

A comparison of emotion-focused therapy and cognitive-behavioural therapy in the treatment of generalised anxiety disorder

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| Submission date 24/10/2017 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 01/11/2017 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 04/02/2022 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Generalised Anxiety Disorder (GAD) is a disorder in which the sufferer feels in a constant state of high anxiety. The aim of this study is to compare the effectiveness of two different therapies for Generalised Anxiety Disorder (GAD). Cognitive Behavioural Therapy (or CBT) is an established approach, while Emotion-Focused Therapy (or EFT) is a new approach for GAD, recently developed. It is believed that both therapies will be helpful. However, by studying how the two therapies compare, this study aims to improve the options available.

Who can participate?

Patients aged 18 and older with GAD

What does the study involve?

Participants are randomly allocated to either the EFT or CBT therapy. Therapy lasts between 16 and 20 weeks. Participants are also asked to meet with the research team at the end of therapy and 6 months after therapy ends in order to complete assessment forms. In addition, sessions are recorded in order that a random selection of sessions can be reviewed to ensure that the therapist is delivering the therapy as expected.

What are the possible benefits and risks of participating?

There are a number of possible risks and benefits for participants. As with any psychological therapy, there is no guarantee that therapy will be helpful for everyone, and research has shown that a small number of people get worse while in therapy. Although early results for EFT are promising, it is still a new treatment for anxiety, and while CBT has been shown to be effective, it is not always so. While every care will be taken to ensure confidentiality will be respected and that data will be stored securely, there is a degree of risk involved in the transfer and storage of confidential data. In addition, though not a risk per se, attending the additional assessment meetings with the research team is an extra time commitment and participants may have some anxiety about the fact that sessions are being recorded. Regarding benefits, participants will be

offered therapy that will be closely supervised by experts in that particular therapy, and for a duration that is more than twice as long as is normally provided by CIPC. It is hoped therefore that participation in either intervention will be more beneficial than routine care provided.

Where is the study run from?

The study is being conducted by researchers from the School of Psychology in Trinity College Dublin in conjunction with the HSE's Counselling in Primary Care service

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

December 2016 to December 2019

Who is funding the study?

Health Research Board (Ireland)

Who is the main contact?

Dr Ladislav Timulak

Contact information

Type(s)

Scientific

Contact name

Dr Ladislav Timulak

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Contact details

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2

Additional identifiers

Protocol serial number

HRA-POR-2015-1052

Study information

Scientific Title

A comparison of emotion-focused therapy and cognitive-behavioural therapy in the treatment of generalised anxiety disorder: a randomised controlled trial

Study objectives

The overall aim of the project is to contribute to the planning of a definitive, non-inferiority trial that would establish the relative efficacy of Emotion-Focused Therapy (EFT) in comparison to Cognitive Behavioural Therapy (CBT) as a treatment for Generalised Anxiety Disorder (GAD). The

current project will provide first comparison data that, if suggesting comparable or better outcomes for the experimental intervention, should help to plan a definitive non-inferiority trial. It will test recruitment, adherence, and acceptability/retention rates, as well as providing estimates of comparative outcomes, that can be used to inform power calculations for a definitive, non-inferiority trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Health Service Executive North East Area Research Ethics Committee (REC), 12/07/2017
2. The School of Psychology Research Ethics Committee, Trinity College Dublin, Dublin, Ireland, 19/10/2017

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Generalised anxiety disorder (and some potential co-morbid symptoms/conditions)

Interventions

Participants will be randomly allocated to one of two active parallel interventions: an experimental intervention (Emotion-Focused Therapy for GAD; EFT for GAD), and a well-established benchmark comparison (Cognitive Behavioural Therapy; CBT for GAD). Participants will be randomly assigned to either EFT or CBT intervention with a 1:1 allocation, nested within therapists, as per a computer generated randomisation schedule (online randomiser: <https://www.random.org/lists/>).

1. The EFT for GAD intervention is based on the protocol developed by Timulak and McElvaney (2015)
2. The CBT for GAD protocol used will be based on the model developed by Dugas and Robichaud (2007) based on their theory of the role of intolerance of uncertainty in GAD

Both interventions will be up to 16 sessions in duration. Therapy will last between 16 and 20 weeks. Participants will also be asked to meet with the research team at the end of therapy and 6 months after therapy ends in order to complete assessment forms. In addition, sessions will be recorded in order that a random selection of sessions can be reviewed to ensure that the therapist is delivering the therapy as expected.

Intervention Type

Behavioural

Primary outcome(s)

Severity of Generalised Anxiety Disorder symptoms, assessed using the GAD-7 questionnaire (Spitzer, Kroenke, Williams and Löwe, 2006) at pre-treatment, post-treatment, and at 6 month follow-up

Key secondary outcome(s)

- (1) The Clinical Outcome in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2000);
- (2) The Generalised Anxiety Disorder Severity Scale (GADSS; Shear, Belnap, Mazumdar, Houck and Rollman, 2006); and
- (3) The Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001).
- (4) In addition, a subset of items (e.g. questions 10 - 17) from the Counselling in Primary Care (CIPC) Client Satisfaction Survey, which is routinely administered to all CIPC clients at end of therapy, will be analysed.

1. Psychological distress across four domains (subjective well-being, problems or symptoms, life functioning and risk), measured using the Clinical Outcome in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2000) at pre-treatment, post-treatment, and at 6 month follow-up
2. GAD specific symptom severity, measured using the Generalised Anxiety Disorder Severity Scale (GADSS; Shear, Belnap, Mazumdar, Houck and Rollman, 2006) at pre-treatment, post-treatment, and at 6 month follow-up
3. Severity of depression symptoms, assessed using the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) at pre-treatment, post-treatment, and at 6 month follow-up
4. Client satisfaction with various aspects of therapy and service delivery, measured using a subset of items (e.g. questions 10 - 17) from the Counselling in Primary Care (CIPC) Client Satisfaction Survey at end of therapy

Completion date

20/10/2020

Eligibility

Key inclusion criteria

1. Participants will be recruited from medical card holding, adult (18 years and older) clients, referred by their GP to the HSE Counselling in Primary Care (CIPC) service (a service offered by the Irish public health service provider)
2. Participants must meet criteria for a primary diagnosis of Generalised Anxiety Disorder on the Structured Clinical Interview for DSM-V
3. Participants must agree to be part of the study and consent to study conditions (including giving consent for sessions to be recorded and agreeing to attend appointments for follow up assessments)
4. Clients on medication will be allowed to enter the study provided that their medication has been stabilised for at least 6 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

59

Key exclusion criteria

1. Concurrent treatment
2. Suicide risk, or risk of harm to others (as indicated by items on the CORE-OM)
3. Substance abuse
4. Psychosis
5. Organic brain syndrome

Date of first enrolment

08/12/2017

Date of final enrolment

20/12/2019

Locations**Countries of recruitment**

Ireland

Study participating centre

HSE Counselling in Primary Care (HSE CHO Area 1/8)

34 Brews Hill, Navan, Co. Meath

Navan

Ireland

C15 VP66

Sponsor information**Organisation**

HSE Counselling in Primary Care

ROR

<https://ror.org/04zke5364>

Funder(s)

Funder type

Government

Funder Name

Health Research Board

Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Ireland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ladislav Timulak. Coded participant level data will be stored for 10 years in keeping with Trinity College Dublin research data management policy. Once results have been published, relevant data and materials can be made available on request to other researchers, in keeping with the funder's, Health Research Board, policy.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Results article | | 03/02/2022 | 04/02/2022 | Yes | No |
| Protocol article | protocol | 19/09/2018 | | Yes | No |