

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 depression

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|----------------------------------------|---------------------------------------------------------------|-----------------------------------------------------------------|
| Submission date 27/09/2024 | Recruitment status Recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 08/10/2024 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 07/07/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Depression 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 depression.

Who can participate?

Adults (16+ yrs) experiencing depression symptoms (≥ 10 p on the Patient Health Questionnaire PHQ-9) who are suitable for step 1 or step 2 treatments (such as GSH 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?

First, the participants will be randomly assigned to one of two intervention groups: face-to-face CBT or GSH. Second, the participants will be 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 throughout 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 depression 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?
HUS Psychiatry Center

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?
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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 depression: 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 depression symptoms at the primary measurement point (six months after enrollment) in both study interventions: 1) a stepped care model (sequential guided self-help followed by face-to-face CBT for non-responders) and 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 depression symptoms (baseline score of ≥ 10 p 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 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 profile for psychotherapy can be used to predict responses to treatment.

S5. Primary care patients with depression 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 depression symptoms at the primary measurement point (six months after enrollment) in both study interventions: 1) a stepped care model (sequential guided self-help followed by face-to-face CBT for non-responders) and 2) direct admission to face-to-face CBT.

Secondary hypotheses

S1. The effectiveness of the stepped care model (sequential 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 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 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 profile for psychotherapy can be used to predict responses to treatment.

S5. Primary care patients with depression 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, Helsinki, 00029, Finland; +358 9471 71607; eetinen.toimikunta@hus.fi), ref: HUS/6234/2023

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Other, Prevention, Treatment, Efficacy

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 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 depression
2. Face-to-face CBT: approximately 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 the 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(s)

Depression symptoms measured using the Patient Health Questionnaire (PHQ-9) 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

Key secondary outcome(s)

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 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 workability is measured 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. The number of intervention sessions attended is measured using data recorded at post-treatment (T2)
12. The patient's experience of the intervention is measured 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

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 depression in the first assessment
3. PHQ-9 ≥ 10 p

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 years

Upper age limit

120 years

Sex

All

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 depression
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

Tampere

Finland

33101

Sponsor information**Organisation**

Helsinki University Hospital

ROR

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

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

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 |