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Effectiveness of stepped care guided self-help followed by face-to-face cognitive behavioral therapy versus standalone internet-delivered or face-to-face cognitive behavioral therapy for anxiety

Submission date
13/09/2024

Recruitment status
Recruiting

Registration date
20/09/2024

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 one of the most common mental health conditions, especially in Western countries. Access to treatment, such as cognitive behavioral therapy (CBT), in publicly funded primary care settings is often inadequate. This study aims to evaluate the effectiveness and cost-effectiveness of three treatments for anxiety 1) A stepped care model: sequential guided self-help (GSH) followed by face-to-face CBT for non-responders 2) internet-delivered CBT (iCBT), and 3) face-to-face CBT, within the Finnish public healthcare.

Who can participate?
Adults (16+ yrs) experiencing anxiety symptoms (> 4 p on the GAD-7) who are suitable for step 1 or step 2 treatments (such as GSH, iCBT, or CBT) in the Finnish public healthcare system. Individuals who are already receiving psychological treatment, have severe suicidal thoughts, or have substance abuse issues may not be eligible.

What does the study involve?
Participants will be randomly assigned to one of three groups: face-to-face CBT, iCBT, or GSH. Those who do not respond adequately to GSH will be offered further treatment with face-to-face CBT. Participants will complete symptom measures, such as the Generalized Anxiety Disorder scale (GAD-7), and the Patient Health Questionnaire (PHQ-9) 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 improve access to effective, evidence-based treatments for anxiety in public healthcare. All participants will receive treatment that is at least as good as the standard care they would receive outside the study. The potential risks are minimal and comparable to current treatment options, but if symptoms worsen, participants will be directed to appropriate care.

Where is the study run from?
The study will be conducted within several wellbeing service counties in Southern Finland and Western Finland. It is part of the Finnish First-Line Therapies –initiative in Finland's public healthcare system.

When is the study starting and how long is it expected to run for?
The study is set to begin in autumn 2024, with recruitment expected to continue until summer 2026, with long-term follow-ups extending up to five years or more.

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 (VN/29619/2023 and VN/29613/2023). Additional funding may be provided by HUS (Helsinki University Hospital) and other research foundations.

Who is the main contact?
Professor Suoma E. Saarni, MD, PhD, who serves as the principal investigator, is based at Helsinki University Hospital (HUS) and Tampere University, suoma.saarni@hus.fi

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
VN/29619/2023, VN/29613/2023

Study information

Scientific Title
Effectiveness and cost-effectiveness of stepped care guided self-help followed by face-to-face cognitive behavioral therapy versus standalone internet-delivered or face-to-face cognitive behavioral therapy for anxiety: a randomized controlled non-inferiority trial of the finnish first-line therapies–initiative

Acronym
FLT-Step

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

Primary hypothesis
P1. A stepped care model (sequential GSH followed by face-to-face cognitive behavioral therapy (CBT) for non-responders), and internet-delivered cognitive behavioral therapy (iCBT) are non-inferior (non-inferiority margin 1.7 points on the Generalized Anxiety Disorder scale, GAD-7) to CBT for treating clinical anxiety symptoms (baseline score of ≥10 on the GAD-7) at primary outcome measurement point (6 months after enrollment).

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.

S2a. Stepped care is more cost-effective than directing all patients with anxiety symptoms (baseline score ≥10 p on GAD-7) directly to fCBT assessed six months after enrollment.
S2b: iCBT is more cost-effective than directing all patients with anxiety symptoms (baseline score of ≥10 p on GAD-7) directly to fCBT assessed six months after enrollment.

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 profile for psychotherapy can be used to predict responses to treatment.

S5. Longer waiting times for the study interventions are associated with poorer treatment response for those with baseline score of ≥10 on the GAD-7.
S6. Patients seeking treatment with subclinical anxiety symptoms (baseline score of 5-9 on the GAD-7) benefit from psychotherapeutic interventions, in terms of reduced risk of developing clinical episodes and reduced total long-term societal costs.

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Previous study objectives:

Primary hypothesis
P1. A stepped care model (sequential GSH followed by face-to-face cognitive behavioral therapy (CBT) for non-responders), and internet-delivered cognitive behavioral therapy (iCBT) are non-inferior (non-inferiority margin 1.7 points on the Generalized Anxiety Disorder scale, GAD-7) to CBT for treating clinical anxiety symptoms (baseline score of ≥10 on the GAD-7) at primary outcome measurement point (6 months after enrollment).

Secondary hypotheses:
S1. Effectiveness of stepped care (sequential GSH followed by CBT for non-responders) is better compared to directly admitting patients to CBT when treating clinical anxiety symptoms (baseline score of ≥10 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 or iCBT.
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 profile for psychotherapy can be used to predict responses to treatment.
S5. Longer waiting times for the study interventions are associated with poorer treatment response for those with baseline score of ≥10 on the GAD-7.
S6. Patients seeking treatment with subclinical anxiety symptoms (baseline score of 5-9 on the GAD-7) 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 9471 71607; eetinen.toimikunta@hus.fi), ref: HUS/6234/2023

Study design
Randomized controlled non-inferiority 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
To follow

Health condition(s) or problem(s) studied
Treatment and prevention of anxiety symptoms in mental health services

Interventions
Participants will be randomized in the following three treatment arms (1:1:1) :
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. Therapist guided internet delivered CBT (iCBT, 8 sessions)
3. Face-to-face cognitive behavioral therapy (CBT average number of sessions 7)

We use stratified randomization to avoid potential biases in the data. The stratification will be done by symptom severity (5-9 p on the GAD-7; ≥10 p on the GAD-7) and by research location.

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
3. Internet-delivered CBT: approximately 3 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 same for all study arms:
• Four months after randomization
• Six months after randomization (primary outcome measurement point)
• Eight months after randomization
• Twelve months after randomization
• Follows ups at two and five 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 time points (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 (T4), 8-month, 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 (T4), 8-month, 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 8-month, 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 (T4), 8-month, 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 8-month, 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 (T4), 8-month, 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 (T4), 8-month, 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 (PSSS-R) at baseline (T0), 4-month follow-up (T3), 6-month follow-up (T4), 8-month, 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 (T4), 8-month, 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 (T4), 8-month, 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).

Additionally, data from Finnish national registries will be used to gather direct and indirect healthcare, social care, employment, and societal costs, as well as to create population-matched controls.

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 (guided self-help, iCBT or CBT intervention) for anxiety in the first assessment
3. GAD-7 ≥5

Participant type(s)
Patient

Age group

Adult

Lower age limit
16 Years

Upper age limit
120 Years

Sex
Both

Target number of participants
948 with clinical symptoms (PHQ-9>9p), convenience sample of patients with subclinical symptoms (PHQ-9 5-9p)

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
City of Helsinki Mental health Services
Helsinki
Finland
00100

Study participating centre
Wellbeing service county of Keski-Uusimaa
Finland
02070

Study participating centre
Wellbeing service county of Länsi-Uusimaa
Finland
02070

Study participating centre
Wellbeing service county of Vantaa Kerava
Finland
01030

Study participating centre
Wellbeing service county of Päijät-Häme
Finland
00100

Study participating centre
Wellbeing service county of Satakunta
Finland
00200

Study participating centre
Wellbeing service county of Varsinais-Suomi
Finland
00250

Study participating centre
Harjun Terveys
Finland
00100

Sponsor information

Organisation
Helsinki University Hospital

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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
The results are planned to be published in a peer-reviewed academic journal after the end of the trial.

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