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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

Registration date
08/03/2019

Overall study status
Stopped

Last Edited
22/10/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
anne.kouvonen@helsinki.fi

Study website
https://www.helsinki.fi/fi/tutkimusryhmat/helsinki-health-study/nuorten-aikuisten-masennus-ja-sairauspoissaolot-nettiterapian-vaikuttavuus-masennusoireiden-hoidossa-daqi

Contact information

Type(s)
Scientific

Contact name
Prof Anne Kouvonen

ORCID ID
http://orcid.org/0000-0001-6997-8312

Contact details
Faculty of Social Sciences
PO Box 54
Unioninkatu 37
Helsinki
Finland

00014
+358 (0)504487113
anne.kouvonen@helsinki.fi

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2

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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
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)

Overall study start date
01/01/2019

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
34 Years

Sex
Both

Target number of participants
580

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

Sponsor details
PO Box 3
Fabianinkatu 33
Helsinki
Finland
00014
+358 (0)2941 911
firstname.lastname@helsinki.fi

Sponsor type
University/education

Website
https://www.helsinki.fi/en

ROR
https://ror.org/040af2s02

Funder(s)

Funder type
University/education

Funder Name
Academy of Finland

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Results and Publications

Publication and dissemination plan

Protocol has been published in a peer-review journal. The results will be published in peer-reviewed journals, lay publications and in conference and seminar presentations. The researchers aim to publish peer-reviewed papers in open access journals.

Intention to publish date
01/05/2025

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