

Effectiveness of internet-delivered cognitive behaviour therapy (iCBT) in reducing sickness absence among young employees with depressive symptoms

Submission date 07/03/2019	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/03/2019	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/10/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Depression is a very common condition. It is one of the conditions causing the most sickness absence from work. Depression usually begins in early adulthood. It can be effectively treated with cognitive behavioral therapy (CBT). Unfortunately, such therapy is often difficult to access. This may be because it is difficult to find a therapist, or because of high costs. Some are afraid of stigma. Today, there is also CBT that is delivered over the internet (iCBT). iCBT is more easily available than conventional CBT. Young adults particularly may find iCBT an attractive alternative to conventional CBT. In many studies, iCBT has been shown to help with depressive symptoms. However, more research is needed. For example, it is not yet known whether iCBT can help reduce sickness absence among those employees who have depressive symptoms. This study investigates whether participation in an iCBT program "Mental Hub for Depression" helps reduce sickness absence among 18 to 34-year-old public sector employees. The study also aims to find out whether iCBT works as part of occupational health care. If iCBT shows to be an effective treatment, it can be used more widely. The findings of the study can help enhance the treatment of mental disorders, especially for young workers.

Who can participate?

18-34-year-old employees of the City of Helsinki (Finland), who have been continuously employed at least 6 months and who score more 9 or more points in the Beck Depression Inventory-IA completed at their visit with a nurse at Occupational Health Helsinki

What does the study involve?

Participants are randomly allocated to one of two groups: control group or treatment group. Those in the control group receive care-as-usual (CAU), which is the care that occupational health care usually provides to employees with depressive symptoms. Those in the second group receive CAU as well, but in addition, they attend iCBT. iCBT involves one-hour therapy session once a week for 7 weeks. Sessions can be completed using a smartphone, tablet or computer. The purpose of the sessions is to provide the skills to manage depressive symptoms. Sickness

absence of each participant is monitored for six months from the study entry. A longer follow-up of sickness absence is possible in future studies. All information is obtained from the employer's and national administrative records. To find out whether participation in iCBT reduces sickness absence days, the numbers of sickness absence days in the two groups are compared.

What are the possible benefits and risks of participating?

Participation in the study is not considered harmful. All participants receive appropriate treatment for their depressive symptoms during the study. Participants have contact with health care professionals, who evaluate their health. Those in the iCBT group may benefit, but the benefits are individual and cannot be guaranteed in advance. All participants help increase the knowledge of the benefits of iCBT for the treatment of depressive symptoms, which is an important contribution.

Where is the study run from?

The University of Helsinki runs the study. Recruitment of participants takes place at the Occupational Health Helsinki, which provides primary care services for all of City of Helsinki employees. The use of services is free of charge for all the employees at the point of delivery.

When is the study starting and how long is it expected to run for?

January 2019 to August 2024

Who is funding the study?

Academy of Finland

Who is the main contact?

Prof. Anne Kouvonen

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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Study information

Scientific Title

Depression and sickness Absence in young adults: a Quasi-experimental trial and web-based treatment Intervention (DAQI)

Acronym

DAQI

Study objectives

The Mental Hub for Depression iCBT plus CAU compared to CAU, will produce a decrease in depressive symptoms among young employees and, in turn, a decrease in sickness absence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/05/2020, Coordinating Ethics Committee of the Hospital District of Helsinki and Uusimaa (PO Box 705, 00029 HUS, Finland, +358 (0)504279345, eettiset.toimikunnat@hus.fi), ref: HUS/974/2019.

Study design

Randomised controlled single-centre service-based trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild depressive symptoms (score ≥ 9 on the Beck Depression Inventory-IA)

Interventions

This study is a randomised controlled single-centre service-based trial of an existing iCBT program ("Mental Hub iCBT for Depression"). The aim is to examine if this treatment can reduce the number of sickness absence days in 18–34-year-old public sector employees who are presenting at occupational health service with mild depressive symptoms (score ≥ 9 on the Beck Depression Inventory-IA).

Participants will be randomly assigned to parallel groups in 1:1 ratio. Randomisation will be handled by a computerised random number generator administered by an independent person who is not involved in the study. The numbers corresponding to the treatment group (1=iCBT) and the control group (0=CAU), respectively, will be placed in sequentially numbered opaque sealed envelopes by a research assistant. The randomisation envelopes will be then manually assigned to all Occupational Health Helsinki nurses, who will in turn assign them to participants after the eligibility has been determined, trial discussed and written informed consent obtained. All researchers and nurses will be blind during the randomisation scheme; however, blinding for treatment allocation will not be possible as it will be clear to the referring nurse as well as the patient whether the patient has been allocated to iCBT treatment or the control arm. The allocation list will be stored in a password-protected file on the University of Helsinki server.

