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Published in:
The Lancet Healthy Longevity

DOI:
10.1016/S2666-7568(24)00001-1

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2024

Group schema therapy combined with psychomotor therapy for older adults with a personality disorder: an open-label, multicentre, randomised controlled trial

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Summary

Background Although several types of psychotherapy effectively reduce psychological distress associated with personality disorders, randomised controlled trials (RCT) have systematically excluded older patients. We aimed to examine the effectiveness of group schema therapy combined with psychomotor therapy (GST + PMT) in later life compared with treatment as usual (TAU).

Methods We did an open-label, multicentre, RCT in eight outpatient clinics for geriatric psychiatry in the Netherlands. Adults aged 60 years or older with a full or subthreshold cluster B or C personality disorder according to DSM criteria were included and randomly assigned 1:1 to GST + PMT or TAU by an independent researcher applying a computer-generated sequence per study site when 8 to 16 patients had given informed consent; investigators and interviewers were kept blinded until end of follow-up. Included individuals received 20 weekly sessions of GST + PMT or TAU with 1 year of follow-up. The primary outcome was psychological distress, measured with the 53-item Brief Symptom Inventory. The trial was registered with International Clinical Trials Registry Platform, NTR6621.

Findings Of the 145 study participants recruited between Feb 21, 2018, and Jan 21, 2020, 102 patients (median age of 69 years [IQR 63–71], 62 [61%] female) who concluded therapy before the COVID-19 pandemic (cutoff March 20, 2020) were included in the intention-to-treat analysis (51 in each study group), because COVID-19 measures substantially disrupted delivery of group therapy. GST + PMT significantly improved psychological distress compared with TAU over the 6-month treatment period (Cohen's *d* 0·42, 95% CI 0·16 to 0·68; p=0·0016). The pre-post effect of GST + PMT remained stable during follow-up, whereas patients receiving TAU further improved, resulting in a non-significant difference between groups at 1 year (Cohen's *d* 0·21, 95% CI –0·07 to 0·48; p=0·14). No patients reported adverse events.

Interpretation Psychotherapy focused on personality disorders is effective in later life, resulting in a faster improvement in psychopathology than TAU. Future studies should focus on increasing effectiveness by intensifying or prolonging treatment.

Funding Netherlands Organization for Health Research and Development.

Introduction

The potential for psychological therapies to reduce psychological distress and to improve interpersonal, social, and occupational functioning in people with personality disorders has progressed substanially.[1] Because personality disorders persist into old age, the question of up to what age people with longstanding personality problems are capable of change arises.

In later life (55–65 years), the presence of personality disorders is still associated with a lowered quality of life, high levels of psychological distress, increased suicide risk, and increased consumption of medical and informal care.[2] In a representative population-based survey in the USA, the prevalence of a personality disorder in later life was estimated at 13·2% for individuals aged 65–74 years, 10·4% for those aged 75–84 years, and 10·7% for those aged 85 years or older.[3] These prevalences increased to nearly 50% among people referred to specialised mental health care or people with affective disorders.[4–6]

Due to the absence of grade A evidence (ie, no randomised controlled trials or meta-analyses) on the effectiveness of psychotherapy for personality disorders in later life, guidelines do not mention potential effectiveness in this age group,[7] or explicitly mention that generalisation to age groups outside 20–40 years is limited.[8] Moreover, large observational studies on the treatment of patients with personality disorders in daily practice show that this treatment is rarely offered to patients aged 55 years and older.[9] Even though the effectiveness of cognitive behavioural therapy (CBT) has been proven for depressive and anxiety disorders in older

Lancet Healthy Longev 2024; 5: e245–54

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For the Dutch translation of the abstract see **Online** for appendix 1

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Research in context

Evidence before this study

We conducted a systematic literature search of the electronic databases EMBASE, PsycINFO, Web of Science, MEDLINE and COCHRANE on March 1, 2022, without language or date restrictions, to identify all empirical studies in which schema therapy was applied. The following search terms were used: "schema focused therapy", "maladaptive schema", "young schema questionnaire", "schema modes", "maladaptive modus", "schema mode inventory", and synonyms. Studies were included when schema therapy was the intervention, or a main component of the intervention, being examined and a measure of symptom change was included. Of the 101 studies identified that reported empirical data of patients receiving schema therapy, only 30 had a randomised controlled design. Although some of these trials included patients up to 60 or 65 years of age, they rarely included older people (≥55 years). Two case reports and four case series showed that schema therapy is feasible for older people with personality disorders and is appreciated by patients.

Added value of this study

This is the first randomised controlled trial evaluating schema therapy among older adults and shows evidence that mental health problems related to longstanding maladaptive personality traits can be treated effectively in later life. This first evidence might contribute to ending the unwarranted but widespread exclusion of older people from psychotherapy targeting (longstanding) personality pathology.

