

# Assessing the efficacy of emotion-focused therapy in the treatment of depression, anxiety and related disorders

<b>Submission date</b> 02/01/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/06/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Over the last few decades, a widespread practice in psychotherapy and counselling research has been to develop specific psychotherapeutic treatments for specific psychological problems. So for example different versions of Cognitive Behaviour Therapy (CBT) have been developed for depression and for social anxiety. However, research has shown that individuals with mental health difficulties often struggle with more than one psychological problem at the same time (e.g., a patient might suffer from both depression and social anxiety). Research also indicates that while these different problems may look different, they often share common causes and can be maintained by common processes. For these reasons, a recent development in psychotherapy research has been to develop what are called 'transdiagnostic' interventions, whereby the same intervention can be used to treat patients presenting with a range of different problems and/or patients struggling with more than one problem. To date most transdiagnostic interventions are adaptations of CBT. However not all patients benefit from or prefer CBT, and so there is an argument that patient well-being can be improved by increasing the range or choice of evidence-based interventions available. Emotion-focused Therapy (EFT) is an evidence-based intervention that has been shown to be effective for a range of psychological problems. The current study seeks to adapt EFT as a transdiagnostic treatment for depression, anxiety and a number of related disorders. It also seeks to test the effectiveness of the adapted model by comparing the outcomes (that is, the extent to which participants experience a change in their symptoms) for 20 patients treated with EFT in a community-based counselling service with the outcomes for 20 patients placed on a waiting list. Waiting list patients will get therapy at a later point. Video-recordings of therapy and interviews with participants will be studied in order to further develop the model.

### Who can participate?

Individuals who are 18 years or older. Individuals who meet criteria for one or more of the following conditions; depression (major depressive disorder or persistent depressive disorder), anxiety (social anxiety, generalised anxiety, specific phobia, agoraphobia, panic disorder), obsessive-compulsive disorder (i.e., OCD) or a trauma related disorder (including Post Traumatic Stress Disorder).

What does the study involve?

Participants will be allocated randomly to one of two conditions: either (1) active condition – approx. 16 sessions of emotion-focused therapy, or (2) waitlist/delayed intervention. Participants allocated to the waitlist condition will be given an appointment to begin therapy in 16 weeks.

What are the possible benefits and risks of participating?

Participants will be offered psychotherapy already established as a treatment of depression and potentially anxiety by certified EFT therapists and/or psychologists who are closely supervised by an expert in EFT. Therapy will be provided free of charge.

As with any psychological therapy, not everyone may find therapy helpful, and a small number of people may get worse while in therapy. The research procedure may be time consuming, and the therapy or research procedure may stir difficult emotions. You will also be randomly allocated to either therapy or waitlist/delayed intervention and if allocated to the waitlist condition will have to wait 16 weeks before therapy begins. We will attend to these risks by endeavouring to be respectful and supportive at all times through the process.

Where is the study run from?

The premises of the Institute of Emotion-Focused Therapy Ireland.

When is the study starting and how long it is expected to run for?

September 2018 to June 2025

Who is funding the study?

This study is being conducted by researchers at the School of Psychology in Trinity College Dublin in conjunction with the Institute of Emotion-Focused Therapy Ireland.

Who is the main contact?

Dr. Ladislav Timulak [timulakl@tcd.ie](mailto:timulakl@tcd.ie)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ladislav Timulak

### ORCID ID

<http://orcid.org/0000-0003-2785-0753>

### Contact details

School of Psychology  
Trinity College Dublin  
Dublin  
United Kingdom

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

SPREC102018-18

## **Study information**

### **Scientific Title**

Emotion-Focused Therapy as a Transdiagnostic treatment for depression and anxiety and related disorders: An initial randomised control trial.

### **Acronym**

EFT-T

### **Study objectives**

EFT-T will be more effective than wait-list control.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Trinity College Dublin's School of Psychology Research Ethics Committee, 14/12/2018, ref. SPREC102018-18.

### **Study design**

Interventional, randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

See additional files

### **Health condition(s) or problem(s) studied**

Depression and anxiety and related disorders (such as obsessive-compulsive disorders and trauma/stressor related disorders).

