The Effects of Peer Co-led Educational Group Intervention for Adults With Attention-Deficit Hyperactivity Disorder (ADHD)

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: NCT03547843

Recruitment Status: Not yet recruiting
First Posted: June 6, 2018
Last Update Posted: June 6, 2018
See Contacts and Locations

Sponsor:
Norwegian University of Science and Technology
Collaborator:
St. Olavs Hospital

Information provided by (Responsible Party):
Norwegian University of Science and Technology

Study Description

Brief Summary:

Peer co-led education describes educators who are expert patients, user representatives or former patients, participating and teaching in educational interventions in cooperation with health care professionals. Peer co-led education is included in the Norwegian national guidelines for treatment of mental disorders, but despite some promising results for the treatment of other conditions, still little is known about the efficacy of peer co-led educational group interventions interventions for adults with attention deficit and hyperactivity disorder (ADHD).

This pilot trial will evaluate patient satisfaction with and preliminary efficacy of a 2-session peer co-led educational group program designed to address specific challenges faced by adults diagnosed with ADHD at an outpatient clinics in mid-Norway.

| Condition or disease | Intervention: Group-based education | Behavioral: Standard treatment |

Study Design

Go to ▼

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 60 participants
Allocation: Randomized
Intervention Model: Crossover Assignment

Intervention Model Description: Pilot randomized clinical trial

Masking: None (Open Label)

Primary Purpose: Other

Official Title: The Effects of Peer Co-led Educational Group Intervention for Adults With Attention-Deficit Hyperactivity/Impulsivity Disorder

Estimated Study Start Date: June 10, 2018

Estimated Primary Completion Date: December 2021

Estimated Study Completion Date: December 2021

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Educational intervention Patients randomized to the intervention group will start with a group-based educational program immediately after the randomization.</td>
<td>Behavioral: Group-based education The group-based educational program consists of two sessions that run over two consecutive weeks. Each session consists of a lecture from a recruited expert on the topic of the session and by expert patients with a following discussion of the topic facilitated by the course leader. Other Name: Patient education Other: Standard treatment Diagnostic treatment with medication. In addition, some patients receive cognitive behavioral therapy (not systematically given to every patient). If needed, patients are also offered assistance with regard to economy, housing, education, and work as well as contact with family and network. Other Name: Treatment as usual</td>
</tr>
<tr>
<td>Active Comparator: Waiting list Participants randomized to the waiting list control group receive no educational intervention for the duration of the 10 weeks. During this period participants can receive standard treatment, consisting of diagnostic treatment with medication.</td>
<td>Behavioral: Waiting list No educational intervention for the duration of the 10 weeks. During this period participants can receive standard treatment. Other: Standard treatment Diagnostic treatment with medication. In addition, some patients receive cognitive behavioral therapy (not systematically given to every patient). If needed, patients are also offered assistance with regard to economy, housing, education, and work as well as contact with family and network. Other Name: Treatment as usual</td>
</tr>
</tbody>
</table>

Outcome Measures

Primary Outcome Measures:
1. Change in client Satisfaction [Time Frame: from baseline to 2-weeks follow-up]

   Client satisfaction will be measured with Client Satisfaction Questionnaire, short form (Attkisson & Zwick, 1982). The scale consists of 8 items scored on a Likert scale from 1 (low satisfaction) to 4 (high satisfaction). Total scores range from 8 to 32, with higher scores indicating greater satisfaction.

2. Change in patient activation [Time Frame: from baseline to 10-weeks follow-up]

   Patient activation will be measured with the Norwegian version of the Patient Activation Measure Mental Health (PAM-MH) (Green et al 2010)

Secondary Outcome Measures:

1. Change in general self-efficacy [Time Frame: from baseline to 10 weeks follow-up]

   General Self-Efficacy Scale, 6-item scale ranging from 1 (‘not at all true’) to 4 (‘exactly true’). Total scores range from 6 to 24, with higher scores indicating greater self-efficacy. (Romppel et al 2013)

2. Change in ADHD-related symptoms [Time Frame: from baseline to 10 weeks follow-up]

   Hopkin's Symptom Checklist (SCL), 9-items scale with high scores on SCL-9 indicating ADHD-related symptom burden (Eich et al 2011)

3. Change in ADHD-related symptoms [Time Frame: from baseline to 10 weeks follow-up]

   Norwegian version of the WHO Adult ADHD Self-report scale, ASRS Short Form (Kessler et al 2005)

4. Change in Quality of Life [Time Frame: from baseline to 10 weeks follow-up]

   Adult Attention Deficit/Hyperactivity Disorder Quality of Life Scale, AAQoL short Form (Brod et al 2006)

Other Outcome Measures:

1. Use of health services and work participation [Time Frame: through study completion, an average of 24 weeks]

   Self-reported work participation and received services: 3 questions about both work status and received treatment
Eligibility Criteria

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: 18 Years to 67 Years (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Confirmed ADHD-diagnosis
- Speaking a Scandinavian language

Exclusion Criteria:
- Unable to give informed consent
- Psychosis
- Severe learning difficulties

Contacts and Locations

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): NCT03547843

Contacts

Contact: Mariela L. Lara-Cabrera, PhD 004748280188 mariela.lara@ntnu.no
Contact: Terje Torgersen, PhD 004793419909 terje.torgersen@ntnu.no

Locations

Norway
Tiller DPS
Trondheim, Norway, 7055

Sponsors and Collaborators

Norwegian University of Science and Technology
St. Olavs Hospital

Investigators

Study Director: Anne-Lise Løvaas, md phd St. Olavs Hospital

More Information

Responsible Party: Norwegian University of Science and Technology
ClinicalTrials.gov Identifier: NCT03547843 History of Changes
Other Study ID Numbers: 2017/2405 REK
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 Norwegian University of Science and Technology:
Behavior therapy
Peer groups
Patient satisfaction
Feasibility studies

Additional relevant MeSH terms:

Disease
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Pathologic Processes
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders

Mental Disorders
Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms