GGZ inteRvention In Prevention of suicidal behavior; A study investigating the effect of cognitive behavioral therapy for suicide prevention added to treatment as usual (TAU)

Published: 01-11-2018
Last updated: 19-03-2025

The main objective of this randomized controlled study is to investigate whether CT-sp in combination with treatment as usual (TAU) is more effective in reducing the severity and intensity of suicide ideation and suicidal behavior than only...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Suicidal and self-injurious behaviours NEC
Study type	Interventional

Summary

ID

NL-OMON48958

Source
ToetsingOnline

Brief title
GRIP

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
Suicidal ideation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive behavioral therapy, RCT, Specialized mental health care, Suicide prevention

Outcome measures

Primary outcome

The primary outcome measure is defined as the reduction of suicide ideation and suicidal behavior in terms of severity and intensity as measured by the Columbia-Suicide Severity Rating Scale (C-SSRS). Assessments of severity and intensity of suicidal ideation and behavior will be made at baseline, after 6 and 12 weeks, and 9 months after the baseline measurement.

Secondary outcome

To refine the grid of suicidal ideation and behavior, several other explicit and implicit measures of suicidal behavior will be used as secundary study parameters. Furthermore, levels of depression and anxiety will respectively be mapped, as well as quality of life, and severity of the mental illness of the patient.

Lastly to enhance our understanding of the underlying factors that bring about suicidal behavior, three theories of how suicidal behavior might arrise will be investigated by the use of questionnaires:

- Interpersonal Theory of Suicide using the Interpersonal Needs Questionnaire (INQ) and the Acquired Capability for Suicide Scale - Fearlessness About Death

(ACSS-FAD)

- Suicidal Crisis Syndrome, using the Suicide Crisis Inventory (SCI)

- An amplified sense of self-agency nurtures a positive attributional style to self and self-control, which may buffer against effects of hopelessness. This possible underlying mechanism will be investigated using the Pearlin Mastery Scale (PMS)

Psychometric properties of the Dutch translations of the INQ, ACSS-FAD, and SCI will be assessed.

At assesment T2, participants will be asked to evaluate the suicide prevention interventions received during the study via a short questionnaire. At all assessments, participants will be asked to what extent they think they are able to cope with their own suicidality, using the Suicide-Related Coping Scale.

Study description

Background summary

Recent reviews pointed out that psychosocial and behavioral interventions that treat suicidality directly have a better prognostic value than interventions targeting suicidality indirectly by, for example, treating a major depressive disorder (MDD) when the patient is suicidal and simultaneously suffering from MDD. In this study we will act upon these findings through the implementation of a promising cognitive behavioral intervention meant to directly reduce and prevent suicidal ideation and behavior (the CT-sp protocol) among patients in specialized mental health care (sGGZ), the Dutch equivalent of outpatient mental health care for patients with complex psychological problems.

Study objective

The main objective of this randomized controlled study is to investigate whether CT-sp in combination with treatment as usual (TAU) is more effective in reducing the severity and intensity of suicide ideation and suicidal behavior than only receiving treatment as usual.

Study design

This study is designed as a randomized controlled trial. Patients in the experimental condition will receive CT-sp protocol delivered by a trained psychologist in 12 sessions, as an add-on to their treatment as usual without interruption. In the control condition patients will also remain in treatment as usual with attention paid to suicidal behavior, albeit not in a specific intervention.

There are 4 measurement moments: T0 (baseline), T1 (6 weeks after T0), T2 (12 weeks after T0) and T3 (9 months after T0).

Intervention

Ten sessions of CT-sp delivered face-to-face by a trained psychologist.

Study burden and risks

Participants in the experimental condition will be offered 12 sessions of CT-sp added to their treatment as usual (TAU) aiming to reduce the severity and intensity of their suicidal ideation and behavior. Participants are informed that they can cancel their participation at any time without disclosing reasons for their cancellation and without negative consequences for their future care. Participants in the control condition will not be subjected to an additional intervention to TAU, but are not restricted in the use of mental health care. Data will be collected at two assessments in the course of treatment and at 9 months after the baseline measurement. The baseline assessment lasts approximately 2 hours and 30 minutes. Each assessment after that lasts about 1 hour.

Contacts

Public
VUmc

Oldenaller 1
Amsterdam 1081 HJ
NL
Scientific

VUmc

Oldenaller 1
Amsterdam 1081 HJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18
- Patient is newly referred to or in care at a participating sGGZ mental health care center
- Severe suicidal ideation in the last month, and/or a history of suicide attempt
- Speaking the Dutch language

Exclusion criteria

• Active (manic-)psychotic episode or cognitive impairment due to chronic (psychotic) disorganization, dementia, or mental retardation
• Insufficient mastery of the Dutch language
• Has previously had cognitive behavioral therapy for suicide prevention

Study design

Design

Study type: Interventional

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2019
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25696
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65579.029.18
OMON	NL-OMON25696