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Promoting Psychological Adaptivity and Well-being of Patients with Personality Disorders with Creative Arts and Psychomotor Therapies: Protocol of an Intervention Mapping Study

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Promoting Psychological Adaptivity and Well-being of Patients with Personality Disorders with Creative Arts and Psychomotor Therapies: Protocol of an Intervention Mapping Study

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PROMOTING PSYCHOLOGICAL ADAPTIVITY AND WELL-BEING

Article Summary

Introduction. Personality disorders (PDs) cause much suffering. In treating patients with PDs, it is important to not only focus on reducing symptoms, but also on promoting psychological adaptivity and well-being. The experiential nature of creative arts and psychomotor therapies (CAPTs) contribute to working on psychological adaptivity and improving well-being, although more evidence is needed. This protocol paper describes a study to develop and evaluate a CAPTs-intervention aimed at promoting psychological adaptivity and well-being in people with PDs.

Methods and analysis. The CAPTs-intervention will be developed using the Intervention Mapping method. A mixed method design will be used for the evaluation of this intervention, using a multiple baseline single case experimental design (MBSCED). At least 17 participants with a PD will be included. Quantitative measures that will be completed weekly are the Generic Sense of Ability to Adapt Scale (GSAAS), the Self-Expression and Emotion Regulation in Art Therapy Scale (SERATS) and the Schema Mode Inventory (SMI, healthy adult and happy child). The Mental Health Continuum Short Form (MHC-SF), the Brief Symptom Inventory (BSI) and the SMI (complete) will only be completed at week 1 and 10 of the intervention. Qualitative instruments are an online survey for experience experts, focus groups for CAPTs-therapists, psychologists, managers and referrers, and semi-structured interviews with patients. Quantitative outcomes will be analysed with linear mixed models. Qualitative analysis will be performed using thematic analysis.

Ethics and dissemination. This study has been approved by the Research Ethics Committee of the HAN University of Applied Sciences (ref: ECO 471.07/23). All participants will sign an Informed Consent and data will be treated confidentially. Study findings will be published Open Access in peer reviewed journals.

Trial registration number. This study has been registered at https://www.ClinicalTrials.gov (trial registration number NCT06219122).

Keywords

Personality disorders, creative arts and psychomotor therapies, positive adaptivity, well-being.

Strengths and limitations of this study

+ This study focuses on positive mental health outcomes

+ In this study, an CAPTs-intervention is developed with the intervention mapping method

+ This study includes quantitative data as well as patients' and therapists' experiences and preferences

- Limitations: patients with cluster A PDs are difficult to reach, hence difficult to enrol.

- Limitations: the repeatedly measured outcomes require patients to complete a larger number of questionnaires during a prolonged period, which is burdening and is likely to result in missing data.

Promoting Psychological Adaptivity and Well-being of Patients with Personality Disorders with Creative Arts and Psychomotor Therapies.

Protocol of an Intervention Mapping Study

PROMOTING PSYCHOLOGICAL ADAPTIVITY AND WELL-BEING

Introduction

Personality disorders (PDs) are severe psychiatric disorders with a persistent course. In the Netherlands, the estimated prevalence of PDs ranges between 5% to 10%[1]. PDs are characterised by persistent, rigid and maladaptive patterns of inner experiences and behaviours, which are often the result of genetic predisposition and coping with negative (early) childhood experiences[2]. Maladaptive patterns in behaviour, feelings, and thoughts lead to long-term disruption of intra- and interpersonal relationships[3,4]. This results in difficulties in strengthening their own well-being, sometimes even resisting positive experiences[5]. Furthermore, having a PD is often accompanied by comorbidity of other psychopathology such as depression, anxiety and addiction and causes much personal suffering[1,5,2]. Specialised treatment for PDs is warranted and should not only focus on decreasing PD symptoms such as maladaptive patterns, but also on improving well-being and psychological adaptivity. This has often been referred to as the two-continua model (e.g. focusing on both mental illness and mental health[6]).

In treating patients with PD, there are several ways to work on psychological adaptivity. A commonly used psychotherapy is Schema-Focused Therapy (SFT), which has been developed by Jeffrey Young[7] for patients with PD. In SFT, Young distinguishes between schemas and modes. Feelings and thoughts are guided by schemas[7-9], whereas modes are the affective states brought about by schemas. Patients with PDs have dysfunctional schemas and dysfunctional modes[10]. SFT aims to work on decreasing these dysfunctional schemas and modes and developing functional and positive ones. In SFT terminology, Happy Child and Healthy Adult functioning are specifically described as functional modes and these focus on fulfilling emotional needs in a healthy and adaptive way[9-11].

Positive Psychology also focusses on psychological adaptivity by targeting mental health, well-being, strength, reinforcement of positive affect, and flow [12-14]. In the model of sustainable mental health[15] positive psychology and mental well-being are integrated into mental healthcare. Huber[16] states that health is a dynamic ability to adapt and control oneself as much as possible considering the social, mental and physical challenges of life. Therefore, it is important to not only focus on symptom reduction in treatment, but also on strengthening well-being by focusing interventions on positive behaviours, emotions and thoughts[15,17-20]. Recent studies show that these

types of interventions contribute to decreases in psychological symptoms and increases in well-being in clinical populations[21].

While SFT and other forms of psychotherapy are more cognitive in nature and focuses on cognitions and perceptions, creative arts and psychomotor therapies (CAPTs) are more experiential and focus on sensations, emotions and behaviours. CAPTs are often offered to reduce clinical symptoms and improve psychological well-being of PDs and other psychological disorders[22-24]. These therapies include visual art, drama, music, dance and psychomotor therapy. Thoughts, feelings and behavioural patterns can be expressed or elicited through e.g. drawing/painting, creating, bodily awareness, theatre/role-playing or music. Awareness and (self-)reflection are stimulated and new skills and roles are practiced in an accessible and secure setting[25-28]. The experiential, creative, playful and "as if"-nature of the CAPTs contributes to working on psychological challenges of PDs and improving psychological well-being[22]. CAPTs have the potential to diminish dysfunctional schemas and strengthen functional ones, and patients can develop more adequate ways of coping with daily life situations[9]. Hence combining CAPTs with SFT could be beneficial in the treatment of PDs.

To date, few CAPTs-interventions exist aimed at improving psychological adaptivity, and there has been little practice-based research on the treatment of PDs with CAPTs. There is a growing demand for evidence-based CAPTs-interventions, with these interventions often perceived as positive in practice by patients and therapists. According to professionals, patients and research results, CAPTs show promise for promoting psychological adaptivity and well-being of patients with PDs. In March 2021, we conducted a survey in which CAPTs-therapists expressed a preference for an intervention that aligns with SFT. Therefore, we will develop a CAPTs-intervention based on SFT and positive psychology interventions. Haeyen[29] published a book with this focus containing many practice based working methods. These methods form the basis for development of a CAPTs-intervention. The goal of this intervention will be to reinforce psychological adaptivity and well-being by strengthening helpful schemas and modes.

Research aims

- *To develop a CAPTs-intervention based on SFT and positive psychology that is aimed at promoting psychological adaptivity and well-being.*

- *To evaluate the effectiveness of the CAPTs-intervention in promoting psychological adaptivity and well-being in patients with PDs.*

Methods and analysis

Design

This Intervention Mapping (IM) study will combine quantitative and qualitative methods. IM is a systematic method for developing, implementing and evaluating healthcare interventions[30]. Each step includes certain tasks integrating theory and evidence and results in a product that is the guide for the next step. These steps are used to arrive at an intervention that promotes health[30].

Step 1 and 2 (Needs assessment & Change Objectives) starts with a literature review of working mechanisms in CAPTs in PDs. Subsequently, 6 focus groups will be held: 5 consisting of the different disciplines of CAPTs-therapists (visual art, music, dance, drama and psychomotor) and one focus group of psychologists, psychotherapists and managers, all of them specialised in the treatment of patients with PDs. Lastly, a survey will be held among experience experts. Based on the input of the data collection in Step 1, we will produce a Matrix of Change Objectives in step 2.

In Step 3 and Step 4 (Theoretical methods and practical strategies & Intervention development) two art therapists will make an initial selection of practical strategies. The chosen methods and assignments will then be viewed by other CAPTs-therapists from all disciplines, to increase inter-rater reliability. This is an integrative process in which the expertise of different CAPTs-therapists is combined. This will result in an CAPTs-intervention and practical guidance for professionals so that they can use the intervention in the treatment of patients with PDs. Once the intervention has been developed, in **Step 5 (Implementation),** we will conduct interviews with program managers, CAPTs-therapists and psychiatrists to test the conditions for implementation. In addition, we will test the feasibility of the CAPTs-intervention with students in the university's CAPTs program and with patients in a treatment setting.

