Traumatized Youths in Residential Care: Exploring the Dysregulation of Biological Stress Systems and Testing a Gameful Relaxation Intervention to Normalize These Stress Systems.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28675

Source
Nationaal Trial Register

Brief title
Traumatized Youths in Residential Care

Health condition

adolescents, ANS, biological stress system, cortisol, gameful intervention, HPA-axis, neurofeedback, posttraumatic symptoms, residential care, serious game, stress, trauma.

Sponsors and support

Primary sponsor: Pluryn, Research & Development
Radboud University Nijmegen
VU Medical Center Amsterdam
Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: Dr. Couvee Fonds
Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

• Posttraumatic symptoms (self- and mentor-report)

• Stress (self-report)

Secondary outcome

• HPA-axis activity:

o Cortisol reactivity to a stress-inducing task, measured with salivary cortisol samples

o Resting cortisol, measured with HCC

• ANS activity:

The ANS consist of a dynamic interplay of sympathetic and parasympathetic activity, thus, we will not only measure RSA, but also other ANS parameters, both resting levels and reactivity to a stress-inducing task.

o RSA (parasympathetic activity)

o Pre-ejection period (PEP; sympathetic activity)

o Heart rate (HR; sympathetic and parasympathetic activity)

o Hearth rate variability parameters (HRV; sympathetic and parasympathetic activity)

o Skin conductance levels (SCL; mainly sympathetic activity)

o Skin conductance response (SCR; mainly sympathetic)

• Psychopathology:

o Depression (self-report)

o Anxiety (self-report)

o Aggression (self- and mentor-report)

o Executive functioning (mentor-report)

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 behavioral problems.

This RCT aims to test the effectiveness of Muse on posttraumatic symptoms, stress, and biological stress reactivity. It is hypothesized that Muse is effective in decreasing posttraumatic symptoms and stress (primary outcomes), as well as in normalizing dysregulated biological stress systems and reducing depression, anxiety, and aggression (secondary outcomes).

Participants are adolescents (age 10-18 years) with clinical levels of posttraumatic symptoms (n =80). The intervention consists of twelve biweekly 15-minute sessions during which participants in the experimental condition play Muse, a relaxation video game intervention. Participants in the control condition receive TAU; the kind of treatment that is normally being delivered in their situation.

Study objective

This RCT aims to test the effectiveness of Muse on posttraumatic symptoms, stress, and biological stress reactivity. It is hypothesized that Muse is effective in decreasing posttraumatic symptoms and stress (primary outcomes), as well as in normalizing dysregulated biological stress systems and reducing depression, anxiety, and aggression (secondary outcomes).

Study design

T1: Baseline measurement (week 1)

T2: Posttreatment measurement (week 8)

FU: Follow-up measurement (week 20)

Intervention

Muse (developed by InteraXon, Toronto, Canada) is a gameful meditation app that is played on an Ipad. Muse provides 17 tutorials teaching relaxation techniques. The relaxation tutorials resemble elements of cognitive-behavioral therapy (e.g., deep-breathing techniques; Weisz & Kazdin, 2010). Each tutorial is followed by a short meditation session during which players are provided with real-time neurofeedback on their level of calmness. The brain-sensing headband converts brain activity to gradations in the nature environment that is shown on the device. When the players' mind is calm, the environment shows calm and settled wind, but when the players' mind becomes active the winds will pick up and blow.

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Contacts

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Eligibility criteria

Inclusion criteria

• Age between 10 and 18 years.

• Being able to speak the Dutch language, to ensure that participants are able to give informed consent and understand the questionnaire administered in the interview and task instructions.

• Admitted to residential treatment within youth mental health care, the youth welfare system, or care for youth with ID.

• CRIES-13 score of 30 or higher at T0.

Exclusion criteria

• 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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-12-2017
Application type:	First submission

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
NTR-new	NL6689
NTR-old	NTR6859
Other	CMO Regio Arnhem-Nijmegen : 2016-2696

Study results