Implications of all the available evidence

Effectiveness of schema therapy in adult life and our promising results in later life argue for implementation and surveillance studies in geriatric mental health services. Both for older patients with personality disorders and for those suffering from therapy-resistant affective disorders, because more than half of these disorders are complicated by comorbid personality disorders.

adults, these findings cannot be generalised to schema therapy. Schema therapy is an integrative psychotherapy beyond, but also including, CBT techniques and is aimed at longstanding personality pathology for which specific randomised controlled trials (RCTs) are needed. Older patients have been systematically excluded from RCTs evaluating schema therapy; these RCTs included patients aged up to 60 years or 65 years and rarely included any patients older than 55 years.[1,10]

Several lines of research suggest that schema therapy might be promising for treatment of older adults with personality disorders. First, the effectiveness of schema therapy was found to be independent of age among younger and middle aged patients.[11,12] Second, among existing psychotherapies for personality disorders, schema therapy can be considered most relevant for geriatric practice, because it reduces psychological distress and affective symptoms associated with comorbid, often longstanding affective disorders.[10,13] Third, uncontrolled studies have shown that schema therapy is feasible in later life, including a case-report of a cognitively impaired nursing home resident,[10] a multiple-baseline study of eight older people with cluster C personality disorder,[10] and two observational studies on group schema therapy for mixed personality disorders, which showed that improvement of maladaptive schemas precedes improvement of psychological distress in older adults.[13,14]

Schema therapy addresses the influence of early maladaptive schemas on daily life and interpersonal relationships. Schemas are formed in childhood and pertain to one's core conceptions of self, others, and the world. In case of adverse circumstances, maladaptive schemas and associated coping styles will develop to survive (emotionally), which in a healthier environment can lead to interpersonal dysfunctional coping and emotional instability. Schema therapy aims to help patients identify their most important maladaptive schemas and to respond in a more adaptive manner when these schemas are triggered in daily life.[15] Schema therapy was originally developed for the treatment of chronic psychiatric disorders, but has primarily been applied in borderline personality disorder.[10] To date, 101 studies, including 30 RCTS, have provided empirical data on patients receiving schema therapy.[10] These 30 RCTs suggest good effectiveness for nearly all personality disorders and chronic affective disorders, although this has not been confirmed by robust meta-analysis, probably due to heterogeneity in study populations and treatment manuals used. Furthermore, the median age of study participants in the 30 RCTs was 33 years, and none included patients aged 60 years or older,[10] hampering generalisation to older adults.

We aimed to compare the effect of group schema therapy combined with psychomotor therapy with treatment as usual among older patients with a cluster B or C personality disorder in specialised mental health care.

Methods

Study design and participants

We did an open-label RCT at eight outpatient clinics for geriatric psychiatry throughout the Netherlands (University Medical Center Groningen, Lentis, GGZ Friesland, GGZ Drenthe, GGZ Rivierduinen, Molemann mental health, Stichting Dimence, and Mediant; appendix 2 p 17). Detailed methods have been published previously,[16] and the study protocol is available on the Rob Giel Onderzoekcentrum's website.

See Online for appendix 2

For the **protocol** see www.rgoc.nl/downloads

People were eligible if they had a (subthreshold) cluster B or C personality disorder confirmed by the Structured Clinical Interview for DSM-5 for personality disorders (SCID-5-PD),[17] were 60 years of age or older, and mentally able to adhere to group treatment and to fill out schema (mode) questionnaires. We included so-called subthreshold personality disorders, defined as the presence of a personality disorder which falls one criterion short for the presence of a specific cluster B or C personality disorder, because older patients generally endorse fewer specific personality disorder criteria than younger patients while the latent variable structure for each disorder suggests a similar severity level of personality pathology.[18,19] Exclusion criteria were severe current mental illness, an established neurodegenerative disorder, a Montreal Cognitive Assessment (MoCA) score of less than 23 points, having received schema therapy in the previous year or during the current illness episode, and suicide risk interfering with adequate treatment delivery. Physical restraints were not an exclusion criterion, because psychomotor therapy was adjusted to the individual capacity of participants.

All participants gave written informed consent. The study was approved by the Medical Ethics Committee of the University Medical Center Groningen (M17.212189). There was no Data Monitoring Committee, as such a requirement was implemented in our hospital after the start of the study. Data handling is described in the appendix 2 (p 5).

Randomisation and masking

An independent, centralised, computer-generated randomisation sequence (QuickCalcs randomization software of GraphPad 18) was used by an independent randomisation statistician to randomly assign patients 1:1 to one of two parallel treatment groups—20 sessions of group schema therapy combined with psychomotor therapy (GST+PMT) delivered over a 6-month period versus treatment as usual (TAU). Participants were assigned per study site when 8–16 patients had given informed consent, and randomisation was stratified according to presence of a full versus subthreshold personality disorder (appendix 2 p 4). Unused allocations (in case of uneven numbers in the stratum) were carried forward to a randomly selected participant of the next randomisation in the same stratum. Blinding of participants was not possible. Because most outcome parameters were self-reported or gathered by telephone interviews, interviewers (who were not involved in treatment) were masked to treatment allocation, and interviewees were instructed not to mention type of therapy received.

Procedures

All patients with a suspected cluster B or C personality disorder were referred to a psychologist trained in administering the SCID-5-PD and MoCA, to be informed about the study, and to check the inclusion and exclusion criteria. Study participants received a pre-treatment assessment before randomisation.