Step 6 (Evaluation) the test-phase of the study, comprises a mixed method approach consisting of a multiple-baseline single-case experimental design (MBSCED) and qualitative interviews that together allow us to evaluate the intervention's effectiveness. In a MBSCED, participants are monitored over time and repeated measurements are conducted, in our case weekly.

Participants will be randomised for the time at which they start the treatment, resulting in baselines varying from 5 to 7 weeks. All patients will then start the intervention for 10 weeks, with a follow-up period of 5 weeks. By randomising the baseline period each participant functions as his/her own control, enabling us to isolate treatment effects[31]. The MBSCED accounts adequately for threats to internal validity (e.g., maturation, history and regression to the mean – instead of the CAPTs-intervention – as rival explanations for improvement rather than CAPTs treatment). Based on a power analysis for an MBSCED, assuming a medium effect size (Cohen's d=0.6) and an α of 5%, inclusion of 10 participants yields 80% power[32]. Measurements in the intervention period will be compared with measurements at baseline and follow-up. The intervention will conclude with semi-structured interviews exploring the perceived effects and experiences of patients and therapists.

Study Setting

The study will last 24 months, with preparation from February 2023 to publication of findings in February 2025. The test-phase will be conducted in three mental health facilities, specialised in the treatment of patients with PDs. We verified the potential number of eligible participants and concluded that including at least 17 patients is feasible. Depending on the number of therapy groups, x number of different CAPTs-therapists will be involved in implementing the intervention, two per therapy group. The CAPTs-intervention will be given in addition to usual treatment. This may include outpatient treatment, part-time treatment or inpatient treatment for PDs.

Eligibility criteria

Students in Step 5 of IM will be recruited through the university's CAPTs program. Patients in Step 5 and 6 of IM will be enrolled by art therapists and clinicians. The eligibility criteria will be as follows: (1) being diagnosed with one or more PD according to the DSM-V criteria, (2) age between 18 and 65 years, (3) being motivated for CAPTs, and (4) able to participate in group therapy. The patient's multidisciplinary treatment panel will, in consultation with the patient, determine whether the criteria are met. Exclusion criteria include: (1) acute psychosis or crisis, (2) prominent PTSD symptoms which require specialised trauma treatment, (3) a possible eating disorder defined as a BMI lower than 18.

Procedure

All recruited participants will sign an Informed Consent which has been ethically approved by the ethics committee of the HAN University of Applied Sciences. The Informed Consent explains the data collection, management procedures and other ethical aspects, and emphasises that participation is voluntary (for an example, see Appendix D). All participants will be informed verbally about the study by researchers before enrolment. Participants can stop participating in the study at any time.

In Step 1 and 2 of IM, the experience experts who participate in the online survey, will be invited through an online platform for mental health care patients and their families (MIND). Furthermore, participating CAPTs-therapists, psychologists and managers in the 6 focus groups, will be recruited through the Federation of Dutch CAPTs-therapist, through the participating institutions and an earlier survey. Information will be collected about the needs and preferences of professionals who work with people with PD. In these focus groups the treatment of people with PD, (working mechanisms of) the CAPTs, the potential form and nature of the intervention and psychological adaptivity will be discussed.

The CAPTs-therapists participating in Step 3 and 4 of IM, are being recruited among participants in focus groups and through our own network. The program managers, CAPTs-therapists and psychiatrists who will be participating in interviews to test the conditions for implementation in Step 5 of IM, will be recruited through the participating institutions. Participating students in Step 5 of IM, will be informed via e-mail and an information letter about the intervention and the meetings in which they will experience the intervention.

Participating CAPTs-therapists who will implement the intervention in Step 6 of IM, will be recruited from the various participating mental health facilities. They require to be certified in CAPTs, work in mental healthcare clinics and have experience with SFT and treating patients with PD. They will be instructed by one of the researchers about the to-be developed CAPTs-intervention and the data collection methods. Participating CAPTs-therapists will be provided with the practical guidelines about the intervention. To discuss any insights or problems that arise, they will be asked to join online supervision sessions. On completion of the intervention, the CAPTs-therapists will be asked to participate in a focus group about the use and effects of the intervention, their experiences and about the working mechanisms of the CAPTs- intervention. The

psychologists that referred to the patients will also participate in a focus group together, to ask if and why people should be referred to the CAPTs and discuss their experiences with the intervention.

Participating patients in Step 5 and 6 of IM will be recruited at attending mental health facilities, by their treating clinician when the CAPTs-intervention is in line with their treatment goals. The intervention is complementary to their treatment as usual. Patients will be informed through their treating clinician about the study and through an information letter. At the start of the intervention, patients will receive a patient number and a computer-generated, randomised baseline period lasting 5-7 weeks, followed by the CAPTs-intervention (10 weeks) and follow-up (5 weeks). One researcher will create the numbers, another researcher will do the allocation of the computer-generated baseline periods. Each week, patients will complete the relevant questionnaires (GSAAS, SERATS, SMI healthy adult and happy child). The MHC-SF, BSI and SMI (complete) will also be completed at the start of the intervention and after the final therapy session. After follow-up, 15 patients will be interviewed by a researcher, focusing on perceived effects of the CAPTs-intervention (see Figure 1).

Figure 1. Timeline of Test-Phase.

[Insert Figure 1]

Note. Visualisation of the MBSCED design.

Measures

Quantitative measures

Primary outcome

Participants' ability to adapt will be measured using the Generic Sense of Ability to Adapt Scale (GSAAS)[33] consisting of 10 items. Items are phrased as follows: *I can cope well with adverse circumstances,* and *I see plenty of interesting challenges,* with responses given on a 5-point Likert scale from *not at all* (0) to *always* (4). The total average score reflects the overall sense of adaptability. The scale showed good internal consistency (Cronbach's $\alpha = 0.89$) and moderate to strong correlations between the GSAAS and concurrent validation measures confirmed convergent validity[33].

Secondary outcomes

Participants' well-being will be measured using the Mental Health Continuum – short form (MHC-SF)[34], consisting of 14 items aimed at positive mental health. The MHC-SF measures three dimensions of well-being: emotional, psychological and social well-being. Items are phrased as follows: *In the past week, how often did you feel*… (e.g., *happy*), with responses given on a 6-point Likert scale (from *never* to *every day*). The total score of the MHC-SF has sufficient to high internal consistency. Cronbach's α ranges from 0.76 to 0.91 across studies[35]. Confirmatory factor analysis confirmed the three-factor structure of emotional, psychological and social well-being, with convergent validity among these three dimensions[36].

Self-expression and emotion regulation through the CAPTs

Participants' capacity for self-expression and emotion regulation through CAPTs will be measured using the Self-Expression and Emotion Regulation in Art Therapy Scale (SERATS)[37], consisting of nine items (e.g., *In art therapy, I can express my feelings*) measured on a 5-point Likert scale from (*almost) never* to (*almost) always*. A single total score is calculated. SERATS has been found to show high internal consistency (Cronbach's α=0.94) and high convergent validity[37].

Schema modes

Participant's schema modes will be measured using the Schema Mode Inventory (SMI)[38], consisting of 118 items divided into 14 subscales. Items are phrased as follows: *I deny myself pleasure because I don't deserve it,* and *I feel content and at ease*, with responses given on a 6-point Likert scale from *never or almost never* (1) to *all of the* time (6). The 14 subscales result in acceptable internal consistencies (Cronbach's α ranges from 0.79 to 0.96)[38]. The subscales of the adaptive modes, the healthy adult and the happy child, will be measured weekly. The maladaptive modes will be measured twice, before and after the intervention.

Psychological symptoms

The Brief Symptom Inventory (BSI) is used to measure psychological symptoms. It consists of 53 items covering nine symptom dimensions and three global indices of distress. The global indices respectively measure intensity of symptoms, current or past level of

symptomatology and number of reported symptoms[39]. Items are phrased as follows: *In the past week, how often did you experience…* (e.g., *the idea that another person can influence your thoughts* or *nervousness*) with responses given on a 5-point Likert scale (from *not at all* (0) to *extremely* (4)). The BSI shows high total internal consistency (Cronbach's α 0.96)[40].

Qualitative measures

Experience experts in Step 1 of IM will complete an online survey. They will be asked about their preferences and needs in working on psychological adaptivity and well-being. Also, a few questions will be about the CAPTs, verbal therapy and SFT in general, to find out what helped them in the past and what not.

