39.0%)
Sex <i>n</i> (%)	
Males	163 (73.1%)
Females	60 (26.9%)
Race <i>n</i> (%)	
Caucasian/White	208 (93.3%)
African American	7 (3.1%)
Asian	2 (0.9%)
Native American	2 (0.9%)
Unknown	4 (1.8%)
Comorbidity per CDISC <i>n</i> (%)	
None	88 (39.5%)
ODD alone	115 (51.6%)
GAD alone	4 (1.8%)
ODD + GAD combined	16 (7.2%)
Family income median	\$50,000–74,999
Less than \$20,000	43 (19.3%)
\$20,000–\$49,999	68 (30.5%)
\$50,000–\$74,999	37 (16.6%)
\$75,000 or more	75 (33.6%)

PCP, primary care provider; CDISC, Computerized Diagnostic Interview Schedule for Children; ODD, oppositional defiant disorder; GAD, generalized anxiety disorder.

provided over VTC by a child psychiatrist who also provided psychoeducation on the neurobiology of ADHD. The second component consisted of six sessions of a caregiver behavior training protocol adapted from evidence-based guidelines for treating children with ADHD (Chronis et al. 2004) and conducted in person with the caregiver by a community therapist. Therapists were trained and supervised remotely by a clinical psychologist at the research hub using telecommunication technologies.

Children assigned to the control condition, Group B, received treatment as usual with the PCP enhanced with a single consultation session over VTC with a child telepsychiatrist who then made treatment recommendations to referring PCPs. The decision to implement this active control condition was made because several of the study sites were long-time participants in our Seattle Children's Hospital (SCH) telepsychiatry services, such that we could not ethically deprive them of available community services. A single consultation session is common in many telepsychiatry programs nationally (Cruz et al. 2005; Hilty et al. 2006).

Research assessments

Outcomes. Baseline and outcome assessments at four time points were collected from caregivers and children ages 10.0–12.9, as noted in Table 3. Measures captured ADHD symptoms (Wolraich et al. 1998, 2003), and symptoms of comorbid externalizing (Wolraich et al. 1998; Achenbach and Rescorla 2001; Wolraich et al. 2003) and internalizing disorders (Messer et al. 1995; March 1997), and level of functional impairment (Bird et al. 1993; Bird 1999; Barkley 2000). Teachers also reported on children's ADHD symptoms (Wolraich et al. 1998). In a second set of assessments, caregivers reported on their own distress (Koren et al. 1992; Abidin 1995; Brannan et al. 1997; Kroenke et al. 2001) and satisfaction with the treatment received (Attkisson and Zwick 1982). All measures comprised well established scales with solid psychometric properties. Fidelity to treatment protocols was assessed for the telepsychiatrists, therapists, and caregivers.

TABLE 3. MEASURES AND TIMELINE (T1-T5) FOR ASSESSMENTS

Assessment domain	Measure	Screening and diagnosis	T1	T2	T3	T4	T5
ADHD Screen	CBCL's DSM-IV oriented ADHD index	X					
ADHD Diagnosis	DISC-IV parent version	X					
Comorbid diagnoses: Anxiety, ODD	DISC-IV parent version;	X					
ADHD symptoms	VADPRS VADTRS		X	X	X	X	X
ODD symptoms	VADPRS VADTRS		X	X	X	X	X
Functional impairment	CIS-P, HSQ, SSQ CIS-C		X	X	X	X	X
Parents' distress	PHQ-9; PSI, CSQ, FES		X	X	X	X	X
Children's anxiety	MASC-P MASC-C		X	X	X	X	X
Children's depression	MFQ-P MFQ-C		X	X	X	X	X
Treatment satisfaction	CSQ (ADHD)					X	X