The development of our treatment protocol has been described before and piloted for feasibility (appendix 2 pp 21–28;[14] full protocol [in Dutch] available from corresponding author). Briefly, our intervention was based on the group protocol by Broersen and van Vreeswijk,[20] a short-term treatment programme with proven effectiveness in younger adults. This protocol is primarily cognitive-based and was adapted according to their subsequently developed version of experiential schema focused therapy,[21] by including experiential imagery and rescripting and chair interventions. Geriatric themes like loss of societal roles, loss of loved ones, comorbid somatic diseases, and sociocultural beliefs about treatment of older people were integrated in the treatment protocol. The protocol was supplemented with PMT, because cognitive techniques can become less effective with increasing age. PMT is an experiential therapy in which psychotherapeutic techniques are translated into experiential exercises, using physical means. It is performed by qualified PMT therapists, and primarily in groups. The PMT sessions enabled patients to experience how their schemas influence their behaviour and feelings. The learning by doing approach in a gym offers patients the possibility to discover the origin of their feelings and physical sensations as well as opportunities to experiment with new behaviours in interaction with group members.

All participants received two individual pre-treatment sessions before the group sessions to familiarise them with schema therapy and to make a personal treatment plan based on their own three dominant schemas and coping styles (so-called modes) as assessed with the Young Schema Questionnaire and short Schema Mode Inventory.[22,23] The subsequent group interventions comprised 18 weekly sessions combined with psychomotor therapy and two verbal follow-up sessions given at weeks 22 and 26. The weekly group sessions consisted of a 2-h verbal session followed by a 1-h psychomotor therapy session, divided by a 15-min break.

The verbal sessions were led by a psychologist with a minimum of 2 years post-graduate clinical training and a co-therapist, either a psychologist or nurse practitioner experienced in group therapy. Psychomotor therapy was delivered by a registered psychomotor therapist, additionally trained in schema therapy. One psychologist was co-therapist in the contiguous psychomotor session to guarantee continuity between both sessions. Recruitment of study locations and therapists for the verbal and psychomotor sessions was based on availability of both types of therapists at the outpatient clinic for geriatric psychiatry. All therapists received a 2-day training to familiarise them with the treatment protocol, which included a detailed description of all verbal and

psychomotor therapy sessions. During the study they received biweekly supervision by SDMvD and RB.

If needed, patients in the intervention group could consult a psychiatrist in case of crisis (suicidality) or a potential need to change psychotropic medication.

Treatment as usual (TAU) was unrestricted, except for group schema therapy. It was indicated and delivered by the multidisciplinary team treating the patient.

All outcome parameters were assessed at pre-treatment, post-treatment (six months after pre-treatment), and at 6-month and 12-month follow-ups. We did not systematically assess adverse outcomes of the psychotherapy. No adverse events were reported by participants or observed by therapists or investigators.

Patient characteristics were assessed during verification of the inclusion and exclusion criteria and the pre-treatment assessment. The screening procedure included the assessment of cluster B or C personality disorders (SCID-5-PD), comorbid mental disorders using a clinical checklist, and cognitive functioning (MoCA). Sex, age, education, and chronic somatic diseases were assessed by self-report in the pre-treatment assessment (appendix 2 pp 3–4).[16]

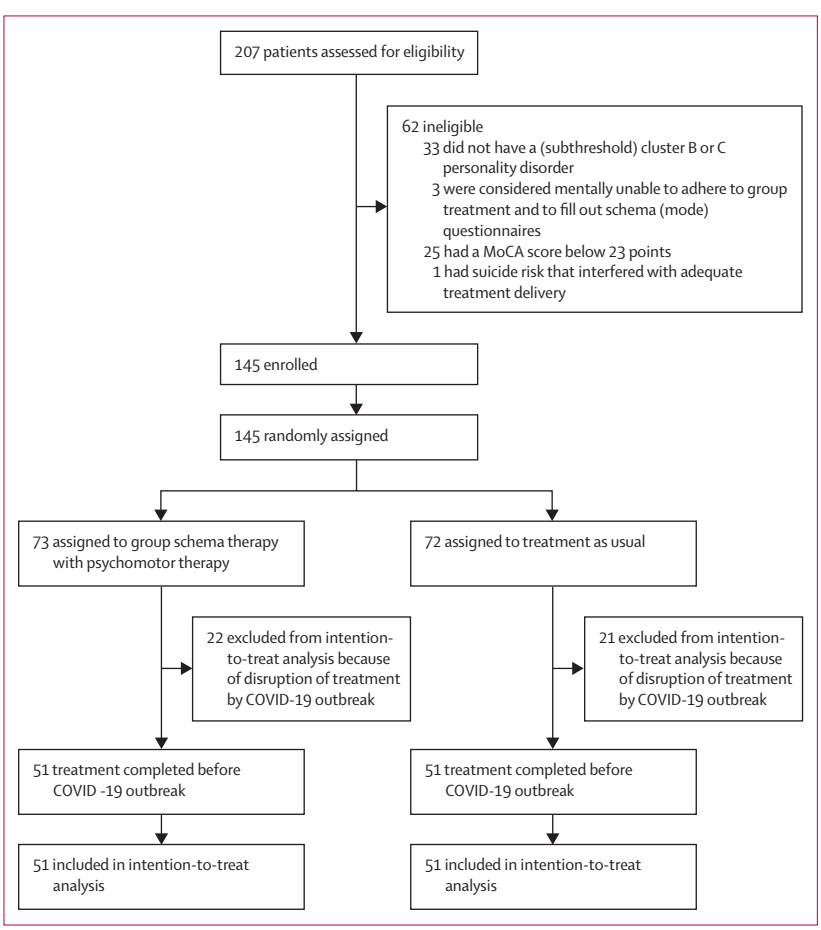

Figure 1: **Study profile**
MoCA=Montreal Cognitive Assessment.

