Pre-Intervention Monitoring of Affect and Relationships in Youth

Published: 15-07-2020
Last updated: 27-04-2024

Primary objectives:1) Investigate the effectivity of PRIMARY on BPD related problems (especially self-harm, emotion regulation and social relationships)Secondary objectives:1) Understanding the underlying mechanisms (especially social relationships...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON52385

Source
ToetsingOnline

Brief title
PRIMARY

Condition

- Personality disorders and disturbances in behaviour

Synonym
emotion regulation personality disorder, problems with affect

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Borderline personality disorder, Emotion regulation, Self-harm, Social relationships

Outcome measures

Primary outcome

(Thoughts about) Self-harm

Emotion regulation

Social relationships

Secondary outcome

Social relationships (support and conflict)

Emotions (positive and negative)

(thoughts about) self-harm

Quality of life

Usability of the online monitor

Satisfaction with PRIMARY

Study description

Background summary

Borderline personality disorder (BPD) is a disorder with serious symptoms as well as negative consequences in the long term, especially for mental health. Although the first symptoms of BPD usually develop during adolescence, therapists mainly diagnose patients with BPD in adulthood. For a long time, also research mainly focused on adulthood, but more research is now focusing on adolescents at risk for BPD as well. Besides, early intervention programs for this target group are rising. However, these programs are still limited, which means that many adolescents are on waiting lists for a suitable intervention. With our research project, we aim to test a new intervention (PRIMARY) for adolescents at risk for BPD. PRIMARY works through an online monitor and aims to help adolescents with BPD symptoms - while they are on the waiting list - to

gain more insight in their emotions and hazardous situations.

Study objective

Primary objectives:
1) Investigate the effectivity of PRIMARY on BPD related problems (especially self-harm, emotion regulation and social relationships)

Secondary objectives:
1) Understanding the underlying mechanisms (especially social relationships) of the development of BPD symptoms
2) Investigate the effect of PRIMARY on the treatment program called HYPE
3) Investigate the satisfaction with PRIMARY

Study design

The study is a randomized controlled trial (RCT) with control group. We use the Experience Sampling Method (ESM): patients fill out a short questionnaire on their smartphone 5 times a day, for 4 weeks long. Furthermore, they fill out questionnaires three times: at start (T1), at the end (T2) and a couple of weeks after PRIMARY (T3).

Intervention

PRIMARY is an online monitor which asks participants to register their emotions, social relationships and behavior (5 times a day, for 4 weeks). Once a week, a researcher discusses the data from the past week with the participant, using graphs. We expect that this enlarges the understanding of emotions, improves emotion regulation and social relationships, and diminishes self-harm.

Study burden and risks

The intervention group fills out a short questionnaire (2-3 minutes) 5 times a day, for 4 weeks. Once a week, they will have an appointment with a researcher to discuss the data on a secure online platform; this takes 15 minutes. The intervention* and control group fill out questionnaires three times (T1-T3), which takes 45-60 minutes each time. The risks associated with the research are negligible.

Contacts

Public
GGZ Centraal (Amersfoort)

Westsingel 41
Amersfoort 3811BB
NL
Scientific
GGZ Centraal (Amersfoort)

Westsingel 41
Amersfoort 3811BB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 12 and 25 years
- Sufficient skills in the Dutch language
- Self-harm in the past 4 weeks
- At risk for borderline personality disorder

Exclusion criteria

Not applicable.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2021
Enrollment:	158
Type:	Actual

Ethics review

Approved WMO Date:	15-07-2020
Application type:	First submission
Review commission:	METC NedMec
Not approved Date:	15-04-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-12-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-09-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-04-2024
Application type:	Amendment

Review commission: METC NedMec

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	NL73936.041.20