Group schematherapy for patients with addiction and comorbid personality disorder. A mixed-methods pilot study of feasibility and clinical potential

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The aim of this study is to explore GST + CRA in outpatients with PD and SUD. In addition, we will explore the relationship between childhood trauma, severity of SUD and PD and treatment response. The expectation is that GST, delivered alongside CRA…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56878

Source
ToetsingOnline

Brief title
Group schematherapy for patients with addiction and personality disorder.

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym
addiction, substance abuse

Health condition

stoornis in middelengebruik

Research involving
Human

Sponsors and support

Primary sponsor: De Grift (verslavingszorg, Arnhem)
Source(s) of monetary or material Support: Ministerie van OC&W,Het onderzoek wordt gefinancierd door IrisZorg en middels een subsidie van 10.000 euro die verstrekt is door de Vereniging voor Schematherapie.

Intervention

Keyword: Addiction, Group schematherapy, Personality disorder

Outcome measures

Primary outcome

Main study parameter/endpoint

The feasibility of GST will be explored and expressed qualitatively in terms

of:

1. Descriptions of the nature of obstacles and facilitators experienced by

participants, as assessed at one-week post-intervention follow-up in a

semi-structured interview based on the Patients Perceptions of Corrective

Experiences in Individual Therapy interview protocol (PPCEIT).

2. Participating therapists' experiences regarding the treatment program,

suggestions for improvement and recommendations for further implementation, as

assessed during a focus group interview after the data collection in

participating clients has been completed. If a participating therapist decides

to stop participating in the study early, he/she will be contacted for an

individual interview regarding his/her experiences with GST.

The feasibility of GST will be explored and expressed quantitatively in terms of:

1. The average number (and SD + range) of ST and GST sessions missed.

2. The number of participants who dropout from treatment (absence of 30% or more of the GST sessions (nine or more of total GST sessions missed) is considered a treatment dropout. It is then assumed that a patient has missed too many and that this negatively affects the effect of therapy.

3. Protocol adherence: after each GST session, participating therapists are required to write down the extent to which they adhered to the treatment manual and, if not, how they deviated and the reason. The data from this will be used as talking points for the focus group interview

Secondary outcome

Changes in quantitative outcomes of weekly repeated measures (from baseline (T0), over the course of treatment (T1-T4)), with regard to the potential clinical efficacy of GST:

-Average substance use (in grams (drugs) or units (alcohol)) in the past week, assessed with the MATE, section 1.

-Average craving in the past week, assessed with the MATE-Q1.

Changes in quantitative outcomes of periodic repeated measures (from baseline (T0), over the course of treatment (T1-T4) and follow up (T5)), with regard to the potential clinical efficacy of GST:

-Severity and treatment needs of addiction, assessed with the MATE-1.

-Quality of life, assessed with the WHOQoL-BREF . -

Severity indices in personality problems, assessed with the SIPP-SF

-The 16 core beliefs (early maladaptive schemas), assessed with the YSQ-S3.

-Schema modes, assessed with the SMI.

Other parameters in this study will be assessed in:

The severity and type of childhood trauma experienced, assessed with the CTQ

(baseline only).

Study description

Background summary

Substance use disorders (SUD) and personality disorders (PD) often co-occur. Among patients in addiction care, the prevalence of a comorbid PD is 34% to 73% (Verheul, 2001). The lifetime prevalence of comorbid disorders in alcohol use is about five times higher among patients with a PD than in the general population, while the risk of developing a comorbid disorder in drug use is even 12 times increased (Trull et al., 2010). In a study by Walter et al. (2015), a comorbid PD was seen in 46% of patients with SUD with antisocial personality disorder (16%) and borderline personality disorder (BPD) (13%) being the most common, followed by cluster C (particularly avoidant) and cluster A (particularly paranoid) PD (Rounsaville et al., 1998). For example, Kienast et al. (2014) found that about 78% of adults with BPD develop a dependence on substances at some point in their lives. Most research has been done on BPD and addiction.

