

Promoting Resilience in Youth through Mindfulness mEditation

Published: 10-01-2023

Last updated: 18-01-2025

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON53899

Source

ToetsingOnline

Brief title

PRYME

Condition

- Psychiatric disorders NEC

Synonym

Internalising problems, psychological distress

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: internalising problems, mindfulness, self-referential processing, youth

Outcome measures

Primary outcome

Total internalizing problems as measured using the Adult Self Report (ASR) is the primary outcome variable.

Secondary outcome

In a clinical interview, participants will be screened for DSM-5 diagnoses using the Mini International Neuropsychiatric Interview - Screen for DSM-5 (MINI-S-DSM-5). Mindfulness skills will be measured using The Five Facets of Mindfulness Questionnaire - short form (FFMQ - SF) and self-compassion will be measured using the Self-Compassion Scale (SCS). Overall mental well-being will be measured using the Mental Health Continuum - short form (MHC-SF). Rumination will be measured using the Rumination-Reflection Questionnaire (RRQ) - Brooding subscale. Stress levels will be measured using the Perceived Stress Scale - 10 item (PSS-10). Resilience will be measured using the Connors-Davidson Resilience Scale (CD-RISC). Self-esteem will be measured using the Rosenberg Self Esteem Scale (RSES). Adaptive self-concepts will be measured using the Adaptive Self-Concepts Questionnaire (ASCQ). Experiential avoidance will be measured using the Acceptance and Action Questionnaire (AAQ-II).

Demographic data will be collected and the degree to which people adhere to the training curriculum (and continue mindfulness practice after completing the training) will be recorded using the Mindfulness Adherence Questionnaire (MAQ).

In addition, a number of experimental tasks will be administered inside and outside of the MRI scanner. The Self-Referent Encoding Task (SRET), which measures biases in positive and negative self-related information processing, will be performed in the scanner. An escape and avoidance task designed to measure automatic avoidance behaviours will be performed outside the scanner. In addition, participants have the option to perform an online Pavlovian to Instrumental Transfer (PIT) task and controllability task (CBU).

Study description

Background summary

The majority of mental illnesses (75%) emerge before the age of 25 and many have a life-long impact on (mental) health and psychosocial functioning. Early intervention is crucial to improve outcomes and prevent long-term chronicity. The early stage of (serious) mental illness is typically characterized by mild, non-specific complaints such as anxiety, worrying, low mood, and social withdrawal. These *internalizing problems* are increasingly common in youth and associated with various adverse outcomes. Early intervention in help-seeking youth may slow or prevent these early complaints from progressing into a psychiatric disorder.

Mindfulness-based interventions (MBIs) have been proven effective in a range of mental illnesses including internalizing disorders (i.e., anxiety and depression). MBIs employ a variety of techniques designed to focus and maintain attention on present-moment experience in a non-judgmental way. The deliberate focusing of attention on thoughts, emotions, and bodily sensations in the present moment, while not clinging to their content or valence, allows people to experience their internal experiences in a new way: as transient mental phenomena rather than reflections of absolute reality. This process of decentering - a stepping back from mental experience - may increase awareness of automatic patterns including fixed or schematized narratives about the self and the world. This process may counteract negativity biases in self-referential processing.

Self-related information is processed by brain regions in the cortical midline comprising the Default Mode Network (DMN). Hyperactivity of the DMN during self-referential processing and rumination has been shown in various

psychiatric disorders. Research has shown that mindfulness meditation reduces the activity of the DMN during self-referential processing. Mindfulness training may thus normalize the underlying deficits in self-referential processing and thereby reduce risk for mental illness development

Study objective

The aim of this study is to determine if mindfulness-based early intervention reduces internalizing symptoms in help-seeking youth and prevents their development into (serious) psychiatric illnesses. In addition we will examine putative changes in self-referential processing and associated brain regions.

Study design

The Promoting Resilience in Youth through Mindfulness mEditation (PRYME) study is a Randomized Controlled Trial (RCT) that compares care as usual (e.g., supportive counseling by a student psychologist or mental health nurse-practitioner) with care-as-usual + mindfulness training. Participants will be randomized to one of the two groups. Data is collected at baseline, after the mindfulness training, at 2 months follow-up and at 6 months follow-up. Multiple measurements will be conducted using questionnaires, experimental tasks, and MRI scans. The aim is to include approximately 150 youth in this study.

Intervention

We will offer a mindfulness training program designed specifically for youth with internalizing problems. The Learning to Offset Stress (LOS) (in Dutch: Leren Omgaan met Stress) training program consists of a standard protocol based on mindfulness based cognitive therapy (MBCT) combined with mindful physical activity and yoga exercises. The 8-week training consists of weekly 2-hour sessions and daily home practice. The 8th session will signify the end of the training. After this last session participants are encouraged to continue home self-practice. After 8 weeks a 2 hour booster session is provided to reinforce mindfulness skills and to trouble-shoot with participants who experience problems with their practice. The control group will receive treatment as usual, mostly consisting of supportive counseling. When the study ends they will be offered to participate in the mindfulness training.

Study burden and risks

The risks and discomfort associated with participating in this study are estimated as low. Mindfulness training is acceptable and well-tolerated by youth and adults and shows no harmful effects. The burden mainly constitutes repeated assessments, including a diagnostic interview, questionnaires and experimental tasks. In addition, two MRI scans will be performed. MRI is a safe

and non-invasive technique. Participants may experience some discomfort as a result of lying down in a confined and noisy space. Therefore, we provide ear protection and participants are screened for claustrophobia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Inclusion criteria

1. Youth between 16 and 25 years of age
2. Provide written informed consent
3. Adequate mastery of Dutch language

Exclusion criteria

1. Lifetime diagnosis of severe major depression, bipolar disorder, schizophrenia spectrum disorder, personality disorder, and post-traumatic stress disorder
2. History of major medical illness or neurological illness
3. Participation in a mindfulness programme in the past year
4. Current participation in another intervention study
5. Contraindications for MRI scanning (e.g., ferrous objects in or around the body including braces, metal fragments, pace-maker, claustrophobia, body weight > 250kg)
6. Moderate to severe substance use disorders (i.e., we will allow for mild substance use)
7. Current active suicidality, current psychotic symptoms above clinical cut-off for psychosis, or current trauma-related complaints above clinical cut-off for PTSD.
8. Diagnosed or suspected (mild) intellectual disability (estimated IQ < 75)

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:	Recruiting
Start date (anticipated):	07-07-2023
Enrollment:	155
Type:	Actual

Ethics review

Approved WMO

Date:	10-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	22-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	26-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	12-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL82568.091.22