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E-COMPARED - internet-supported CBT for depression

Submission date	Recruitment status	[_] Prospectively registered
20/03/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/06/2025	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

About a quarter of the UK population will experience some kind of mental health problem in the course of a year, with mixed anxiety and depression as the most common mental disorder. In the UK between 8-12% of the population experience depression in any year. Half of people in need of mental care for depression do not have access to care services, do not always receive evidence-based treatments, or are confronted with long waiting lists. Internet-supported treatments have the potential to address the drawbacks of standard care and keep depression treatment of high quality and affordable. Blending face-to-face treatment with computer-based treatment components is a powerful strategy that may increase the cost-effectiveness of treatment for depression, increase access and decrease waiting times. The primary aims of this study are to assess the acceptability and feasibility of Blended Cognitive Behavioural Therapy (CBT) in IAPT services in the UK, and to compare the clinical and cost-effectiveness of Blended CBT with treatment as usual (TAU) for adults with major depressive disorder (MDD). The secondary aims are to assess the acceptability and satisfaction of the blended approach by patients and therapists, and to assess the therapeutic alliance between patients and therapists in both arms.

Who can participate?

Adult participants with a clinical diagnosis of Major Depression Disorder (MDD). The study will be conducted in community settings, and will recruit participants from Improving Access to Psychological Services (IAPT) in London.

What does the study involve?

Participants will be randomly allocated to either the blended intervention group or the treatment as usual (TAU) group. Internet-based blended depression treatment combines individual face-to-face cognitive behavioural therapy (CBT) with CBT delivered through an internet-based treatment platform with mobile phone components (online CBT). Treatment as usual consists of face-to-face sessions only. The intervention for both groups will last 11 weeks. Outcome questionnaires will be completed by both groups at the start of the study, at the end of treatment (12 weeks), and 6 months and 12 months later, either online or over the phone.

What are the possible benefits and risks of participating?
Participation in this study will help further our understanding of non-medical treatments for depression. This will help us improve the care people with depression receive. Participants may benefit from using the internet platform to learn more about depression and how to manage its symptoms at their own time and pace. This study does not pose a risk to the participating patients.

Where is the study run from?
The London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
March 2015 to December 2016

Who is funding the study?
European Union Commission, Seventh Framework Programme

Who is the main contact?
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Study website
http://www.e-compared.eu

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT02542891, NCT02389660, NCT02361684, NCT02449447, NCT02410616, NCT02796573

Secondary identifying numbers
DRKS00006866, NTR4962

Study information

Scientific Title
E-COMPARED - internet-supported CBT for depression: a randomised, pragmatic, feasibility trial

Acronym
E-COMPARED

Study objectives
The trial hypothesis is that a computer-supported intervention for depression (face-to-face CBT blended with internet-delivered CBT) will lead to similar (non-inferior) clinical improvements as treatment as usual (face-to-face CBT), but that the blended approach can be more accessible and offered at a significantly lower cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camden & Kings Cross, 17/04/2015, ref: 15/LO/0511

Study design
Pragmatic randomized controlled single-blind parallel-group non-inferiority feasibility trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Participants will be randomly allocated to the blended intervention arm or the treatment as usual (TAU) arm.

The trial intervention is a blended approach of face-to-face Cognitive Behaviour Therapy (CBT) for depression with internet-delivered CBT. The internet-based intervention will be supported by a platform called MoodBuster that comprises three elements:
1. A web-based interface providing the patients with access to CBT
2. A web-based portal for therapists, where they can view patient progress and give feedback
3. A mobile phone component which enables daily EMA monitoring of mood state, cognitions, activities, social interaction, and sleep of the patients.

The core components of the CBT treatment are:
1. Psycho-education
2. Cognitive restructuring
3. Behavioural activation
4. Relapse prevention

Blended depression treatment will be provided by IAPT therapists who will receive training on how to deliver the treatment.

Treatment as usual consists of face-to-face sessions only. The intervention for both arms will last 11 weeks.

Intervention Type
Other

Primary outcome measure
The primary outcome measure will be Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a nine-item mood module that can be used to screen and to diagnose patients with depressive disorders. Outcomes will be measured on both arms at baseline, end of treatment (12 weeks), 6 months and 12 months.

Secondary outcome measures
1. MINI - A diagnosis of depression will be assessed with the MINI International Neuropsychiatric Interview (M.I.N.I) version 5.0.
2. QIDS - The 16-item self-report version of the Quick Inventory of Depressive Symptomatology Self-Report (QIDS-16-SR) US Translation (Rush et al., 2003) is used in addition to the PHQ-9 because it is a promising questionnaire for assessing depressive symptoms.
3. Quality-adjusted life-years (QALYs) will be assessed with the EQ-5D-5L (EuroQol).
4. TiC-P - Health service uptake and loss of productivity due to illness, which allow us to estimate indirect economic costs, is measured with the Trimbos and iMTA Questionnaires on Costs

Associated with Psychiatric Illness.
5. WAI -The therapeutic alliance between therapists and patient will be assessed with the short version of the Working Alliance Inventory.
6. CEQ - Patients' expectancy of treatment will be assessed with the Credibility and Expectancy Questionnaire.
7. CSQ-8 - Patient's satisfaction with the treatment will be assessed with Client Satisfaction Questionnaire.
8. SUS - Satisfaction with the platform will be evaluated with the system usability scale.
9. HAq-II – The Helping Alliance questionnaire is a widely used questionnaire that measures the strength of the therapeutic alliance between the therapist and the patient.

Outcomes will be measured on both arms at baseline, end of treatment (12 weeks), 6 months and 12 months.

Overall study start date
23/03/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Scoring more than 5 points on PHQ-9
3. Meet DSM-IV diagnostic criteria for Major Depression Disorder as confirmed by the telephone administered MINI International Neuropsychiatric Interview version 5.0

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Current high risk for suicide according to the MINI Interview section C
2. Serious psychiatric co-morbidity that requires alternative treatment including substance dependence, bipolar affective disorder, psychotic illness or obsessive compulsive disorder as established at the MINI interview
3. Currently receiving psychological treatment for depression in primary or specialised mental health care

4. Being unable to comprehend, speak, read or write English
5. Not having access to a fast internet connection (i.e., broadband or comparable)
6. Not having or being unable to set up an email address that can be used to communicate with the therapist and research team

Date of first enrolment
06/04/2015

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
United Kingdom
WC1E 7HT

Study participating centre
Camden and Islington NHS Foundation Trust
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The trial will be published in peer-reviewed medical journals to be confirmed at a later date. Abstracts will be submitted to identified relevant conferences to inform other researchers of the work.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/08/2016		Yes	No

Results article	Qualitative working alliance results	23/09/2020	25/09/2020	Yes	No
Results article	Practitioners' experience of the working alliance	25/07/2022	26/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Secondary analysis	31/05/2024	03/06/2024	Yes	No
Other publications	Secondary analysis	21/03/2022	09/06/2025	Yes	No