

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25251

Source

NTR

Brief title

TBA

Health condition

Substance use disorders

Sponsors and support

Primary sponsor: Nu funding.

Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

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 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.

Secondary outcome

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. Each procedure component receives a numeric score (1: poor performance, 2: needs improvement, 3: satisfactory, 4: very good and 5: excellent) which represents the quality of certain measurable and observable therapist behaviours. The competence score is the average score for each therapist on each procedure in a given session with a given patient. Competence scores of all sessions that are rated in the context of fidelity monitoring will be calculated. In this context, six sessions per therapist are rated. These sessions are selected by randomisation every other month during 1 year.

2. Patient outcome, measured during treatment initiation (T0) and then every three months for up to a year (T1, T2, T3, T4):

- The number of total units of substance use consumed in the past 30 days as rated by the Measurements in Addictions for Triage and Evaluation (MATE 1)
- The severity of patient-reported problematic substance use during the past twelve months as rated by the Measurements in Addictions for Triage and Evaluation (MATE 1)
- Patient-reported quality of life as rated by the Community Reinforcement Approach Happiness Scale (CRA-HS)
- Patient-reported severity of symptoms related to depression, anxiety and stress in the past 7 days as rated by the Measurements in Addictions for Triage and Evaluation (MATE 1)

3. Working alliance:

Patients assess the working alliance every session. The Outcome Rating Scale (ORS) and the Session Rating Scale (SRS) are used for this. The ORS is filled in by the patient at the start of the session and the SRS is filled in at the end of the session. Patients' treatment trajectories will differ in length. Measurements are made up to a maximum of one year.

Study description

Background summary

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.

Study objective

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.

Study design

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 from 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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	05-07-2020
Enrollment:	260
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	24-08-2021
Application type:	First submission

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
NTR-new	NL9746
Other	METC Radboudumc : CMO dossiernummer: 2020-6404

Study results