ADHD, attention-deficit/hyperactivity disorder; ODD, oppositional defiant disorder; CBCL, Child Behavior Checklist; DISC-IV, Diagnostic Interview Schedule for Children-IV, parent version; VADPRS, Vanderbilt ADHD Parent Rating Scale; VADTRS, Vanderbilt ADHD Teacher Rating Scale; HSQ/SSQ, Home and School Situations Questionnaire; CIS-P, Columbia Impairment Scale-Parent Version; CIS-C, CIS-Child Version; MASC, Multidimensional Anxiety Scale for Children; MFQ, Moods and Feeling Questionnaire; PHQ-9, Patient Health Questionnaire-9; PSI, Parenting Stress Inventory; FES, Family Empowerment Scale; CSQ, Caregiver Strain Questionnaire; CSQ (ADHD), Client Satisfaction Questionnaire (adapted to ADHD).

Intervention fidelity. To assess the telepsychiatrists' and therapists' fidelity to their intervention protocols, all treatment sessions for Groups A and B were recorded. Random samples were then selected to rate fidelity: Two telepsychiatry sessions and one of the caregiver training sessions for each Group A family, and the single telepsychiatry sessions for half of the Group B families.

Technology

The successful implementation of an RCT that coordinated clinical care and research activities for multiple distant sites with telepsychiatrists at the research hub, community therapists at the spoke sites, and referring PCPs in the communities was accomplished by using several technologies.

VTC. Telepsychiatry services to each of the sites were provided in real time using high bandwidth (384 Kbits/sec to 1.0 MB/sec) connections through a secure T1 line with high resolution flat screen monitors with 30 frames per second that approximate an in-person session. Each participating community had existing VTC equipment at a local clinic either because of their participation in our telepsychiatry clinic, or used for educational and administrative activities. Weekly team meetings of the staff at the research hub with all the therapists at the spoke sites were also conducted through VTC. All technical training of clinicians and staff and the management of technical difficulties were provided by the audio/visual (AV) staff at SCH. The VTC units were used to record each telepsychiatry session at the hub and each therapist caregiver behavior training session at the spoke sites.

Coordinating activities of research clinicians: WebCATTS. As the telepsychiatrists were located at the hub and therapists were located at the spoke sites, ensuring documentation and integration of clinical care was a challenge. We adapted a web-based program (Unützer et al. 2002), to a real-time portal that performed three functions. WebCATTS contained a decision-making tool based on established medication algorithms for the treatment of ADHD alone or with selected comorbidities (Pliszka et al. 2006). These algorithms from the Texas Medication Algorithm Project provided telepsychiatrists with choices for medica-

tion treatment based on any comorbidity diagnosed with ADHD and the child's prior medication trials, and then tracked the telepsychiatrists' adherence to these consensus-based guidelines.

WebCATTS was also used to document clinical care and share the information in real time. Both the telepsychiatrists and therapists entered session-specific information collected during each of the six intervention sessions for Group A. Therapists at the spoke site collected information from the child and caregiver at the start of each session, such as vital signs, scores on rating scales, and quiz scores, and then entered the information into WebCATTS for the telepsychiatrist to use in making treatment decisions. At the end of each session, the telepsychiatrist and therapist entered results of their treatment session into WebCATTS, such as medications prescribed, side effects, medication adherence, families' concerns, the content of each caregiver training session, the psychoeducation module provided, and assigned homework.

WebCATTS tracked all the clinical information and integrated it into a templated ADHD management plan that was sent to families to prepare for the next session and to referring PCPs to keep them informed of their patients' progress. The final ADHD management plan included follow-up steps for the PCPs to complete over the ensuing 2 months, and other child-specific issues.

Communication between research staff and therapists: HubCATTS. We created a secure password-protected online portal, HubCATTS, to facilitate communication between research staff at the hub and therapists at the spoke sites. HubCATTS was used to efficiently upload and share documents. HubCATTS electronically stores study consent and release forms, treatment session materials and intervention curricula, study protocols, and technical assistance files. It also contains contact information for telepsychiatrists, research team, information services help-desk, and the AV team.

Data Management: DataCATTS. Collecting screening and assessment data from participants living in multiple widely dispersed sites posed new challenges to conducting an RCT. We decided to use secure portals to collect data from families using their personal computers.

