Traumatized youths in residential care: Exploring the dysregulation of biological stress systems and testing a gamified relaxation intervention.

Published: 15-11-2017
Last updated: 14-04-2024

Study I aims to explore dysregulation of biological stress systems among traumatized youths with and without ID in residential care, and compare them with a healthy control group. Study II aims to conduct a randomized controlled trial (RCT) to test...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43297

Source
ToetsingOnline

Brief title
Traumatized youths in residential care.

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

Synonym
trauma; cardiovascular activity; cortisol activity

Health condition

autonomic nervous system activity; hypothalamic-pituitary-adrenal system activity

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Pluryn;Couvee fonds;Innovatiefonds

Intervention

Keyword: biological stress systems, gamified interventions, residential care, trauma

Outcome measures

Primary outcome

The focus of this project is on the one hand on the parameters of the HPA axis

(i.e. cortisol) and ANS activity (i.e. RSA and PEP), both under resting and

social stress conditions. On the other hand, we focus on posttraumatic

symptoms, stress, depression, anxiety, and aggression.

Secondary outcome

nvt

Study description

Background summary

Many youths in residential institutions have posttraumatic symptoms that interfere with their development and functioning, but that remain untreated. Their traumatic experiences may have resulted in alterations of their biological stress systems (i.e. the hypothalamic-pituitary-adrenal [HPA] axis and autonomic nervous system [ANS] activity) that are likely to play a role in the development and maintenance of psychological and behavioural problems.

Study objective

Study I aims to explore dysregulation of biological stress systems among traumatized youths with and without ID in residential care, and compare them with a healthy control group. Study II aims to conduct a randomized controlled

trial (RCT) to test the effectiveness of a gamified relaxation intervention on posttraumatic symptoms, stress, and biological stress systems.

Study design

This project consists of (study I) a cross-sectional study to examine biological stress systems among traumatized youths with and without ID, and healthy controls, and (study II) a RCT with treatment as usual (TAU) as a control group.

Intervention

The intervention consists of twee biweekly 15-minute sessions during which participants in the experimental condition play Muse. Participants in the control condition receive TAU; the kind of treatment that is normally being delivered in their situation.

Study burden and risks

The study comprises several assessments: questionnaires, psychophysiological tasks, saliva and hair collection. There are no risks associated with participation.

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525 HR
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525 HR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Both clinical and control sample:
- age between 10 and 18 years
- being able to speak the Dutch language, to ensure that participants can understand the task instructions and questionnaires, are able to give informed consent or assent, and can participate in the diagnostic interview;Clinical sample:
- admitted to residential treatment within youth mental health care, the youth welfare system or care for youth with intellectual disability (ID)
- score of 30 or higher on the CRIES-13, a questionnaire to screen for posttraumatic symptoms

Exclusion criteria

Both clinical and control sample:
- current or recent (within the last 3 months) EMDR or CBT treatment specifically targeting post-traumatic symptoms
- simultaneous participation in another clinical intervention study
- psychotic symptoms
- negative clinician advice, for example the clinician fears that participation in the study would have negative effects on the participant or that the participants has not the capacities to take part in the study (we have no exclusion criteria based on IQ, to promote external generalizability);Control sample:
- presence of any Axis I disorder
- current or recent (withing the last 3 months) psychological treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2018
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58674.091.16