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Four-day intensive treatment for obsessive-compulsive disorder - a feasibility study

Submission date
09/06/2022

Recruitment status
No longer recruiting

Registration date
10/06/2022

Overall study status
Completed

Last Edited
10/06/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obsessive compulsive disorder (OCD) is a common mental health condition where a person has obsessive thoughts and compulsive behaviours. OCD can affect men, women and children. Some people start having symptoms early, often around puberty, but it usually starts during early adulthood.
Bergen 4 Day Treatment (B4DT) is a concentrated exposure treatment (cET) developed to treat OCD. It has proven to be highly acceptable and effective in other settings. In this feasibility study we investigate the implementation, feasibility, and preliminary outcomes of B4DT treatment in HUS psychiatry settings in 5-7 therapy groups.

Who can participate?
Adult patients who have been diagnosed with obsessive compulsive disorder.

What does the study involve?
The study involves a pre-screening interview, the actual intensive treatment period in four consecutive days in HUS outpatient clinic within a group of 3-6 patients and at least the same number of therapists, and a follow-up at 10 days and at 3 months after the treatment.

What are the possible benefits and risks of participating?
Based on previous research results, we assume the Bergen 4 Day Treatment model will be an effective and safe treatment that is well suited for the Finnish treatment environment.
Participating in the study may be beneficial for you and ameliorate your OCD symptoms.
As the exact same treatment has been in use in other Scandinavian countries for some years and shown to be safe and effective, it is unlikely to have any unexpected adverse events.

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

When is the study starting and how long is it expected to run for?
November 2021 to April 2023

Who is funding the study?
Helsinki University Hospital (Finland)

Who is the main contact?
Suoma Saarni, PhD, suoma.saarni@hus.fi

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Bergen 4 Day Treatment (B4DT) for Obsessive-Compulsive Disorder (OCD) – an observational feasibility study

Acronym
B4DT-HKI-I

Study objectives
We investigate the implementation, feasibility, and preliminary outcomes of B4DT treatment in HUS psychiatry settings in Finland

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2022, Helsinki and Uusimaa Hospital District (HUS) Ethics Committee (PO BOX 705, 00029, Finland; +358 40 617 5386; mirka.salin@hus.fi), ref: HUS/1085/2022

Study design
Observational feasibility study

Primary study design
Observational

Secondary study design
Cohort study

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
Obsessive-compulsive disorder

Interventions
The patients will receive a concentrated exposure treatment (cET) conducted in four consecutive days in HUS psychiatry outpatient clinic according to Bergen four day treatment for OCD (B4DT) manual. After ten days and three weeks after treatment, patients are offered a short follow-up session to discuss their experiences during and after the active treatment period.

Intervention Type
Behavioural

Primary outcome measure
Within-individual decline in Y-BOCS score before the intervention vs. after the treatment and at three months.

Secondary outcome measures
Measured before the intervention vs. after the treatment and at three months.
1. OCD symptoms measured with OCI-R and DOCS-SF
2. Depression (PHQ-9)

3. Anxiety (GAD-7)
4. Sleeping problems (BIS)
5. Functionality (WSAS)
6. Well-being (WEMWBS)
7. Client satisfaction (CSQ-8)

Overall study start date
09/11/2021

Completion date
20/04/2023

Eligibility

Key inclusion criteria
DSM-5 Obsessive-compulsive disorder

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
30

Key exclusion criteria
1. Concurrent psychotic disorder
2. Substance use disorder
3. Imminent risk of suicide
4. Congenital disability
5. New antidepressant or antipsychotic pharmacotherapy trial started within the last six weeks
6. Use of benzodiazepines is allowed only for insomnia
7. Ongoing other evidence-based psychotherapy for OCD

Date of first enrolment
01/05/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital
HUS Brain Center
Department of Psychiatry
P.o.Box 590
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Sponsor information

Organisation
Helsinki University Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.hus.fi/en

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Hospital

Results and Publications

Publication and dissemination plan
Intended to be published in a peer-reviewed scientific journal

Intention to publish date
01/12/2023

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