SELFIE: Een nieuwe smartphone gestuurde zelfhulp interventie om zelfbeeld te verhogen in jongeren die tijdens de jeugd ingrijpende gebeurtenissen hebben meegemaakt.

No registrations found.

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

Summary

ID

NL-OMON28387

Source
Nationaal Trial Register

Brief title
SELFIE

Health condition

self-esteem, mental health, childhood trauma, trauma, youth, adolescence, young adulthood, mHealth, ecological momentary intervention, EMI, experience sampling methodology, ESM, randomized controlled trial, RCT

Sponsors and support

Primary sponsor: Maastricht University, Department of Psychiatry and Neuropsychology
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The primary outcome for the efficacy of the new SELFIE intervention will be the level of self-esteem as measured with the RSES and ESM

Secondary outcome

The secondary study parameters will be positive, negative and implicit self-esteem, positive and negative schematic beliefs of self, resilience, emotional well-being, appraisal of emotions, general psychopathology, functioning, quality of life, incidence of clinical symptoms, health-related quality of life, and service use and cost measured with ESM and other validated measures

Study description

Background summary

Background: The majority of mental disorders first emerge in youth and, as such, contribute substantially to disease burden. Three quarters of 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.

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’) 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).

Study population: Youth aged 12-26 with prior exposure to childhood trauma will be recruited and assessed over a study period of 4 years.

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

Primary study parameters/outcome: Primary outcomes will be the level of self-esteem as measured with the RSES and ESM.

Secondary study parameters/outcomes: Secondary outcomes will be will be positive, negative and implicit self-esteem, positive and negative schematic beliefs of self, resilience, emotional well-being, appraisal of emotions, general psychopathology, functioning, quality of life, incidence of clinical symptoms, health-related quality of life, and service use and cost measured with ESM and other validated measures.

Study objective

It is hypothesized that, compared with the control condition (treatment-as-usual (TAU)), levels of self-esteem measured with the Rosenberg Self-Esteem Scale (RSES) and Experience Sampling Methodology (ESM) will be greater in the experimental condition (SELFIE intervention +TAU) at post-intervention, 6-month, 18-month and 2-year follow-up, while controlling for levels of self-esteem at baseline.

Study design

- Pre-intervention measurement: T0

- Post-intervention measurement: T1

- 6-month follow-up : T2

- 18-month follow-up : T3

- 24-month follow-up: T4

Intervention

Participants allocated to the experimental condition will receive the manualized SELFIE intervention within a 6-week period in addition to treatment-as-usual (TAU). The intervention will consist of three to four sessions with a trained clinical psychologist, on-demand e-mail

contact, and the SELFIE App using a guided self-help approach administered through a smartphone to allow for interactive, personalized, real-time and real-world transfer of intervention components in individuals' daily lives.

Participants allocated to the control condition will receive TAU only.

Contacts

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Scientific
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Eligibility criteria

Inclusion criteria

• Aged between 12 and 26 years

• Prior exposure to childhood trauma (measured with CTQ, RBQ, and/or CECA (section Parenal Conflict)

• Self-esteem below average (measured with RSES)

• Willingness to participate in the SELFIE intervention

• Ability to give written informed consent

• Parental consent for minors

Exclusion criteria

• Insufficient command of Dutch

• Severe endocrine, cardiovascular or brain disease

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	174
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52597
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7129
NTR-old	NTR7475
CCMO	NL64393.068.17
OMON	NL-OMON52597

Study results

Summary results
N/A