The (cost-)effectiveness of mindfulness-based cognitive therapy and cognitive-behavioral treatment in adolescents and young adults with deliberate self-harm

Published: 13-08-2007
Last updated: 08-05-2024

To study the effects and costs of the total individual CBT package and one of the components of the total CBT treatment package (i.e. mindfulness training) in a group format compared to Treatment-as-Usual (TAU) on the short and long term.

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

Summary

ID

NL-OMON31032

Source
ToetsingOnline

Brief title
Short-term psychological treatments of deliberate self-harm

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
deliberate self-harm; suicidal behavior

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: ZorgOnderzoek Nederland Medische Wetenschappen

Intervention

Keyword: cognitive-behavioral treatment, deliberate self-harm, depression, mindfulness training

Outcome measures

Primary outcome

As in the previous study patients are asked for the exact number of episodes of

DSH during the past 3 months using a semi-structured interview.

Secondary outcome

Also the same secondary outcome measures as in he previous study will be used (

depression (BDI-II), anxiety (SCL-90), self-concept (RSC-Q), and suicide

cognitions (SCS)). In addition at all assessments health-related quality of

life, use of medical resources and loss of productivity will be assessed

(EuroQol, VAS and TTO). Also, problems in emotion regulation will be assessed

before and after treatment (AMT and DERS).

Study description

Background summary

In recent years, there has been a marked rise in the frequency of young people engaging in Deliberate Self-Harm (DSH). DSH refers to all kinds of self-harming behaviour, with and without suicidal intent. Early identification and treatment of persons who engaged in DSH is important because every episode of DSH increases the risk of future episodes and, eventually, suicide. A number of comprehensive treatment programmes have been developed and proven to be effective in reducing DSH in adults. Especially the modification of inadequate emotion regulation strategies seems to be essential in the prevention of future episodes of DSH. The first short-term results of a Dutch time-limited and structured individual cognitive-behavioral treatment (CBT) for DSH in

adolescents and young adults (ZonMw project Program Prevention/Innovation projectnr. 21000068) also showed positive effects on repetition of DSH and associated problems.

Study objective

To study the effects and costs of the total individual CBT package and one of the components of the total CBT treatment package (i.e. mindfulness training) in a group format compared to Treatment-as-Usual (TAU) on the short and long term.

Study design

Multi-center randomized controlled clinical trial with repeated measurements at baseline (M0), and posttreatment (M6)), 12 (M12) and 18 months (M18) after baseline.

Intervention

Participants are randomly allocated to CBT, Mindfulness-Based Cognitive Therapy (MBCT) or Treatment-as-Usual (TAU). The CBT treatment consists of up to 12 weekly sessions of individual treatment mainly consisting of emotion regulations skills, cognitive restructuring, and behavioural skills training.
The MBCT training consists of 8 2-hour sessions in a group format within a three months time frame.

Study burden and risks

From a previous study we learned that of the approximately 80 persons with DSH referred to both participating centres each year about 50% is traceable, eligible and willing to participate. Following the two additional treatments (MBCT (20 hours of treatment) or CBT (12 hours of treatment)) involves no special risks. Study participants will be assessed with self-report questionnaires and semi-structured interviews at four time points during a period of 18 months (total testing time 6-8 hours). In a previous study using a similar assessment strategy, this frequency and intensity of measurements proved to be feasible.
Suicidal risk and crises of study participants is monitored by the main therapist. In cases where research assistants discover serious suicidal risk the research assistant will directly contact the main therapist after discussing this with the study participant involved. When there is no main therapist (as can be the case in the TAU condition) study participants will be directly referred to the emergency department of the medical hospital or mental health institution for a psychiatric consultation and crisis interventions will be arranged.

Contacts

Public
Universiteit Leiden

P.O. Box 9555
2300 RB Leiden
NL
Scientific
Universiteit Leiden

P.O. Box 9555
2300 RB Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adolescents and young adults aged 15-35 years who recently engaged in self-harming behaviour, regardless of the intent (e.g. trying to hurt or kill oneself), will be included after referral to the Leiden University Medical Center, Rivierduinen or the University Medical Centre St. Radboud following their act of DSH .

Exclusion criteria

Persons (a) reporting severe psychiatric disorders requiring intensive inpatient treatment (such as schizophrenia or problems with alcohol and drugs), (b) unable to converse in Dutch,

(c) manifesting serious cognitive impairments, or (d) living outside the region of Leiden or Nijmegen will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	126
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18117.058.07