Targeting suicidality in young adults: a randomized, controlled pragmatic, multicentre trial evaluating the (cost)-effectiveness of Attachment Based Family Therapy compared to Treatment as Usual

Published: 05-06-2023
Last updated: 21-12-2024

In the proposed study, we conduct a randomized controlled trial to evaluate the (cost-)effectiveness of ABFT compared to Treatment As Usual (TAU) on suicidality, as delivered in daily practice. We hypothesize that, compared to TAU, ABFT will lead to...

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

Summary

ID

NL-OMON53903

Source
ToetsingOnline

Brief title
REPAIR study

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
Suicidality; suicide

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: BeNeFit (ZonMw)

Intervention

Keyword: attachment, family, intervention, Suicidality, young adults

Outcome measures

Primary outcome

Change suicidality as measured with the SIQ-JR, pre-post at baseline, 5.5, 8.5, 11.5 and 17.5 months after baseline.

Secondary outcome

The secondary outcomes are (fatal) suicide attempts (SCID-S), depression (SCID-S,PHQ-9, and CDI-2), disability (WHODAS 2.0), family functioning (SRFF), non-suicidal self injury (NSSI), young adult attachment (SBS), entrapment (E-SF), autonomy (My Parents and I: a combination of items van de EAS en de PSI), childhood trauma (CTQ), working alliance (WAI-12), ABFT treatment fidelity (TBRS-3), treatment adherence (TPC), cost-effectiveness and health care costs (EQ-5D-5L, TiC-P). The secondary study parameters will be analysed using Generalized Linear Mixed Modelling with adequate link functions, using all five assessment time points of the primary outcome measure cost-effectiveness analyses.

Study description

Background summary

Young adult suicidality is worldwide and certainly in Belgium and the Netherlands a prevalent mental health problem, and number one cause of death in this group with devastating consequences for young adults and their families. The economic costs of this health issue are substantial. However, the currently recommended psychological treatments and guidelines targeting treatment of suicidal youth at ultra-high risk for completed suicide have only limited effectiveness. Counter-intuitively, the use of antidepressants in youth can in some cases even increase suicide risk. In keeping with the WHO*s recommendation to involve the family in treatment of these youth, Attachment Based Family Therapy (ABFT) proved in several studies in the US promising effectiveness on suicidality. In the Netherlands and Belgium, this treatment has been implemented in mental health care settings in the past years and is becoming increasingly popular among therapists. However, the (cost-) effectiveness of ABFT in our countries has not been studied in young adults.

Study objective

In the proposed study, we conduct a randomized controlled trial to evaluate the (cost-)effectiveness of ABFT compared to Treatment As Usual (TAU) on suicidality, as delivered in daily practice. We hypothesize that, compared to TAU, ABFT will lead to stronger reduction of suicide risk, will be more cost-effective, will improve family functioning and young adult attachment, and that this effect will hold at follow-up. The primary objective is change in suicidality, that is, suicidal ideation, attempts and suicide as assessed by the Suicidal Ideation Questionnaire Junior (SIQ-JR), and as reported by therapists during treatment. Secondary objectives are cost-effectiveness, process, working alliance and adherence during treatment, and change in young adult depressive symptoms, family functioning, and young adult attachment.

Study design

A randomized, controlled, pragmatic, multicentre, trial in the Netherlands and Belgium with 16 participating sites.

Intervention

Attachment Based Family Therapy (ABFT): ABFT is a manualized treatment, that emerges from interpersonal theories that suggest suicide can be precipitated, exacerbated, or buffered against by the quality of family relationships. Therefore, ABFT focuses on strengthening parent-child attachment bonds to create a protective and secure base for young adult development. Sessions are scheduled weekly, and the intervention lasts on average 16 weeks.

Treatment as usual (TAU): Participants in both arms will receive TAU, in the experimental condition ABFT will be delivered as an add-on. Most treatment centres* clinical practices rely heavily on the use of antidepressants and/or

CBT or DBT. All regular interventions are allowed in TAU, except for systemic family therapy of more than 4 sessions in total. Parents are allowed to be involved in the treatment, which is part of treatment as usual, and can comprise for instance psycho-education or parental support or skill training.

Study burden and risks

There is no known risk associated with study participation. Patient burden comprises four 30-45 minute assessment interviews, which can be held online of by phone, and one questionnaires-only assessment, over the course of 17.5 months. The participants will be rewarded for their participation with vouchers. The project will contribute to improving the care for suicidal young adults with high mortality risk. Treatment of suicidal young adults is understudied in the Netherlands and Belgium. Results will inform clinical guidelines and policy makers and improve treatment of suicidal young adults in The Netherlands and Belgium. Specifically, the involved national suicide prevention foundations (i.e. 113.NL, the Flemish Expertisecentre Suicideprevention (VLESP- Flanders), Un pas dans L*Impasse) (Suicide prevention Wallonia), patient organisations and postdoctoral training centres will guarantee further dissemination to daily treatment of suicidal young adults.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participants are suicidal young adults and their family. The young adults are between 16 and 30 years old and seek mental health treatment. Participants will be recruited from 16 participating sites.
Eligible participants meet the following inclusion criteria:
a) Aged between 16 and 30;
b) have a score of 31 or more on the SIQ-JR (the cut-off for suicidality);
c) have at least one primary parent or caregiver that participates in the assessment and treatment. This could be a biological parent, stepparent, grandparent, other relative, or a foster parent.

Exclusion criteria

a) a) Other DSM-5 disorders: severe alcohol or cannabis use disorder, all other substances: moderate or severe substance use disorder, severe conduct disorder, evidence of psychotic features or prior psychosis (assessed with the SCID-S);
b) severe cognitive impairment (e.g., mental retardation, severe developmental disorders) as evidenced by educational records, parental report and/or clinical impression;
c) other circumstances that might affect participation (e.g., severe medical disorder, relocation).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2023
Enrollment:	71
Type:	Actual

Ethics review

Approved WMO Date:	05-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL82274.018.22