Therapists asked informed consent from their therapy group to audiotape the therapy sessions. For each consenting group, two recorded sessions were randomly selected and rated by an independent psychologist on protocol adherence. All interventions listed in the treatment protocol for a selected session were evaluated on delivery and quality of delivery of the intervention, as rated on a scale ranging from 0 (not delivered) to 10 (delivered excellently). Protocol adherence was assessed by the average percentage of interventions delivered and the mean quality rating of delivery.

Outcomes

Psychological distress in the past week, as indicated by the sum score on the Brief Symptom Inventory 53 item version (BSI-53),[24] was the primary outcome parameter.[16] Secondary outcomes were mental wellbeing assessed with the Warwick-Edinburgh Mental Well-being Scale, personality functioning assessed with the Severity Indices of Personality Problems—Short Form, life satisfaction assessed with Cantril's ladder, and psychotropic drug use assessed by telephone interview (appendix 2 pp 2–3).[16]

Statistical analysis

The study was powered to detect a medium-sized between-group difference (Cohen's d of 0·5), which required 63 patients per study group when applying a two-sided alpha of 0·05 and a power of 80%. We aimed to include 140 patients to compensate for 10% dropouts.

Because COVID-19 measures substantially interfered with the possibility to deliver group treatment, we first checked whether results differed between patients who completed the intervention before the COVID-19 pandemic and those who did not.

Analyses were conducted according to the intention-to-treat principle. Differences between the experimental and control group on the primary and secondary outcomes were analysed by (generalised) linear mixed-models using SPSS version 28 (appendix 2 p 6), more specifically (logistic) random coefficient analysis, which accounts for missing observations. Study site and patient were included as random effects (with observations nested in patients and patients nested in study sites) and study group and full versus subthreshold personality disorder as fixed effects. Interactions were tested between time of observation and study group and between this interaction and full versus subthreshold personality disorder to check whether the intervention effect is different for patients with a full versus subthreshold personality disorder. Because we had only one, a-priori determined, primary outcome parameter, we did not adjust for multiplicity of secondary outcomes. All analyses were controlled for potential pre-treatment differences.

This study is registered with the International Clinical Trial Registry Platform, NTR6621.

Role of the funding source
The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Feb 21, 2018, and Jan 21, 2020, we screened 207 referred patients, 145 of whom were included; 73 were assigned to GST+PMT and 72 to TAU (figure 1). 102 participants (70%) completed treatment (ie, were more than 6 months past their pre-treatment assessment) before the start of the COVID-19 pandemic, whereas treatment for 43 participants (30%) was disturbed by the COVID-19 outbreak. Change in psychological distress (primary outcome) between the study groups differed between participants who completed the intervention before the COVID-19 pandemic and those who did not (whole study period F=2·82, df=3, 340, p=0·039; between pre-treatment and post-treatment assessment *t*=2·32, df=342, p=0·021). We therefore restricted our analyses to the 102 participants treated before the COVID-19 pandemic (51 in both study groups; appendix 2 p 14) and present the results for the 43 whose treatment was interrupted by COVID-19 in appendix 2 (p 8).

The median age of the 102 participants was 69 years (IQR 63–71; range 60–80) and 62 (61%) were female (table 1). 81 (79%) participants had a cluster C personality disorder, including avoidant personality disorder (52 [51%]) or obsessive-compulsive personality disorder (38 [37%]), and 36 (35%) had a cluster B personality disorder, including borderline personality disorder (29 [28%]; table 1). 69 participants (68%) had a full personality disorder, and 33 (32%) had one or more subthreshold personality disorders. 81 participants (79%) had one or more comorbid mental disorders, particularly depressive disorder (66 [65%]), post-traumatic stress disorder (15 [15%]) and generalised anxiety disorder (11 [11%] ; appendix 2 p 13). 79 (77%) participants used psychotropic medication (table 1), particularly an antidepressant (60 [59%]) or an anxiolytic or sedative (38 [37%]). Of the 51 patients in the experimental group, eight (16%) ceased participation in the therapy group before the end of the 18 weekly sessions.

Of the ten therapy groups that completed therapy before the implementation of COVID-19 measures, seven gave informed consent to audio recording of their therapy sessions. The treatment protocol listed a mean number of seven therapeutic interventions per session (SD 2). 79 (96%) of 82 interventions were delivered in the sessions rated, and the mean quality rating of delivery was 8·3 (SD 2·0), indicating very good delivery of interventions. No adverse events in the GST+PMT group were reported by participants or observed by therapists or investigators.

