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

Submission date
02/01/2019

Recruitment status
No longer recruiting

Registration date
07/01/2019

Overall study status
Completed

Last Edited
14/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 couselling 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

Contact information

Type(s)
Scientific

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Protocol serial number
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

Study type(s)
Treatment

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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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.

Intervention Type
Behavioural

Primary outcome(s)
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 ± 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.

Key secondary outcome(s))
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 ± 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 ≥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).

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Ireland

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

ROR
https://ror.org/02tyrky19

Organisation
Institute of Emotion-Focused Therapy, Ireland

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Protocol article		13/02/2020	11/07/2022	Yes	No
Participant information sheet		03/01/2019	07/01/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes