Participant Information Leaflet

Study Title: Emotion-focused therapy as a transdiagnostic treatment for depression, anxiety and related disorders: A proof of concept study.

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You have expressed an interest in taking part in a research study to be carried out at the Institute of Emotion-Focused Therapy Ireland in collaboration with a research team based in the School of Psychology in Trinity College Dublin. Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family or friends. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'. You will also be asked to discuss the study with your GP as participation requires a referral to the study from your GP. If you decide to proceed, you will be provided with further opportunities to discuss the study with members of the research team before therapy actually commences and at any of these points, you can also change your mind about continuing.

Why is this study being done?

Research indicates that while different psychological problems (e.g., depression or anxiety) 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 (or therapy) can be used to treat individuals presenting with a range of different problems and/or individuals struggling with more than one problem. To date most transdiagnostic interventions are adaptations of cognitive behavioural therapy (CBT). However not all individuals benefit from or prefer CBT, and so there is an argument that client well-being can be improved by increasing the range or choice of evidence-based transdiagnostic interventions available. EFT has been shown to be effective for a range of psychological problems, including depression, anxiety, and trauma. It is also well established as a Couples therapy. The current study seeks to adapt EFT as a transdiagnostic treatment for depression, anxiety and a number of related disorders including Obsessive Compulsive Disorder (OCD) and Post Traumatic Stress Disorder (PTSD) and to test the effectiveness of this model. The current study is a treatment development study and we are still exploring how the therapy may best be adapted for different issues. Data collected in the present study will be used for outcome research (i.e., comparing scores on questionnaires before and after therapy to see what extent therapy is helpful for participants); process research (e.g., analysing video recordings to see what is happening in therapy); process-outcome research (e.g., analysing the relationship between what is happening in therapy and outcomes); qualitative research (e.g., analysing videos of session and audio-recording of interviews to understand what is helpful or not helpful for participants); and case study research (e.g., looking at how individual participants progress across the course of therapy). It is likely that the current study will be followed by further studies comparing the developed model against established treatments.

Who is organising this 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. The current project builds on a decade of research at Trinity College Dublin researching the efficacy of Emotion-Focused Therapy as an evidence-based psychotherapeutic intervention. As the current study progresses the research team will seek research funding to further advance the study.

Who is eligible to 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).
- Individuals may or may not be on psychotropic medication; however individuals who are on psychotropic medication must be stable on that medication for 6 weeks prior to participation in the study and must be willing with GP consent to remain on the same medication and same dose of medication until therapy finishes (a period of approximately 4-8 months depending upon whether one is in the active or waitlist condition).

Psychotropic medication refers to medication taken for psychological problems such as anxiety or depression. There is no requirement regarding medications that an individual might take for any other health related purpose.

Participation in the study requires referral by your GP who should be able to suggest whether you may meet the above criteria.

Are there any exclusion criteria?

The proposed model of therapy is not intended as a treatment for bipolar disorders, psychosis, substance misuse, or organic brain syndrome. Participants must not be in another psychological therapy, must not be at risk of suicide, and must not be at risk of causing harm to others.

What do I need to do if I am interested in participating?

1. Email the provided email address (you probably have already done this)
2. Read the Participant Information Sheet (the sheet you are currently reading)
3. Attend GP, give GP the GP information sheet, and discuss participation in the study with GP
4. Once in receipt of a referral from GP, email the research team
5. Attend an initial 30-minute meeting with a member of the research team to establish potential eligibility for the study.
6. If potentially eligible for the study attend a 3-hour assessment with a member of the research team

What will involvement in the study involve?

