An ecological momentary compassion-focused intervention for enhancing resilience in help-seeking youths

Published: 12-10-2017
Last updated: 11-04-2024

The overall aim of the current study is to investigate the efficacy and clinical feasibility of a novel, accessible, transdiagnostic, ecological momentary, compassion-focused intervention for improving emotional resilience to stress (*EMOCOMPASS*)...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45680

Source
ToetsingOnline

Brief title
EMOCOMPASS

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
psychotic symptoms, psychotic-like experiences

Health condition

angst en depressieve symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Mondriaan Zorggroep (Heerlen)
Source(s) of monetary or material Support: NWO

Intervention

Keyword: CFI, EMI, ESM, youth

Outcome measures

Primary outcome

Stress sensitivity, psychotic, anxiety and depressive symptoms measured with Ecological Momentary Assessment (EMA) and other validated measures will be the primary outcomes, which will be obtained before randomization (*baseline*), at the end of the 3-week intervention period (*post-intervention*), and after a 4-week and 10-week follow-up period (*follow-up*). Our primary hypothesis relates to endpoints at the end of treatment.

Secondary outcome

The secondary study parameters will be threat anticipation, appraisal of emotions, interpersonal sensitivity, and general psychopathology, measured with EMA and other validated measures. As the primary outcomes, secondary outcomes will be obtained before randomization (*baseline*), at the end of the 3-week intervention period (*post-intervention*), and after a 4-week and 10 week follow-up period (*follow-up*).

Study description

Background summary

Most mental disorders first emerge in youth and, as such, contribute

substantially to global disease burden. Therefore, interventions that aim to prevent mental health problems should be targeting youth. In recent years, this has become particularly evident for psychotic disorders. There is now increasing evidence that risk for psychotic disorder manifests already at a developmentally earlier stage in the form of subclinical psychotic experiences, which have been reported to be common among adolescents. Contemporary models of psychosis have proposed several psychological mechanisms that may contribute across different phenomenological and temporal stages to the development of psychosis. To date, the psychological mechanism most widely studied in daily life is elevated stress sensitivity, characterized by intense emotional reactions to minor stressors and routine daily hassles.
Recent research further suggests that subclinical psychotic experiences often co-occur with anxiety and depression, which may reflect a transdiagnostic phenotype associated with a range of subsequent psychopathological outcomes. Thus, screening for, and targeting the underlying mechanisms of, this transdiagnostic phenotype of psychosis, anxiety and/or depression in youth is a promising selective prevention strategy for preventing adverse outcomes later in life.
Psychological help, however, remains difficult to access for youth and has limited efficacy under real-world conditions, calling for novel approaches. The recent rapid technological advances provide a unique opportunity to deliver youth-friendly, accessible, personalized, real-time mobile health interventions, most prominently, ecological momentary interventions.

Study objective

The overall aim of the current study is to investigate the efficacy and clinical feasibility of a novel, accessible, transdiagnostic, ecological momentary, compassion-focused intervention for improving emotional resilience to stress (*EMOCOMPASS*) in an exploratory randomized controlled trial in help-seeking youth with psychotic symptoms and/or symptoms of common mental disorders (i.e., mood or anxiety disorders).

Study design

In an exploratory randomized controlled trial, youth aged 15-26 with psychotic, anxiety and/or depressive symptoms referred to Virenze, Mondriaan Maastricht and GGzE Eindhoven will be randomly allocated to the ecological momentary, compassion-focused intervention (EMOCOMPASS) in addition to treatment as usual (TAU) (experimental condition) or a control condition of TAU only over a study period of 2,5 years. Data will be collected before randomization (*baseline*), at the end of the 3-week intervention period (*post-intervention*), and after a 4-week and a 10-week follow-up period (*follow-up*).

Intervention

Participants in the experimental condition will receive the ecological momentary, compassion-focused intervention (EMOCOMPASS),which will consist of three face-to-face sessions (1 training session, 1 follow-up *booster* session 2 weeks later, and 1 review session at the end of the 3-week intervention period) with a trained psychologist (supervised by an expert clinical psychologist in compassion-focused therapy), on-demand e-mail/phone contact, and a 3-week compassion-focused ecological momentary intervention administered through an App on a dedicated electronic device to allow for interactive, 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 four assessments of our main study parameters using questionnaires and six-day ESM periods. These measurements will be equal for all groups and require a time investment of approximately 14 hours in total, divided over a period of 3,5 months. Given that all participants are expected to benefit from participation, the burden is deemed to be justifiable.
Participants randomised in the EMOCOMPASS group will receive in addition 3 therapeutic sessions of 15 minutes to 1 hour and are expected to practice EMOCOMPASS exercises daily under the guidance of the PsyMate.

Contacts

Public
Mondriaan Zorggroep (Heerlen)

John F. Kennedylaan 301
Heerlen 6419 XZ
NL
Scientific
Mondriaan Zorggroep (Heerlen)

John F. Kennedylaan 301
Heerlen 6419 XZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age from 15 until 26 years
2. Score of 6 or above on the PQ, a T-score of 63 or above on the BSI, and/or a score above the cutoff on the SQ-48 (i.e., on the social phobia (>9), depression (>8), or anxiety (>11) subscale)
3. Willingness to participate in the compassion-focused ecological momentary intervention
4. Ability to give written informed consent independently

Exclusion criteria

1. Insufficient command of Dutch so that the compassioned-focused ecological momentary intervention cannot be followed and outcomes cannot be reasonably assessed in Dutch
2. Clinical diagnosis of alcohol or substance dependency, severe endocrine, cardiovascular or organic brain disease

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	12-10-2017
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL60031.068.16