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Effectiveness of the internet-based Unified Protocol mental health intervention for depression, anxiety, and related difficulties

Submission date
07/09/2021

Recruitment status
No longer recruiting

Registration date
13/09/2021

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will look at how effective a new online intervention will be for treating people with mental health such as depression (characterized by feeling low most of the time, loss of interest in pleasurable activities, and fatigue) and anxiety (characterized by excessive fear, apprehension, and worry) and related disorders. These kinds of mental health problems are the most common psychological issues people present to their GP within Ireland today, but many people have difficulties accessing the appropriate face-to-face treatments for various reasons. This online treatment programme has been based on a well-established therapy known as the 'Unified Protocol' (or 'UP' as it is known).
The face-to-face UP therapy has good evidence behind it, which means that many studies have already tested it and found it significantly effective for treating emotional disorders (for more information about the UP, please visit this website: http://www.unifiedprotocol.com/About/49/). This new intervention called 'iUP' combines traditional UP with cutting edge online technology developed by a company called SilverCloud Health (for more information about SilverCloud Health and what they do, please visit this website: https://www.silvercloudhealth.com). The reason the researchers are doing this research now is to try to improve accessibility to intervention, reduce waiting lists, and determine a cost-effective new option for treating emotional difficulties.

Who can participate?
People who are over 18 years of age who are experiencing some difficulties which may relate to anxiety and/or depression, and are not undergoing any other psychological treatment at present.

What does the study involve?
Participants are randomly allocated into one of two groups: treatment (using the online iUP intervention) or an enhanced waiting list control group (known as eWLC), which is normally a default position in the service. For those in the initial treatment group (the intervention will be an online mental health intervention and will last 12 weeks), their progress will be compared against those who remain on a waiting list. If the participant is allocated to the control group they will have access to the intervention after the waiting period.

What are the possible benefits and risks of participating?
Taking part in this study can benefit participants as the iUP intervention should be suitable for the relief of distress. This study may help us to better understand internet-based interventions and may result in new, more accessible treatment approaches. This is a long-term research project, so the benefits of the research may not be seen for several years.
As with any psychological intervention, not everyone may find the intervention helpful, and a small number of people may experience some negative effects of the intervention on their symptoms. Although previous research examining internet-based interventions has been promising, this mode of delivery of iUP does not yet have the wide evidence base as the face-to-face version of this intervention. However, it is important to note that this approach has been based on a well-established therapy and early pilot studies of this therapy show promising results, so the risk of adverse effects this treatment is quite low. Furthermore, the research procedure may be time-consuming, and the therapy or research procedure may stir some difficult emotions. There will be weekly monitoring through the assigned supporter of the participant's well-being.

Where is the study run from?
Trinity College Dublin (Ireland)

When is the study starting and for how long is it run?
September 2020 to August 2025

Who is funding the study?
Trinity College Dublin (Ireland)

Who is the main contact?
Dr Ladislav Timulak, timulakl@tcd.ie

Contact information

Type(s)
Scientific

Contact name
Dr Ladislav Timulak

ORCID ID
https://orcid.org/0000-0003-2785-0753

Contact details
School of Psychology
Trinity College Dublin
Dublin
Ireland
2
+353 (0)18961489
timulakl@tcd.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPREC052021-03

Study information

Scientific Title
Effectiveness of the internet-based Unified Protocol transdiagnostic intervention for the treatment of depression, anxiety, and related disorders in a primary care setting: a randomised controlled trial

Study objectives
The internet-based Unified Protocol (iUP) intervention will be significantly more effective than the enhanced waiting-list control group in treating depression, anxiety and related disorders among clients in public primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2021, the School of Psychology Ethics Committee, Trinity College Dublin (Faculty of Arts, Humanities and Social Sciences, The University of Dublin, Dublin 2, Ireland; +353 (0)1 896 1886; psychology@tcd.ie), ref: SPREC052021-03

Study design
Parallel-group randomized controlled 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
Depression, anxiety, and related disorders in a primary care setting

Interventions
The current study will employ a parallel-groups, randomised controlled trial design. Participants will be randomly assigned to a) the internet-based Unified Protocol (iUP), or b) enhanced waiting list control (eWLC). Randomization will follow a 2:1 allocation ratio, with sample size calculations suggesting a required sample of 120 (iUP=80; eWLC=40). Assessments will take place at baseline, 4 weeks, 8 weeks and 12 weeks from baseline. For ethical reasons the eWLC group participants will be offered iUP treatment after 12 weeks. iUP group participants will be followed up at 16 weeks, 20 weeks and 24 weeks from baseline.

