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The PRIMARY study: a study into the effectiveness of daily registration of emotions, social context, activities and weekly feedback for young people who self-harm

Submission date
10/10/2022

Recruitment status
No longer recruiting

Registration date
26/10/2022

Overall study status
Completed

Last Edited
02/12/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Self-harm is a major health concern and is associated with a higher risk of mental health problems. Self-harm comprises all intentional acts of self-poisoning or self-injury, irrespective of the type of motive one has for this behavior. Rates of self-harm in young people have been increasing over the past decade, with the age of onset often in early adolescence in females and late adolescence in males. Among adolescents who are receiving mental health care, prevalence rates of self-harm between 13 and 35% have been found. Repeated self-harm in this group has been connected to personality pathology, with over 60% of these adolescents meeting criteria for a personality disorder. Borderline personality disorder (BPD) has especially been linked to repetitive self-harm. BPD is a severe mental disorder characterized by instability in emotions and relationships, and is associated to persistent impairments in social and vocational functioning and even premature mortality. Besides the harmful effect of self-harm on its own, self-harm has also been posited as a risk marker for severe pathology such as BPD. Both self-harm and BPD represent core problems in emotion regulation. It is therefore perhaps not surprising that self-harm has been found as predictive of later BPD features.

Taken together, there is a need for early identification and treatment of young people who self-harm, especially given its association with psychopathology and BPD specifically. Thus far, there is little evidence for the effectiveness of interventions for young people who engage in self-harm. The current study aims to test the effectiveness of a smartphone-based short-term pre-intervention aimed at enhancing insight into the relationship between emotions, activities and social context in young people who self-harm. This in turn may lead to the termination of self-harm. The intervention was developed in collaboration with people with lived experience and designed as a pre-intervention to further treatment given the long waiting lists young people face. The intervention is called PRIMARY (an acronym for Pre-Intervention Monitoring Affect and Relationships in Youth) and entails an online monitor and brief structured weekly online feedback sessions. The online monitor asks participants five times a day, at varying times, to register their emotions, social contacts and activities. In combination with the feedback sessions,

the PRIMARY intervention intends to promote awareness and insight into emotion regulation, and thereby decrease the frequency of self-harm. By comparing young people who use PRIMARY to those who do not use this intervention (i.e. randomized controlled trial) the effectiveness of PRIMARY can be examined

Who can participate
Young people aged 12 – 25 years (inclusive) who were referred to GGz Centraal or Mondriaan (mental health institutions in The Netherlands) and have self-harmed at least once in the past year.

What does the study involve?
Participants are randomly allocated to either the intervention or control group. Both groups fill out a set of questionnaires at inclusion and after four weeks. The intervention group will use the PRIMARY intervention after inclusion. The PRIMARY intervention includes an online monitor, in which a person registers emotions, social contacts an activities, five times a day for four weeks. In addition, a researcher will provide feedback once a week via a structured protocol based on the online monitor. The control group will receive care as usual.

What are the possible benefits and risks of participating?
Participants in both groups will fill out questionnaires, the answers hereon can be used by their subsequent clinicians as there is a link to the patient care system. This can help with starting the diagnostic process and treatment. The intervention group (i.e., using the PRIMARY intervention) has the opportunity to enhance their insight into emotional processes. As the study takes place during the usual waiting period for the start of care within the institution, offering an intervention can be considered an improvement. The small burden of completing the questionnaires is reimbursed by immediately making the results available for clinical care. In addition, the research project donates 5 euros to a good cause (i.e., animal welfare or patient federation) after a participant completes the study. The participants gets to choose which of the two good causes the donation is given to. There are no risks involved with participation in the study.

Where is the study run from?
GGz Centraal HYPE, Centre of Expertise on Early Intervention for Borderline Personality Disorder, Amersfoort, The Netherlands.

When is the study starting and how long is it expected to run for?
September 2018 to October 2025

Who is funding the study?
ZonMw (The Netherlands)

Who is the main contact?
Dr Christel Hessels, c.hessels@ggzcentraal.nl

Contact information

Type(s)
Principal investigator

Contact name
Dr Christel Hessels

ORCID ID
https://orcid.org/0000-0002-1937-1085

Contact details
Westsingel 41
Amersfoort
Netherlands
3811BB
+31 0623436534
c.hessels@ggzcentraal.nl

Additional identifiers

Protocol serial number
636310013

Study information

Scientific Title
Pre-Intervention Monitoring of Affect and Relationships in Youth (PRIMARY): a Randomized Controlled Trial (RCT) into the effectiveness of an Ecological Sampling Method (ESM) intervention in combination with weekly feedback for young people who self-harm

Acronym
PRIMARY

Study objectives
1. The PRIMARY intervention (i.e., daily monitoring and weekly feedback on emotions, social context and activities) enhances emotion regulation in young people who self-harm (i.e., the PRIMARY intervention versus control group).
2. Early intervention for personality pathology will be more effective if the PRIMARY intervention was completed as a pre-intervention (i.e., the PRIMARY intervention versus control group).
3. Explore underlying mechanisms of personality pathology development (i.e., network analyses on Experience Sampling Method data).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/07/2020, Medical Ethical Board Utrecht Medical Centre (Heidelberglaan 100, 3584 CX Utrecht, the Netherlands;+31 88 75 56 376; metc@umcutrecht.nl), ref: NL73936.041.20.