1. Once your GP has referred you to the study, you can inform us by email and we will give you a call to schedule an initial meeting.
2. You will be asked to attend a 30 minute meeting with a member of the research team. During this meeting we will ask you to complete a number of self-report questionnaires to check your potential eligibility for the study. It is also an opportunity to ask any questions you might have about the study.
3. Assuming that you are potentially eligible to proceed, you will then be asked to attend for a longer assessment one week later again with a member of the research team. This interview-style assessment will take between 2 and 3 hours. The purpose of this interview is to establish the nature of the difficulties you are experiencing (e.g., depression or social anxiety), to ensure that you are right for the study (i.e., that you meet eligibility criteria), and to ensure that the study is right for you (i.e., that the therapy is an appropriate intervention for you given the nature of the difficulties you are experiencing). This interview will be audio-recorded and may later be checked to ensure that it was conducted in a reliable way. If it is agreed that you are proceeding to the study, you will also be asked to complete some additional questionnaires.
4. You will then be allocated randomly to one of two conditions: either (1) active condition, or (2) waitlist/delayed intervention. If you are allocated to the active condition, you will begin therapy as soon as possible (e.g., the following week). If you are allocated to the waitlist condition, you will be given an appointment to begin therapy in 16 weeks. Whichever condition you are allocated to, you will receive the same number of therapy sessions. The only difference is whether therapy begins immediately or after 16 weeks.
5. The research team will write to your GP to say that you are participating in the study and will inform your GP whether you are in the active or waitlist/delayed intervention condition.
6. Therapy will consist of 16-20 sessions of Emotion-Focused Therapy (EFT), each lasting approximately 50 minutes. All therapists will be psychologists or psychotherapists certified in EFT.
7. Therapy session are video-recorded/audio-recorded for analysis by the research team. Recordings of sessions will be transferred to a secure, encrypted hard-drive directly after the session and will be viewed only by members of the research team all of whom will be psychologists or psychologists in training. No identifying information (e.g., names or contact details) will be stored with recordings. If you do not wish for a particular session to be recorded, or if you would like a session that has been recorded to be deleted, you can let your therapist know so that your wish can be accommodated.
8. At the end of therapy, you will be asked to complete some questionnaires. This is to see whether things have changed for you as a result of attending therapy. You will also be interviewed about your experience of therapy (e.g., you will be asked whether therapy was helpful or not, as well as what aspects of therapy were helpful or unhelpful). This meeting will take approximately 30 minutes. This interview will be recorded for use in research.
9. After 6 months you will be contacted by a member of the research team and asked to meet to fill out the same questionnaires. This is to see whether any benefits from therapy have continued to last in the long term.
10. If you drop out of the therapy we will still try to meet you after 16 week and after 6-months as we will try to contact everyone who began therapy whether they finish therapy or not.
11. At all times the information you provide us, and the data we have about you, will remain confidential (limits to confidentiality are detailed below). All data will be anonymised. You will never be personally identified in any publication arising from the study.

What are the risks?

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.

What are the benefits?

You 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.

Is the study confidential?

All information will be kept strictly confidential and will be available only to members of the research team. The research team will consist of the main researchers named in this Information Sheet, as well as post-doctoral researchers, masters and doctoral level psychologists in training and research assistants.

You will be assigned a code and all questionnaires completed by you will be identifiable only by this code. Your individual anonymised results from questionnaires will be pooled with others for analysis. The main publications resulting from this study will present results from pooled data only (in other words no individual data). In any subsequent publication where individual data might be reported (e.g., case studies), in keeping with ethical guidelines, all possible efforts will be made to conceal participants' identities by disguising details of cases or by combining details from multiple cases.

All data will be stored in a locked filing cabinet in a secure office in iEFT and/or the School of Psychology, TCD. Paper copies of all measures will be identifiable only by the study and/or trial codes. All identifying paper data (e.g., GP referral information, signed consent forms; and contact information) will be stored in a separate locked filing cabinet to all other anonymised data, and will be accessible only to the Principal Investigator (or a designated member of the research team); contact information (only) for participants will be available to additional members of the research team involved in pre-therapy and post-therapy assessments. All audio/video and electronic data will be stored on encrypted hard-drives in locked filing cabinets.

Please note: while psychological work is confidential, limits to confidentiality are set by the Psychological Society of Ireland's Code of Professional Ethics (namely risk to self and/or risk to others), child protection (mandatory reporting of child abuse) and by the law. Particular examples of the limits of confidentiality are where there is a risk to a client's health or life; where a client may be of risk to others; where, in the context of child sexual abuse, the abuser is identifiable and a potential risk to children exists; or where data is requested by court.

How long will data from the study be retained?

In accordance with the General Data Protection Regulation (GDPR), completed measures and other paper documentation will not be kept for longer than is necessary for the purpose for which they were collected. As stated above, data collected in this study will be used for outcome research (i.e., comparing scores on questionnaires before and after therapy to see what extent therapy is helpful for participants); process research (e.g., analysing video recordings to see what is happening in therapy); process-outcome research (e.g., analysing the relationship between what is happening in therapy and outcomes); qualitative research (e.g., analysing videos of session and audio-recording of interviews to understand what is helpful or not helpful for participants); and case study research (e.g., looking at how individual participants progress across the course of therapy).

All paper documentation (with the exception of signed consent forms) and audio recordings of assessments and interviews will be retained for a period of twelve months after the publication of the relevant reports resulting from the study. This data will then be destroyed in accordance with standard Trinity College Dublin procedures. It is anticipated that video/audio recordings of sessions will be used for research studies for a number of years after the main study finishes but that after relevant reports are published, this data will also be destroyed. In some cases, the research team may seek consent to use some recordings for training purposes but this consent will be sought in particular cases only and will be a separate consent process, which participants can agree or not agree to. Under the Freedom of Information Act (2014), you are entitled to access any information we store about you. However, as a research participant in this project you can access any information we have about you simply by writing to the address below.

Can I withdraw from the study at any time?

Yes. You can withdraw from the study at any time. You can also request that your data be removed from the study. This will be possible up until the point in time when your (anonymised) data is pooled with data from other participants and analysed for reports or publications. The timing of this will vary from participant to participant, depending upon when you take part in the study, but will be approximately 6 months after you finish therapy. After this you can request that your data be removed from any further studies where analysis has not yet been completed. A member of the research team will discuss this with you.

Where can I get further information?

If you need any further information now or at any time in the future, please contact:

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