Control participants will be offered CAU, with no constraints on the range of treatments. The active condition will consist of seven weekly modules of iCBT, with support from a web therapist. iCBT involves a one-hour therapy session once a week for seven weeks. Sessions can be completed using a smartphone, tablet or computer. The purpose of the sessions is to provide the skills to manage depressive symptoms. Sickness absence of each participant is monitored for six months from the study entry. A longer follow-up of sickness absence is possible in future studies. All information is obtained from the employer's and national administrative records. To find out whether participation in iCBT reduces sickness absence days, the numbers of sickness absence days in the two groups are compared.

Intervention Type

Behavioural

Primary outcome(s)

Participants' all-cause sickness absence (cumulative length of sickness absence in days) measured from the employer's and national administrative records up to 6 months from study entry

Key secondary outcome(s)

Current secondary outcome measures as of 04/03/2020:

Measured from the Finnish Social Insurance Institution's administrative records and employer's records up to 6 months from study entry:

1. Long-term sickness absence (over 11 calendar days) for mental disorders
2. Long-term sickness absence (over 11 calendar days) for musculoskeletal disorders
3. Psychotropic medication use
4. Short-term sickness absence spells (up to 11 days)

Previous secondary outcome measures:

Measured from the Finnish Social Insurance Institution's administrative records and employer's records up to 6 months from study entry:

1. Long-term sickness absence (over 11 calendar days) for mental disorders
2. Musculoskeletal disorders
3. Psychotropic medication use
4. Self-certified short sickness absence spells (up to 3 days)

Completion date

31/08/2024

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 04/03/2020:

1. Visiting a nurse at Occupational Health Helsinki
2. Being 18- to-34 years old at the time of recruitment
3. Continuously employed by the City of Helsinki for at least 6 months before recruitment
4. Score ≥ 9 on the Beck Depression Inventory-IA (BDI-IA)

Previous participant inclusion criteria from 04/06/2019 to 04/03/2020:

1. Visiting a nurse at Occupational Health Helsinki
2. Being 18- to-34 years old at the time of recruitment
3. Continuously employed by the City of Helsinki for at least 6 months before recruitment
4. Score ≥ 9 on the Beck Depression Inventory 21

Previous participant inclusion criteria:

1. Visiting an Occupational Health nurse
2. Being 18- to-34 years old at the time of recruitment
3. Continuously employed by the City of Helsinki for at least 4 months before recruitment
4. Score ≥ 9 on the Beck Depression Inventory 21

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

34 years

Sex

All

Key exclusion criteria

Current participant exclusion criteria as of 04/03/2020:

1. Current high risk for suicide
2. Psychiatric co-morbidity: substance dependence, bipolar affective disorder, psychotic illness, obsessive-compulsive disorder, personality disorder
3. Not able to read Finnish (the intervention is only available in Finnish)

Previous participant exclusion criteria:

1. Current high risk for suicide
2. Psychiatric co-morbidity: substance dependence, bipolar affective disorder, psychotic illness,

obsessive-compulsive disorder

3. Not able to read Finnish, Swedish or English well (the intervention is only available in these languages)

Date of first enrolment

01/10/2019

Date of final enrolment

31/03/2023

Locations

Countries of recruitment

Finland

Study participating centre

Occupational Health Helsinki

Helsinginkatu 24

PO Box 5600

Helsinki

Finland

00530

Sponsor information

Organisation

University of Helsinki

ROR

<https://ror.org/040af2s02>

Funder(s)

Funder type

University/education

Funder Name

Academy of Finland

Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Finland

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 04/06/2019:

The EU General Data Protection Regulation (GDPR) and Finnish legislation pose strict requirements for the data processing and use for secondary purposes. Thus, unless fully anonymised, research data cannot be shared with unspecified third parties for unspecified secondary uses without new protocols, consents and authorisations. The data can be analysed jointly with the Helsinki Health Study team on the University of Helsinki server. All outcome data are register-based and their use requires the investigators to apply a permit to use the data and sign separate confidentiality agreements with each data owner (i.e. the Finnish Social Insurance Institution, Finnish Centre for Pensions, and Statistics Finland).

Previous IPD sharing statement:

The datasets generated and analysed during the current study will be available upon request from Prof Anne Kouvonen (anne.kouvonen@helsinki.fi) from 01/01/2023 to 31/12/2030. Non-identifiable data can be shared within the EEA/EU but can be analysed and published only in collaboration with the Helsinki Health Study research group. Consent will be obtained from participants.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/11/2019	08/11/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes