The additive effect of Imaginary Rescripting for treating depressive symptoms in childhood trauma related depression in adolescence: A multiple baseline study among 15 adolescents

Published: 02-05-2023
Last updated: 13-05-2024

The primary goal is to investigate the effectiveness of Imagery Rescripting as an add-on intervention to care as usual (CAU) for treating clinical symptoms of depression of 15 adolescents who have been exposed to childhood trauma. The secondary…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON53322

Source
ToetsingOnline

Brief title
ImRs as add-on treatment for depressed adolescents with childhood trauma

Condition

- Mood disorders and disturbances NEC

Synonym
Major Depressive Disorder; Depression; Childhood Trauma

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)
Source(s) of monetary or material Support: GGZ Oost Brabant

Intervention

Keyword: Adolescence, Childhood trauma, Depression, Imagery Rescripting

Outcome measures

Primary outcome

The primary outcome measure is defined as depression symptom severity measured with the self-report PHQ-9 three times a week during all phases and measured with the IDS-SR at four time points: before phase A1, between phase A1 and phase B, between phase B and phase A2, and after phase A2.

Secondary outcome

Secondary outcome measures are depression diagnosis and PTSD-diagnosis assessed with a structured interview held at the start and at the end of the study. The level of distressing mental images, suicidal ideation, post-traumatic stress symptoms, resilience are measured at the four time points as described above.

Study description

Background summary

Depression in adolescence is a major mental health concern. Childhood trauma (CT) is a well-established risk factor for poor (mental) health and, more specifically, depression. Results indicate that CAU for depression is insufficient for treating patients with depression who have been exposed to childood trauma (c.q. childhood trauma related depression). This might suggest that childhood trauma related depression asks for additional treatment. Imagery Rescripting seems to be promising. In Imagery Rescripting negative childhood memories are edited via imagination by rescripting them into a more benign image, for example, by sending the patient*s alter ego in the image to comfort

or defend oneself as a child. Imagery Rescripting is already proven to be an effective psychotherapeutic technique for a broad range of psychiatric disorders in adults. There is some evidence for the effectiveness in treating depressive disorder among adults. However, literature is scarce, especially for adolescents.

Study objective

The primary goal is to investigate the effectiveness of Imagery Rescripting as an add-on intervention to care as usual (CAU) for treating clinical symptoms of depression of 15 adolescents who have been exposed to childhood trauma. The secondary objective is to examine other clinical outcomes related to Imagery Rescripting.

Study design

A Nonconcurrent Multiple-Baseline design with three within-series conditions (phase A1, phase B and phase A2) and a randomization of units in staggered intervention introductions will be used.

Intervention

During all three phases participants will receive CAU, weekly sessions (60 minutes) according to the Multidisciplinary Guidelines for Depression - Addendum Youth. During phase B (intervention phase) the Imagery Rescripting will be added and the effect will be investigated. Participants will receive 6 to 10 weekly sessions (90 minutes) of Imagery Rescripting with a focus on processing childhood trauma related memories.

Study burden and risks

Imagery Rescripting is already proven to be an effective and safe treatment technique in treating a broad range of psychiatric disorders. Participation may be beneficial for patients, since they will receive an add-on intervention with Imagery Rescripting that seems to be a promising technique for treating childhood truama related depression.
The potential burden for patients is that they are asked to participate in data collection by regularly filling in a short online self-report questionnaire (three times a week), by filling in a set of online self-report questionnaires at four time points and by a face-to-face interview held at the start and the end of the study. Despite that the study population concerns a vulnerable group of adolescents with clinical levels of depressive symptoms and possibly suicidal ideation, we are convinced that the risks associated with participants are minimal. Participation is embedded in a specialized mental health care institution where (suicide) risk assessment and management is standard practice

of care.

Contacts

Public
GGZ Oost Brabant (Rosmalen)

Gezondheislaan 65
Oss 5432JW
NL
Scientific
GGZ Oost Brabant (Rosmalen)

Gezondheislaan 65
Oss 5432JW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Adolescents aged between 16 and 23 years in care at GGZ Oost Brabant
• Mastery of Dutch language
• Moderate to severe depression after 3 months of Care As Usual (CAU) for depression:
o Score > 26 on the IDS-SR (Bernstein et al., 2007)
o DSM-5 diagnosis of depression, confirmed with the MDD part of the Mini International Neuropsychiatric Interview - Simplified (MINI-S), Dutch version

1.1. for DSM-5 (Overbeek & Schruers, 2019).
• Moderate to severe childhood trauma (CT) before the age of 16
o At least one score above validated cut-offs for the CT subtypes of the Childhood Trauma Questionnaire - Short Form (CTQ-SF; Bernstein & Fink, 1998; physical neglect: score >10; emotional neglect: score >15; sexual abuse: score >8; physical abuse: score >10; emotional abuse: score >13)
• In the case of suicidal ideation: The patient is in possession of an up to date safety plan
• Patient is inclined to give written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• There is still immediate physical threat/harm/violence in the adolescent*s life which acquires attention
i• There is a history of trauma-focused therapy with EMDR, imagery exposure or Imagery Rescripting in regard to the traumatic childhood event
• There is alcohol/drug dependence or other sever psychiatric comorbidity (e.g. bipolar disorder, psychotic disorder) that requires clinical attention
• There is a primary DSM-5 diagnosis of PTSD or Acute Stress disorder (ASD)
• There is acute suicide risk with an indication for hospitalization (further elaborated in the research protocol p.18)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2023
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2023
Application type:	First submission
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	NL83743.091.23