

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

Submission date 09/06/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/06/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Dr Suoma Saarni

ORCID ID

<https://orcid.org/0000-0003-3555-9958>

Contact details

HUS Brain Center
Department of Psychiatry
It-psychiatry and psychosocial treatments
P.o.Box 590
Helsinki
Finland
00029 HUS
+358 9 4711
suoma.saarni@hus.fi

Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

Completion date

20/04/2023

Eligibility**Key inclusion criteria**

DSM-5 Obsessive-compulsive disorder

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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

Helsinki

Finland

00029 HUS

Sponsor information

Organisation

Helsinki University Hospital

ROR

<https://ror.org/02e8hzhf44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Helsinki University Hospital

Results and Publications

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