ISRCTN17244156 https://doi.org/10.1186/ISRCTN17244156

A randomised controlled trial of a custom-developed computer game to improve executive functioning in 4- to 6-year-old children exposed to alcohol in utero

Submission date
31/05/2018

Recruitment status
No longer recruiting

Registration date
12/06/2018

Overall study status
Completed

Last Edited
10/06/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 26/03/2019:
Background and study aims
Alcohol exposure during pregnancy negatively affects a baby's brain development. It can also lead to Fetal Alcohol Spectrum Disorders (FASD). The aim of this study is to see if it is possible to improve the brain development of children exposed to alcohol by using a computer game specifically designed to do this.

Who can participate?
Children between 4 and 6 years old who were exposed to alcohol during pregnancy, and a group of unexposed children

What does the study involve?
Alcohol-exposed children are randomly allocated to one of two groups. One group of children are given the opportunity to play the game twice a week for 6 months. The other group and the unexposed children receive no intervention. All participants receive psychological assessments.

What are the possible benefits and risks of participating?
Children in the intervention group may improve their brain functioning over the course of the intervention. They also receive two psychological assessments, and the results are shared with their parents to help them assist the child with any identified problems. The other two groups also receive the assessments and their parents also receive the information. They do not directly benefit from the intervention however. No significant risks are expected. There is a risk of stigmatisation of the mothers and children in an already marginalised/vulnerable population. The inclusion criteria are kept confidential to ensure no one outside of the study will be able to identify which participants were exposed to alcohol.

Where is the study run from?
FARR West Coast (South Africa)

When is the study starting and how long is it expected to run for?
February 2018 to October 2019

Who is funding the study?
The study is being funded by the Aware.org, a registered non-profit organisation in South Africa

Who is the main contact?
Mr Jaco Louw

Previous plain English summary:
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Mr Jaco Louw

Contact information

Type(s)
Scientific

Contact name
Mr Jaco Louw

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South Africa
7535

Additional identifiers

Protocol serial number
N16/05/063

Study information

Scientific Title
A randomised controlled trial of a custom-developed computer game to improve executive functioning in 4- to 6-year-old children exposed to alcohol in utero

Study objectives
Primary:
1. At baseline alcohol exposed children (both intervention and control groups) will perform significantly worse on psychometric assessments than unexposed children
2. Post intervention the Intervention group will score higher on psychometric assessment domains than the control group, but lower than the normative group
3. Post intervention the Intervention group will show greater improvement in psychometric assessment domains than the control and intervention groups

Secondary:
1. Improvement in game performance will be correlated with improvement in psychometric assessment scores

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Ethics Committee at Stellenbosch University, 18/08/2016, ref: N16/05/063

Primary study design
Interventional

Study design
Single-center randomised control trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Fetal Alcohol Spectrum Disorder (FASD)

Interventions
There will be three groups recruited from Early Childhood Development (ECD) centers in the study area. There will be an intervention group of alcohol exposed children (40 participants), a control group of alcohol exposed children (40 participants) and a group of unexposed children to provide normative data (40 participants).

The alcohol exposed children will be identified through maternal interviews with the mothers of children in the ECD centers. If alcohol use during pregnancy is confirmed they will be allocated to either the control group or the intervention group using block randomization. Sampling will continue until 40 participants have been randomized into each group. After these groups have been filled 40 participants will be randomly selected from the non-alcohol exposed children to make up a normative group.

All three groups will receive baseline assessments looking at cognitive function.

The intervention group will play a custom developed computer game 2 times a week for six months. The game has been designed to tax executive functions and improve them through training. The game sessions will be overseen by a community worker and will take place at the ECD centers the participants were recruited from.

There will be no intervention/treatment given to the control and normative groups.

All three groups will receive post-intervention assessments.

Intervention Type
Other

Primary outcome(s)
NEPSY II psychometric assessment at baseline and post-intervention (roughly 6 months later)

Key secondary outcome(s)
Performance in game tracked by game logs post intervention

Completion date
30/10/2019

Eligibility

Key inclusion criteria
To be included in the intervention or control group particpants must be between 4 and 6 years old. There must also be documented exposure to alcohol in utero. Based on the maternal interview a mother must confirm using 3 or more standard units of alcohol at least once during pregnancy.

To be included in the normative group children must be between 4 and 6 years old, and there should no documented exposure to alcohol in utero.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
All

Total final enrolment
116

Key exclusion criteria
Children with a physical disability which will hamper their interaction with the program will be excluded, for example severe problems with sight

Date of first enrolment
01/04/2018

Date of final enrolment
09/11/2018

Locations

Countries of recruitment
South Africa

Study participating centre
FARR West Coast
Cnr. Church & Main Rd
Vredenburg
South Africa
7380

Sponsor information

Organisation
Foundation for Alcohol Related Research

Funder(s)

Funder type
Other

Funder Name
Aware.org

Funder Name
PAAIR

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/10/2019	10/10/2019	Yes	No
Preprint results	non-peer-reviewed results	16/03/2021	10/06/2021	No	No