CAPTs-therapists, psychologists and managers will participate in focus groups, using the method of Raats[41]. In Step 1 of IM they will be asked about what the intervention should look like, working mechanisms of CAPTs and their knowledge about psychological adaptivity. In Step 6 they will be asked about their experiences and the use and effects of the CAPTs-intervention.

Participating patients in Step 6 of IM will be asked about their experiences with the CAPTs-intervention. The patients will be interviewed individually using a semi-structured interview based on the *change interview*, focusing on identifying change processes in therapy[42]. An interview guide with a topic list will be used to prevent important topics from being neglected. The aim of the interviews is to evaluate the experiences with the CAPTs-intervention.

Data management

Researchers from the Research Group for Arts and Psychomotor Therapies in Health Care at the HAN University of Applied Sciences will manage the data in accordance with the 'FAIR Guiding Principles for scientific data management and stewardship'. A data management plan has been assessed and approved by the ethics committee (ECO 471.07/23) of the HAN University of Applied Sciences. Data will be stored on a secured research drive and entered twice to ensure accuracy. Informed consent forms will be stored on a secured research drive of the HAN University of Applied Sciences. The research team will be able to access participant data based on participant number only. Only the research team will have access to the final data set.

Data analysis

Demographic and clinical characteristics

Participants' demographic and clinical characteristics will be summarised with descriptive statistics (means and SDs for interval variables, median and IQR for ordinal variables, numbers and percentages for nominal variables). The following demographics of participants will be reported: age, gender, diagnosis (type of PD) and number of CAPTs sessions attended. Of the participating therapists, the following demographic data will be reported: age, gender, CAPTs discipline, years of working experience, target population and setting.

Quantitative data

Quantitative data will be analysed using MultiSCED. This is an application built with Shiny[43], a framework to create interactive web apps that provide a user-friendly interface for R functionalities[44]. The application will allow for the analysis of repeatedly measured data collected at 16–18 time points. The outcomes as measured by the GSAAS, MHC-SF, SERATS, SMI and BSI are the dependent variables. These outcomes reflect clinical symptoms and well-being. Time, phase (control vs treatment period) and the interaction between them (time×phase) will be included as the independent variables.

Two analyses will be performed in MultiSCED. First, analysis at the level of aggregated data involves a linear mixed model. A random intercept and slope will be included to account for the dependence of observations within participants at different time points. Mean differences in outcomes between the baseline period, intervention period and follow-up period will be calculated. Hypothesis testing for the fixed effects of linear mixed models in MultiSCED will be performed using a t-test with the Kenward-Roger approximation for df[45]. Linear mixed models are well equipped to handle missing data under the assumption of 'missing at random'. In the primary analysis, we will adopt an intention-to-treat approach that includes all participants, regardless of treatment fidelity, therapy compliance and being lost to follow-up. The secondary analysis will only include those participants with adequate treatment fidelity and compliance. In a sensitivity analysis, the robustness of the findings will be analysed by repeating the analysis with only those participants without missing data (complete-case analysis) and without multivariate outliers (Mahalanobis distance).

Second, an analysis will be performed at the level of the individual participants. This analysis will involve ordinary least squares regression with the outcomes of the SERATS, GSAAS, SMI, MHC-SF and BSI included as the dependent variables. Time, phase (control vs treatment period) and the interaction between time×phase will be included as the independent variables. MultiSCED provides participant-specific regression coefficients, together with their SEs, t values and p values. Lastly, the individual trajectories and overall outcomes will be visualised in graphs.

Since the MHC-SF, BSI and SMI (complete) will only be administered twice (T7 and T16), the mean within-subject difference over time for these measures will be tested using a paired sample t-test. In all analyses, an α of 5% will be adopted.

Qualitative measures

The results of the survey will be analysed in ATLAS.ti for Windows (v.23.0). The focus groups with the therapists, the interviews with managers and psychologists, as well as the interviews with participants and therapists, will be audio-recorded, transcribed verbatim and analysed in ATLAS.ti. Consistent with the principles of Grounded Theory[46], we will apply three coding steps (open, axial and selective coding). All codes will be displayed in a code tree, then compared and renamed to develop core and subcategories of themes.

Integration of quantitative and qualitative results

Individual MBSCED trajectories will be analysed through the lens of the interview outcomes. Inter- and intrapersonal similarities and differences in outcomes will be explored. Based on these findings, the effectiveness of the CAPTs-intervention will be assessed, and recommendations made regarding its use in clinical practice.

Monitoring

This study has an external advisory board consisting of a psychologist, a manager of one of the mental health facilities, a psychology professor from the University of Twente, a music therapist, a patient representative of the Client Advisory Board of the Dutch Federation of Arts Therapies, and a patient and relatives representative of MIND, a national platform for people in mental health care. The external advisory board will meet with the principal researcher every 3 months during the project period.

The intervention will be created by two art therapists. To ensure that the intervention connects with professional practice, the outcomes of the focus groups with CAPTs-therapists will be used to develop the intervention. Subsequently, the working methods in the intervention will be presented to a few CAPTs-therapists of every discipline to check if they fit the goals of the sessions. Later, the intervention will be tested with a group of students and patients and the experiences will be collected. Based on this, the intervention will be adjusted again. In this way we ensure that the quality of the intervention remains guaranteed.

One of the researchers will monitor weekly whether participants fill out the questionnaires. If necessary, participants will be contacted and requested to complete the questionnaires and therapists will help remind them to complete the questionnaires. In addition to the questionnaires, a researcher will ask participants how they are doing halfway through the intervention. This is to monitor the well-being of the participants and manage adverse events. The question will be asked by a researcher to prevent the participant from giving socially desirable answers to the therapist.

The participating therapists will receive supervision from another art therapist every 3 weeks. Here they can discuss how the implementation of the intervention is going, what they encounter and how they experience the implementation.

Patient and public involvement

Patients' representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies and MIND will be involved in the development of the study proposal and research question. In addition, we will develop a questionnaire about their experiences with psychotherapy and CAPTs. We will use the outcomes in the intervention's development.

Ethics and dissemination

The local medical ethical committee (METC Oost-Nederland) indicated that this study is not subject to the Dutch Medical Research Involving Human Subjects Act (2023-16438). The study was approved by the official Research Ethics Committee of the HAN University of Applied Sciences (ref: ECO 471.07/23). All participants will be given study information through an information letter and verbal explanation by the researcher before written informed consent was obtained. Personal data will be processed confidentially in encrypted files and stored on a secured research drive of the HAN University of Applied Sciences. Any deviations from the study protocol

will be described in an appendix in the final publication. Study results will be disseminated to professionals and students through presentations and publications. Also, results will be disseminated to the study participants on request. Access to the full participant-level dataset will be handled by the principle investigator upon reasonable request.

Funding

This study is funded by Regieorgaan SIA: Raak Publiek (RAAK.PUB10.003). The study funder is not involved in the execution of the study, in data analysis and interpretation or in the decision to submit results.

Competing interests statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

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Author contribution statement

SH, KT, HW and JH conceived of the presented idea. SH, IW, KT, HW and JH contributed to the design and the writing of the study protocol. KT and IW carried out the ethical procedures. SH, KT, IW and JH will take care of the implementation of the research. SH and KT will develop the intervention. IW and KT will monitor the therapists' procedures and patients' procedures. HW will conduct the statistical analysis. SH as principal investigator oversees the research process and connects with the advisory board. IW wrote the first draft of the manuscript, SH, KT, HW and JH critically reviewed the manuscript for intellectual content.

Date and version Identifier

Non applicable since the intervention is yet to be developed.

Word Count: 3991 (Introduction-Acknowledgements).

