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A deep learning probability model to deliver feedback-informed, internet-delivered psychotherapy for depression and anxiety

Submission date
27/10/2021

Recruitment status
No longer recruiting

Registration date
02/11/2021

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Depression and anxiety are common mental health problems, which are not only detrimental to a person's wellbeing, but they are also costly for both individuals and society. There are several effective treatments for depression and anxiety including talking therapies using cognitive behaviour therapy (CBT). In recent years, CBT has been transferred to online delivery methods and these interventions have proven successful for people being treated with symptoms of depression and anxiety. Moreover, feedback-informed therapy (FIT), where the therapist is given feedback on the progress of their client, has been shown to enhance traditional CBT, as well as internet-delivered CBT. In recent years, FIT has been benefitting from advances in machine learning (ML), which allows for more complex models to be built to assist in the detection, diagnosis, and treatment of mental health problems. Using ML to enhance FIT initiatives especially for technology-delivered interventions such as iCBT and within service settings that routinely collect outcome data could prove beneficial to overall service performance and client outcomes. We have recently developed one such deep learning model (DLM) that uses data from the first three assessments to calculate a probability of whether a patient is likely to reliably improve or not at the end of treatment. The current study will utilise a randomized controlled trial design, where the Psychological Wellbeing Practitioners at one IAPT site (Berkshire Talking Therapies) will be randomised in two groups; supporters in group one will have access to the algorithm and probability scores from the DLM while supporters in group 2 will practice as usual. The aim is to assess the performance and acceptability of this tool in enhancing delivery of iCBT for depression and anxiety.

Who can participate?
All psychological wellbeing practitioners (PWPs) who give clinical support to clients in IAPT at NHS Berkshire will be eligible to participate in the research.

What does the study involve?
PWPs will be randomised to DLM or control groups and will complete questionnaires as part of their participation. The PWPs in the DLM group will be able to use the DLM tool to enhance their regular interactions with clients. Follow up is for 12 weeks.

What are the possible benefits and risks of participating?
The goal of implementing the feedback informed therapy tool is to support the clinical decision making of the PWPs while using SilverCloud. A hypothesized benefit of this tool is that it may help them in reviewing the progress of their clients and making clinical decisions about their course of treatment.

Where is the study run from?
Berkshire Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to April 2022

Who is funding the study?
SilverCloud Health (Ireland)

Who is the main contact?
Dr Derek Richards, derek.richards@amell.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299656

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

CPMS 50695, IRAS 299656

Study information

Scientific Title
A deep learning probability model to deliver feedback-informed, internet-delivered psychotherapy for depression and anxiety: A randomised-controlled trial within routine clinical practice

Acronym
DLM FIT RCT

Study objectives
The primary objectives are to understand the effectiveness and the acceptability of the deep learning probability model (DLM) tool. This will be done by answering the following questions:
1. Is there a greater percentage of clients demonstrating a reliable change in the DLM psychological wellbeing practitioner (PWP) group [i.e. pre-post changes in PHQ-9 and GAD-7 scores]?
2. Do PWPs find the DLM tool acceptable? We will aim to answer this questions through the use of our technology acceptance survey with questions based on the Technology Acceptance Model and adapted from the Acceptability Questionnaire of Nadal et al. (2021).

Our secondary objective is the following:
1. Are PWPs engaging in higher levels of deliberate practice as a result of the DLM? We will aim to answer this questions by looking at quantitative data (e.g., length and number of reviews given to users with certain DLM probabilities) and qualitative data (e.g. survey questions about engaging in deliberate practice and effect of DLM tool on clinical decision making) to measure if the tool is enhancing the PWPs own practice

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2021, Health Research Authority (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 21/PR/1367

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Initial performance and overall acceptability of a DLM for feedback-informed outcome probability in iCBT for depression and anxiety.

Interventions
All PWPs who give clinical support to clients in IAPT at NHS Berkshire will be eligible to participate in the research. We will seek to recruit all current PWPs to the study and the ones randomly assigned to the DLM condition will use the feedback-informed outcome probability across all their clients during a 6-month period. PWPs will attend a short information session and then will be emailed an information sheet. PWPs will be asked to indicate consent online through Qualtrics. The ones who consent to the study will be randomized to DLM or control groups and will complete questionnaires (control group received questionnaires at baseline and 12 weeks, and DLM group received questionnaires at baseline, 4 weeks, and 12 weeks). Explicit consent will not be sought from each client as the research falls within the rubric of service development and evaluation.

PWPs will be randomized between those who will have access to the DLM probabilities and those will not. Randomisation will be based on experience using SilverCloud, i.e. how many clients the PWP has seen on SilverCloud prior to the start of the trial. Based on experience, there will be 2 categories of supporters: novices (1 to 40 clients) and experienced (over 40 clients on SCH). There will be equal proportions of novice and experienced PWPs in both DLM and control conditions. Qualtrics will be used to randomly assign supporters to the intervention or control groups after consenting to the study. The DLM tool will be on for all clients of the PWPs in the intervention arm.

Intervention Type
Other

Primary outcome measure
Depressive and anxiety symptoms will be measured with PHQ-9 and GAD-7. As part of their routine treatment, clients complete these scales every 7 to 10 days throughout the duration of their treatment.

Secondary outcome measures
PWPs acceptance of the tool, as well as the impact of the tool on deliberate practice will be measured qualitatively through survey questions. PWPs will complete surveys at baseline, 4 weeks, and 12 weeks from the start of the study.

Overall study start date
27/10/2021

Completion date
30/04/2022

Eligibility

Key inclusion criteria
All PWPs who give clinical support to clients in IAPT at NHS Berkshire will be eligible to participate in the research

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
96 PWPs with a minimum of 21 clients each

Key exclusion criteria
PWPs who do not provide clinical support through SilverCloud to clients in IAPT at NHS Berkshire or who do not consent to the study.

Date of first enrolment
01/11/2021

Date of final enrolment
15/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
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Sponsor information

Organisation
SilverCloud (Ireland)

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Sponsor type
Industry

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ROR
https://ror.org/05319p535

Funder(s)

Funder type
Industry

Funder Name
SilverCloud Health

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2022

Individual participant data (IPD) sharing plan
The individual participant data will be available upon request after publication.
Dr Derek Richards, derek.richards@amell.com
Anonymous participant level data and survey responses from PWPs will be made available after the completion of the study (April 2022) for secondary analysis. More information on this will be available at a later point since data sharing agreements regarding the level of data sharing are currently being finalized. Consent will be obtained from PWPs but not from clients since this data is routinely collected as part of service evaluation.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/05/2024	10/06/2024	Yes	No