

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/06/2021	Condition category Other	<input type="checkbox"/> 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

ORCID ID

<http://orcid.org/0000-0001-7812-2524>

Contact details

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Belville
Cape Town
South Africa
7535

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

Performance in game tracked by game logs post intervention

Overall study start date

01/02/2018

Completion date

30/10/2019

Eligibility

Key inclusion criteria

To be included in the intervention or control group participants 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

Age group

Child

Lower age limit

4 Years

Upper age limit

6 Years

Sex

Both

Target number of participants

Total of 120 children: intervention group 40; control group 40; normative group 40

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

Sponsor details

42 Bloemhof Road

Belville

Cape Town

South Africa

7535

+27 (0)216862646

info@farrsa.org.za

Sponsor type

Research organisation

Website

www.farrsa.org.za

Funder(s)

Funder type

Other

Funder Name

Aware.org

Funder Name
PAAIR

Results and Publications

Publication and dissemination plan

1. Effectiveness of a custom developed computer game to improve executive functioning in 4 to 6-year-old children exposed to alcohol in utero: Study protocol for a randomised control trial. This article will be submitted to the journal Trials by October 2018
2. Maternal risk factors for alcohol exposed pregnancies in a South African community. This article will be submitted to the journal Alcoholism Clinical and Experimental Research by October 2019
3. Executive functioning in prenatally alcohol exposed children in a South African population. This article will be submitted to the journal Child Neuropsychology by October 2019
4. Comparing performance in a cognitive training game to NEPSY II scores in children with FASD. This article will be submitted to Games for Health by October 2019
5. Computer based cognitive training programme for FASD. Comparing pre and post intervention NEPSY II scores of prenatally alcohol exposed children. This article will be submitted to Child Neuropsychology by October 2019
6. Performance of prenatally alcohol exposed children in a cognitive training game: A factor analysis. This article will be submitted to the journal Games for Health by October 2019

Intention to publish date

01/04/2021

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