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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# Contact information

**Type(s)**
Scientific

**Contact name**
Mr Jaco Louw

**ORCID ID**
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**Contact details**
42 Bloemhof Road
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Cape Town
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

**Study design**
Single-center randomised control trial

**Primary study design**
Interventional

### 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 |