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Group schema therapy for borderline personality disorder

Submission date
15/01/2018

Recruitment status
No longer recruiting

Registration date
22/01/2018

Overall study status
Completed

Last Edited
27/10/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Borderline personality disorder (BPD) is a severe mental disorder characterized by instability of self-image, instability of mood, tumultuous relationships, and recurrent episodes of self-harm. Patients with BPD are also prone to depression, anxiety and substance use disorders, and are commonly severely psychosocially disabled. There is a great need for effective psychosocial interventions for BPD. Schema therapy is a promising psychotherapeutic treatment for BPD. It has been investigated in traditional individual treatment format, but little research exists about a more cost-effective group format that has been recently developed. The aim of this study is to investigate the effectiveness of group schema therapy for the treatment of psychiatric outpatients with BPD.

Who can participate?
Psychiatric outpatients with BPD receiving treatment in the Mood Disorder Division of Department of Psychiatry, Helsinki University Hospital, in Finland

What does the study involve?
Participants are randomly allocated to either usual psychiatric treatment alone, or usual psychiatric treatment with group schema therapy. The usual psychiatric outpatients treatment received by both groups generally involves 1-2 appointments per month with a professional (commonly a psychiatric nurse or a psychologists), plus drug treatment prescribed by a psychiatrist (antidepressants, low-dose antipsychotics, or mood stabilizers). Group schema therapy involves 20 consecutive weekly two hour therapy sessions over a period of five months, with up to eight patients and two therapists per group. The therapists have been trained in the treatment format and are regularly supervised. Participants' BPD symptoms are compared before and after the therapy.

What are the possible benefits and risks of participating?
The benefits of participation include receiving a promising psychotherapeutic treatment, and careful evaluation of symptoms and other factors related to treatment needs. The risks include the need to discuss psychologically distressing problems, which may occasionally be stressful.

Where is the study run from?
Helsinki University Hospital (Finland)

When is the study starting and how long is it expected to run for?
September 2017 to May 2020 (as of 04/10/2018)

Who is funding the study?
Helsinki and Uusimaa Hospital District (Finland)

Who is the main contact?
Prof. Erkki Isometsa

Contact information

Type(s)
Scientific

Contact name
Prof Erkki Isometsä

ORCID ID
http://orcid.org/0000-0001-5956-2399

Contact details
PO Box 22
Helsinki
Finland
00014

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Group schema therapy for borderline personality disorder: a randomized study

Acronym
GST-BPD

Study objectives

Group schema therapy plus usual psychiatric treatment result in greater decline in borderline personality disorder symptoms than usual psychiatric treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki and Uusimaa Hospital District (HUS) Ethics Committee, 16/11/2017; research permit within the HUS Department of Psychiatry 08/01/2018

Study design
Randomized intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Borderline personality disorder

Interventions
Consenting BPD patients were randomized in blocks of three by using the Research Randomizer® in ratio 2:1 to group schema therapy plus usual psychiatric treatment vs. usual psychiatric treatment alone. Because blinding of psychotherapy is impossible, patients are aware of their allocation. All the outcomes are self-reported questionnaires (therefore, no blinding of assessment).

The usual psychiatric outpatients treatment received by both groups generally involves 1-2 appointments per month with a professional (commonly a psychiatric nurse or a psychologists), plus pharmacotherapy prescribed by a psychiatrist (antidepressants, low-dose antipsychotics, or mood stabilizers).

Group schema therapy involves 20 consecutive weekly two hour therapy sessions over a period of five months, with up to eight patients and two therapists per group. The therapists have been trained in the treatment format and will be regularly supervised.

Intervention Type
Behavioural

Primary outcome measure
Within-individual change in borderline personality symptoms, measured using the BSL-23 scale score before and after the intervention

Secondary outcome measures
Within-individual change before vs after intervention in:
1. Borderline personality criteria symptoms, measured using the MSI-BPD score
2. Depressive symptoms, measured using the PHQ-9 score
3. Anxiety symptoms, measured using the OASIS score
4. Alcohol use, measured using the AUDIT score
5. Disability, measured using the Sheehan Disability Score
6. Schema modes, measured using the Schema Mode Inventory

Overall study start date
15/09/2017

Completion date
31/05/2020

Eligibility

Key inclusion criteria
Psychiatric outpatients receiving treatment within the facilities of Helsinki University Hospital Department of Psychiatry, Mood Disorder Division, having a principal clinical diagnosis of borderline personality disorder

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
64

Total final enrolment
42

Key exclusion criteria
1. Psychotic symptoms
2. Imminent risk of suicide
3. Principle diagnosis of or uncontrollable substance use disorder
4. Any illness or symptoms that would hamper participation in treatment
5. Other ongoing specific psychotherapy

Date of first enrolment

15/01/2017

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital
Department of Psychiatry
Mood Disorder Division
Helsinki
Finland
00029

Sponsor information

Organisation
Helsinki and Uusimaa Hospital District

Sponsor details
HUH Psychiatry Center
Välskärinkatu 12
Helsinki
Finland
00029 HUS

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/020cpqb94

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination plan
Intended to be published in a psychiatric journal in 2019-20.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The data will be held by the Helsinki and Uusimaa Hospital District, and it will not be available because of limitations caused by the Finnish data protection legislation, content of consent requested, and research permit.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2021	27/10/2020	Yes	No