The treatment prognosis of comorbid SUD and PD is unfavorable. SUD are more severe, and relapses are more frequent. In addition, this group experiences more psychiatric symptoms and impulsive and risky behaviors. There are more interpersonal problems, negative feelings and lower quality of life. These patients are also, on average, less adherent to treatment (Hasin et al., 2011; Newton-Howes & Foulds, 2017). Kienast et al. (2014) also found that patients were more likely to terminate their treatment prematurely and had shorter abstinence periods, and therefore advocated for an integrated approach to the combination of SUD and BPD. The Dutch Guideline on diagnostics and treatment of PD also recommends integrated treatment of SUD and PD because treatment of only one of the two disorders gives limited results (Bosch & Verheul, 2007; Fridell & Hesse, 2006; Zanarini et al. 2004b). However, there has been limited research

on integrated treatment of SUD and PD.

Several explanations have been suggested for this high degree of comorbidity. One is its relationship to Adverse Childhood Experiences (ACEs). Among other things, Dijkhuizen (2013) wrote that common etiological factors such as genetic or neurobiological vulnerability (impulsivity, emotion regulation) and early childhood traumatic experiences can explain both PD and SUD development. Edwards et al. (2003) also cite the relationship between ACEs and the likelihood of mental health problems later in life as an explanation for high levels of comorbidity. A meta-analysis by Porter et al. (2019) also confirmed that exposure to ACEs is associated with BPD. Findings from a meta-analysis by Pilkington et al. (2020) support the theory that early childhood neglect and traumatization is associated with Early Maladaptive Schemas (EMS) in adulthood. EMS are described by Young (2003) as deeply ingrained patterns of thoughts, feelings and behavior that develop during childhood and may persist into adulthood. In particular, the association between history of emotional abuse in childhood and EMS have the most empirical support. In addition, Borgert et al. (2022) found that ACEs are more likely to develop SUD. Thus, the relationship between ACEs in both personality problems and addiction is a possible explanation for the high co-morbidity. It is therefore important to investigate effective treatment for this co-morbidity that takes trauma history into account.

Schematherapy (ST) offers an interesting opportunity for treating patients with SUD and co-morbid PD, because it explicitly addresses ACEs. ST was developed by Jeffrey Young in 1980's as a pioneering integration of cognitive behavior therapy with gestalt, object relations, and psychoanalytic approaches (Young, 1990). It is based on the concept of EMS, and it is hypothesized that these schemas arise from unmet needs (physical and emotional neglect) or traumatic experiences (sexual, physical and emotional abuse) in early life. These early maladaptive schemas in turn make people vulnerable for developing mental illness (Masley et al., 2012). Processing childhood memories through experiential techniques is a central focus of schema therapy (Hoffart, Lunding & Hoffart, 2016). This focus on early life experiences distinguishes schema therapy from traditional cognitive approaches (Simard et al., 2011).

Dual Focus Schematherapy (DFST) approach was developed specifically for patients with SUD and PD by Ball (1998)., The fundamental assumption underlying DFST is that failed attempts to satisfy important basic needs can lead to the development of maladaptive schemas and harmful coping strategies such as addictive behaviors. Therefore, patients and therapists focus on identifying and inhibiting schemas, followed by detecting the underlying basic needs and satisfying them appropriately. DFST interprets substance use as a dysfunctional coping strategy to deal with "difficult" moods or conflicts.

A few studies on integrated treatment of SUD and PD have focused on Ball's (1998) and Ball & Young's (2000) DFST approach. However, several studies found

varying results (Ball, 2007, Ball et al., 2011). Criticism by Lee & Arntz (2013) of the 2011 study conducted by Ball et al. was that it was difficult to draw reliable conclusions, in part because of a high dropout rate and because the treatment was not implemented as intended. For example, schemamodi were not used, which is however used and recommended in published studies on the treatment of a PS with ST (Farrel et al., 2009; Giesen-Bloo et al., 2006; Nadort et al., 2009). Schema modes can be viewed as intense states of mind that arise when one or more schemas are activated. Working with schema modes in therapy provides common language and concrete clues to change because they are often easily identifiable (Farrell et al., 2015).