## Interventions

Current intervention as of 11/07/2022:

Emotion-Focused Therapy – Transdiagnostic (EFT-T)

The EFT-T intervention will follow a recently developed model (Timulak, 2015; Timulak & Keogh, 2018) integrating EFT adaptations for various disorders (e.g., Elliott & Shahar, 2017; Greenberg & Watson, 2006; Paivio & Pascual-Leone, 2010; Timulak & McElvaney, 2017; Watson & Greenberg, 2017) using a unique transdiagnostic framework. The transdiagnostic model, conceptually based on a model of emotional transformation processes in psychotherapy (see Timulak, 2015 and Timulak & McElvaney, 2017), uses (1) elements of a modular approach targeting symptom level presentations (i.e., with some interventions used in the context of certain primary diagnoses /presentations) and (2) an underlying emotional vulnerability approach that targets the chronic painful (feared) emotions of sadness/loneliness, shame, and fear/terror present in depression, anxiety and related disorders. The EFT-T model uses a specific case conceptualisation which postulates that symptoms of depression and anxiety signal difficulty (e.g., dysregulation /avoidance) in processing specific chronic painful feelings (e.g., sadness/loneliness, shame, and primary fear/terror) triggered in the client's interaction with the environment.

Therapy will last 16 to 20 sessions. Therapists will be instructed to finish therapy at session 16, but will have flexibility based on their clinical judgement to extend therapy to a maximum of 20 sessions.

The design of the study is a randomised controlled trial (RCT) with two groups (EFT and wait-list with an ensuing delayed intervention-EFT). Clients (n=40) will be randomized to two groups. Participants will be recruited via GP referral and the trial will be promoted by an advertisement on the hosting clinic's website. Participants will then be seen in a private clinic offering psychological therapy to people with depression, anxiety and related disorders.

Waitlist group will undergo the same therapy 16 weeks after they are put on the waitlist.

Where continuing Covid-19-related restrictions mean that pre-therapy and post-therapy assessments cannot be conducted in person (or if the restrictions are eased but the participant /researcher prefers not to meet in person), these assessments are conducted via phone, and/or via secure Zoom. Where continuing Covid-19-related restrictions mean that therapy cannot be conducted in person (or if the restrictions are eased but the client/therapist prefers not to meet in person), therapy is provided through secure Zoom.

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Previous intervention:

Emotion-Focused Therapy – Transdiagnostic (EFT-T)

The EFT-T intervention will follow a recently developed model (Timulak, 2015; Timulak & Keogh, 2018) integrating EFT adaptations for various disorders (e.g., Elliott & Shahar, 2017; Greenberg & Watson, 2006; Paivio & Pascual-Leone, 2010; Timulak & McElvaney, 2017; Watson & Greenberg, 2017) using a unique transdiagnostic framework. The transdiagnostic model, conceptually based on a model of emotional transformation processes in psychotherapy (see Timulak, 2015 and Timulak & McElvaney, 2017), uses (1) elements of a modular approach targeting symptom level presentations (i.e., with some interventions used in the context of certain primary diagnoses /presentations) and (2) an underlying emotional vulnerability approach that targets the chronic painful (feared) emotions of sadness/loneliness, shame, and fear/terror present in depression, anxiety and related disorders. The EFT-T model uses a specific case conceptualisation which

postulates that symptoms of depression and anxiety signal difficulty (e.g., dysregulation /avoidance) in processing specific chronic painful feelings (e.g., sadness/loneliness, shame, and primary fear/terror) triggered in the client's interaction with the environment.

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## **Intervention Type**

Behavioural

## **Primary outcome measure**

To be measured at pre-therapy, post therapy (16 weeks; but also post last session in cases where the last session falls outside the range of  $16 \pm 2$  weeks) and at 6-month follow up:

1. Anxiety severity will be measured using the Anxiety Severity and Impairment Scale (OASIS; Norman, Cissell, Means-Christensen, Stein, 2006).
2. Depression severity will be measured using the Overall Depression Severity and Impairment Scale (ODSIS; Bentley, Gallagher, Carl, & Barlow, 2014).
3. Psychological distress will be measured using the CORE-OM will also be used by all participants pre-, post, and at 6-month follow-up.