To collect self-administered assessment questionnaires remotely, Catalyst WebQ, a secure sockets layer encrypted web

questionnaire system hosted by the University of Washington, was selected (Geyer et al. 2011). Staff at the research hub sent an e-mail to the family with a secure link and an individual access code to request their assessment, which the WebQ software then built and displayed in the participant's browser. Upon completion of the questionnaire, the participant clicked a link to submit the responses via a secure Internet connection directly into the outcomes database, where they were stored with a unique identifier.

Results

The feasibility of conducting a large randomized trial across multiple community sites via VTC was evaluated through documentation of referrals made to the study by PCPs, recruitment of participants, treatment retention in both the intervention and control groups, participants' completion of assessments, dependability of VTC technology, and study clinicians' adherence to empirically based treatment protocols.

Referrals

A total of 530 youth were referred to the trial by 150 PCPs in their respective spoke communities. Of these, 307 youth, referred by 62 PCPs, were deemed ineligible because of: Inability to contact the family or stated lack of interest in participation (99), failure to complete screening (54), psychiatric comorbidity (45), age (39), medical illness (34), lack of evidence for ADHD (15), sibling enrolled in the study (6), language (6), being in state custody (5), and homeschooling (4). Most PCPs referred 1–3 participants.

Study enrollees

The final enrolled sample is summarized in Table 3. Participants consisted of 223 youth, with 163 boys, and a mean age of 9.25 (± 1.99 ; range: 5.5–12.9 years) who were referred by 88 PCPs. The majority of the children were Caucasian 93.3% ($n=208$), whereas 4.9% ($n=11$) were described as being of another racial heritage, and the race of 4 (1.8%) children was not reported. On the CDISC, comorbidity was diagnosed in 135 (60.5%) participants, predominantly ODD ($n=131$, 58.7%; ODD). The two randomized groups did not vary by age, sex, income, ethnicity, or comorbidity.

Retention in interventions

All of the 223 children and caregivers completed their clinical interventions and research assessments: 103 in Group A and 110 in Group B. Retention in the clinical intervention was high. Participants randomized to Group A attended an average of 5.3 out of 6 possible sessions. Of participants randomized to Group B, 96% attended their single teleconsultation session. The high rate of completion of the clinical sessions is echoed in caregivers' satisfaction with the care received. On the Client Satisfaction Questionnaire (Attkisson and Zwick 1982), which we adapted to caregivers' satisfaction with their child's ADHD treatment, caregivers rated their satisfaction as 38 out of a possible total score of 40.

Completion of research assessments

Caregivers, children 10.0–12.9 years of age, and teachers completed five waves of assessments regarding participants' symptoms, behavior, and functioning. Caregivers and children in both intervention groups completed an average of 4.8 of 5.0 assessments. Overwhelmingly, families in both intervention groups completed

their assessments online through DataCATTS (96%). The remainder of the families completed their assessments by telephone. Teachers completed an average of 3.3 out of 5 assessments with no difference by intervention group. All (100%) of teachers completed assessments online.

Fidelity to intervention protocols

The clinicians' adherence to their intervention protocols was high. Telepsychiatrists adhered to the Group A intervention protocol with $91.6\% \pm 9.5\%$ reliability and to the single Group B consultation with $89.3\% \pm 9.6\%$ reliability. Therapists adhered to their intervention protocol with $94.2\% \pm 9.7\%$ reliability.

Dependability of technology

All sessions were recorded, and 217 sessions were randomly selected for independent rating of technical difficulties. Of these, 158 (73.0%) showed no problems during the telepsychiatry sessions. Technical difficulties were rated as follows: 24 (11.0%) had some visual difficulties, such as pixilation or blurring of the video signal, most considered mild interference; 21 (9.6%) had occasional Interruptions or freezing of the video signal, mostly of mild severity; 10 (4.6%) showed difficulties that required assistance calling the AV team or requiring rebooting of the system, although the sessions were then successfully completed; and 4 (1.8%) had mild desynchrony of the video and audio signals. Of the 59 recordings rated as having some technical difficulties, 5 (2.4%) were rated as having severe technical difficulties.

