Group Training for Parents Whose Children Suffer From ADHD and Comorbidity Using a Behavioral-Dynamic Approach (SPBT)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified June 2016 by Assuta Hospital Systems

Sponsor:
Assuta Hospital Systems

Collaborator:
Tel Aviv University

Information provided by (Responsible Party):
Assuta Hospital Systems

ClinicalTrials.gov Identifier:
NCT02824796

First received: June 29, 2016
Last updated: July 3, 2016
Last verified: June 2016
History of Changes

Purpose

The purpose of this study is to determine whether a new parent training protocol for children with Attention Deficit Hyperactivity Disorder (ADHD) can over perform the state of the art Parent Training protocol (PBT) by increasing the long term effectiveness of the treatment, reducing the dropout rate and reducing the comorbidities.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>Behavioral: Schema Parent Behavioral Training</td>
</tr>
<tr>
<td></td>
<td>Behavioral: Parent Behavioral Training</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Subject)
Primary Purpose: Treatment
Official Title: Group Training for Parents Whose Children Suffer From ADHD and Comorbidity Using a Behavioral-Dynamic Approach: A Randomized Controlled Trial

Further study details as provided by Assuta Hospital Systems:

Primary Outcome Measures:
- Change from baseline in parent-teacher-rated ADHD symptoms [ Time Frame: baseline, 12 weeks, 25 weeks, 3 months, 6 months, 12 months ] [ Designated as safety issue: No ]
  The Child Behavior Checklist (CBCL)-Attention Problem Scale (Child Behavior Checklist)

Secondary Outcome Measures:
- Dropout rate [ Time Frame: baseline, 12 weeks, 25 weeks ] [ Designated as safety issue: No ]
  Group dropout rate during treatment
- Change from baseline in parent-teacher-rated Comorbidities symptoms [ Time Frame: baseline, 25 weeks, 3 months, 6 months, 12 months ] [ Designated as safety issue: No ]
  CBCL Internalizing score (Child Behavior Checklist)

Estimated Enrollment: 140
Study Start Date: July 2016
Estimated Study Completion Date: July 2020
Estimated Primary Completion Date: July 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
An enhanced protocol which combines a Schema Focused Therapy (SFT) and Behavioral Parent Training (PBT) |
| Active Comparator: Parent Behavioral Training | Behavioral: Parent Behavioral Training  
Usually medication & The usual PBT treatment |

A state of the art Parent Behavioral Treatment (PBT) for Children who suffer from ADHD symptoms
Eligibility

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

Criteria

Inclusion Criteria:
- Parents to children 6-12 with ADHD symptoms according to the criteria of Diagnostic and Statistical Manual of Mental Disorders - 5th edition (DSM-V)
- The child was diagnosed in the past as ADHD by MD

Exclusion Criteria:
- Parents with psychotic symptoms or suicidality
- Parents with active manic episode
- Parents with substance dependence
- Parents with autism spectrum disorder

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02824796

Contacts

Contact: Malka Solan +97298924271 solan_m@mac.org.il

Sponsors and Collaborators

Assuta Hospital Systems
Tel Aviv University

More Information

Publications:

Responsible Party: Assuta Hospital Systems
ClinicalTrials.gov Identifier: NCT02824796 History of Changes
Other Study ID Numbers: 2015096
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Health Authority: Israel: Health Ministry
Individual Participant Data

Plan to Share IPD: No

Keywords provided by Assuta Hospital Systems:
ADHD

ClinicalTrials.gov processed this record on July 06, 2016