An open clinical trial of an adapted inpatient addiction treatment with group Schema Therapy and milieu therapy

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

Samenvatting

ID

NL-OMON22685

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Personality disorder, substance use disorder

Ondersteuning

Primaire sponsor: No sponsors
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Dysfunctional core belief strength (visual analog scale 0-100)

Toelichting onderzoek

Achtergrond van het onderzoek

In this study, we will do further research of Schema Therapy (ST) and SafePath, a milieu-therapeutic form of ST, for double-diagnosed (substance abuse plus personality disorder) patients in a clinical setting at de Hoop. De Hoop has already implemented this therapeutic approach for several years under the supervision of D. Bernstein. All enrolled patients will receive the same treatment as not enrolled patients. This proposal represents an open trial in which we will test the already implemented treatment model on a clinical ward, involving a case series design (Kazdin, 2010) in which each patient forms its own individual control based on their own natural waiting list baseline.

Doel van het onderzoek

In terms of effectiveness, we hypothesized that for each patient during treatment:
1 Compared to a waiting list baseline, the intensive inpatient treatment with adapted ST interventions together with ST milieu therapy during 12 weeks results in larger improvements in core PD cognitions over time (interaction effects condition*time; primary outcome).

2 Compared to a waiting list baseline the treatment phase results in larger improvements in healthy schema modes (Healthy Adult and Happy Child) and larger decreases Schema Modes, especially ‘the Detached Protector’, ‘the Detached Self-soother’, ‘impulsive child’ and EMSs in the DR domain and ‘Insufficient Self-control’, over time (interaction effect condition*time on observed behavior problems; secondary outcomes).

3 Compared to a waiting list baseline, the treatment phase result in larger improvements in craving and general complaints. (interaction effect condition*time on observed behavior problems; secondary outcomes).

4 Compared to a waiting list baseline, the treatment phase, results in larger decreases in negatively valued cognitive and affective aspects of God representations and larger increases in supportively valued cognitive and affective aspects of God representations in patients with a Christian religious affiliation over time (interaction effect condition*time on observed behavior problems; secondary outcomes).

5 Visual inspection of slopes and effect sizes during different measurements time points, shows that increases in healthy schema modes (Healthy Adult and Happy Child) and supportive religious representations and decreases in problematic schema coping, especially avoidant coping, problematic Schema Modes, especially ‘the Detached Protector’, ‘the Detached Self-soother’, and EMSs, in the DR domain and ‘Insufficient Self-control’, and negative religious representations go together with decreases in reported PD-cognitions, PD

pathology, general complaints, and craving (SUD pathology) within patients.

Onderzoeksopzet

Weekly measurements start from inclusion (dysfunctional core belief strength; PACS; God cognition strength). For remaining variables, three measurement points (after inclusion, at start of treatment, and at end of treatment).

Onderzoeksproduct en/of interventie

A therapeutic approach, including a group Schema Therapy as well as SafePath (a milieu-form of ST) aimed at substance use disorder and personality disorder provided in a clinical setting during 12 weeks.

Contactpersonen

Publiek

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Theodoor Kraker

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria are that patients have an indication for treatment in an inpatient setting for SUD (substance use disorder) at the 4life clinic at the Hoop ggz, following the Dutch guidelines (De Beer & Van de Glind, 2009). Patients have a diagnosis of DSM-5 SUD and have minimally five PD traits (this is seen as clinically significant for PD (Verheul, Bartak, & Widiger, 2007)), age 18-65 years, with an indication of at least a normal intelligence based

on a completed primary and secondary education and clinical impression, and a willingness to participate in the study confirmed by a signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are an severe autism spectrum disorder, schizophrenia or other psychotic disorders, and the presence of significant risk for suicide based on psychiatric evaluation. Other exclusion criteria are the current use of heroin, methadone or another heroin replacement, acute delirium symptoms, or have otherwise specific medical needs. These clients are refered to a more medical oriented inpatient detoxification.
Further, we exclude patients whose waiting list times are less than two weeks, because that allows insufficient time to gather three necessary baseline observations.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-12-2019
Aantal proefpersonen:	12
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:	28-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8191
Ander register	ERCPN Maastricht : ERCPN- 201_05_11_2018

Resultaten