Building on the research of Ball (1998, 2000, 2007), incorporating the criticisms of Lee and Arntz (2013), a multiple baseline study of ST in 20 patients with an alcohol use disorder and BPD was recently conducted (Boog, 2022). Three months after the termination of ST, 68% of patients showed remission of BPD and a significant decrease in drinking days. This suggests that ST may be effective in treating patients with these comorbidities. Research on groupwise ST (GST) in patients with a PD without diagnosed SUD shows positive results on PD recovery and improvement in general functioning, psychopathological symptoms and quality of life (Dickhaut et al. 2014; Farrell et al. 2009). However, to date, no research has been conducted regarding GST in patients with SUD and PD. Arntz et al (2022) showed that the combination of individual ST and GST is the most effective ST format in BPD, compared to TAU (the best available treatment at the study site at the time (TFP, MBT, CCT, STEPPS, DBT, CBT or CAT)) and GST without individual ST. Given the high prevalence of PD in patients with SUD, the poor treatment prognosis of this comorbidity, and preliminary findings suggesting that GST may be an effective treatment for this target population, there is clear clinical relevance to further exploratory research on treatment through individual ST and GST (hereafter GST), in patients with SUD and comorbid PD.

There is little research on patients' perspectives regarding ST and, to the authors' knowledge, none at all on GST in patients with SUD and PD. Such information is important because it provides insight into how therapy is experienced by patients, and the limiting and facilitating factors they encountered. Qualitative research by De Klerk et al. (2016) on both patient and therapist perspectives on individual ST in personality problems showed that the involved therapeutic relationship, the transparent and clear theoretical model, and specific ST techniques were deemed important and helpful by patients. Several patients felt that 50 sessions were not enough, however. Moreover, they felt they were no

Study objective

The aim of this study is to explore GST + CRA in outpatients with PD and SUD. In addition, we will explore the relationship between childhood trauma, severity of SUD and PD and treatment response.

The expectation is that GST, delivered alongside CRA has clinical potential, and is associated with significant reductions in SUD and improvement of personality functioning and an increase in quality of life from baseline to follow-up.
We also explore participants' and therapists' experiences with GST (in addition to CRA) and identify what factors they have found to be facilitating or limiting.

Study design

This pilot study uses a single group, repeated measures A (baseline)-B (intervention) follow-up design. This combines both repeated measures on a group level (within subjects, T0-T5, from baseline to three-month follow-up) as well as a Single Case Experimental Design (SCED; within subjects, weekly assessments during the A-B part of the study). A mixed method approach to data collection is used whereby qualitative data is collected in a targeted selection of participants within one week of finishing the B* phase using a semi-structured interview and a focus group with therapists at the end of the data collection phase of the study. Data collection will start in March 2024 at three outpatient addiction care facilities of IrisZorg in Nijmegen, Arnhem and Doetinchem/Zevenaar and will be completed by the end of 2025. The data collection is spread over different phases and moments of measurement (see Figure 1):

T0 (start baseline).
Phase A (baseline, duration 3-10 weeks): CRA + 3 pre-sessions case conceptualization
T1 start of intervention
Phase B (junior phase (weeks 1-10 intervention phase)): GST + CRA
T2 (between phase B and B')
'Phase B' (phase medior (week 10-20 intervention phase): GST + CRA
T3 (between phase B' and B'')
Phase B'' (phase senior (week 20-30 intervention phase): GST + CRA
T4 end of intervention
T5: follow-up 3 months after end of GST: CRA (or disenrollment)

Clients will be assigned to a baseline period of at least three to a maximum of 10 weeks based on the moment of enrollment versus the length of the waiting list.

Intervention

Prior to the group sessions, during the baseline phase, participants will have three weekly pre-sessions with one of the group therapists to develop a global case conceptualization, creating a model of the primary modes with the participant and outlining goals for the group. Boog and colleagues (2022) did

not find any effect on personality functioning or substance use during this phase of case conceptualization.

GST will be offered phase oriented. A total of 30 weekly sessions is provided, mainly based on Farrel and Shaw (2012, 2014) and Tjoa and Muste (2021). The outline comes from Tjoa and Muste's (2021) treatment manual developed for people with cluster C personality disorder. For this study, we have added elements that specifically address addiction using schematherapeutic techniques. For an overview of these interventions see Appendix 1-3 or see the manual, Appendix 4.
Group Schematherapy:
The initial 10 GST sessions constitute the 1st (junior) phase, followed by 10 sessions for the 2nd (medior) phase and subsequently 10 sessions for the 3rd (senior) phase. The junior phase primarily focuses on awareness and healing. Subsequently, in the following phases, there is a gradual shift towards independent recognition of active modes in different situations (medior phase) and managing them (senior phase). All phases will encompass a blend of cognitive, experiential, and behavioral interventions. Initially, emphasis will be on comprehension (cognition), followed by experiential processing in the middle phase, and finally, in the last phase, emphasis will be on managing different modes (behavioral change) (Tjoa & Muste, 2021).

