Group-based treatment of Adolescent Female Conduct Disorder: The Central Role of Emotion Regulation

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Primary objective:To investigate the efficacy of a 12-week group-based training for female adolescents with CD (DBT-CD-A) compared to treatment as usual (TAU) within youth welfare institutions. It is hypothesised that add-on highly structured DBT-CD…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON44669

Source
ToetsingOnline

Brief title
START NOW

Condition

- Personality disorders and disturbances in behaviour

Synonym
behavioural problems, Conduct Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: FP7

Intervention

Keyword: Conduct Disorder, DBT-CD-A, Female, RCT

Outcome measures

Primary outcome

The main purpose of the current study is to investigate the efficacy of a 12-week group based DBT-CD-A training for female adolescents with CD compared to treatment as usual (TAU) within youth welfare institutions.

Primary endpoints: Response to intervention: pre-post treatment change in number of fulfilled CD/ODD diagnostic criteria

Secondary outcome

Further objectives of the current trial are to assess pre-post change in CD-related outcome measures after the 12-week group based DBT-CD-A training compared to TAU. We destinguish between subjective, behavioural and neurobiological endpoints. I refer to the study protocol for a description of these endpoints.

Study description

Background summary

To date, treatment programs are not widely implemented and evaluated in adolescence, although adolescence is one of the key periods for intervention due to the increasing prevalence of CD. In addition, no randomised controlled trial (RCT) studies have been performed with female adolescents living in the youth welfare system. Thus, there is an urgent need to study new promising psychotherapeutic intervention approaches for CD, especially in female adolescents.

Study objective

Primary objective:
To investigate the efficacy of a 12-week group-based training for female adolescents with CD (DBT-CD-A) compared to treatment as usual (TAU) within youth welfare institutions. It is hypothesised that add-on highly structured DBT-CD-A training will result in improved emotion regulation skills and thus in overall CD symptom reduction, as compared to TAU (including no group intervention).

Secondary objectives:
To assess pre-post change in CD-related outcome measures after a 12-week DBT-CD-A group based training for female adolescents with CD compared to TAU within youth welfare institutions; to investigate behavioural and neurobiological predictors of treatment success; and to delineate mechanisms of change in DBT-CD-A in a pre-mid-post treatment design.

Study design

Prospective, confirmatory, cluster-randomised, parallel group, multi-centre and international phase III-trial.

Intervention

START NOW is a group based 12-week intervention in which several psychotherapeutic approaches are combined (CBT+DBT+mindfulness+trauma sensitive care). It aims to reduce behavioural problems and to improve emotion regulation in adolescent girls.

Study burden and risks

Direct benefits resulting from study participation includes: expected therapeutic benefit from a cognitive-behavioural group training program/ symptom reduction; reduced stress, enhanced self-efficacy and enhanced psychosocial adjustment. No risk for severe injury is associated with participation in this study. Participants might experience fatigue caused by the study protocol. We will monitor the well being of our participants any time, and will insert brakes whenever necessary. Participation in the brainimaging protocol can cause stress for the participant. Only those participants who feel totally comfortable with a visit to the MRI scan will participate in this part of the study.

Contacts

Public
Vrije Universiteit Medisch Centrum

Rijksstraatweg 145
Duivendrecht 1115 AP
NL
Scientific
Vrije Universiteit Medisch Centrum

Rijksstraatweg 145
Duivendrecht 1115 AP
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

- Female sex
- age 13 - 20 years
- Diagnosis of Conduct Disorder within the 12 months prior to institutionalisation OR current diagnosis Oppositional Defiant Disorder and lifetime CD
- sufficient writing and reading skills (Dutch)

Exclusion criteria

- History of or current clinical diagnosis of autism spectrum disorder
- History of or current clinical diagnosis of schizophrenia
- Current clinical diagnosis of Bipolar Disorder or Mania
- Fetal Alcohol Syndrome
- Known monogenetic disorder or genetic syndrome
- Any chronic or acute neurological disorder
- IQ < 70

- severe medical condition interfering with therapy
- concurrent group based psychotherapy

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):	15-02-2015
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2018
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	NL52038.029.14