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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 depression

Submission date
13/09/2024

Recruitment status
Recruiting

Registration date
18/09/2024

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
Depression 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 depression 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 depression symptoms (> 4 p on the PHQ-9) 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 Patient Health Questionnaire (PHQ-9) and the Generalized Anxiety Disorder scale (GAD-7), 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 depression 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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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 depression: 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 Patient Health Questionnaire, PHQ-9) to CBT for treating clinical depression symptoms (baseline score of ≥10 on the PHQ-9) 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 depression symptoms (baseline score of ≥10 p on PHQ-9), assessed at six months after enrollment.

S2a. Stepped care is more cost-effective than directing all patients with depression symptoms (baseline score ≥10 p on PHQ-9) directly to fCBT assessed six months after enrollment.
S2b: iCBT is more cost-effective than directing all patients with depression symptoms (baseline score of ≥10 p on PHQ-9) 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 PHQ-9.
S6. Patients seeking treatment with subclinical depressive symptoms (baseline score of 5-9 on the PHQ-9) 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 Patient Health Questionnaire, PHQ-9) to CBT for treating clinical depression symptoms (baseline score of ≥10 on the PHQ-9) 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 depression symptoms (baseline score of ≥10 on PHQ-9), 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 depression 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 PHQ-9.
S6. Patients seeking treatment with subclinical depressive symptoms (baseline score of 5-9 on the PHQ-9) 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 depression 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 PHQ-9; ≥10 p on the PHQ-9) 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 both anxiety and depression.
2. Face-to-face CBT: approximately 2 months for both anxiety and depression.
3. Internet-delivered CBT: approximately 3 months for anxiety and 2 months for depression.

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
Within-individual change in depression symptoms measured by the PHQ-9. The PHQ-9 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 participant self-report at T0, T3, T4, T5, and all optional follow-ups
2. Employment status is measured using participant self-report at T0, T3, T4, T5, and all optional follow-ups
3. Income in the previous year is measured using participant self-report at T0, T5, and all optional follow-ups
4. Alcohol use is measured using the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C/AUDIT) at T0, T3, T4, T5, and all optional follow-ups
5. Healthcare visits over the previous 12 months are measured using participant self-report at T0, T5, and all optional follow-ups
6. Severity of anxiety symptoms is measured using the Generalized Anxiety Disorder-7 (GAD-7) at T2, T3, T4, T5, and all optional follow-ups and weekly from the beginning of the intervention for 16 weeks
7. Subjective work ability is measured using participant self-report at T0, T2, T3, T4, T5, and all optional follow-ups
8. Perceived social support is measured using the Perceived Social Support Scale-Revised (PSSS-R) at T0, T3, T4, T5, and all optional follow-ups
9. Functional impairment is measured using the Work and Social Adjustment Scale (WSAS) at T0, T3, T4, T5, and all optional follow-ups
10. Quality of life is measured using the EQ-5D-5L and Euro Health Interview Survey (Euro-HIS) at T0, T3, T4, T5, and all optional follow-ups
11. The number of intervention sessions attended is measured using participant records at T2
12. Patient experience of the intervention is measured using participant self-report at 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 (guided self-help, iCBT or CBT intervention) for depression in the first assessment
3. PHQ-9 ≥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
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
00100

Study participating centre

Wellbeing service county of Länsi-Uusimaa
Finland
02070

Study participating centre
Wellbeing service county of Itä-Uusimaa
Finland
00100

Study participating centre
Wellbeing service county of Vantaa Kerava
Finland
01030

Study participating centre
Wellbeing service county of Päijät-Häme
Finland
15110

Study participating centre
Wellbeing service county of Satakunta
Finland
00100

Study participating centre
Wellbeing service county of Varsinais-Suomi
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Study participating centre
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Organisation
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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