

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	<input type="checkbox"/> Prospectively registered
Registration date 02/11/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 (PWP) 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 PWP's 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

Contact name

Dr Derek Richards

ORCID ID

<https://orcid.org/0000-0003-0871-4078>

Contact details

Head of Research

One Stephen Street Upper

Dublin

Ireland

D08DR9P

+35315549771

derek.richards@amwell.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

299656

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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 who 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Berkshire Healthcare NHS Foundation Trust

Fitzwilliam House

Skimped Hill Lane

Bracknell

United Kingdom

RG12 1JX

Sponsor information**Organisation**

SilverCloud (Ireland)

ROR

<https://ror.org/05319p535>

Funder(s)**Funder type**

Industry

Funder Name

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes