Improving self-esteem in traumatized youth: a transdiagnostic ecological momentary intervention trial (SELFIE)

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

Summary

ID

NL-OMON52597

Source
ToetsingOnline

Brief title
SELFIE

Condition

- Other condition

Synonym
mental health problems; childhood adversity

Health condition

transdiagnostic study population, i.e., all youth exposed to childhood trauma)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: EMI, ESM, youth

Outcome measures

Primary outcome

Primary outcomes will be the level of self-esteem as measured with Ecological Momentary Assessment using the PsyMate® App, the Rosenberg Self-Esteem Scale, and semi-structured interviews.

Secondary outcome

Secondary outcomes will be implicit self-esteem, positive and negative schematic beliefs of self, resilience, self-compassion, emotional well-being, general psychopathology, functioning, and quality of life. Given that exposure to trauma and response to treatment may be reflected at the biological level in distinct epigenetic signatures, levels of DNA methylation in NR3C1 (i.e. glucocorticoid receptor 1 gene) and SLCA4 (i.e. the serotonin transporter gene) will be measured using targeted sequencing.

Study description

Background summary

The majority of mental disorders first emerge in youth and, as such, contribute substantially to disease burden. Three quarters of adult mental disorders emerge before the age of 25, and 50% before the age of 16. This onset phase disrupts critical age-specific developmental, interpersonal, occupational and educational milestones and indicates a need for close scrutiny of the complex

interplay between risk and protective factors in childhood, and the value of a preventive intervention to improve well-being, enhance resilience and prevent morbidity later in life. Evidence has accrued linking childhood trauma as a major risk factor, with a range of mental disorders via pathways through self-esteem. Therefore, targeting low self-esteem in youth exposed to childhood trauma is a promising strategy for preventing adult mental disorder, but our current psychological help strategies remain difficult to access and accept for youth, calling for novel, youth-friendly approaches. The recent rapid advances in information and communication technologies have led to the development of mobile Health (mHealth) and, most prominently, ecological momentary interventions (EMIs), which provide a unique opportunity to deliver youth-friendly, personalized, real-time, guided self-help interventions.

Study objective

The overall aim of the current study is to investigate the efficacy of a novel, accessible, transdiagnostic ecological momentary intervention for improving self-esteem (*SELFIE*) and examine underlying epigenetic mechanisms in youth with prior exposure to childhood trauma.

Study design

In an exploratory randomized controlled trial with two conditions, participants will be randomly allocated to i) the SELFIE intervention in addition to treatment as usual (TAU) (experimental condition) or ii) TAU only (control condition). Participants who received the SELFIE-intervention will be asked by the contact person of the site to partake in a single interview for qualitative data collection. If so, a separate appointment will be made for the one-hour interview.

Intervention

Participants allocated to the experimental condition will receive the manualised SELFIE with a trained clinical psychologist within a 6-week period after randomization in addition to TAU. The intervention will consist of three to four sessions with a trained clinical psychologist, on-demand e-mail contact, and the SELFIE using a guided self-help approach administered through a smartphone-based PsyMate® App to allow for interactive, personalized, real-time and real-world transfer of intervention components in individuals* daily lives.

Study burden and risks

There are no health-risks associated with participation. The total time investment for participation during the intervention period depends on group relatedness. There will be five assessments of our main study parameters using

clinical interviews, questionnaires and six-day EMA periods. These measurements will be equal for all groups and require a time investment for each participant of approximately 18-20 hours hours for all assessments over a period of 2 years and 2 months. Given that all participants are expected to benefit from participation, the burden is deemed to be justifiable. Participants randomised in the SELFIE group will receive in addition 3 therapeutic sessions of 45-60 minutes and are expected to practice SELFIE exercises using the PsyMate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1. Aged between 12 and 26 years
2. Score on questionnaires:

* RSES <26
* CTQ of:
- Emotional abuse * 13
- Physical abuse * 10
- Sexual abuse * 8
- Physical neglect * 10
- Emotional neglect * 15
* and/or RBQ score of:
- Reported being bullied "sometimes", "frequently" or "constantly" and/or
- Classified the experience as *quite serious* or *extremely serious"
* and/or CECA (parental conflict) score of:
- Frequency score of "regularly" or "often" and/or
- Severity score of *serious* or *violent"
3. Willingness to participate in the SELFIE intervention
4. Ability to give written informed consent (parental consent in case of <16 years)

Exclusion criteria

1. Insufficient command of Dutch so that the self-esteem EMI cannot be followed and outcomes cannot be reasonably assessed in Dutch
2. Psychiatric symptoms due to an organic cause

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2018

Enrollment:	174
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-10-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28387
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64393.068.17
OMON	NL-OMON28387