

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

<b>Submission date</b> 07/09/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/05/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:timulakl@tcd.ie)

## Contact information

**Type(s)**

Scientific

**Contact name**

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## 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  $\geq 8$  on OASIS (Norma et al., 2006; Campbell-Sills et al., 2009) and/or a score of  $\geq 8$  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?
<a href="#">Protocol article</a>		31/08/2022	01/09/2022	Yes	No