APPENDICES

Appendix A: Summary of clinical trial registration

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT06219122
Date of registration in primary registry	December 2023
Secondary identifying numbers	Unique protocol ID: NDPD - SU1606
Source(s) of monetary or material support	RAAK Publiek, Regieorgaan SIA RAAK.PUB10.003
Primary sponsor	RAAK Publiek, Regieorgaan SIA RAAK.PUB10.003
Secondary sponsor(s)	-
Contact for public queries	*Dr. Suzanne Haeyen*, [suzanne.haeyen@han.nl]
Public title	The Effectiveness of a Creative Arts and Psychomotor Therapy Intervention for People With Personality Disorders. From Negative Thinking to Positive Doing. (NDPD)
Scientific title	The Effectiveness of a Creative Arts and Psychomotor Therapy Intervention for People With Personality Disorders to Enhance Psychological Adaptation and Wellbeing, a Multiple Baseline Single Case Experimental Design

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Countries of recruitment	The Netherlands
Health condition(s) or problem(s) studied	Personality Disorders
Intervention(s)	Creative Arts and Psychomotor Therapy Intervention
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no Inclusion criteria: adult patient (≥ 18 years), being eligible for group therapy, having a personality disorder. Exclusion criteria: excessive dissociation, conversion disorder, excessive destructive and suicidal behaviour, present psychosis.
Study type	Interventional Allocation: patients randomised for the time at which they start the intervention: CONSORT recognises this design as an N=1 Trial, please refer to https://www.consort-statement.org/extensions/overview/n-of-1 Intervention model: Multiple baseline single case experimental design Masking: None (Open Label)

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	Primary purpose: Treatment Phase: N/A
Date of first enrolment	January 31, 2024
Target sample size	17
Recruitment status	Recruiting
Primary outcome(s)	- GSAAS
Key secondary outcomes	- SERATS - SMI adaptive scales, weekly - SMI complete, 2 measures - MHC-sf - BSI

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Appendix B: Sponsor contact information

Trial Sponsor: HAN University of Applied Sciences

Contact name: Suzanne Haeyen

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Telephone: (024) 35 31 575

Email: suzanne.haeyen@han.nl

Appendix C: Organisational structure

Principle Investigator and research team

This research is led by the research group "Arts and psychomotor therapies in health care" from the HAN University of Applied Sciences.

Tasks of this research group include:

- Setting up the study
- Preparation of study protocol
- Managing the execution of the study protocol
- Data management
- Analysing results
- Publication of study reports

The research group is led by Suzanne Haeyen, the main applicant. In authors contribution, other group members' contributions can be viewed.

GGNet Scelta

GGNet Scelta is an expert centre for diagnosis and treatment of personality disorders and an important collaborative partner. At GGNet, several patients will be selected to participate in this study.

Mediant De Boerhaven

Mediant De Boerhaven is a mental health institution for diagnosis and treatment of patients with personality disorders. At Mediant, several patients will be selected to participate in this study.

University of Twente

The University of Twente is a pioneer in connecting technology, science and engineering with social sciences to make a difference in the world around us.

MIND

MIND is an independent social organization that advocates for a psychologically healthier Netherlands and gives a voice to all people with (incipient) mental health symptoms and their loved ones.

Appendix D: Patient Consent Form

Research title: from Negative Thinking to Positive Doing

Dear Sir/Madam,

In this information letter we request your participation in a scientific study and provide information about what it entails.

We are asking you to participate because you are being treated at your mental health care facility for personality problems, trauma or other psychological complaints. The treatment includes creative arts and psychomotor therapies. By creative arts and psychomotor therapy, we mean art therapy (drawing/painting), music therapy, drama therapy (acting), dance therapy or psychomotor therapy (sports and movement). This study takes place at your mental health care facility.

Participation is voluntary. You decide whether you want to participate or not. In this letter you will find all the information you need to decide. If you have any questions, feel free to ask the researchers or your therapist.

Have you decided to participate? Then please fill out the consent form found in Appendix 1.

Why this study?

Creative arts and psychomotor therapy are commonly used within the treatment of personality disorders, often because it works differently than talk therapy. Creative arts and psychomotor therapy work more by doing and experiencing. It can therefore be an important addition to treatment. There is still too little research into creative arts and psychomotor therapy. Moreover, research is important to improve creative arts and psychomotor therapy. In this research we want to further investigate **the effect of creative arts and psychomotor therapy**.

Possibly, creative arts and psychomotor therapy can reduce your symptoms. It may also enhance your well-being. We want to find out more about that.

What do we ask of you?

Participating in this study means that you will attend ten sessions of creative arts and psychomotor therapy of 1.5 hours each time. These are specially designed to increase your well-being. The intervention is schema-oriented and mainly aimed at alleviating symptoms and negative patterns. We will work on how to do this in an appropriate and healthy way. Therapy sessions consist of combined forms of creative arts and psychomotor therapy, in which two different disciplines (art, music, drama, psychomotor or dance) work together. The sessions consist of different forms of creative therapy focused on the goals set for you. These sessions are carried out during your regular treatment, in the creative arts and psychomotor therapy time. Treatment is followed in a group.

The treatment is followed in a group. In this study, all research participants are offered the arts and psychomotor therapy treatment. Only the time when someone starts depends on chance.

For the study, we ask you:

- To complete weekly questionnaires for 5-7 weeks before the start of the creative arts and psychomotor therapy treatment. Depending on chance, you will then start treatment after 5, 6, or 7 weeks. These questionnaires are about well-being, symptoms and how you see yourself. We think it will take 10 minutes each time to complete these questionnaires.
- During the creative arts and psychomotor therapy treatment, we will also ask you to fill out questionnaires. One time each week. Because the creative arts and psychomotor therapy program itself lasts ten weeks, this means ten questionnaires will be completed. The weekly questions are about well-being, how you see yourself and what you experience (these are called modes such as the "healthy adult" and "happy child" for example) and creative arts and psychomotor therapy as a treatment. These take about 10 minutes to complete. At the beginning (start of intervention) and end (after 10 sessions) there are some additional questions. These questionnaires take a little longer to complete (max. 45 min.)
- After completing the creative arts and psychomotor therapy treatments, we will ask you to complete the questionnaires you were used to filling out during the therapy program

five more times. With the questionnaires we want to find out if and which symptoms you experience, how you deal with situations, about your well-being (whether you feel good), what you think and what your experiences are during the creative arts and psychomotor therapy. We think that completing these questionnaires will take ten minutes each time. So, in total, you will have completed the set of questionnaires a maximum of 19-23 times. The random start is important. This allows us to know if creative arts and psychomotor therapy is effective and not that it was because of something else that happened by chance.

You do not have to remember yourself when it is time to complete the questionnaires. We will send you an email with a link and remind you.

- An interview at the end of the therapy. The interview has several questions and topics focused on the treatment. You can also add important issues of your own. Your own experience with the creative arts and psychomotor therapy treatment is central. The interview takes about three quarters of an hour. Of course, this interview may be shorter if you find it too long.

The questionnaires are used to investigate the effect of the creative arts and psychomotor therapy intervention. The data from the questionnaires are processed confidentially. Other people do not know what you have filled out.

An audio recording will be made of the interview. We do this to transcribe the interview completely. This is important for a reliable result. The interview is also processed confidentially. Again, other people do not know what you have said. Only the researcher who asked the questions knows what you answered.

The results of the study are processed in a research article. This is published in a scientific journal. The research is also presented to other creative arts and pyschomotor therapists and psychologists/psychiatrists. For example, at a conference.

What are the advantages and disadvantages for you?

The benefits of participating in this study are:

- Your participation allows us to improve creative arts and psychomotor therapy as a treatment.
- You can participate in a treatment aimed at reducing symptoms and increasing well-being.

The disadvantages of participating in this are very small. We will ask you to complete several questionnaires. This will take you about 10 minutes each week on average. For start and finish it will take about an hour. You may find some of the questions annoying. Please feel free to let the researcher know.

What if you don't want to join or quit?

It is your decision whether to participate in the study. **If you do not want to participate, you do not have to do anything.** You do not have to tell us why you do not want to participate. Nor do you have to sign anything. Your choice will not affect your treatment.

You can stop participating in the study at any time. You do not have to say why you want to stop. If the study has not yet started, we will remove your data. Do you stop while the study is in progress? We will still include the data collected up to that point in the study. If you do not want this, you can indicate this, and we will destroy your data.

What happens to the data collected?

For this study, your personal data will be collected, used and stored. This includes name, contact information, gender, age and number of sessions of creative arts and psychomotor therapy attended. The data will be processed in encrypted files and your data will be kept confidential. The researchers involved can only see which research data belongs to a participant with a password. Thus, the data cannot be traced to anyone else. These files are used exclusively for this study. We keep the research data for 10 years and then it is deleted. We keep your personal data for at least 6 months and up to 2 years, after which it is deleted.

The completed consent forms and the encrypted files will be stored on the specially research-created, extra-secure Researchdrive of the relevant University of Applied Sciences: HAN University of Applied Sciences. The folder containing these files is only accessible to the

actively involved researchers. Naturally, in reports and publications about the research, the data cannot be traced back to you in any way.

The collection, use and retention of your data is necessary to answer the questions asked in this study. After all, we want to be able to answer what effects the patient group experiences. To do this, we need a representative group that represents all clients receiving treatment. A representative group consists of both men and women, of various age groups and of various personality disorders. We ask for your permission to use this data.