Content of TAU was assessed for 46 (90%) of 51 participants in the control group who completed the post-treatment interview before the COVID-19 pandemic.

	GST+PMT group (n=51)	TAU group (n=51)
Median age (IQR), years	68 (63–71)	70 (63–71)
Sex		
Female	34 (67%)	28 (55%)
Male	17 (33%)	23 (45%)
Educational level		
Low	8 (16%)	16 (32%)
Medium	24 (47%)	16 (32%)
High	19 (37%)	18 (36%)
Median number of somatic diseases treated (IQR)	2 (1–2)	2 (1–3)
Personality disorders*†		
Avoidant	29 (57%)	23 (45%)
Dependent	5 (10%)	7 (14%)
Obsessive compulsive	18 (35%)	20 (39%)
Histrionic	3 (6%)	1 (2%)
Narcissistic	3 (6%)	5 10%)
Borderline	16 (31%)	13 (25%)
Antisocial	1 (2%)	1 (2%)
Cluster		
Cluster B only	10 (20%)	11 (22%)
Cluster C only	33 (65%)	33 (65%)
Cluster B and C	8 (16%)	7 (14%)
Any full personality disorder	34 (67%)	35 (69%)
Median number of full or subthreshold personality disorders (IQR)	1 (1–2)	1 (1–2)
Comorbid mental disorders†		
Depressive disorder	32 (63%)	34 (67%)
Anxiety disorder	11 (22%)	13 (25%)
Somatic symptom or related disorder	6 (12%)	3 (6%)
Obsessive compulsive disorder	2 (4%)	2 (4%)
Post-traumatic stress disorder	7 (14%)	8 (16%)
Any comorbid mental disorder	39 (76%)	42 (82%)
Median number of comorbid mental disorders (IQR)	1 (1–2)	1 (1–2)
Psychosocial functioning		
Psychological distress	1·3 (0·7)	1·2 (0·6)
Mental wellbeing	40·1 (8·5)	39·5 (7·2)
Personality functioning†‡	2·9 (0·5)	2·8 (0·4)
Life satisfaction	5·2 (1·7)	5·2 (1·5)
Cognitive functioning	26·5 (2·0)	26·1 (1·7)
Psychotropic drug use	38 (75%)	41 (80%)
Antidepressant	30 (59%)	30 (59%)
Sedative or anxiolytic	18 (35%)	20 (39%)
Antipsychotic	8 (16%)	17 (33%)
Other	6 (12%)	10 (20%)

Data are n (%) or mean (SD) unless otherwise specified. GST+PMT=group schema therapy combined with psychomotor therapy. TAU=treatment as usual. *Full or subthreshold. †Further details in the appendix (p 13). ‡Mean domain score. Individual domain scores presented in appendix (p 13).

Table 1: **Baseline characteristics of study sample (n=102) treated before the COVID-19 pandemic**

	GST+PMT group (n=51)			TAU group (n=51)			Difference		
	Effect size (95%CI)	*t*	p value	Effect size (95%CI)	*t*	p value	Effect size (95%CI)	*t*	p value
Psychological distress									
Post-treatment	0·68 (0·49 to 0·86)	7·28	<0·0001	0·25 (0·07 to 0·44)	2·68	0·0078	0·42 (0·16 to 0·68)	3·20	0·0016
6-month follow-up	0·55 (0·36 to 0·74)	5·67	<0·0001	0·34 (0·15 to 0·53)	3·58	0·0004	0·21 (–0·06 to 0·48)	1·56	0·12
12-month follow-up	0·59 (0·40 to 0·78)	6·01	<0·0001	0·38 (0·19 to 0·58)	3·89	0·0001	0·21 (–0·07 to 0·48)	1·48	0·14
Mental wellbeing									
Post-treatment	0·59 (0·34 to 0·83)	4·67	<0·0001	0·22 (–0·03 to 0·47)	1·74	0·083	0·37 (0·02 to 0·72)	2·06	0·040
6-month follow-up	0·61 (0·35 to 0·87)	4·63	<0·0001	0·24 (–0·01 to 0·49)	1·86	0·064	0·37 (0·01 to 0·73)	2·03	0·043
12-month follow-up	0·58 (0·32 to 0·84)	4·39	<0·0001	0·33 (0·07 to 0·59)	2·50	0·013	0·25 (–0·12 to 0·62)	1·34	0·18
Personality functioning									
Post-treatment	0·48 (0·28 to 0·68)	4·78	<0·0001	0·29 (0·10 to 0·50)	2·94	0·0037	0·19 (–0·09 to 0·47)	1·31	0·19
6-month follow-up	0·58 (0·38 to 0·79)	5·56	<0·0001	0·28 (0·08 to 0·48)	2·80	0·0056	0·30 (0·01 to 0·59)	2·06	0·040
12-month follow-up	0·60 (0·39 to 0·81)	5·70	<0·0001	0·47 (0·27 to 0·68)	4·51	<0·0001	0·13 (–0·16 to 0·42)	0·87	0·39
Life satisfaction									
Post-treatment	0·48 (0·20 to 0·76)	3·36	0·0009	0·28 (0·00 to 0·57)	1·95	0·052	0·20 (–0·20 to 0·60)	0·98	0·33
6-month follow-up	0·50 (0·20 to 0·80)	3·33	0·0010	0·37 (0·08 to 0·66)	2·51	0·013	0·13 (–0·28 to 0·55)	0·63	0·53
12-month follow-up	0·42 (0·13 to 0·72)	2·80	0·0055	0·42 (0·12 to 0·71)	2·76	0·0062	0·01 (–0·41 to 0·43)	0·03	0·97

