Save and Strong after sexual trauma - psychomotor therapy for people with mild intellectual disability or borderline intellectual functioning who were sexually abused

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON56577

Source
ToetsingOnline

Brief title
Save and Strong after sexual trauma for people with MID-BIF

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
body experience, sexual trauma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek van 's Heeren Loo

Intervention

Keyword: Intervention research, Mixed-method single case experimental design, Psychomotor therapy, Sexual trauma

Outcome measures

Primary outcome

The primary outcome measures are hypothesized changes in achievement of individually set treatment goals, improvement in body experience and coping skills and reduction of arousal regulation problems.

Secondary outcome

Secondary outcome measures are reduction in trauma symptoms and psychological problems (particularly anxiety, somatic complaints and depression). With these outcome measures, we test for each client whether there is a clinically relevant change in scores over time and whether this corresponds to the course as revealed by the primary outcome measures.

In addition, the changes in the client's daily life and the effective factors of treatment are outcomes of the qualitative study.

Study description

Background summary

The consequences of sexual abuse, especially in people with mild intellectual disability or borderline intellectual functioning (MID-BIF), can manifest in complex behavioral, psychological and health problems with broad and long-term

impact on functioning. An important but often insufficiently recognized effect of sexual abuse involves body experience. From recent research focused on body experience of people with MID-BIF, there is an indication that particularly in the domain of body awareness, more problems are experienced when there has been sexual abuse (Smit et al., 2023). People with MID-BIF who have experienced sexual abuse are more aware of their body signals, but are less able to pay adequate attention to, tolerate and interpret these body signals than people with MID-BIF who have not experienced sexual abuse (Smit et al., 2023). Problems in body experience are related to difficulty feeling, recognizing and regulating arousal and emotions and indicating needs and boundaries within social relationships. Disturbances in body experience are related to the consequences of sexual abuse such as trauma-related symptoms, psychological symptoms and coping skills. Psychomotor therapy (PMT) is an experiential treatment with specific attention to disturbed body experience, arousal and emotion regulation, and learning to set boundaries. PMT is often used in general mental health care (GGZ) for (sexual) trauma with valuable scientific results for effectiveness of this form of treatment (van de Kamp et al., 2019, 2023). PMT has been integrated into the treatment offerings within the care of people with intellectual disabilities, with experiential treatment matching the target group. But to date, the scientific evidence for effectiveness and well-described experiences about PMT of people with MID-BIF is lacking.

Study objective

The aim of the proposed research is to test the effect and evaluate the PMT module Safe and Strong, a psychomotor intervention targeting the consequences of sexual abuse in people with MID-BIF and improving the body experience and psychological health.
1) a) Does the use of the PMT module Safe and Strong have an effect on the body experience, arousal complaints, coping skills and the treatment goals of clients as reported by clients themselves, caregivers and relatives?
b) Does the use of the PMT module Safe and Strong have an effect on trauma-related complaints and psychological problems of clients?
2) a) What is the social validity (suitability for daily life) of the PMT module Safe and Strong?
b How is the PMT module Safe and Strong evaluated by clients themselves, caregivers and relatives and which elements are mentioned as most effective?*

Study design

In cooperation with psychomotor therapists from different regions of 's Heeren Loo, the PMT module Safe and Strong will be offered. To realize the implementation and advice, experts by experience with MID-BIF and an expert group consisting of people from different disciplines within 's Heeren Loo will be involved in the research.
We use a 'multi-method design' to test the effect and evaluate the treatment:

- An N=1 design with a controlled non-concurrent multiple baseline across subjects experimental design quantitatively tests the effect of treatment. Appropriate to this study design, frequent repeated measurements are caried out with the clients and also with the (in)formal network during a randomized baseline period, an intervention period with three phases of treatment and post-intervention period. The frequently repeated measurements focus on, achievement of individually set treatment goals, coping skills and arousal regulation complaints. Within this N=1 design, measurements in the baseline period are compared with measurements in the intervention period for each individual client, which allows clients to serve as their own control. The replicability of the effect is tested by applying this design to multiple clients with different starting points of the intervention. In this multiple baseline design, the effect is tested from client to client through a randomization test. In addition, trauma-related symptoms, psychological problems and body experience are measured with standardized questionnaires in the client and network at six points in time.
It is expected that with inclusion of fifteen clients even with dropout of clients -during treatment and at follow-up- a total of at least twelve N=1 studies can be realized (Bouwmeester & Jongerling, 2020). In combination with the research design, the number of repeated measurements, the randomly assigned baseline period and the analysis plan, we expect to be able to make statements about the individual effect of the PMT module and by using a randomization test, statements about replicability become possible.
- The qualitative part of the research, as an in-depth and supplement to the quantitative part, focuses on the experiences and perceptions of the clients, caregivers and relatives during and after the psychomotor intervention. Based on semi-structured interviews, we answer the question of how those involved assess the social validity (suitability for daily life) and efficacy of the treatment and what their considerations are.

Intervention

At the request of PMT practitioners working in the care of intellectual disabilities, the PMT module Safe and Strong was developed with the help of experts by experience and focus groups of psychomotor therapists working in the care of intellectual disabilities. The PMT module was developed for individual treatment of people with MID-BIF who have experienced sexual abuse with the involvement of a support network. The PMT module focuses on positively influencing body experience, arousal and emotion regulation and learning to actively set boundaries. The PMT module Safe and Strong is composed of three phases and lasts between 26 and 44 sessions and was examined for feasibility and efficacy in an initial pilot study with five participants

The pilot study is approved by the Social Sciences Ethics Committee of Radboud University under No. ECSW-2020-116 and publication in preparation.

Study burden and risks

The intervention involves a protocolized offering of treatment elements that are already present in treatment practice. For this reason, the risk is not increased with respect to regular treatment. As far as possible, the questionnaires will be included in the existing procedures for diagnosis and treatment. The burden on the clients, caregiver and relative consists of completing a short self-report questionnaire twice a week (5 minutes), completing several standardized questionnaires at six times (30-45 minutes) (largely integrated into the treatment sessions) and participating in an interview after the module (30-60 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

The inclusion of participants in the study consists of two steps.
Step 1: There is a positive decision by the multidisciplinary treatment team of the locations involved regarding the indication for PMT. Clients meet all of the following criteria:
• The client has an MID-BIF; an IQ between 50-85 with deficits in adaptive skills;
• The client is 18 years or older;
• The client experiences at least two complaints in the area of, body experience (such as physical complaints, problems in perceiving body signals, feelings of hatred towards one's own body, shame about one's own body), complaints regarding arousal regulation, mood, emotion regulation (such as physical aggression), self-harm, avoidance (such as avoiding physical activities), setting boundaries and/or standing up for their own needs;
• The preconditions are met to start therapeutic treatment, such as a sufficiently stable living environment, stable network and motivation for treatment.
Step 2: To participate in the study, clients must also meet the following criteria:
• The client has recent or past experiences with sexual abuse and the above complaints are the result of the sexual abuse;
• The client is able to complete questionnaires suitable for people with MID-BIF;
• The client has a clinical score for trauma-related complaints and/or psychological problems (a score on the BSI-18 and/or the TS-LVB higher than the cut-off point, see measuring instruments);

Exclusion criteria

A potential participant who meets one of the following criteria cannot participate in the study:
• The client is in acute psychosis;
• There is no caregiver and/or a relative available who can be involved in the treatment and research.
• At intake, the client does not score any clinical values on the standardized questionnaires for trauma-related complaints and/or psychological problems.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2023
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84321.018.23