Access to your data for audit purposes

Persons who will have access to your transcripts for verification purposes are only the interviewer involved with you and the actively involved researchers. They will keep your data confidential. We ask that you give them permission to do so. Authorised bodies may also have access to your data, such as the Health and Youth Inspectorate.

May we contact your general practitioner or specialist?

During the study, we may happen to find something important to your mental health. If that happens, we will be happy to contact your treatment team. You consent to informing your treatment team with the form.

Retention and use of data.

Audio recordings of the interviews will be destroyed after typing them out, no more than six months after the interview was conducted.

Regarding the retention of data: the typed-out audio recordings and data (name, contact details, gender, age and diagnosis) will be retained for further analysis and may be relevant for follow-up research on creative arts and psychomotor therapy after the end of this study. For this purpose, these data will be kept for 10 years by the actively involved researchers, on the secure digital environment for research of the university of applied sciences involved. You can indicate on the consent form if you consent to this. If you do not consent, your data will not be stored for follow-up research. You can still participate in the current study.

Withdrawal of consent

You can withdraw your consent to the use of your data at any time. This applies to this study and to storage and use for future research. Research data collected up to the time you withdraw your consent will be destroyed.

More information about your rights in data processing

For general information about your rights when processing your personal data, please consult the website of the Personal Data Authority. For questions about the processing of your personal data, please contact the principal investigator. In case of complaints, you can also contact the Data Protection Officer of the institution concerned, see Appendix A for contact details.

The results of the study will be published. If you want to be notified about this, you can indicate this on the consent form.

Who can you contact with questions?

The research is being conducted by Karin Timmerman, MSc., of the University of Twente (executive researcher), Suzanne Haeyen (principal researcher) and Imke Wiersma (junior researcher) of the Research Group Arts & Psychomotor Therapies in Health Care of the HAN University of Applied Sciences.

Do you have any questions about the research? You can always ask the executive researcher involved. Below you will find our contact details:

Karin Timmerman, MSc.

E: k.timmerman@mediant.nl

Reachable: via mail

Good to know

This research has been reviewed and approved by the HAN Research Ethics Committee. In addition, this research has also been assessed by the Medical Ethical Review Committee Oost-Nederland (METC Oost-Nederland). Among other things, this committee assesses whether the researchers handled the (data of) participants with care. The METC Oost-Nederland thinks this research does not fall within the scope of the WMO Act.

Do you have complaints about the way the researcher handles you or your data? You can discuss this with the researcher herself. If you do not want to or if this does not help, you can contact the confidential advisor for scientific integrity of HAN: Richele Wind in Nijmegen (E: richele.wind@han.nl).

In case of complaints about the way the researcher handles your privacy, you can contact HAN's data protection officer (E: privacy@han.nl).

Your decision

If you want to participate, please complete and sign the consent statement.

You can find the consent statement in Appendix 1. You can complete the consent statement and turn it in to one of the researchers collaborating in this study.

Appendix 1: Statement of consent

Consent to participate in research 'From Negative Thinking to Positive Acting'.

I consent to participate in this study:

- I have read the information letter. I understand what this research is about. I also know what participation in the study entails. I commit to completing the questionnaires and participating in an interview. I understand the advantages and disadvantages of participating and what they mean to me.
- I was able to ask the researcher questions, and my questions were adequately answered. I also had enough time to decide whether to participate.
- I know I can quit this study whenever I want. I do not then have to explain why I am stopping.
- I consent to the collection and use of my data to answer the research question in this study.
- I choose to participate in this research.
- I know what data will be collected from me. It is clear to me how the researcher will handle it securely. I also know how long my data will be kept.
- I know that an audio-recording will be made of me if I am interviewed by one of the researchers. This recording is only used to write down what I said. The recording will be destroyed within 6 months.
- My information may be shared with the treatment team.

I **WOULD/NOT*** like to be kept informed about the (final) publication of this study. For this purpose, my contact data (first name, last name, e-mail address and phone number) will be kept longer than 6 months with a maximum of two years.

I **GIVE/DON'T GIVE*** permission to keep my contact data to contact me for participation in follow-up research.

I **GIVE/DON'T GIVE*** permission to share important information about my health (when found) with my treatment team.

*Striking out what does not apply.

PROMOTING PSYCHOLOGICAL ADAPTIVITY AND WELL-BEING

Name of participant: **Date:**

Signature:

To be completed by the executive investigator

I certify that I have fully and truthfully informed the research participant about the study.

Name of researcher: **Date:**

Signature:

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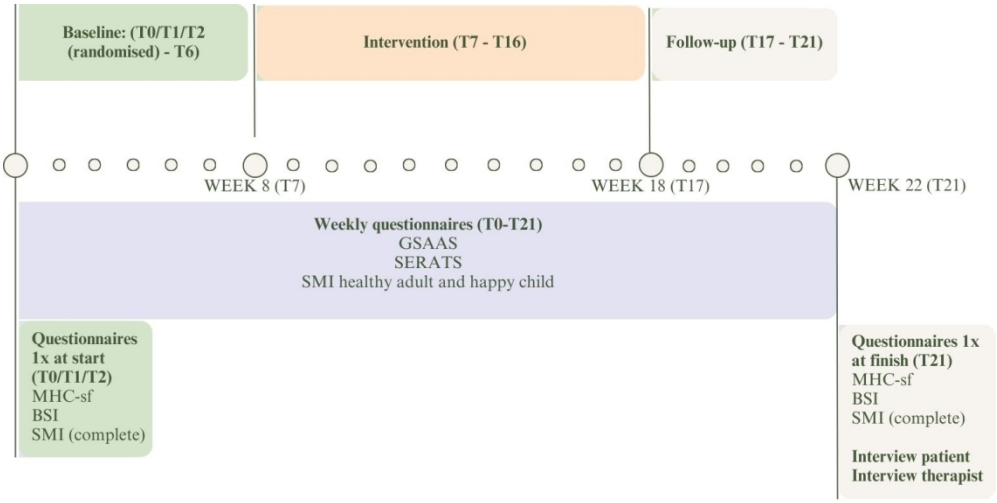

Note. Visualisation of the MBSCED design.

207x105mm (192 x 192 DPI)

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Promoting Psychological Adaptability and Well-being of Patients with Personality Disorders with Creative Arts and Psychomotor Therapies: Protocol of an Intervention Mapping Study

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Promoting Psychological Adaptability and Well-being of Patients with Personality Disorders with Creative Arts and Psychomotor Therapies: Protocol of an Intervention Mapping Study

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PROMOTING PSYCHOLOGICAL ADAPTABILITY AND WELL-BEING

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PROMOTING PSYCHOLOGICAL ADAPTABILITY AND WELL-BEING

Article Summary

Introduction. Personality disorders (PDs) cause much suffering. In treating patients with PDs, it is important to not only focus on reducing symptoms, but also on promoting psychological adaptability and well-being. The experiential nature of Creative Arts and Psychomotor Therapies (CAPTs) contributes to working on psychological adaptability and improving well-being, although more evidence is needed. This protocol paper describes a study to develop and evaluate a CAPTs-intervention aimed at promoting psychological adaptability and well-being in people with PDs.

Methods and analysis. The CAPTs-intervention will be developed using the Intervention Mapping method. A mixed method design will be used for the evaluation of this intervention, using a multiple baseline single case experimental design (MBSCED) with at least 17 participants with a PD included. Quantitative measures that will be completed weekly are the Generic Sense of Ability to Adapt Scale (GSAAS), the Self-Expression and Emotion Regulation in Art Therapy Scale (SERATS) and the Schema Mode Inventory (SMI, healthy adult and happy child). The Mental Health Continuum Short Form (MHC-SF), the Brief Symptom Inventory (BSI) and the SMI (complete) will only be completed at week 1 and 10 of the intervention. Qualitative instruments are an online survey for Experts by Experience, focus groups for CAPTs-therapists, psychologists, managers and referrers, and semi-structured interviews with patients. Quantitative outcomes will be analysed with linear mixed models. Qualitative analysis will be performed using thematic analysis.

Ethics and dissemination. This study has been approved by the Research Ethics Committee of the HAN University of Applied Sciences (ref: ECO 471.07/23). All participants will sign an Informed Consent and data will be treated confidentially. Study findings will be published Open Access in peer reviewed journals.

Trial registration number. This study has been registered at https://www.ClinicalTrials.gov (trial registration number NCT06219122).

Keywords

Personality disorders, Creative Arts and Psychomotor Therapies, positive adaptability, well-being.