The effect size (Cohen's *d*) represents the mean difference from pre-treatment, standardised by SD of outcome pre-treatment in the total sample (n=145). For all outcomes a positive effect size indicates improved functioning. It is adjusted for sex, age, level of education, number of chronic somatic diseases treated, cognitive functioning, number of mental disorders, and cluster B or C personality disorder. GST+PMT=group schema therapy combined with psychomotor therapy. TAU=treatment as usual.

Table 2: **Outcome differences between study groups in change from pre-treatment in the intention-to-treat sample (n=102) treated before the COVID-19 pandemic**

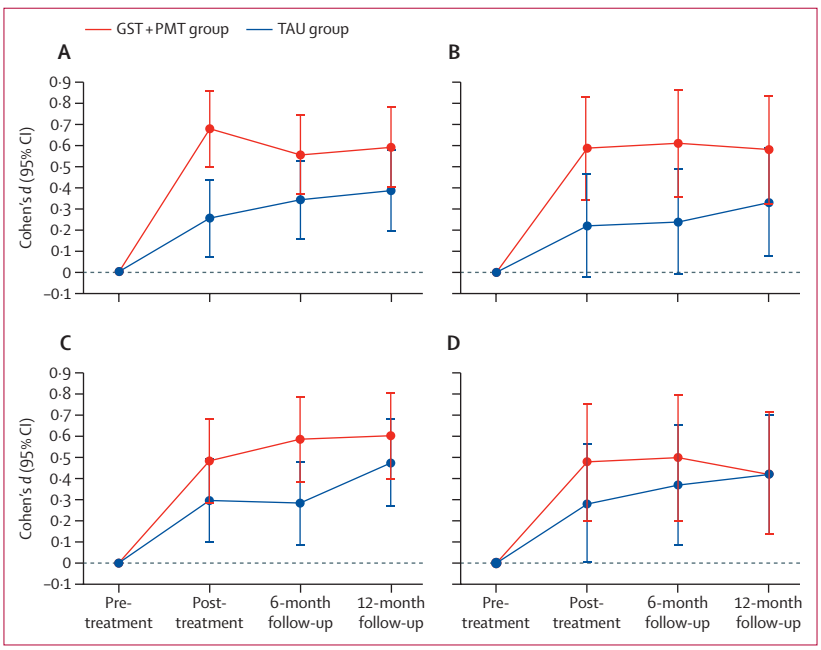

Figure 2: **Outcome measures in the intention-to-treat sample (n=102) treated before the COVID-19 pandemic**
Cohen's *d* effect size for psychological distress (A), mental wellbeing (B), personality functioning (C), and life satisfaction (D). GST+PMT=group schema therapy combined with psychomotor therapy. TAU=treatment as usual.

The interview covered treatment received in the past 3 months. TAU primarily consisted of psychotropic medication (38 [83%] of 46), contacts with a psychiatrist (21 [46%]), a psychologist or psychotherapist (38 [83%]), or a nurse practitioner or case manager (12 [26%]). Additionally, six patients (13%) received psychiatric day treatment, and five (11%) visited a day activity centre.

For psychological distress (primary outcome), a treatment effect for GST+PMT versus TAU of 0·42 (95% CI 0·16–0·68; p=0·0016) was observed from pre-treatment to post-treatment (table 2; figure 2). For mental wellbeing, the treatment effect was 0·37 (0·02 to 0·72; p=0·040) over this period. Due to later improvements in the TAU group, these between-group differences became non-significant from 6-month follow-up onward for psychological distress (0·21, 95% CI –0·06 to 0·48; p=0·12) and from 12-month follow-up for mental wellbeing (0·25, –0·12 to 0·62; p=0·18). For personality functioning, changes occurred somewhat later than for the other outcomes, resulting in a small treatment effect that appeared at the 6-month follow-up (0·30, 0·01 to 0·59; p=0·040). However, due to an even later increase in the TAU group, this between-group difference became non-significant at the 12-month follow-up. For life satisfaction, no differences between the study groups were found. These changes in outcomes did not differ between participants with a full or subthreshold personality disorder (appendix 2 p 7). Additionally, the use of psychotropic medication did not differ between groups (table 3). These findings were not replicated in the 43 participants whose first 6 months of treatment were interrupted by the onset of the COVID-19 pandemic, in whom no significant differences were seen for the outcomes, with the exception of an improvement in psychological distress in the TAU group compared with

