ISRCTN14990924 https://doi.org/10.1186/ISRCTN14990924

Impact of waiting time on the effectiveness and cost-effectiveness of stepped care guided self-help followed by face-to-face cognitive behavioral therapy versus standalone face-to-face cognitive behavioral therapy for anxiety

Submission date
27/09/2024

Recruitment status
Recruiting

Registration date
08/10/2024

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anxiety is among the most prevalent mental health conditions, particularly in Western countries. Access to treatments such as cognitive behavioral therapy (CBT) in publicly funded primary care settings is frequently insufficient and delayed. This study aims to assess the impact of waiting times on the effectiveness and cost-effectiveness of a stepped care approach, which begins with guided self-help (GSH) followed by face-to-face CBT, compared to directly referring patients to face-to-face CBT for anxiety.

Who can participate?
Adults (16+ years) experiencing anxiety symptoms who are suitable for step 1 or step 2 treatments (such as GSH or CBT) in the Finnish public healthcare system

What does the study involve?
First, the participants will be randomly assigned to one of two intervention groups: face-to-face CBT or GSH. Second, the participants will be randomly allocated into two waiting time groups, i. e. <4 weeks and >5 weeks. Those who do not respond adequately to GSH will be offered further treatment with face-to-face CBT. Participants will complete symptom measures at various stages over the course of the study to track changes in their mental health.

What are the possible benefits and risks of participating?
The study aims to enhance access to effective, evidence-based, and timely treatments for anxiety within public healthcare systems. All participants will receive treatment that is at least equivalent to the standard care available outside the study. The potential risks are minimal and comparable to existing treatment options; however, if symptoms worsen, participants will be promptly referred to appropriate care.

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

When is the study starting and how long is it expected to run for?
June 2024 to December 2029

Who is funding the study?
The study is primarily funded by EU-Next Generation grants distributed from the Ministry of Social Affairs and Health in Finland.

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

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Prof Suoma Saarni

ORCID ID
https://orcid.org/0000-0003-3555-9958

Contact details
HUS Psychiatry, Välskärinkatu 12
Helsinki
Finland
00029
+358 (0)94711
suoma.saarni@hus.fi

Type(s)
Public

Contact name
Dr Katariina Mattila

Contact details
HUS Psychiatry, Välskärinkatu 12
Helsinki
Finland
00029
+358 (0)94711
katariina.m.mattila@hus.fi

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Impact of waiting time on the effectiveness and cost-effectiveness of stepped care guided self-help followed by face-to-face cognitive behavioral therapy versus standalone face-to-face cognitive behavioral therapy for anxiety: a randomized controlled trial of the Finnish firstline therapies initiative

Acronym
FLT-Step

Study objectives
Current study objectives as of 07/07/2025:

Primary hypothesis:
P1. Longer waiting times for the study interventions are associated with poorer treatment response in anxiety symptoms at the primary measurement point (6 months after enrollment) in both study interventions:
1. A stepped care model (sequential guided self-help followed by face-to-face cognitive behavioral therapy [CBT] for non-responders)
2. Direct admission to face-to-face CBT

Secondary hypotheses:
S1. If non-inferiority is demonstrated, effectiveness of the stepped care model (sequential GSH followed by fCBT for non-responders) is superior compared to directly admitting patients to fCBT when treating clinical anxiety symptoms (baseline score of ≥10 p on GAD-7), assessed at six months after enrollment.
S2. The cost-effectiveness of stepped care (sequential GSH followed by CBT for non-responders) is better than directing all patients with anxiety symptoms directly to CBT regardless of the waiting time.
S3. The studied stepped care model (sequential GSH followed by CBT for non-responders) is cost-saving in the long term compared to matched population controls, when direct and indirect health care, social care, employment, and societal costs are controlled.
S4. Data collected by the Finnish Therapy Navigator, a digital tool to help assess individual needs and symptom profiles for psychotherapy can be used to predict responses to treatment.
S5. Primary care patients with anxiety symptoms benefit from psychotherapeutic interventions, in terms of reduced risk of developing clinical episodes and reduced total long-term societal costs.

S6. Longer waiting times for the study treatments are associated with poorer overall long-term outcomes when direct and indirect health care, social care, employment, and societal costs are considered

———

Previous study objectives:

Primary hypothesis:
P1. Longer waiting times for the study interventions are associated with poorer treatment response in anxiety symptoms at the primary measurement point (6 months after enrollment) in both study interventions:
1. A stepped care model (sequential guided self-help followed by face-to-face cognitive behavioral therapy [CBT] for non-responders)
2. Direct admission to face-to-face CBT

Secondary hypotheses:
S1. The effectiveness of the stepped care model (sequential guided self-help [GSH] followed by face-to-face CBT for non-responders) is better compared to directly admitting patients to CBT regardless of the waiting time when treating clinical anxiety symptoms (baseline score of ≥10 GAD-7), assessed at 6 months after enrollment.
S2. The cost-effectiveness of stepped care (sequential GSH followed by CBT for non-responders) is better than directing all patients with anxiety symptoms directly to CBT regardless of the waiting time.
S3. The studied stepped care model (sequential GSH followed by CBT for non-responders) is cost-saving in the long term compared to matched population controls, when direct and indirect health care, social care, employment, and societal costs are controlled.
S4. Data collected by the Finnish Therapy Navigator, a digital tool to help assess individual needs and symptom profiles for psychotherapy can be used to predict responses to treatment.
S5. Primary care patients with anxiety symptoms benefit from psychotherapeutic interventions, in terms of reduced risk of developing clinical episodes and reduced total long-term societal costs.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/06/2024, Helsinki University Hospital (HUS) Regional Committee on Medical Research Ethics (PO BOX 705, 00029, Finland, Helsinki, 00029, Finland; +358 (0)9471 71607; eetinen.toimikunta@hus.fi), ref: HUS/6234/2023