Strengths and limitations of this study

PROMOTING PSYCHOLOGICAL ADAPTABILITY AND WELL-BEING

+ This study focuses on positive mental health outcomes

+ In this study, an CAPTs-intervention is developed with the intervention mapping method

+ This study includes quantitative data as well as patients' and therapists' experiences and preferences

- Limitations: patients with cluster A PDs are difficult to reach, hence difficult to enrol.

- Limitations: the repeatedly measured outcomes require patients to complete a larger number of questionnaires during a prolonged period, which is burdening and is likely to result in missing data.

Promoting Psychological Adaptability and Well-being of Patients with Personality Disorders with Creative Arts and Psychomotor Therapies.

Protocol of an Intervention Mapping Study

Introduction

Personality disorders (PDs) are severe psychiatric disorders with a persistent course. In the Netherlands, the estimated prevalence of PDs ranges between 5% to 10%[1]. PDs are characterised by persistent, rigid and maladaptive patterns of inner experiences and behaviours, which are often the result of genetic predisposition and coping with Adverse Childhood Experiences[2]. Maladaptive patterns in behaviour, feelings, and thoughts lead to long-term disruption of intra- and interpersonal relationships[3,4]. This results in difficulties in strengthening their own well-being, sometimes even resisting positive experiences[5]. Furthermore, having a PD is often accompanied by comorbidity of other psychopathology such as depression, anxiety and addiction and causes much personal suffering[1,5,2]. Specialised treatment for PDs is warranted and should not only focus on decreasing PD symptoms such as maladaptive patterns, but also on improving well-being and psychological adaptability. This has often been referred to as the two-continua model (e.g. focusing on both mental illness, and mental health[6]).

In treating patients with PD, there are several ways to work on psychological adaptability. A commonly used psychotherapy is Schema-Focused Therapy (SFT), which has been developed by Jeffrey Young[7] for patients with PD. In SFT, Young distinguishes between schemas and modes. Feelings and thoughts are guided by schemas[7-9], whereas modes are the affective states brought about by schemas. Patients with PDs have dysfunctional schemas and dysfunctional modes[10]. SFT aims to work on decreasing these dysfunctional schemas and modes and developing functional and positive ones. In SFT terminology, Happy Child and Healthy Adult functioning are specifically described as functional modes and these focus on fulfilling emotional needs in a healthy and adaptive way[9-11].

Positive Psychology also focusses on psychological adaptability by targeting mental health, well-being, strength, reinforcement of positive affect, and flow [12-14]. In the model of sustainable mental health[15] positive psychology and mental well-being are integrated into mental healthcare. Huber[16] states that health is a dynamic ability to adapt and control oneself as much as possible

considering the social, mental and physical challenges of life. Therefore, it is important to not only focus on symptom reduction in treatment, but also on strengthening well-being by focusing interventions on positive behaviours, emotions and thoughts[15,17-20]. Recent studies show that these types of interventions contribute to decreases in psychological symptoms and increases in well-being in clinical populations[21].

While SFT and other forms of psychotherapy are more cognitive in nature and focus on thoughts and perceptions, Creative Arts and Psychomotor Therapies (CAPTs) are experiential and focus on sensations, emotions and behaviours. CAPTs are often offered to reduce clinical symptoms and improve psychological well-being of PDs and other psychological disorders[22-24]. These therapies include visual art, drama, music, dance and psychomotor therapy. Thoughts, feelings and behavioural patterns can be expressed or elicited through e.g. drawing/painting, creating, bodily awareness, theatre/role-playing or music, in specific working methods of the CAPTs. Awareness and (self-)reflection are stimulated and new skills and roles are practiced in an accessible and secure setting[25-28]. The experiential, creative, playful and "as if" nature of the CAPTs contributes to working on psychological challenges of PDs and improving psychological well-being[22]. CAPTs, like psychotherapy, can be Schema-Focused. CAPTs working methods elicit patients' own dysfunctional schemes and modes and provides insight therein[9,29]. Subsequently, patients with PDs can learn to replace these dysfunctional schemes and modes and practice functional and adaptive ones such as the Healthy Adult, which promotes the Happy Child mode by fulfilling their basic emotional needs in connection with themselves and others[9,29]. The CAPTs working methods convey various manners to stimulate positive schemas and adaptive modes, such as reappraising sensory stimuli, improvising thus trying new behaviour, and resolving conflict between basic needs and dysfunctional modes[29]. Through the creative, playful and experiential nature of CAPTs, patients can develop more adequate ways of coping with and adapt to daily life situations[9]. Hence combining CAPTs with SFT could be beneficial in the treatment of PDs.

To date, few CAPTs-interventions exist aimed at improving psychological adaptability, and there has been little practice-based research on the treatment of PDs with CAPTs. There is a growing demand for evidence-based CAPTs-interventions, with these interventions often perceived as positive in practice by patients and therapists. According to professionals, patients and research results, CAPTs show promise for promoting psychological adaptability and well-

being of patients with PDs. In March 2021, we conducted a survey in which CAPTs-therapists expressed a preference for an intervention that aligns with SFT (unpublished data). Therefore, we will develop a CAPTs-intervention based on SFT and positive psychology interventions. Haeyen[30] published a book with this focus containing many practice based working methods. These methods form the basis for development of a CAPTs-intervention. The goal of this intervention will be to reinforce psychological adaptability and well-being by strengthening helpful schemas and modes.

Research aims

- *To develop a CAPTs-intervention based on SFT and positive psychology that is aimed at promoting psychological adaptability and well-being.*
- *To evaluate the effectiveness of the CAPTs-intervention in promoting psychological adaptability and well-being in patients with PDs.*

Methods and analysis

Design

This Intervention Mapping (IM) study will combine quantitative and qualitative methods. IM is a systematic method for developing, implementing and evaluating healthcare interventions[31]. Each step includes certain tasks integrating theory and evidence and results in a product that is the guide for the next step. These steps are used to arrive at an intervention that promotes health[31].

Step 1 and 2 (Needs assessment & Change Objectives) starts with a literature review of working mechanisms in CAPTs in PDs. Subsequently, 6 focus groups will be held: 5 consisting of the different disciplines of CAPTs-therapists (visual art, music, dance, drama and psychomotor) and one focus group of psychologists, psychotherapists and managers, all of them specialised in the treatment of patients with PDs. Lastly, a survey will be held among Experts by Experience. Based on the input of the data collection in Step 1, we will produce a Matrix of Change Objectives in step 2.

In Step 3 and Step 4 (Theoretical methods and practical strategies & Intervention development) two art therapists will make an initial selection of practical strategies. The chosen methods and assignments will then be viewed by other CAPTs-therapists from all disciplines, to increase inter-rater reliability. This is an integrative process in which the expertise of different

CAPTs-therapists is combined. This will result in a CAPTs-intervention and practical guidance for professionals so that they can use the intervention in the treatment of patients with PDs. Once the intervention has been developed, in **Step 5 (Implementation),** we will conduct interviews with program managers, CAPTs-therapists and psychiatrists to test the conditions for implementation. In addition, we will test the feasibility of the CAPTs-intervention with students in the university's CAPTs program and with patients in a treatment setting. Students and patients will participate in five different therapy sessions of the CAPTs-intervention, to test whether the sessions are feasible in time and if the variety of working methods works.

Step 6 (Evaluation) the test-phase of the study, comprises a mixed method approach consisting of a multiple-baseline single-case experimental design (MBSCED) and qualitative interviews that together allow us to evaluate the intervention's effectiveness. In a MBSCED, participants are monitored over time and repeated measurements are conducted, in our case weekly. Participants will be randomised for the time at which they start the treatment, resulting in baselines varying from 5 to 7 weeks. All patients will then start the intervention for 10 weeks, with a follow-up period of 5 weeks. By randomising the baseline period each participant functions as his/her own control, enabling us to isolate treatment effects[32]. The MBSCED accounts adequately for threats to internal validity (e.g., maturation, history and regression to the mean – instead of the CAPTs-intervention – as rival explanations for improvement rather than CAPTs treatment). Based on a power analysis for an MBSCED, assuming a medium effect size (Cohen's d=0.5), an autocorrelation of 0.2, at least 20 measurements, and an α of 5%, inclusion of 10 participants yields >80% power[33]. Measurements in the intervention period will be compared with measurements at baseline and follow-up. The intervention will conclude with semi-structured interviews exploring the perceived effects and experiences of patients and therapists.

Study Setting

The study will last 24 months, with preparation from February 2023 to publication of findings in February 2025. The test-phase will be conducted in three mental health facilities, specialised in the treatment of patients with PDs. We verified the potential number of eligible participants and concluded that including at least 17 patients is feasible. We expect to start at least three therapy groups involving six different CAPTs-therapists, two per therapy group. The CAPTs-

intervention will be given in addition to usual treatment. This may include outpatient treatment, part-time treatment or inpatient treatment for PDs.