	GST+PMT group (n=51)			TAU group (n=51)			Difference		
	Odds ratio (95% CI)	*t*	p value	Odds ratio (95% CI)	*t*	p value	Odds ratio (95% CI)	*t*	p value
Pre-treatment	1 (ref)	..	..	1 (ref)	..	..	1 (ref)	..	..
Post-treatment	1·15 (0·30–4·51)	0·21	0·84	2·33 (0·49–11·0)	1·07	0·28	0·50 (0·06–3·91)	0·67	0·50
6-month follow-up	0·48 (0·12–1·90)	1·05	0·29	0·93 (0·22–3·91)	0·10	0·92	0·52 (0·07–3·78)	0·65	0·51
12-month follow-up	2·03 (0·48–8·51)	0·97	0·33	3·32 (0·66–16·7)	1·46	0·15	0·61 (0·07–5·31)	0·45	0·65

Odds ratios are adjusted for sex, age, level of education, number of chronic somatic diseases treated, cognitive functioning, number of mental disorders, and cluster B or C personality disorder. GST+PMT=group schema therapy combined with psychomotor therapy. TAU=treatment as usual.

Table 3: **Changes in psychotropic medication use from pre-treatment in the intention-to-treat sample (n=102) treated before the COVID-19 pandemic**

the GST+PMT group at 12 months (–0·43, 95% CI –0·84 to –0·02; p=0·039; appendix 2 p 14).

Discussion

To our knowledge, this is the first randomised controlled trial evaluating schema therapy in later life. Patients who received GST+PMT showed medium (0·42) to large (0·68) improvements on all outcomes, and over all follow-up periods. The between-group effects were in favour of GST+PMT, with medium effect sizes directly after treatment on psychological distress and mental wellbeing, and at 6-month follow-up on mental wellbeing and personality functioning. The between-group differences, however, decreased and became statistically non-significant at the 12-month follow-up, due to later improvements in the control group.

Short-term GST seems consistently to be effective in improving psychopathology.[25] Our effect size in the experimental group was comparable to those found in uncontrolled studies with younger patients with mixed personality disorders,[11,26] who received 20 sessions of group schema therapy according to the Broersen and van Vreeswijk protocol.[20] Regarding uncontrolled studies in older age groups, we found a higher pre-post effect-size (d=0·68) on psychological distress compared with cognitive based schema group therapy for patients with either personality disorder features and mood disorders (d=0·54)[13] or a primary personality diagnosis (d=0·20).[25] The latter study was based on the same protocol as our verbal protocol. Our larger effect size could be explained by the addition of experiential techniques to the verbal protocol and the addition of psychomotor therapy.

Retrospectively, duration of treatment might have been too short for robust personality changes. Several studies indicate that short-term GST might be insufficient to achieve changes in personality functioning in patients with a severe personality disorder.[27] For this severe group longer or more intensive treatment is needed to recover.[28] We found improvement of personality functioning at 6-month follow-up, indicative of personality changing potential in later life. Nonetheless, the between-group effect sizes remained small and became statistically non-significant at 12-month follow-up. Although the significant effect at 6 months might be explained by the inclusion of subthreshold as well as full personality disorders, this seems unlikely, because we found no differential effects between these subgroups. From a stepped-care perspective, however, the treatment of patients with a personality disorder could start with short-term (group) schema therapy, and in case of insufficient remission, long-term or more intensive treatment would then be indicated.

The differential state-trait effect we found by delivering short-term schema therapy contrasts with those reported in the largest randomised controlled trial on group schema therapy among adults with a mean age of 34 years (range 18–61).[29] This trial reported a larger effect size for personality functioning than for psychopathology. The difference cannot be directly attributed to age, owing to several methodological differences with our study, including a more homogeneous sample of patients with borderline personality disorder only, a much longer duration of treatment (2 years), more intensive treatment (starting with two sessions per week), and finally combining group treatment with individual sessions. The difference between schema therapy and usual care, however, emerged from 1·5 years onwards,[29] whereas we found a statistically significant difference at 6 months between group schema therapy and usual care, while providing only weekly sessions and no individual sessions at all. Moreover, their personality outcome parameter was borderline symptom severity, which directly targeted the inclusion criteria of their homogeneous sample. Having included a heterogeneous group of patients with personality disorder, we measured personality functioning according to the alternative DSM-5 model for personality disorders. These differences might be explained by enrichment of our protocol with psychomotor therapy. Group exercises in a gym require complex social interactions and provoke spontaneous behaviour. Therapists, but also other group members, can directly confront patients when early maladaptive schemas are triggered or dysfunctional modes become active.[14] Nonetheless, between-group differences decreased during follow-up in our trial, which still argues for extending treatment duration to achieve robust and durable effects on personality functioning.

43 patients had recently started treatment at the outbreak of the COVID-19 pandemic, when safety

measures precluded delivery of group therapy. By study protocol, patients assigned to the experimental group had just changed from their familiar practitioner to the new group therapist. These therapists were instructed to provide the best care possible considering the safety measures of their organisation and mostly delivered individual schema therapy online or by telephone or online group sessions in one centre. Therefore, contrary to the patients in the control group, patients in the experimental group were confronted with a new therapist while being distressed by the start of a confrontational group therapy. These stressors and the inability to deliver GST+PMT according to protocol might explain the lack of effect during the start of the COVID-19 pandemic. From a clinical point of view, these findings underline the importance of a stable, safe environment when providing group therapy.

