The effect of CRA Plus Training on treatment model adherence, treatment outcomes and interaction with the working alliance in outpatient addiction care: a RCT

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

Samenvatting

ID

NL-OMON25251

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Substance use disorders

Ondersteuning

Primaire sponsor: Nu funding.
Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is CRA treatment adherence in terms of the mean number of individual CRA procedures completed by therapists in sessions with each individual patient (range 0-12). Adherence is measured by therapists self-reported adherence per session. The CRA Session Report is used for measuring CRA treatment adherence. Therapists report their use of CRA procedures every session. The treatment trajectories will differ in length. Measurements are made up to a maximum of one year.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Community Reinforcement Approach (CRA) is an evidence-based, manualized type of behavioral therapy used in addiction care. CRA adherence is highly relevant for its effectiveness. However, we recently observed major differences in the delivery of CRA procedures between individual therapists. Delivery of CRA procedures as intended was associated with more advanced training. Thus, continued coaching after completing a basic training might be important to increase proficiency and fidelity to interventions.

Objectives: This study aims to investigate whether CRA coaching and feedback for therapists after their certification, the so called ‘CRA Plus Training’ (CRA+), increases CRA adherence and competence. In addition, we will investigate the relationship between adherence / competence, treatment outcome, and the working alliance. Our hypotheses are that compared to therapists without continued coaching and feedback, therapists who receive CRA Plus Training a) deliver a larger variety of CRA procedures and have higher levels of CRA adherence and competence, b) have better treatment outcomes in their patients, and c) have a more positive working alliance with their patients.

Study design: This study is a semi-blinded (patient and raters), prospective RCT in which data will be collected from therapists (N = 28) and their patients (N = 260) in outpatient settings. Therapists are randomized over two study conditions: 1. No CRA Plus Training (CRA- = control group) and 2. CRA Plus Training (CRA+ = experimental group).

Study population: This study includes two research populations: 1. therapists who recently started working within the participating addiction care facility, work with outpatients with addiction, using CRA, and 2. Adult patients with an addiction treated by participating therapists.

Intervention (if applicable): After completing the CRA certification process (baseline phase) therapists are assigned to one of two groups via randomization: an experimental group receiving continued CRA coaching and feedback, and a control group not receiving continued

coaching and feedback after basic certification.

Main study parameters/endpoints: The primary outcome measure is CRA adherence which is defined as the number of individual CRA procedures delivered by therapists to their individual patients. Secondary outcome measures are: abstinence rates in patients at 3, 6 and 9 months follow-up, and an index of working alliance between therapist and patients, as perceived by the therapists and their patients.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Therapists of both groups continue making audio recordings of their sessions after completing basic CRA training. They also register which CRA procedures they use each session. Further, patients and therapists value the working alliance per session. Patients are assessed on patient outcome at the same time points. Therapists of both groups benefit from the structured reflection process as part of the CRA approach implemented here. Therapists of the experimental group get continued coaching and feedback which is expected to further improve their skills and optimize treatment. This is also in the interest of patients. We expect no risks or negative effects for neither therapists nor patients.

Doel van het onderzoek

Our hypotheses are that therapists who receive the CRA Plus Training deliver a larger average number of CRA procedures and have significantly higher levels of competence. We expect that therapists of the experimental group will improve their CRA skills more than those in the control condition and that they will also maintain higher adherence and competence levels. We expect that higher levels of treatment adherence and competence are associated with better patient outcomes and more positive ratings of the working alliance.

Onderzoeksopzet

Time points primary outcome:
The main study parameter is CRA treatment adherence in terms of the mean number of individual CRA procedures completed by therapists in sessions with each individual patient (range 0-12). Adherence is measured by the CRA Session Report per session after completion of the intake phase. The treatment trajectories will differ in length. Measurements are made up to a maximum of one year.

Time points secondary outcomes:
1. CRA competence in terms of the quality of the therapist’s performance of procedures as reported on the CRA Procedure Checklist by independent raters which is part of the CRA coding manual. Six sessions per therapist are rated, one every other month during 1 year form the moment of entry.
2. Patient outcome, measured during treatment initiation (T0) and then every three months for up to a year (T1, T2, T3, T4). See Secondary outcomes for further information on the components of these measures.
3. Working alliance:
Patients assess the working alliance every session after completion of the intake phase. The

Outcome Rating Scale (ORS) and the Session Rating Scale (SRS) are used for this. Patients' treatment trajectories will differ in length. Measurements are made up to a maximum of one year.

Inclusion of the therapists started in july 2020 and is still continues. Inclusion runs to approximately the end of 2023. Publication of the papers is planned for 2024.

Onderzoeksproduct en/of interventie

The intervention of the study is de CRA Plus Training. As an addition to the existing CRA training model, we set up a standardized training for therapists after completing basic certification. The basic certification, which is part of the existing CRA training model, is the study baseline phase. We based the CRA Plus Training on the A-CRA training model described by Godley, Garner, Smith, Meyers & Godley (2011). The CRA Plus Training consists of two phases. During the first phase therapists receive two weekly coaching sessions by an expert coach regarding the delivery of all CRA procedures and therapeutic skills. Meanwhile, therapists work towards proficiency in the remaining CRA procedures which weren’t rated during the basic certification process. Phase 1 lasts six months. The second phase consists of ongoing CRA fidelity monitoring which means that every other month a random taped session is rated for fidelity and also lasts six months.
In parallel, each month a taped session is drawn by an independent rater at random and rated for fidelity. A fixed set of CRA procedures is rated in both therapist groups. The rating proceeds for a year.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a therapist must meet the following criteria:

· No previous experience with CRA,

· ≤18 months since start of working at IrisZorg,

· Completed CRA certification within 12 months after completing the CRA basic training,

· Working at an outpatient facility,

· Working with adult patients,

· Written informed consent.

In order to be eligible to participate in this study, a patient must meet the following criteria:

· A primary diagnosis of substance use (meeting the DSM-5 criteria),

· Age 18+,

· Sufficient Dutch language proficiency,

· Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For therapist subjects there are no additional exclusion criteria. Patients who suffer from severe, current (since intake) psychiatric symptoms (especially manic, psychotic, suicidal and aggressive symptoms) that may endanger themselves or others and jeopardize study adherence will be excluded.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-07-2020
Aantal proefpersonen:	260
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:	24-08-2021
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	NL9746
Ander register	METC Radboudumc : CMO dossiernummer: 2020-6404

Resultaten