Co Morbid Attention Deficit and Hyperactivity Disorder (ADHD) and Developmental Co Ordination Disorder (DCD)

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: NCT03595826

Recruitment Status: Recruiting
First Posted: July 23, 2018
Last Update Posted: July 23, 2018
See Contacts and Locations

Sponsor:
University of KwaZulu

Information provided by (Responsible Party):
Pam Dawson, University of KwaZulu

Study Description

Go to Brief Summary:
This study aims to establish and present the prevalence figures and demographics of the co-morbidity of ADHD and DCD.
It further aims to design an exercise intervention, to be utilised in the management of the symptoms of both conditions.
Furthermore, it aims at establishing the efficacy of this exercise intervention, when compared with the current and most commonly used intervention, that is: neurostimulant drugs.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Procedure: Exercise Intervention</th>
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<tbody>
<tr>
<td>Co-morbid ADHD and DCD</td>
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Detailed Description:
This study is an experimental design, having three phases. The study looks at children, aged 8 to 9, in remedial units or LSEN classes, in and around Durban, Kzn, SA; who have been diagnosed with ADHD/ADD.

Phase 1: Teachers of the children identified with ADHD/ADD, will be asked to complete a modified teacher Conner's rating, to confirm the diagnosis of ADHD/ADD. The parent will then be asked to complete a DCD questionnaire (DCDQ) to give the PI an idea of whether co-ordination difficulties exist. The PI will then administer a Motor Assessment Battery for Children (MABC) to confirm the diagnosis of DCD. From the scores derived from the 3 above tests, co-morbidity will be diagnosed. The prevalence figures of co-morbidity will be calculated and presented. Demographics of prevalence figures will be given: Gender, Population group, average age.
Phase 2: The exercise intervention will be designed, drawing from the literature and similar interventions already used in various publications.

This programme will be validated by experts (Physiotherapists and O.Ts from special needs schools) and when 70% consensus is reached on all aspects of the programme, the final version will be drafted.

Phase 3: The children found to have both conditions, in co-morbidity, will be assigned to one of 4 groups, according to parental choice, medical advice from paediatricians, GPs etc and an intervention a child is already on.

The four groups will be: medication, exercises, medication plus exercises and a control group. The intervention designed in phase 2 will be administered to the two groups opting for the exercise intervention, for a minimum of 8 sessions. The 3 pre intervention scores (Conner’s, DCDQ and MABC) will be derived from phase 1, post intervention scores will be done 6 months after completion of the intervention, as it is stipulated by the rules of the MABC that the test may not be repeated sooner. The pre and post intervention scores will be compared to calculate improvement and average improvement within each group, will be calculated, to establish which intervention or combination of interventions, is the most effective.

**Study Design**

**Go to**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Interventional (Clinical Trial)</th>
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</thead>
<tbody>
<tr>
<td>Estimated Enrollment</td>
<td>250 participants</td>
</tr>
<tr>
<td>Allocation</td>
<td>Non-Randomized</td>
</tr>
<tr>
<td>Intervention Model</td>
<td>Factorial Assignment</td>
</tr>
<tr>
<td>Intervention Model Description</td>
<td>3 phase quasi experimental design. Diagnosis and intervention.</td>
</tr>
<tr>
<td>Masking</td>
<td>Single (Investigator)</td>
</tr>
<tr>
<td>Masking Description</td>
<td>The Pi will not be involved in post intervention testing of the children/participants.</td>
</tr>
<tr>
<td>Primary Purpose</td>
<td>Treatment</td>
</tr>
<tr>
<td>Official Title</td>
<td>The Effects of Exercise Therapy on the Co-Morbidity of Attention Deficit and Hyperactivity Disorder (ADHD) and Developmental Co-Ordination Disorder. (DCD)</td>
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<tr>
<td>Actual Study Start Date</td>
<td>May 2, 2018</td>
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<tr>
<td>Estimated Primary Completion Date</td>
<td>August 2018</td>
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<tr>
<td>Estimated Study Completion Date</td>
<td>December 2018</td>
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</tbody>
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**Resource links provided by the National Library of Medicine**

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Exercise and Physical Fitness

Drug Information available for: Methylphenidate

U.S. FDA Resources

**Arms and Interventions**

**Go to**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
</table>
| Experimental: 1. Neurostimulant pharmaceutical drugs.. | Procedure: Exercise Intervention  
The Pi will only administer the exercise intervention. The pharmacological therapy will be administered and |
1. Participants receiving medicinal drugs, such as methylphenidate/Ritalin, administered by a medical practitioner, in dosages prescribed by the practitioner, to suit the child. Parents of participants will remain responsible entirely for the monitoring of the pharmacological therapy of their children. Other Name: Neurostimulant drugs (E.g: methylphenidate)

Experimental: 2. Exercise Intervention
Participants receiving a minimum of 8 sessions of exercise intervention, for the duration of an hour each session. Exercises will be to build muscle tone, improve core stability, enhance balance, improve fine and gross motor skills and visual motor integration.