## **Secondary outcome measures**

1. Each participant will also be asked to complete at pre-therapy, post therapy (16 weeks; but also post last session in cases where the last session falls outside the range of  $16 \pm 2$  weeks) and at 6-month follow up, at least one of the following disorder specific measures, as determined by the principal diagnosis assessed at pre-therapy.
  - 1.1. The Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001).
  - 1.2. The Generalised Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006).
  - 1.3. Liebowitz Social Anxiety Scale (LSAS; Liebowitz, 1987).
  - 1.4. The Panic Disorder Severity Scale (PDSS; Shear et al., 1997).
  - 1.5. The Yale-Brown Obsessive Compulsive Scale – Self-Report version (YBOCS-SR; Baer et al., 1993).
  - 1.6. The Post-traumatic Stress Disorder Checklist – Civilian Version (PCL-C; Blanchard, Jones-Alexander, Buckley, & Forneris, 1996).
2. The following measures will be administered during the pre-therapy assessment, with those measures on which a client scores  $\geq 8$  thereafter administered prior to each session, post-therapy and at follow-up:
  - 2.1. The Overall Shame Severity and Impairment Scale (OSSIS).
  - 2.2. The Overall Loneliness Severity and Impairment Scale (OLSIS).
  - 2.3. The Overall Fear Severity and Impairment Scale (OFSIS).
3. The changes a participant has noticed since treatment began will be measured post-treatment using the Client Change Interview (CCI; Elliott et al., 2001).

**Overall study start date**

01/09/2018

**Completion date**

30/06/2025

## Eligibility

**Key inclusion criteria**

1. Meet the criteria for depression, an anxiety disorder and/or related disorder (obsessive-compulsive disorders and trauma/stressor related disorders) as a principal diagnosis.
2. If taking psychotropic medication then must be stabilised on that medication for 6 weeks prior to commencing therapy.
- 2.1. Shows, with their physician's approval, a willingness to maintain this stability in medication use during the period of therapy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Concurrent psychological treatment
2. Suicide risk
3. Risk of harm to others
4. Substance abuse
5. Psychosis
6. Organic brain syndrome

**Date of first enrolment**

01/02/2019

**Date of final enrolment**

31/12/2023

## Locations

**Countries of recruitment**

Ireland

United Kingdom

**Study participating centre**  
**Institute of Emotion-Focused Therapy, Ireland**  
22 South Frederick Street  
Dublin  
United Kingdom  
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## **Sponsor information**

**Organisation**  
Trinity College Dublin

**Sponsor details**  
School of Psychology  
College Green  
Dublin  
United Kingdom  
2

**Sponsor type**  
University/education

**Website**  
<https://psychology.tcd.ie/contact/>

**ROR**  
<https://ror.org/02tyrky19>

**Organisation**  
Institute of Emotion-Focused Therapy, Ireland

**Sponsor details**  
22 South Frederick Street  
Dublin  
United Kingdom  
2

**Sponsor type**  
Other

**Website**  
<http://www.ieft.ie>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

The following peer reviewed publications will be realised from the research.

1. Publication of the trial protocol.
2. Publication of the main outcomes results.
3. One or two publications of qualitative outcomes and clients' perspectives.
4. One or two publications based on process outcome research

It is envisaged that publications will be published in an open access format for which we seek funding.

Members of the team will also attend:

1. One national mental health conference per year where they will inform peers in the national mental health research community about the study, the protocol and preliminary/final findings.
2. At least one relevant international conference on mental health per year where they will inform peers in the international psychotherapeutic research community about the study, the protocol and preliminary/final findings.

It is envisaged that the school of psychology website will provide information about the trial and will provide links to the relevant publications from the trial. Additionally, should the results from the present study prove promising, we will explore options for multi-site trials and collaborations with international collaborators from the EFT and transdiagnostic research communities. Locally this would involve training clinicians in the relevant statutory service (e.g., CIPC) where a trial could be located. Once further testing/validated of the intervention has taken place, it is anticipated that wider training in the intervention could be rolled out to CIPC and/or relevant HSE clinicians.

## Intention to publish date

30/10/2025

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs



Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		03/01/2019	07/01/2019	No	Yes
<a href="#">Protocol article</a>		13/02/2020	11/07/2022	Yes	No