The major strength of the present study is that we examined the effectiveness of GST+PMT in later life with a randomised controlled trial. Furthermore, we evaluated the effectiveness on a comprehensive set of outcomes, including psychological distress, mental wellbeing, personality functioning, life satisfaction, and cost-effectiveness (reported separately). The experimental treatment was also provided by a wide range of therapists, working at eight different mental health services. Differences between study sites were controlled for in the analysis. We opted for schema therapy on the basis of the tradition of schema therapy in the Netherlands. We hope that our positive findings will also encourage evaluation of mentalisation-based therapy and dialectical therapy in this age group.

The first, main weakness of the study is that we could not evaluate the effectiveness of treatment according to protocol in the calculated number of subjects needed to study. Exclusion of the last 43 subjects assigned just before the onset of the COVID-19 pandemic, meant that our study had less statistical power than intended. Nevertheless, we could prove that GST+PMT is superior to TAU directly post-treatment, and that the pre-post effects of GST+PMT remain stable over at least 1 year. Additionally, it was shown that this effectiveness was dependent on the circumstances allowing the delivery of treatment according to protocol, as in the pre-COVID-19 condition. The reduced power by which the effectiveness of GST+PMT was established, in fact underscores the strength of these findings. However, the reduced power might have prevented the observation of differences between, for example, patients with a full and subthreshold personality disorder or between the small study groups in the post-COVID-19 condition.

Second, by choosing treatment as usual as a control instead of, for example, peer support groups, we are not able to adjust for attention bias or social interaction, as needed in an efficacy study. Our trial should be considered a pragmatic effectiveness study, because we compared GST+PMT with usual care. Nonetheless, we consider it more likely that between-group effect sizes have been dampened due to the high level of usual care in the Netherlands,[30] than inflated by not having controlled for attention effects. Additionally, because we only had an intervention group with GST+PMT, we cannot attribute the effects to GST, PMT, or both.

Third, potential inflation of type I error rate by testing over multiple follow-up periods and outcomes was not corrected for.

Fourth, there was a lack of formal diagnostics after treatment or during follow-up, which was considered quite burdensome for patients and not unambiguous regarding recovery from the heterogeneous and often comorbid personality disorders concerned.

Fifth, participants and therapists inevitably knew which treatment was being administered, and this may have affected treatment response. We did, however, keep interviewers blind for treatment allocation, to minimise the chance of researcher bias.

Finally, the inclusion of older patients with a subthreshold personality disorder might be considered both a strength and a weakness of the study. We included patients with a subthreshold personality disorder, because studies showed that older patients with such disorders have a similar severity of personality pathology as younger patients who do fulfil the criteria of a full personality disorder.[18,19] Hence, we made the inclusion criteria more valid for older patients with severe personality pathology. However, this also made our study population more heterogeneous and potentially comprising patients without a so-called true personality disorder. Studies on the validity of personality diagnosis and assessment for older patients are therefore sorely needed.

About a third to half of older people referred to specialised mental health services have a personality disorder.[4] However, personality disorders are rarely the primary diagnosis for treatment in geriatric mental health care,[31] and the availability of psychotherapies is low.[32] Moreover, taking better account of personality pathology in specialised geriatric mental health care might counteract the decreased effectiveness of treatment for mood and anxiety disorders with increasing age.[33,34] In our trial, four of five patients had comorbid mental disorders, which also suggests that schema therapy is effective beyond personality disorders in later life, as proven in younger age groups,[35] should be examined

We conclude that GST+PMT effectively reduces psychological distress compared to TAU in the short-term and might result in an improvement of personality functioning. Because the effect sizes found were a little smaller than a-priori expected and not consistent across the whole follow-up period, future research should focus on increasing effectiveness on both psychological distress and personality functioning. This might be achieved, for example, by providing booster sessions during follow-up to maintain effects on psychological distress or by

evaluating more intensive and longer therapies to target personality functioning.

Contributors

All authors were involved in designing the study. MSV-S and RCOV wrote the first draft of the manuscript. MSV-S and RHSvdB analysed the data. MSV-S, RHSvdB, and RCOV had access to and verified the underlying data. All authors were involved in interpreting the results and critically commented on subsequent drafts. All authors fully consented with publication of the paper as is. The prinicipal investigator of the study, RCOV, had final responsibility for the decision to submit.

Declaration of interests

We declare no competing interests.

Data sharing

This study used the data-management infrastructure of the University Center for Psychiatry of the University Medical Center Groningen, which is a well-equipped, integrated system that meets current guidelines and regulations. After the main outcome and cost-effectiveness analyses have been published, all data will be freely available for other groups through the corresponding author.

Acknowledgments

This study was funded by the Netherlands Organization for Health Research and Development (grant 843001706), and we thank them for their support. We would also like to thank the patients and therapists of the five pilot groups for their helpful feedback. We also thank the Rob Giel Research Center of the University Medical Center Groningen for facilitating the study.

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