Procedure: Exercise Intervention
The Pi will only administer the exercise intervention. The pharmacological therapy will be administered and monitored by medical practitioners, as is the norm with most children diagnosed and treated for ADHD/ADD. Parents of participants will remain responsible entirely for the monitoring of the pharmacological therapy of their children. Other Name: Neurostimulant drugs (E.g: methylphenidate)

Experimental: 3. Neurostimulant drugs plus Exercise intervention
See Arms 1 and 2 above. Both interventions administered together: Pharmaceutical drugs plus exercise intervention

Procedure: Exercise Intervention
The Pi will only administer the exercise intervention. The pharmacological therapy will be administered and monitored by medical practitioners, as is the norm with most children diagnosed and treated for ADHD/ADD. Parents of participants will remain responsible entirely for the monitoring of the pharmacological therapy of their children. Other Name: Neurostimulant drugs (E.g: methylphenidate)

Experimental: 4. Control Group
Participants will not receive any intervention during the research process. They will be given an intervention after the research is completed.

Procedure: Exercise Intervention
The Pi will only administer the exercise intervention. The pharmacological therapy will be administered and monitored by medical practitioners, as is the norm with most children diagnosed and treated for ADHD/ADD. Parents of participants will remain responsible entirely for the monitoring of the pharmacological therapy of their children. Other Name: Neurostimulant drugs (E.g: methylphenidate)

Outcome Measures
Go to ▼

Primary Outcome Measures:

1. The Effect of Exercise Therapy on the Co Morbidity of ADHD and DCD [Time Frame: Approximately 6 months]

   Improvement or regression in symptoms of ADHD will be rated using the modified Conner's teacher rating scale, pre intervention and post intervention:

   10 factors on inattentiveness will be rated 0 (Not at all), 1 (Just a little), 2 (Pretty much) and 3 (Very much); 5 factors on impulsivity will be rated using the same scale as above and 5 symptoms of hyperactivity as well. Percentages will be derived from these ratings. A 70% or more indicates a positive diagnosis for inattention/impulsivity/hyperactivity.
Secondary Outcome Measures:

1. The Effect of Exercise Therapy on the Co Morbidity of ADHD and DCD [Time Frame: Approximately 6 months.]

   Improvement or regression in symptoms of co-ordination, will be rated by the parent, using the Developmental Co-ordination Disorder Questionnaire, pre and post intervention: 15 statements related to co-ordination will be rated on the following scale: 1 (Not at all like child), 2 (A bit like child), 3 (Moderately like child), 4 (Quite a bit like child) and 5 (Extremely like child). The score will be totalled and scores of 55 and above mean that the child does NOT have co-ordination issues, scores below 55 indicate that the child has co-ordination issues.

Other Outcome Measures:

1. The Effect of Exercise Therapy on the Co-Morbidity of ADHD and DCD [Time Frame: Approximately 6 months.]  

   Improvement or regression of motor/co-ordination symptoms, will be tested by the therapist/primary investigator, using the Movement Assessment Battery for Children. 8 age-appropriate motor tests will be administered and scored. A total Motor Impairment score (TOMI) of under 10,5 indicates that the child is fine, scores from 10,5 to 14 indicate that the child is borderline and scores of 14,5 and above indicate definite motor/co-ordination problems.

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: 8 Years to 9 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Age 8 to 9, diagnosed with ADHD, in remedial unit or LSEN class, in mainstream school in Durban Kzn SA.

Exclusion Criteria:

- Any child having an obvious physical disability, neurological condition, musculoskeletal condition, psychiatric disorder or genetic disorder.

Any child below age 8 and above age 9.

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): **NCT03595826**

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**Contacts**

Contact: Pamela M Dawson, M.Physio  0825789986  pdawson@polka.co.za
Contact: Thaya Nadasan, PhD Physio  0844944880  Nadasant@ukzn.ac.za

**Locations**

**South Africa**

Escombe Primary School  
Durban, Kzn, South Africa, 4600  
Contact: Lia Lorimer, B.Ed  031 4640948  fphod.escombeprimary@gmail.com  
Contact: Duncan J Buckthorp, B.Ed  031 4640948

**Sponsors and Collaborators**

University of KwaZulu

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**More Information**

**Publications:**

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**Responsible Party:**  Pam Dawson, Principal Investigator, University of KwaZulu

**ClinicalTrials.gov Identifier:**  **NCT03595826**  **History of Changes**

**Other Study ID Numbers:**  Co Morbid ADHD and DCD

**First Posted:**  July 23, 2018  **Key Record Dates**

**Last Update Posted:**  July 23, 2018

**Last Verified:**  July 2018

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**Individual Participant Data (IPD) Sharing Statement:**

**Plan to Share IPD:**  Yes

**Plan Description:**  I plan to share my protocol, study design, intervention, statistical analysis and results. Pretty much the entire study, once completed.

**Supporting Materials:**  Study Protocol  
Statistical Analysis Plan (SAP)  
Informed Consent Form (ICF)  
Clinical Study Report (CSR)  
Analytic Code

**Time Frame:**  Probably in 2019 and can remain available for as long as is allowed and necessary.

**Access Criteria:**  Clinical trial site.

**URL:**  http://

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

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

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Keywords provided by Pam Dawson, University of KwaZulu:
ADHD/ADD DCD Exercises Neurostimulant Drugs

Additional relevant MeSH terms:
- Attention Deficit Disorder with Hyperactivity
- Motor Skills Disorders
- Attention Deficit and Disruptive Behavior Disorders
- Neurodevelopmental Disorders
- Mental Disorders
- Methylphenidate
- Central Nervous System Stimulants

- Physiological Effects of Drugs
- Dopamine Uptake Inhibitors
- Neurotransmitter Uptake Inhibitors
- Membrane Transport Modulators
- Molecular Mechanisms of Pharmacological Action
- Dopamine Agents
- Neurotransmitter Agents