Recollect the Game: A Novel Treatment for Executive Functioning Deficits in Adults With 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: NCT03437993

Recruitment Status: Not yet recruiting
First Posted: February 19, 2018
Last Update Posted: February 19, 2018
See Contacts and Locations

Sponsor:
McMaster University

Information provided by (Responsible Party):
McMaster University

Study Description

Go to Brief Summary:

Adults who have attention deficit hyperactivity disorder (ADHD) suffer from significant occupational, academic and social problems, many of which are believed to be a result of problems with executive functioning. Executive functioning refers to a group of neuro-psychological functions which include sustained attention, working memory, verbal fluency, as well as motor and mental processing speed. Individuals with ADHD have been shown to have deficits in executive functioning independent of IQ, co-occurring psychiatric disorders, gender, and ADHD subtype. "Recollect" is an application (App) based working memory training video game where participants conduct 3 different adaptive working memory tasks. In each of these tasks participants are presented with a set of stimuli to be remembered while playing a simple platform game where they help navigate an astronaut across the screen and dodge obstacles. Recollect has been designed for all age groups to an interesting, fun and effective brain training activity. The memory tasks included in the game have been independently shown to improve working memory in a manner that transfers to untrained tasks.

The purpose of this study is to evaluate the effects of playing Recollect versus Tetris for 20 minutes per day, 5 days per week over a 4 week period, on executive functioning deficits in individuals who have Adult ADHD.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Other: Recollect, the gameOther: Tetris</th>
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<tr>
<td>Adult ADHD</td>
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Detailed Description:
The primary objective is to evaluate the effects of playing Recollect versus Tetris for 20 minutes per day, 5 days per week over a 4 week period, on executive functioning deficits in individuals who have Adult Attention Deficit Hyperactivity Disorder (ADHD). Consenting participants will be screened using the Mini International Neuropsychiatric Interview for DSM-5 (MINI) to confirm ADHD diagnosis. Participants will be asked to download either Recollect or Tetris on their own mobile device. Following a training/orientation session, they will
be asked to spend 20 minutes per day at least 5 days per week playing Recollect or Tetris over a 4 week period. At
Week 4, study staff will check the time log on the Recollect/Tetris App to confirm how much time was spent
playing the game. Participants will be asked to complete two ADHD symptom severity scales, as well as App-based
neurocognitive testing at baseline (Week 0) and endpoint (Week 4).

**Study Design**

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- **Study Type**: Interventional (Clinical Trial)
- **Estimated Enrollment**: 40 participants
- **Allocation**: Randomized
- **Intervention Model**: Parallel Assignment
- **Masking**: None (Open Label)
- **Primary Purpose**: Treatment
- **Official Title**: Recollect the Game: A Novel Treatment for Executive Functioning
  Deficits in Adults With ADHD

**Anticipated Study Start Date**: April 1, 2018

**Estimated Primary Completion Date**: March 31, 2019

**Estimated Study Completion Date**: June 1, 2019

**Arms and Interventions**

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<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td><strong>Experimental: Recollect</strong></td>
<td>Other: Recollect, the game &quot;Recollect&quot; is a working memory training game</td>
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<tr>
<td>Recollect is a video game which incorporates scientifically supported renditions of N-Back, Item Span, and Multiple-Identity tracking tasks. These tasks are independently shown to improve working memory in a manner that transfers to untrained tasks.</td>
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<td><strong>Sham Comparator: Tetris</strong></td>
<td>Other: Tetris App-based video game where shapes are rotated and placed to fit a grid</td>
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<tr>
<td>Tetris is a video game which has not been shown to have any benefits in the improvement of executive functioning.</td>
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**Outcome Measures**

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**Primary Outcome Measures**:  
1. **Change from baseline on The Behavioral Rating Inventory of Executive Functioning - Adult Version (BRIEF-A) [Time Frame: Change from baseline to week 4]**

   It is a validated, clinician-rated scale, measuring executive functioning. The scale includes 75 items that rates patient symptoms on a 3-point Likert scale (1 = behavior is never observed to 3 = behavior is often observed). Scores range from 75 to 225: Higher scores indicate greater impairment in executive functioning.
Secondary Outcome Measures:

1. Change from baseline on the Barkley Adult ADHD Rating Scale (BAARS-IV) [Time Frame: Change from baseline to week 4]
   
   Self-report scale evaluating ADHD symptoms. Symptom count scores range from 1 to 27, with higher scores indicating more ADHD symptoms. Total scores range from 27 to 108, with higher scores indicating greater severity of symptoms.

2. Change from baseline on an App-based neuro-cognitive battery [Time Frame: Change from baseline to week 4]
   
   A number of neuro-cognitive executive functioning tests, which will be administered via a smartphone application.

Eligibility Criteria

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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 and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Males and females aged 18 and older who own a mobile device such as a Smartphone or tablet.
3. Comorbid psychiatric conditions will be allowed.
4. Medication or psychotherapy must have been stable (no dose changes) for 4 weeks prior to study participation.
5. Must be able to read, write and understand English.

Exclusion Criteria:

1. Participant does not own a Smartphone or tablet.
2. No dose changes during the 4 week study period.
3. No initiation of new psychological therapy or counselling during the 4 week study period.

Contacts and Locations

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Information from the National Library of Medicine

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03437993

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Principal Investigator: Michael Van Ameringen, MD, FRCPC

Sponsors and Collaborators

McMaster University

Investigators

Principal Investigator: Michael Van Ameringen, MD, FRCPC  McMaster University

More Information

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Responsible Party: McMaster University
ClinicalTrials.gov Identifier: NCT03437993  History of Changes
Other Study ID Numbers: Recollect_ADHD
First Posted: February 19, 2018  Key Record Dates
Last Update Posted: February 19, 2018
Last Verified: February 2018

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

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

Keywords provided by McMaster University:
ADHD
executive functioning
game