The ultimate goal of ST is to establish a connection with *the vulnerable child* within and thereby strengthen *the healthy adult*. Throughout all phases, extra attention will be given to modes in which clients use substances, dedicating one session in each intervention phase to this, using techniques such as chair work involving addiction.

It is a semi-open group with an opportunity to enroll after an intervention phase is finished (after 10 sessions). Individual evaluation with the group therapists is planned after each intervention phase, in the presence of the regular addiction treatment provider (to align with individual addiction treatment), and significant others. The evaluation focuses on the predetermined goals and sharpening or adjusting them aimed at the next phase. In addition to GST, participants will receive 10 individual ST sessions with one of the group therapists. In the 1st phase, these sessions occur every two weeks, in the 2nd phase, every three weeks, and in the 3rd phase, every five weeks. These sessions will delve deeper into the group sessions, incorporating extra experiential exercises or engaging in trauma work, for example.

Given the complexity of this target group a relatively high treatment dropout rate is expected. Absence of 30% or more of the GST sessions (nine or more of total GST sessions missed) is considered a treatment dropout. It is then assumed that a patient has missed too many and that this negatively affects the effect of therapy.

Co-intervention CRA:

The Community Reinforcement Approach (CRA) is a behavioral therapy methodology employed in addiction treatment (Meyers & Smith, 1995). It focuses on modifying the existing lifestyle by integrating alternative, reinforcing elements, such as engaging in enjoyable and social activities, thereby fostering a healthier and more rewarding lifestyle that supersedes a lifestyle characterized by excessive substance use. Emphasis is placed on collaboration among the patient, therapist, and significant others of the patient to eliminate positive reinforcement for substance use and enhance positive reinforcement for alternative behaviors.

The fundamental procedures of CRA for treating addiction disorders include:
-Utilizing a quality-of-life questionnaire to formulate personalized treatment goals and monitor progress,
-Functional analysis of substance use,
-Training in communication skills,
-Training in problem-solving skills,
-Training in social networks,
-Sobriety sampling (working toward periods of shorter or longer abstinence to experience and evaluate the effects of abstinence),
-Learning to refuse substances,
-Counseling on social and recreational activities,
-Relapse prevention,
-Medication, and
-Relationship counseling (Roozen, Meyers & Smith, 2022).
The CRA therapist and patient collaboratively determine which modules to employ based on the patient's goals and the required frequency of counseling. In outpatient settings, the intensity typically involves one session per week, with the duration determined by progress in achieving the goals. In addition to these weekly sessions, medication-assisted treatment, group treatment CRA and systemic therapy may be used. Within IrisZorg, an e-health platform is used to aid treatment further.

Study burden and risks

The burden of participating in this study consists of completing questionnaires. Participants will be rewarded/compensated for this by being able to receive vouchers for completed questionnaires. No risks are expected from participating in this study.

Contacts

Public
De Grift (verslavingszorg, Arnhem)

Meester B.M. Teldersstraat 7
Arnhem 6842 CT
NL
Scientific
De Grift (verslavingszorg, Arnhem)

Meester B.M. Teldersstraat 7
Arnhem 6842 CT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participating patients, based on patients* record information:
- Diagnosed with one or more substance use disorders according to DSM-5 criteria.
- Active Substance Use Disorder treatment, at least during groupschematherapy
- Personality Disorder according to DSM-5 criteria (or working hypotheses)
- Age between 18 and 70 years
- At least partial control over substance use; that is, participants can attend sessions sober.
- Written informed consent.

Exclusion criteria

based on information from the patients* record there is no evidence of:
- Inadequate proficiency in the Dutch language.
- Severe, untreated ADHD symptoms due to overlapping features with a personality disorder.
- Psychotic disorder (except for brief reactive psychoses consistent with the

Personality Disorder).
- Neurocognitive functional impairments.
- Bipolar disorder.
- Significant substance use without a desire to achieve abstinence.
- IQ lower than 80

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-07-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86152.091.24