Intervention Type
Behavioural

Primary outcome measure
1. Anxiety measured using the Overall Anxiety Severity And Impairment Scale (OASIS) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group
2. Depression measured using the Overall Depression Severity and Impairment Scale ODSIS (ODSIS) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group

Secondary outcome measures
1. Social Adjustment measured using the Work and Social Adjustment Scale (WSAS) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group
2. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group and also used as a specific measure for clients with a primary diagnosis of generalized anxiety
3. Depression measured using the Patient Health Questionnaire-9 (PHQ-9) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group and also used as a specific measure for clients with a primary diagnosis of depression
4. One of the following measures (depending on the primary diagnosis):
4.1. Only for clients with primary diagnosis of panic disorder, panic disorder symptoms measured using the Panic Disorder Severity Scale-Self Report (PDSS-SR) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group
4.2. Only for clients with primary diagnosis of social anxiety, social Anxiety symptoms measured using the Social Phobia Inventory (SPIN) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group
4.3. Only for clients with primary diagnosis of OCD, OCD symptoms measured using the Obsessive-compulsive Inventory-Revised (OCI-R) at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group
4.4. Only for clients with primary diagnosis of PTSD, PTSD symptoms measured using the PCL-5 at 0, 4, 8, 12, 16, 20, 24 weeks for the iUP group and 0, 4, 8, 12 for the eWL group
5. Client experiences of helpful/unhelpful aspects of the iUP intervention and experiences of changes attributable to the intervention measured using a questionnaire version of the Client Change Interview Protocol (CCIP) at week 12 only the iUP group

Overall study start date
01/09/2020

Completion date
01/08/2025

Eligibility

Key inclusion criteria
1. Minimum age 18 years old
2. Fluent in English
3. Have access to the Internet and an email account
4. Have symptoms of anxiety and/or depression referenced as primary presenting problem(s) on the referral form from the General Practitioner (GP)
5. A score of ≥8 on OASIS (Norma et al., 2006; Campbell-Sills et al., 2009) and/or a score of ≥8 on ODSIS (Bentley et al., 2014)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Randomization will follow a 2:1 allocation ratio, with sample size calculations suggesting a required sample of 120 (iUP=80; eWLC=40).

Key exclusion criteria
1. An increased risk of suicidality intent or ideation (at least moderate scores on the M.I.N.I. [see below about MINI] and/or a score > 2 on item 9 from the PHQ-9 [see below about PHQ-9]),
2. Psychotic disorder, manic or hypomanic episode, bipolar disorder, eating disorder, anti-social personality disorder and/or alcohol/substance use disorder as indicated by the M.I.N.I.
3. References to cognitive impairment on the referral form
4. Receipt of another psychological treatment at the start of the study

Pharmacological treatment during the treatment period will be allowed provided that it was stabilized 6 weeks prior to the start of being involved in the study.

Date of first enrolment
08/10/2021

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Ireland

Study participating centre
Health Service Executive
Grangegorman Primary Care Centre
Upper Grangegorman Road
Grangegorman
Dublin
Ireland
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Sponsor information

Organisation
Trinity College Dublin

Sponsor details
Trinity Research & Innovation
O'Reilly Institute
Dublin
Ireland
2
+353 18962153
innovation.centre@tcd.ie

Sponsor type
University/education

Website
https://www.tcd.ie/

ROR
https://ror.org/02tyrky19

Organisation
SilverCloud (Ireland)

Sponsor details
1 Stephen St Upper
Dublin
Ireland
8
+353 (0)15549771
derek.richards@silvercloudhealth.com

Sponsor type
Industry

Website
http://www.silvercloudhealth.com

ROR
https://ror.org/05319p535

Funder(s)

Funder type
University/education

Funder Name
Trinity College Dublin

Alternative Name(s)
Coláiste na Tríonóide, Baile Átha Cliath, TCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Funder Name
SilverCloud

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Secondary data analyses subsequently.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan

Once results have been published in peer-reviewed academic journals, fully anonymised data and materials will be made available on request to other researchers in keeping with Trinity College Dublin research policy. It is covered by the Information sheet and consent. Please contact Dr Ladislav Timulak (timulakl@tcd.ie).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/08/2022	01/09/2022	Yes	No