Beyond addiction: a randomized controlled trial on the effectiveness of group schema therapy in patients with dual diagnosis

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26670

Bron
Nationaal Trial Register

Verkorte titel
BA

Aandoening

The presence of a Dual Diagnosis (i.e. having a SUD, except only nicotine use disorder, and one or more DSM-5 diagnoses other than a substance use disorder, including at least one Personality Disorder).

Ondersteuning

Primaire sponsor: Parnassia Groep
Overige ondersteuning: Parnassia Group

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the general level of psychopathology. This will be measured by the Symptom Check List (SCL-90; Derogatis, 199); Dutch translation and adaptation by Arrindell & Ettema, 1986), which is a self-report measure that consists of 90 items. Answer categories of the items range from 1 (not at all) to 5 (very much). The total score is calculated by adding up the items, resulting in a score ranging from 90 to 450. The Dutch version of the SCL-90 has been shown to have good psychometric qualities (Arrindell & Ettema, 1986).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The presence of substance use problems in combination with other mental illnesses is associated with negative treatment outcomes. Research shows that integrated treatment for this population is recommended. However, until so far research has only focused on integrated treatment programs that deal with manifest symptoms and not on possible psychological origins, like youth trauma, parenting style and problems in emotion regulation.
Objective: The aim of this study is to compare the effectiveness of Group Schema Therapy (G-ST) and Group Cognitive Behavioral Therapy (G-CBT+MI) on symptoms, emotion regulation and addiction in DD outpatients. Moreover the effect of the severity of childhood maltreatment experiences, parenting style and degree of secure attachment on the effectiveness of G-ST will be investigated. At last, it will be examined whether security of attachment improves during therapy.
Study design: We will conduct a Randomized Controlled Trial (RCT), a pretest-midtest-posttest-3-month-12-month-follow-up-design, with two treatment conditions: the experimental condition (G-ST) and the control condition (G-CBT+MI).
Study population: The study population will consist of 80 Dual Diagnosis patients between 18 and 65 years of age who are willing to participate in the study.
Intervention: Patients assigned to the experimental condition will receive 30 weekly sessions (2 hours) of G-ST, plus 3 preparatory individual meetings. Patients in the control condition will also start with 3 individual meetings, followed by 30 weekly sessions (2 hours) of G-CBT+MI.
Main study parameters/endpoints: The primary outcome measure will be the difference between the two treatment groups on general psychopathology as measured by the Symptom Check List (SCL-90). The secondary outcome measure will be the difference in addiction severity between the two groups. This will be investigated by a subtest of the Addiction Severity Index (ASI). An important process measure will be emotion regulation and will be measured by the Emotion Regulation Questionnaire (EQ).

Doel van het onderzoek

1. G-ST is more effective (less symptoms, less alcohol/drug abuse, better emotion regulation) in treating DD-patients as compared to G-CBT+MI.
2. Since early negative life experiences are, among other things, targeted in G-ST it is expected that there is a positive relationship between the severity of reported youth trauma and effectiveness of G-ST in DD-patients. Moreover we predict that G-ST is more effective when an insecure attachment and negative parenting style is reported.
3. During treatment attachment style will improve significantly (i.e. become more secure). This effect will be larger in de G-ST condition as compared to the G-CGT+MI condition.

Onderzoeksopzet

In order to monitor changes over time on the outcome and process measures semi-structured interviews and self-report questionnaires will be used at five time points: before treatment (T0), after 15 weeks of treatment (T1), at the end of treatment (T2), 3 months after treatment (T3) and 12 months after treatment (T4).

Onderzoeksproduct en/of interventie

Patients in the experimental condition (G-ST) will start their treatment with three preparatory individual meetings, in which they receive psycho-education about ST and group therapy, make a case conceptualisation and set goals. Subsequently they receive 30 weekly group sessions (2 hours) of G-ST, consisting of two cycles of 15 sessions. Each participant follows two cycles, after which they flow out. At the end of each cycle there is the possibility for patients who completed the 30 sessions to leave the group and for new members to flow in. In the first cycle a participant is going through all schema modes, both in terms of recognition and modifying old patterns. Three kinds of interventions will be used: cognitive, behavioral and experiential. Target of these interventions are always the maladaptive schema modes. In the second cycle (also 15 sessions) again all schema modes will be discussed with the same three groups of interventions (i.e. cognitive, behavioural and experiential), but within this scope different techniques are used. In this way, after 30 sessions all participants have completed a varied (but all the same) range of techniques per schema mode. Examples of techniques being used in de G-ST are chair work, imagery, role plays and formulating helpful thoughts with regard to dysfunctional schema modes. Besides the specific ST interventions the therapists use the group dynamic to make the participants aware of their schema modes within the interactional group process. Furthermore, the group serves as a safe place to experiment with new healthy schema modes.
Patients in the control condition also start with three individual meetings, followed by 30 weekly sessions (2 hours) of G-CBT+MI. In the individual meetings the patients receive psycho-education about CGT and group therapy, whereby the therapist uses motivational interviewing as conversation technique (for example by making a pro con analysis of using alcohol and/or drugs). In the group sessions CGT techniques that directly target the addiction behaviour are being used, for example self control techniques (i.e. avoiding situations that trigger substance use, looking for alternative behaviour and using rewards and negative consequence to reinforce desirable behaviour), drafting a functional analysis and formulating

helpful thoughts. In the G-CBT+MI group there is no specific focus on group dynamics.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- the presence of a Dual Diagnosis (i.e. having a SUD, except only nicotine use disorder, and one or more DSM-5 diagnoses other than a substance use disorder, including at least one Personality Disorder)
- between 18 and 65 years of age
- willing to participate in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- an IQ below 80 (in case of doubt an intelligence test is administered)
- problems with speaking, reading and/or writing the Dutch language
- having mental health problems that require other treatment (i.e. the presence of schizophrenia, bipolar disorder type 1, acute suicidality and/or SUD that needs immediate detoxification)
- personality traits (e.g. aggression outbursts, being indifferent to mistreating others) that make it difficult to participate in a group context and

- having received ST and/or CGT for addiction problems for more than three months duration in the past year.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55529

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9816
CCMO	NL62421.058.17
OMON	NL-OMON55529

Resultaten