ISRCTN52689081 https://doi.org/10.1186/ISRCTN52689081

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

Submission date
24/10/2017

Recruitment status
No longer recruiting

Registration date
01/11/2017

Overall study status
Completed

Last Edited
04/02/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
(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

Overall study start date
12/12/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

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

Sponsor details
34 Brews Hill, Navan, Co. Meath
Navan
Ireland
C15 VP66

Sponsor type
Hospital/treatment centre

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
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
It is anticipated that the following publications, published in an open access format in high-impact peer reviewed journals, will be realised from the trial:
1. Publication of the trial protocol
2. Publication of the main outcomes results
3. One or two publications of the qualitative outcomes and clients perspectives

Intention to publish date
01/08/2021

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?
Protocol article	protocol	19/09/2018		Yes	No
Results article		03/02/2022	04/02/2022	Yes	No