Information Leaflet for GP

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

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Your patient has 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 they decide whether or not they wish to take part, they have been encouraged to read the information provided below carefully and, if they wish, to discuss it with family or friends. We encourage all participants in the study to clearly understand the risks and benefits of taking part in this study so that they can make a decision that is right for them. This process is known as 'Informed Consent'. Potential participants are also asked to discuss the study with their GP as participation requires a referral to the study from their GP. If your patient decides to proceed, they 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, they can also change their mind about continuing. A checklist summarising some key points is on page 6 of this Information leaflet.

Why is this study being done?

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) or different versions of Emotion-Focused Therapy (EFT) have been developed for depression and for generalised anxiety. However, research has shown that individuals with mental health difficulties often struggle with more than one psychological problem at the same time. For example, an individual might experience both depression and anxiety. Research also indicates that while these 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 (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 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 is an evidence-based psychotherapy that 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 and is being studied in a number of other contexts including the treatment of eating disorders. 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 and funding 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 lead researcher is director of the Doctorate in Counselling Psychology in Trinity College Dublin, and is an internationally established psychotherapy researcher. 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 related disorders) or a trauma related disorder (including PTSD).
- 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 months for those in the active condition, and 8 months for those in the waitlist condition).

Medication

Please note that this last criteria regarding medication applies to psychotropic medication only. There is no requirement regarding medications that an individual might take for any other health related purpose. Please also note that we ask only that participants are willing with GP consent to remain on the same medication. If for any reason a participant subsequently needs to change their medication, they of course can do so, and they will continue to receive therapy as commenced. The only consequence is that we may need to remove related data from the study.

Are there any exclusion criteria?

The proposed model of therapy is not intended as a treatment for bipolar depression, psychosis, substance misuse, or organic brain syndrome, therefore individuals whose presentation meets any of these diagnostic criteria are not eligible to participate in the study. 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 does my patient need to do if they are interested in participating?

1. Your patient will most likely already have emailed the address provided in promotional materials advertising the trial address. If not, they should be encouraged to do so.
2. Your patient should then read the Participant Information Sheet which will have been forwarded to them.

3. Your patient should discuss with you, their GP, the possibility of their participation in the study. They should discuss with you whether it is appropriate for them to remain on their current (psychotropic) medication regime, or whether they can stabilise on a particular regime and once stabilised on this regime for 6 weeks, then be assessed for the study. They should also discuss with you the fact that participants on the study are randomly allocated to either an active condition (beginning therapy the following week) or a waitlist/delayed intervention condition (beginning therapy 16 weeks after assessment).
4. Once in receipt of a referral from their GP, participants are then asked to email the research team once again.
5. They will then be asked to attend an initial screening meeting with a member of the research team (which will take 20-30 minutes)
6. They will then be asked to attend a diagnostic assessment with a member of the research team (which will take 2-3 hours).

What will involvement in the study involve?

1. Once referred by you (their GP) to the study, your patient can inform us by email and we will give them a call to schedule an initial meeting.
2. They will be asked to attend a 20-30 minute meeting with a member of the research team. During this meeting we will ask them to complete a number of self-report screening questionnaires to check their potential eligibility for the study. It is also an opportunity to ask any questions they might have about the study.
3. Assuming that they are potentially eligible to proceed, your patient will then be asked to attend for a longer diagnostic assessment one week later again with a member of the research team. This interview-style assessment (using the Structured Clinical Interview for DSM-5 Disorders) will take between 2 and 3 hours. The purpose of this interview is to establish the nature of the difficulties they are experiencing (e.g., depression or social anxiety), to definitively ensure that they are right for the study (i.e., that they meet eligibility criteria), and to ensure that the study is right for them (i.e., that the therapy is an appropriate intervention for them given the nature of the difficulties they 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 they are proceeding to the study, they will also be asked to complete some additional questionnaires.
4. Your patient will then be allocated randomly to one of two conditions: either (1) active condition, or (2) waitlist/delayed intervention. If allocated to the active condition, they will begin therapy the following week. If allocated to the waitlist condition, they will be given an appointment to begin therapy in 16 weeks. Whichever condition they are allocated to, they 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 you, the participant's GP, to confirm that they are participating in the study and to inform you whether they 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/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 the recordings. If your patient does not wish for a particular session to be recorded, or if they would like a session that has been recorded to be deleted, they can let their therapist know so that their wish can be accommodated.

8. At the end of therapy, your patient will be asked to complete some questionnaires. This is to see whether things have changed for them as a result of attending therapy. They will also be interviewed about their experience of therapy (e.g., they 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 your patient 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 your patient drops out of therapy we will still try to meet them after 16 week and after 6-months as we will try to contact everyone who began therapy.
11. At all times the information provided to us, and the data we have about your patient, will remain confidential. All data will be anonymised. Your patient 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. Your patient 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?

Your patient will be offered psychotherapy 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.

Your patient will be assigned a code and all questionnaires completed by your patient will be identifiable only by this code. 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(s) 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), participants are entitled to access any information we store about them. However, as a research participant in this project your patient can access any information we have about them simply by writing to the address below.

Can my patient withdraw from the study at any time?

Yes. Your patient can withdraw from the study at any time. They can also request that their data be removed from the study. This will be possible up until the point in time when their (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 they take part in the study, but will be approximately 6 months after they finish therapy. After this your patient can request that their data be removed from any further studies where analysis has not yet been completed. A member of the research team will discuss this with your patient.

Where can I get further information?

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

Name: Dr. Daragh Keogh
Address: School of Psychology, Áras an Phiarsaigh, Trinity College, Dublin 2
Email: keoghd9@tcd.ie
Phone No: (01) 8963911

Please see the next page for a checklist of important issues you may wish to consider

Emotion-focused therapy as a transdiagnostic treatment for depression, anxiety and related disorders: A proof of concept study.	
GP checklist	**Y/N**
Has my patient emailed the research team and received a copy of the Participant and GP information sheets?	
Have I had time to read the GP information Sheet?	
Do I suspect (this will be assessed by the research team) that my patient meets diagnostic criteria for one of the following disorders: 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 related disorders) or a trauma related disorder (including PTSD)?	
Does my patient <u>not</u> meet exclusion criteria regarding excluded disorders: bipolar disorders, psychosis, substance misuse, or organic brain syndrome?	
Based on patient self-report, am I satisfied that my patient is not at risk of suicide or at risk of causing harm to others?	
Have I discussed <u>psychotropic</u> medication with my patient and am I satisfied that they either (a) remain on their current medication regime for the duration of therapy (16 weeks, or 32 weeks if in waitlist condition) or, (b) stabilise on an agreed regime and then proceed to the study in 6 weeks' time?	
Have I discussed with my patient the fact that they will be randomly allocated to either active condition or waitlist/delayed intervention, and in the case of being allocated to the delayed intervention, will not begin therapy for 16 weeks?	
Am I satisfied to write a referral letter for my patient to the study?	
Am I willing to be contacted by the research team (1) to be notified that my patient is proceeding/not proceeding to the study; (2) to be notified that my patient has completed/discontinued therapy; and/or (3) in instances where the research team has concerns for my patient's well-being?	