Eligibility criteria

Students in Step 5 of IM will be recruited through the university's CAPTs program. Patients in Step 5 and 6 of IM will be enrolled by art therapists and clinicians. The eligibility criteria will be as follows: (1) being diagnosed with one or more PD according to the DSM-V criteria, (2) age between 18 and 65 years, (3) being motivated for CAPTs, and (4) able to participate in group therapy. The patient's multidisciplinary treatment panel will, in consultation with the patient, determine whether the criteria are met. Exclusion criteria include: (1) acute psychosis or crisis, (2) prominent PTSD symptoms which require specialised trauma treatment, (3) a suspected eating disorder defined as a BMI lower than 18, (4) an IQ below 85, (5) insufficient command of the Dutch language.

Procedure

All recruited participants will sign an Informed Consent which has been ethically approved by the ethics committee of the HAN University of Applied Sciences. The Informed Consent explains the data collection, management procedures and other ethical aspects, and emphasises that participation is voluntary (for an example, see Patient Consent Form). All participants will be informed verbally about the study by researchers before enrolment. Participants can stop participating in the study at any time.

In Step 1 and 2 of IM, the Experts by Experience who participate in the online survey, will be invited through an online platform for mental health care patients and their families (MIND). Furthermore, participating CAPTs-therapists, psychologists and managers in the 6 focus groups, will be recruited through the Federation of Dutch CAPTs-therapist, through the participating institutions and an earlier survey. Information will be collected about the needs and preferences of professionals who work with people with PD. In these focus groups the treatment of people with PD, (working mechanisms of) the CAPTs, the potential form and nature of the intervention and psychological adaptability will be discussed.

The CAPTs-therapists participating in Step 3 and 4 of IM, are being recruited among participants in focus groups and through our own network. The program managers, CAPTs-

therapists and psychiatrists who will be participating in interviews to test the conditions for implementation in Step 5 of IM, will be recruited through the participating institutions. Participating students in Step 5 of IM, will be informed via e-mail and an information letter about the intervention and the meetings in which they will experience the intervention.

Participating CAPTs-therapists who will implement the intervention in Step 6 of IM, will be recruited from the various participating mental health facilities. They require to be certified in CAPTs, work in mental healthcare clinics and have experience with SFT and treating patients with PD. They will be instructed by one of the researchers about the to-be developed CAPTs-intervention and the data collection methods. Participating CAPTs-therapists will be provided with the practical guidelines about the intervention. To discuss any insights or problems that arise, they will be asked to join online supervision sessions. On completion of the intervention, the CAPTs-therapists will be asked to participate in a focus group about the use and effects of the intervention, their experiences and about the working mechanisms of the CAPTs- intervention. The psychologists that referred to the patients will also participate in a focus group together, to ask if and why people should be referred to the CAPTs and discuss their experiences with the intervention.

Patients who participate in Step 5 and 6 of IM will be recruited at attending mental health facilities, by their treating clinician when the CAPTs-intervention is in line with their treatment goals. The intervention is complementary to their treatment as usual. Patients will be informed through their treating clinician about the study and through an information letter. At the start of the intervention, patients will receive a patient number and a computer-generated, randomised baseline period lasting 5-7 weeks, followed by the CAPTs-intervention (10 weeks) and follow-up (5 weeks). One researcher will create the numbers, another researcher will do the allocation of the computer-generated baseline periods. To prevent questionnaire burden, not every outcome will be assessed each week. Since the Generic Sense of Ability to Adapt Scale (GSAAS), Self-Expression and Emotion Regulation in Art Therapy Scale (SERATS), and Schema Mode Inventory (SMI) healthy adult and happy child are the direct and relevant outcomes for adaptability, these 38 items in total will be assessed every week. The Mental Health Continuum – short form (MHC-SF), Brief Symptom Inventory (BSI) and complete version of the SMI, a total of 165 items will only be completed at the start of the intervention and after the final therapy session. Since well-being (as

measured with the MHC-SF) is expected to increase only after a while, it would not make much sense to administer the MHC-SF every week. The BSI and SMI are lengthy, hence filling these out every week would be time-consuming and burdensome for patients. After follow-up, 15 patients will be interviewed by a researcher, focusing on perceived effects of the CAPTs-intervention (see Figure 1).

Figure 1. Timeline of Test-Phase.

[Insert Figure 1]

Note. Visualisation of the MBSCED design.

Measures

Quantitative measures

Primary outcome

Participants' ability to adapt will be measured using the GSAAS[34] consisting of 10 items. Items are phrased as follows: *I can cope well with adverse circumstances,* and *I see plenty of interesting challenges,* with responses given on a 5-point Likert scale from *not at all* (0) to *always* (4). The total average score reflects the overall sense of adaptability. The scale showed good internal consistency (Cronbach's $\alpha = 0.89$) and moderate to strong correlations between the GSAAS and concurrent validation measures confirmed convergent validity[34].

Secondary outcomes

Self-expression and emotion regulation through the CAPTs

Participants' capacity for self-expression and emotion regulation through CAPTs will be measured using the SERATS [35], consisting of nine items (e.g., *In art therapy, I can express my feelings*) measured on a 5-point Likert scale from (*almost) never* to (*almost) always*. A single total score is calculated. SERATS has been found to show high internal consistency (Cronbach's α=0.94) and high convergent validity[35].

Schema modes

Participant's schema modes will be measured using the SMI [36], consisting of 118 items divided into 14 subscales. Items are phrased as follows: *I deny myself pleasure because I don't*

deserve it, and *I feel content and at ease*, with responses given on a 6-point Likert scale from *never or almost never* (1) to *all of the* time (6). The 14 subscales result in acceptable internal consistencies (Cronbach's α ranges from 0.79 to 0.96)[36]. The subscales of the adaptive modes, the healthy adult and the happy child, will be measured weekly. The maladaptive modes will be measured twice, before and after the intervention.

Mental well-being

Participants' well-being will be measured using the MHC-SF[37], consisting of 14 items aimed at positive mental health. The MHC-SF measures three dimensions of well-being: emotional, psychological and social well-being. Items are phrased as follows: *In the past week, how often did you feel*… (e.g., *happy*), with responses given on a 6-point Likert scale (from *never* to *every day*). The total score of the MHC-SF has sufficient to high internal consistency. Cronbach's α ranges from 0.76 to 0.91 across studies[38]. Confirmatory factor analysis confirmed the three-factor structure of emotional, psychological and social well-being, with convergent validity among these three dimensions[39].

Psychological symptoms

The BSI is used to measure psychological symptoms. It consists of 53 items covering nine symptom dimensions and three global indices of distress. The global indices respectively measure intensity of symptoms, current or past level of symptomatology and number of reported symptoms[40]. Items are phrased as follows: *In the past week, how often did you experience*… (e.g., *the idea that another person can influence your thoughts* or *nervousness*) with responses given on a 5-point Likert scale (from *not at all* (0) to *extremely* (4)). The BSI shows high total internal consistency (Cronbach's α 0.96)[41].

Qualitative measures

Experts by Experience in Step 1 of IM will complete an online survey. They will be asked about their experiences with CAPTs, talking therapy and SFT in general. Questions will be phrased as follows: *what has CAPTs helped you with* or *what has talking therapies helped you with.* The survey will also consist of statements to be answered on a 5-point Likert scale (from *absolutely true* to *not at all true*). Items are phrased as follows: *Multiple forms of CAPTs in the yet-to-be-developed intervention have added value compared to one CAPTs* and *CAPTs helps with sensing*

body signals. In addition, they will be asked about their preferences and needs in working on psychological adaptability and well-being.

CAPTs-therapists, psychologists and managers will participate in focus groups, using the method of Raats[42]. In Step 1 of IM they will be asked about what the intervention should look like, working mechanisms of CAPTs and their knowledge about psychological adaptability. In Step 6 they will be asked about their experiences and the use and effects of the CAPTs-intervention.

Participating patients in Step 6 of IM will be asked about their experiences with the CAPTs-intervention. The patients will be interviewed individually using a semi-structured interview based on the *change interview*, focusing on identifying change processes in therapy[43]. An interview guide with a topic list will be used to prevent important topics from being neglected. The aim of the interviews is to evaluate the experiences with the CAPTs-intervention.