Discussion

This is the first reported investigation of the feasibility of conducting an RCT through TMH with children living in multiple distant underserved communities. PCPs were willing to refer their young patients to TMH to obtain needed care, and families showed a high utilization of services and completion of research assessments. Telepsychiatrists' adherence to intervention protocols indicates that guideline-based psychiatric interventions can be reliably provided through VTC, and therapists' adherence indicates that VTC can be used to train community therapists and, thereby, disseminate evidence-based psychotherapies from academia to the community. These findings suggest that TMH offers a powerful means to redistribute and strengthen the mental health workforce for populations of children living in underserved areas.

This is one of few TMH investigations to use a "superiority trial" design to examine the added value of expert care provided through VTC over treatment as usual in the community (Fortney et al. 2007) and the first such trial to target children with mental health treatment needs. Prior RCTs with adults have used comparability or noninferiority designs to demonstrate that mental health care provided through VTC is as good as mental health care provided in person. With the increasing emphasis on evidence-based practice, studies that demonstrate the superiority of new interventions will help state and federal governments to optimally support and implement innovations in service delivery.

The CATTS trial demonstrated that the VTC technology can be reliably used to provide care. Many of the recordings (27%) were rated as having some degree of technical difficulties, but most difficulties were rated as mild, and did not abort the sessions or compromise participants' continued participation or satisfaction with their treatment. Future trials should include some measure of the impact of these technical shortcomings on participants'

perception of the value of care provided through TMH. Secure online portals are a feasible means of collecting data from families living in distant communities. It is doubtful that participants' adherence to the outcome assessment protocol would have been as high without the convenience and efficiency of an online approach from the convenience of participants' own computers. The increasingly widespread access to broadband should allow future clinical trials to include distant communities and, thereby, enroll study samples that are representative of the national population (National Institutes of Health 2001; United States Department of Health and Human Services 2001).

The CATTs trial also raises some concerns for future investigations. The large number of ineligible referrals indicates that the enrolled sample may not be representative of underserved communities. The enrolled sample may overrepresent families who were willing to obtain care through VTC, willing to obtain treatment from a psychiatrist, or willing to participate in research, and may differ from those who chose not to participate, in terms of educational status, cultural background, compliance with health-care directives, and clinical features. Referral of many ineligible children, including many who did not meet age criteria, suggests that PCPs overreferred complex cases of children with ADHD, in the hopes of obtaining assistance in managing their care, or did not pay attention to eligibility criteria. Future trials should closely work with referring PCPs to ensure understanding of eligibility criteria as well as to establish the advantages of participating in a clinical trial. Alternatively, investigators may consider only accepting referrals from a selected group of PCPs who are familiar with TMH and/or interested in bringing clinical trials to their communities.

Finally, since the CATTs trial was initiated in 2008, newer, lower-end technologies have been developed that offer good performance for most mental health care. These systems operate software on desktop computers providing an affordable alternative that allows the clinical interventions to be conducted in primary care offices and other decentralized locations. These advances should facilitate further studies to establish an evidence base for TMH as an effective service delivery model.

Conclusions

The CATTs study is the first investigation to report the feasibility of conducting an RCT of telemental health with children living in multiple distant underserved communities. Randomized trials are needed to establish the efficacy of an intervention, or a service delivery model, and feasibility establishes the ability to disseminate efficacious interventions to the community, to those children who have been deprived of speciality mental health care services. The CATTs trial indicates that families will participate in TMH to obtain care for their children, but that further attention must be paid to working with referral sources.

Clinical Significance

The CATTs trial points the way for using new technologies to rectify disparities in children's access to needed mental health care. TMH is a medium by which to provide direct services or to train community therapists in new evidence-based psychotherapies. Feasibility of providing a service does not imply efficacy. Treatment outcome studies are now needed.

Disclosures

No competing financial interests exist.

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