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Self-harm

Interventions
A Randomized Controlled Trial (RCT) into the effectiveness of the PRIMARY intervention, an Experience Sampling Method (ESM) intervention in combination with weekly feedback for youth who self-harm. Youth aged 12 – 25 years (inclusive) referred to GGz Centraal (i.e., mental health institution in the Netherlands) are screened for eligibility for inclusion. If included, they are randomly assigned to either the intervention or control condition. The control condition entails a treatment-as-usual-condition. Blinding of researchers and participants was not possible given the design of the study. The study is multicenter.

The PRIMARY intervention comprises Experience Sampling Method (ESM) in combination with structured weekly feedback sessions. The ESM is conceptualized as part of the intervention as participants register their emotions, social contacts and activities five times a day for four weeks (i.e., total duration of treatment). Once a week, participants meet with a researcher to get a structured feedback report on their ESM responses over the past week. The control group receives treatment-as-usual, i.e., unstructured by the research protocol. Stratified block randomization is used to allocate participants to the intervention- or control condition with a 1:1 ratio, incorporating two age groups (i.e., 12 – 15 and ≥16 years).
Randomization commences via an employee who is not directly related to the research project. Both the PRIMARY intervention group and the control group fill out a set of questionnaires at inclusion and after four weeks. After this phase participants go on to receive the regular diagnostic procedures within the mental health institution. Participants who subsequently enter the HYPE treatment program (i.e., early intervention for personality pathology) fill out the set of questionnaires once more 10 weeks after start of HYPE.

Intervention Type
Behavioural

Primary outcome(s)
At baseline, 4 weeks, start of treatment, 10 weeks:
1. Self-harm: five questions concerning the frequency of self-harm, how often medical treatment was necessary after self-harm, age of onset of self-harm, Experience Sampling Method (ESM) question concerning self-harm since the last measurement point
2. Emotion regulation: 18-item version of the Difficulties in Emotion Regulation Scale (DERS; Gratz& Roemer, 2004)
3. Social relationships: 11-item version of the Network of Relationships Inventory-Behavior Systems Version (NRI-BSV; Furman & Buhrmester, 1985), Experience Sampling Method (ESM) question concerning current experience of support or conflict

Key secondary outcome(s))
At baseline, 4 weeks, start of treatment, 10 weeks:
1. Emotions: Experience Sampling Method (ESM) questions regarding positive (e.g., happy, energetic) and negative (e.g., sad, annoyed) emotions
2. Quality of life: short version of the Recovering Quality of Life (ReQoL; Van Aken, De Beurs, Mulder, Der Feltz-Cornelis, & Maria, 2020)
3. Usability of the online monitor: Usability Metric for User Experience (UMUX; Finstad, 2010)

4. Satisfaction with the PRIMARY intervention: Client Satisfaction Questionnaire-4 (CSQ-4; Attkisson & Greenfield, 1995)
5. Psychopathology: a Dutch extension of the Strengths and Difficulties Questionnaire; Screeningsinstrument Psychische stoornissen (SPSY; Goodman, 1997), and the Depression Anxiety Stress Scales (DASS-21; Antony, Bieling, Cox, Enns, & Swinson, 1998)
6. Personality functioning: SCID-II Screener BPD section (Arntz, Kamphuis, & Derks, 2017), Borderline Symptom List – behavioural items (BSL), Personality Inventory for DSM-5 – Brief form (PID-5-BF; Anderson, Sellbom, & Salekin, 2018), Levels of Personalitiy Functioning Scale 2.0 (LPFS-BF 2.0; Hutsebaut, Feenstra, & Kamphuis, 2016)
7. Life experiences: Life Experiences Survey (LES; Sarason, Johnson, & Sieg, 1978)
8. Impulsivity: Short version of the UPPS Impulsive Behavior Scale (S-UPPS; Whiteside & Lynam, 2001)
9. Loneliness: De Jong Gierveld Schaal (De Jong Gierveld & Van Tilburg, 2006)
10. Impact of corona-restrictions: six items regarding the restrictions in the past week
11. Developmental stage: Developmental Tasks Questionnaire (Laceulle et al., in progress)

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Age 12 – 25 years (inclusive)
2. ≥1 act of self-harm in the past year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
25 years

Sex
All

Key exclusion criteria
1. Insufficient Dutch language skills

Date of first enrolment
28/09/2021

Date of final enrolment

07/11/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
GGz Centraal
Westsingel 41
Amersfoort
Netherlands
3811BB

Study participating centre
Mondriaan Team Transitiepsychiatrie
John F. Kennedylaan 301
Heerlen
Netherlands
6419 XZ

Sponsor information

Organisation
GGz centraal

ROR
https://ror.org/01m0gv380

Funder(s)

Funder type
Government

Funder Name
ZonMw, The Netherlands Organisation for Health Research and Development

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from (please provide name and email, type of data, when the data will become available and for how long, by what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism, whether consent from participants was obtained, comments on data anonymisation, any ethical or legal restrictions, any other comments).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/11/2023	16/11/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes