Effectiveness of Collaborative Tele-Mental Health Services for ADHD in Primary Care (ECTSAP)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03559712

Recruitment Status: Recruiting
First Posted: June 18, 2018
Last Update Posted: June 18, 2018
See Contacts and Locations

Sponsor:
Al Jalila Children's Specialty Hospital

Collaborators:
Harvard Medical School
Dubai Health Authority

Information provided by (Responsible Party):
Dr. Ammar AlBanna, Al Jalila Children's Specialty Hospital

Study Description

Go to

Brief Summary:

Aim and objectives:

In this study, our goal is to assess the effectiveness of a collaborative tele-mental health approach for treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD) presenting to primary healthcare centers in Dubai.

Our primary aim is:

To determine if collaborative tele-mental health program improves the clinical and functional outcomes for children with Attention-deficit/hyperactivity disorder (ADHD) in Dubai

Secondary aims:

1. To improve the ability of primary health-care providers to diagnose and treat pediatric ADHD, leading to enhanced community capacity, improving patient access and ensuring sustainability.

2. To enhance parent and child satisfaction with the ADHD assessment and treatment process in Dubai.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHDTelehealthmental Health</td>
<td>Other: Collaborative care, Telemental health</td>
</tr>
</tbody>
</table>

Show Detailed Description
**Study Design**

**Go to ▼**

- **Study Type:** Interventional (Clinical Trial)
- **Estimated Enrollment:** 122 participants
- **Allocation:** Randomized
- **Intervention Model:** Parallel Assignment
- **Intervention Model Description:** Using a collaborative care approach with the aid of teledicine to treat children with ADHD
- **Masking:** None (Open Label)
- **Primary Purpose:** Health Services Research
- **Official Title:** Effectiveness of Collaborative Tele-Mental Health Services for ADHD in Primary Care: A Randomized Trial in Dubai (ECTSAP-Dubai Trial)

**Estimated Study Start Date:** June 7, 2018

**Estimated Primary Completion Date:** December 31, 2018

**Estimated Study Completion Date:** December 31, 2018

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**Resource links provided by the National Library of Medicine**

**MedlinePlus related topics:** Mental Health

**U.S. FDA Resources**

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**Arms and Interventions**

**Go to ▼**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Telemedicine Participants in this arm will be treated by the trained primary health care physicians in the primary health care centers, who will be having weekly supervisions with the specialists for case management.</td>
<td>Other: Collaborative care, Telemental health Children who are referred to the collaborative tele-mental health care arm, Arm (1), will be given a follow-up appointment with the physician at the same primary care center who have successfully completed the pre-trial didactic program designed by Drs. Albanna and Hamoda. The trained child health physician will conduct assessments, treat and manage the patient. All while having weekly clinical supervision with the specialist.</td>
</tr>
<tr>
<td>No Intervention: Control Participants in this arm will experience treatment as usual, which means referral to a specialist.</td>
<td></td>
</tr>
</tbody>
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**Outcome Measures**

**Go to ▼**

**Primary Outcome Measures:**

1. NIHCQ Vanderbilt assessment scale (Parent) [Time Frame: At baseline, 3-month follow-up and 6-month follow-up]
Change in Total Symptom Score for ADHD symptoms in Vanderbilt parent informant form and follow-up forms (at 3 and 6-months follow-up)

Eligibility Criteria

Go to ▼

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 6 Years to 12 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Children ages 6-12 years
- Children who meet DSM-5 criteria for ADHD as determined by both clinical assessment and the Vanderbilt ADHD scales.

Exclusion Criteria:
- Active clinically significant medical illness (e.g. cardiac and seizure disorders).
- Family history of early onset cardiac disease.
- Autism spectrum disorder or clinically significant developmental delay.
- Intellectual disability (IQ of 70 and below, or diagnosis of intellectual disability).
- Active primary psychiatric illness other than ADHD (e.g. mood disorder, anxiety disorder, psychotic disorder, tic disorder).
- Previous ADHD diagnosis and treatment.
- Currently taking psychiatric medications for any indication.

Contacts and Locations

Go to ▼

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03559712

Contacts

Contact: Ammar AlBanna, MD FRCPC IFAPA  00971502030000  aalbanna@ajch.ae
Contact: Karina Soubra, MSc  00971506241550  karina.soubra@ajch.ae

Locations

United Arab Emirates
Dubai Health Authority  Recruiting
Dubai, United Arab Emirates, 4545
Contact: Fatma AlOlama, Dr 00971554569777  fmalolama@dha.gov.ae
Contact: Elize Thottumkal  elizegt@dha.gov.ae

Al Jalila Children's Specialty Hospital  Not yet recruiting
Dubai, United Arab Emirates
Contact: Ammar AlBanna 00971502030000 ext 00971502030000  aalbanna@ajch.ac
Contact: Karina Soubra 00971506241550  karina.soubra@ajch.ac
Principal Investigator: Ammar AlBanna, MD FRCPC IFAPA

Sponsors and Collaborators
Al Jalila Children's Specialty Hospital
Harvard Medical School
Dubai Health Authority

More Information
Go to ▼

Publications:

Responsible Party: Dr. Ammar AlBanna, Head of Child and Adolescent Mental Health Center of Excellence, Consultant Child and Adolescent Psychiatrist, Al Jalila Children’s Specialty Hospital

ClinicalTrials.gov Identifier: NCT03559712  History of Changes
Other Study ID Numbers: 027562-746845-0105
First Posted: June 18, 2018  Key Record Dates
Last Update Posted: June 18, 2018
Last Verified: June 2018

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Dr. Ammar AlBanna, Al Jalila Children's Specialty Hospital:
Attention Deficit Hyperactivity Disorder
Collaborative Care
Teledicine
Telemental Health