Data management

Researchers from the Research Group for Arts and Psychomotor Therapies in Health Care at the HAN University of Applied Sciences will manage the data in accordance with the 'FAIR Guiding Principles for scientific data management and stewardship'. A data management plan has been assessed and approved by the ethics committee (ECO 471.07/23) of the HAN University of Applied Sciences. Data will be stored on a secured research drive and entered twice to ensure accuracy. Informed consent forms will be stored on a secured research drive of the HAN University of Applied Sciences. The research team will be able to access participant data based on participant number only. Only the research team will have access to the final data set.

Data analysis

Demographic and clinical characteristics

Participants' demographic and clinical characteristics will be summarised with descriptive statistics (means and SDs for interval variables, median and IQR for ordinal variables, numbers and percentages for nominal variables). The following demographics of participants will be reported: age, gender, diagnosis (type of PD) and number of CAPTs sessions attended. Of the participating therapists, the following demographic data will be reported: age, gender, CAPTs discipline, years of working experience, target population and setting.

Quantitative data

First, quantitative data will be visually analysed. Individual participants' graphs will be inspected to compare the intervention period with the baseline period and follow-up period using the step-by-step guide of Lane and Gast[44]. After this, the quantitative data will be analysed using MultiSCED. This is an application built with Shiny[45], a framework to create interactive web apps that provide a user-friendly interface for R functionalities[46]. The application will allow for the analysis of repeatedly measured data collected at 16–18 time points. The outcomes as measured by the GSAAS, MHC-SF, SERATS, SMI and BSI are the dependent variables. These outcomes reflect clinical symptoms and well-being. Phase (baseline vs treatment period) will be included. Additionally, time and the interaction between them (time×phase) can be included as the independent variables.

Two analyses will be performed in MultiSCED. First, analysis at the level of aggregated data involves a linear mixed model. A random intercept and slope will be included to account for the dependence of observations within participants at different time points. Mean differences in outcomes between the baseline period, intervention period and follow-up period will be calculated. Hypothesis testing for the fixed effects of linear mixed models in MultiSCED will be performed using a t-test with the Kenward-Roger approximation for df[47]. Linear mixed models are well equipped to handle missing data under the assumption of 'missing at random'. In the primary analysis, we will adopt an intention-to-treat approach that includes all participants, regardless of treatment fidelity, therapy compliance and being lost to follow-up. The secondary analysis will only include those participants with adequate treatment fidelity and compliance. In a sensitivity analysis, the robustness of the findings will be analysed by repeating the analysis with only those participants without missing data (complete-case analysis) and without multivariate outliers. Second, an analysis will be performed at the level of the individual participants. MultiSCED provides participant-specific regression coefficients, together with their SEs, t values and p values. Mean differences in outcomes between the baseline period, intervention period and follow-up period will be calculated.

Since the MHC-SF, BSI and SMI (complete) will only be administered twice (T7 and T16), the mean within-subject difference over time for these measures will be tested using a paired sample t-test. In all analyses, an α of 5% will be adopted.

Qualitative measures

The results of the survey will be analysed in ATLAS.ti for Windows (v.23.0). The focus groups with the therapists, the interviews with managers and psychologists, as well as the interviews with participants and therapists, will be audio-recorded, transcribed verbatim and analysed in ATLAS.ti. Consistent with the principles of Thematic Analysis[48], we will use the six phases of analysis: 1) get familiar with the data, 2) create initial codes, 3) search for themes, 4) assess potential themes, 5) define and name the themes, and 6) reporting.

Integration of quantitative and qualitative results

Individual MBSCED trajectories will be analysed through the lens of the interview outcomes. Inter- and intrapersonal similarities and differences in outcomes will be explored. Based on these findings, the effectiveness of the CAPTs-intervention will be assessed, and recommendations made regarding its use in clinical practice.

Monitoring

This study has an external advisory board consisting of a psychologist, a manager of one of the mental health facilities, a psychology professor from the University of Twente, a music therapist (who is also an Expert by Experience), a patient representative of the Client Advisory Board of the Dutch Federation of Arts Therapies, and a patient and relatives representative of MIND, a national platform for people in mental health care (who is also an Expert by Experience). The external advisory board will meet with the principal researcher every 3 months during the project period.

The intervention will be created by two art therapists. To ensure that the intervention connects with professional practice, the outcomes of the focus groups with CAPTs-therapists will be used to develop the intervention. Subsequently, the working methods in the intervention will be presented to a few CAPTs-therapists of every discipline to check if they fit the goals of the sessions. Later, the intervention will be tested with a group of students and patients and the experiences will be collected. Based on this, the intervention will be adjusted again. In this way we ensure that the quality of the intervention remains guaranteed.

One of the researchers will monitor weekly whether participants fill out the questionnaires. If necessary, participants will be contacted and requested to complete the questionnaires and therapists will help remind them to complete the questionnaires. In addition to the questionnaires, a researcher will ask participants how they are doing halfway through the intervention. This is to monitor the well-being of the participants and manage adverse events. The question will be asked by a researcher to prevent the participant from giving socially desirable answers to the therapist.

The participating therapists will receive supervision from another art therapist every 3 weeks. Here they can discuss how the implementation of the intervention is going, what they encounter and how they experience the implementation.

Patient and public involvement

Patients' representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies and MIND will be involved in the development of the study proposal and research question. In addition, we will develop a questionnaire about their experiences with psychotherapy and CAPTs. We will use the outcomes in the intervention's development.

Ethics and dissemination

The local medical ethical committee (METC Oost-Nederland) indicated that this study is not subject to the Dutch Medical Research Involving Human Subjects Act (2023-16438). The study was approved by the official Research Ethics Committee of the HAN University of Applied Sciences (ref: ECO 471.07/23). All participants will be given study information through an information letter and verbal explanation by the researcher before written informed consent was obtained. Personal data will be processed confidentially in encrypted files and stored on a secured research drive of the HAN University of Applied Sciences. Any deviations from the study protocol will be described in an appendix in the final publication. Study results will be disseminated to professionals and students through presentations and publications. Also, results will be disseminated to the study participants on request. Access to the full participant-level dataset will be handled by the principal investigator upon reasonable request.

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Competing interests statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author contribution statement

SH, KT, HW and JH conceived of the presented idea. SH, IW, KT, HW, JH, MR and GW contributed to the design and the writing of the study protocol. KT and IW carried out the ethical procedures. SH, KT, IW and JH will take care of the implementation of the research. SH and KT will develop the intervention. IW and KT will monitor the therapists' procedures and patients' procedures. HW and KT will conduct the statistical analysis. SH as principal investigator oversees the research process and connects with the advisory board. IW wrote the first draft of the manuscript, SH, KT, HW, JH, MR and GW critically reviewed the manuscript for intellectual content. All authors are responsible for the overall content as guarantor.

Date and version Identifier

Non applicable since the intervention is yet to be developed.

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Figure Legends

Figure 1. Timeline of Test-Phase.

Note. Visualisation of the MBSCED design. GSAAS = Generic Sense of Ability to Adapt Scale, SERATS = Self-Expression and Emotion Regulation in Arts Therapies Scale, SMI = Schema Mode Inventory, BSI = Brief Symptom Inventory, MHC-sf = Mental Health Continuum – Short Form. T0 = Start Baseline period, T7 = Start Intervention period, T17 = Start Follow-up period

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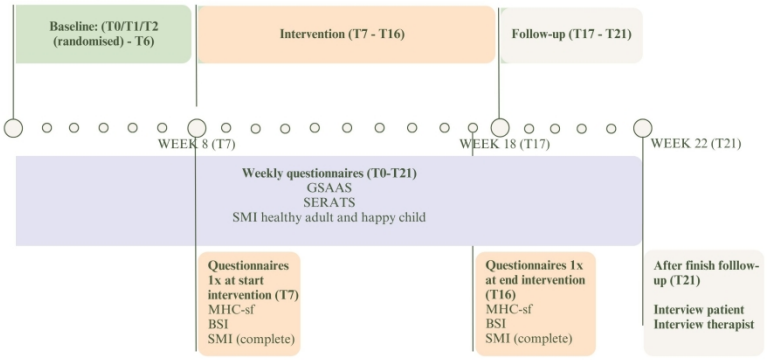

Figure 1. Timeline of Test-Phase. Note. Visualisation of the MBSCED design. GSAAS = Generic Sense of Ability to Adapt Scale, SERATS = Self-Expression and Emotion Regulation in Arts Therapies Scale, SMI = Schema Mode Inventory, BSI = Brief Symptom Inventory, MHC-sf = Mental Health Continuum – Short Form. T0 = Start Baseline period, T7 = Start Intervention period, T17 = Start Follow-up period

270x203mm (300 x 300 DPI)