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Hospital, Internet/virtual, Other

Study type(s)
Other, Prevention, Treatment, Efficacy

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Anxiety

Interventions
Participants will be randomized to the following treatment arms (1:1) (performed using the randomization feature of the REDCap application):
1. Stepped care model: guided self-help (GSH, average number of sessions 3) followed by face-to-face cognitive behavioral therapy (CBT, average number of sessions 7) for non-responders
2. Face-to-face cognitive behavioral therapy (CBT average number of sessions 7)

Both arms will be further randomized to those who begin the intervention:
1. Less than 4 weeks after the randomization and
2. More than 5 weeks after the randomization

The duration of treatments in the study arms are as follows:
1. Sequential treatment of guided self-help and face-to-face CBT (stepped care): approximately 3 months for anxiety
2. Face-to-face CBT: approximately 2 months for anxiety

All study arms have a post-treatment measurement point (at the end of treatment). After that, the following follow-up points after randomization are the same for all study arms:
1. 4 months after randomization
2. 6 months after randomization (primary outcome measurement point)
3. 8 months after randomization
4. 12 months after randomization
5. Follows ups at 2 and 5 years

Intervention Type
Behavioural

Primary outcome measure
Anxiety symptoms measured by the GAD-7. The GAD-7 is administered weekly from the beginning of the intervention for 16 weeks and at follow-up timepoints (e.g. 4, 6, 8, and 12 months as well as 2, 5, 10, 15 and 20 years) to enable ITT (intention to treat) -analysis and modeling the symptom change in time.

Secondary outcome measures
1. Psychotropic medication use is measured using patient self-reports at baseline (T0), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
2. Employment status is measured using patient self-reports at baseline (T0), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
3. Income in the previous year is measured using patient self-reports at baseline (T0) and at 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
4. Alcohol use is measured using the Alcohol Use Disorders Identification Test-Concise (AUDIT-C /AUDIT) at baseline (T0), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).

5. Healthcare visits over the previous 12 months are measured using patient self-reports at baseline (T0) and at, 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
6. Severity of depression symptoms is measured using the Patient Health Questionnaire (PHQ-9) weekly from the beginning of the intervention for 16 weeks, at post-treatment (T2), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
7. Subjective work ability is assessed using patient self-reports at baseline (T0), post-treatment (T2), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
8. Perceived social support is measured using the Perceived Social Support Scale-Revised (PSSSR) at baseline (T0), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
9. Functional impairment is measured using the Work and Social Adjustment Scale (WSAS) at baseline (T0), 4-month follow-up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
10. Quality of life is measured using the EQ-5D-5L and Euro Health Interview Survey (Euro-HIS) at baseline (T0), 4-month follow up (T3), 6-month follow-up, 8-month (T4), 12-month, 2-year follow-ups, and optional 5, 10, 15, and 20-year follow-ups (T5).
11. Number of intervention sessions attended is recorded at post-treatment (T2).
12. Patient's experience of the intervention is assessed using a qualitative measure (method not specified) at post-treatment (T2).
13. Direct and indirect healthcare, social care, employment, and societal costs are measured using Finnish national registries at T0, T3, T4, T5, and all optional follow-ups.

These outcome measures, combined with data from Finnish national registries, will provide a comprehensive overview of the effectiveness and cost-efficiency of the treatments being studied.

Overall study start date
27/06/2024

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Minimum age of 16 years
2. Suitable for step 1-2 treatments (GSH and/or CBT intervention) for anxiety in the first assessment
3. GAD-7 ≥10 p

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
115 with clinical symptoms (GAD-7 ≥10 p)

Key exclusion criteria
General exclusion criteria for step 1-2 treatments (i.e. recommended stepping up):
1. Serious suicidal thoughts, plans or any self-harming act or suicidal attempt within the past 2 months
2. Ongoing other psychological treatment for depression and/or anxiety
3. Cognitive impairment
4. Inability to speak, read and write Finnish
5. Currently symptomatic psychotic illness or bipolar disorder
6. Drug or alcohol dependence

Date of first enrolment
16/09/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Finland

Study participating centre
Wellbeing service county of Pirkanmaa
Finland
33101 Tampere
Tampere
Finland
33101

Sponsor information

Organisation
Helsinki University Hospital

Sponsor details
Välskärinkatu 12
Helsinki
Finland

00029
+358 (0)94711
jesper.ekelund@hus.fi

Sponsor type
Hospital/treatment centre

Website
http://www.hus.fi/en/Pages/default.aspx

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Government

Funder Name
Sosiaali- ja Terveysministeriö

Alternative Name(s)
Ministry of Social Affairs and Health, Social- och Hälsovårdsministeriet

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Finland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/10/2028

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?
Participant information sheet			07/10/2024	No	Yes