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REducing Stress and Preventing Depression (RESPOND)

Submission date
07/10/2014

Recruitment status
No longer recruiting

Registration date
27/10/2014

Overall study status
Completed

Last Edited
17/05/2019

Condition category
Mental and Behavioural Disorders

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

Plain English Summary
Background and study aims
Depression is a health problem all over the world, with a considerable impact on the patient, on society and also economically. There are a number of treatments that work well, but only for about 60% of cases; many people do not receive any treatment at all and between 50-80% of patients that are treated go on to suffer more depression in the future. Preventing the development of depression is therefore important if we want to reduce the number of people suffering from the condition and the burden it places on society. Alternatives to the traditional face-to-face psychotherapy sessions are also needed to make sure that more people have access to treatments. One such approach is internet-based therapy, which has been shown to work in treating depression and anxiety in the past. However, to date, there have been few studies carried out that have looked at internet-based therapy (or intervention) to actually prevent depression. Here, we are investigating an internet-based intervention developed to treat stress, worry and rumination (dwelling on negative thoughts) in young adults. The underlying theory is that by targeting a specific risk factor, namely worry and rumination, people are less likely to develop depression or anxiety in the future. We are testing two different versions of the intervention, one supported by an online coach and the other purely self-help. While previous research has shown that supported therapy works better, self-help interventions could also be beneficial in that they have the potential to reach many more people who wouldnt normally have access to therapy.

Who can participate?
Adults aged 18-24 who are prone to worry or ruminate and who are not currently depressed. Those with a history of depression can participate, provided they are currently well.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 receive the internet-based intervention (i-RFCBT) guided by an online coach. Those in group 2 receive a self-help version of the intervention. Those in group 3 (control group) do not receive any treatment. Participants in group 1 are allocated to a trained online coach who will guide them through the internet therapy, giving feedback on the exercises and the participants themselves can send messages to their coach. The therapy consists of six modules, each taking 1-2 hours to complete online and we recommend spending 1-2 weeks on each module to allow time to practise the

techniques. The modules include psycho-education, mood diaries, on-line experiential exercises using audio-recordings, pictures, and video vignettes of students experiences of the therapy. Each follows the same basic structure: reflection on previous session; introduction of new technique; practical exercises and planning how to practise or implement the technique in daily life. Participants are asked to complete some questionnaires assessing mood and depressive symptoms at the end of each module. The unguided intervention is a self-help version of the internet therapy, which contains the same content but without the therapist contact. There is no-one providing feedback on the exercises, but responses are monitored weekly so that we can check for and follow-up on any risk reported. Participants in the control group are asked to carry on as normal. They are allowed to access any other treatments if necessary throughout the study and will also have access to the unguided version of the intervention at the end of the study if they wish. All participants are contacted at regular intervals (initially at 3 months from entering the study, and then 3 months and 1 year after that first follow-up) and asked to complete a short interview including questionnaires about worry, rumination and symptoms of anxiety and depression.

What are the possible benefits and risks of participating?
We have evidence to suggest that the therapy may be helpful in reducing stress and risk of later depression or anxiety. Participants may therefore find that the therapy helps them to manage their problems better. For those in the control group, involvement in the trial will not take up much of their time. It will only involve completing the measures four times over the course of the study. The regular follow-ups will allow us to track participants mood and tell them if any of their symptoms seem to be worsening. If their responses suggest that their mood requires attention, we may advise them to speak to their GP or a mental health practitioner. The information participants provide may help us to better understand how to prevent depression in young adults. This will hopefully allow us to provide better therapies that help young adults manage their stress and worry and reduce their risk of depression. The risks of participating in the study are minimal. There are no known side effects of the therapy and controls will simply be asked to carry on as normal. However, given the nature of the topic, participants may find answering some of the questions makes them feel uncomfortable. If participants report any suicidal thoughts, we will follow a well-established procedure for assessing and acting on suicide risk to ensure participants get appropriate clinical support.

Where is the study run from?
The University of Exeter (UK)

When is the study starting and how long is it expected to run for?
November 2013 to February 2016

Who is funding the study?
University of Exeter, through a matched funded PhD studentship to a successful Wellcome Trust Capital Bid (UK)

Who is the main contact?
Lorna Cook
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Study website
http://survey.ex.ac.uk/index.php/35592/lang-en

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RESPOND Protocol 4th August 2014 Version 2

Study information

Scientific Title
A randomised-controlled prevention trial comparing guided and unguided internet-based rumination-focused cognitive-behavioural therapy (i-RFCBT) and a no treatment control to prevent depression in high ruminating young adults

Acronym
RESPOND

Study hypothesis
1. Primary aim: to extend a Dutch trial of i-RFCBT to the UK, with the addition of diagnostic interviews, with the primary research question testing whether guided internet RFCBT reduces onset of major depression relative to no treatment control in a high risk group of young adults. The RESPOND study will address the limitations of the Dutch trial by including a well-validated diagnostic interview to increase accuracy in determining current and past diagnostic status, and to allow for stratification on history of depression.
2. Secondary aims: are to assess the effect of i-RFCBT on levels of worry and rumination as well as symptom severity of depression and anxiety. We will also assess the acceptability, adherence, retention, and effect sizes of the unguided version of i-RFBCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the School of Psychology, University of Exeter; ref: 2012/554

Study design
Single (researcher)-blind parallel-group pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

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

Condition
Major Depressive Disorder; Generalised Anxiety Disorder

Interventions
i-RFCBT consists of six modules, each taking around an hour to complete in session and 1-to-2 weeks to practise. It includes psycho-education, mood diaries, on-line experiential exercises using audio-recordings, pictures, and video vignettes of students experiences of the therapy. The modules each follow the same basic structure: reflection on previous session; introduction of new technique; practical exercises and planning how to practise or implement the technique in daily life. The key strategies include coaching participants to spot warning signs for rumination and worry, and then to make IF-THEN plans in which an alternative strategy is repeatedly practised to the warning signs. These strategies include: being more active, slowing things down, breaking tasks down, opposite action, relaxation, concrete thinking, becoming absorbed, self-compassion, and assertiveness.

The intervention is accessed through a secure website, with each participant having a password protected account. Participants log-ins are automatically recorded by the programme, allowing for an automated measure of treatment compliance. Reminder emails will be sent to participants after two weeks if they have not completed the module.

For the guided version, the participant can work through each module at his own pace but can only move from one module to the next once the coach has provided feedback. The coach will provide feedback on these responses within 2 working days, in particular highlighting any positive steps made and encouraging participants to sustain these as well as pointing out areas

to focus on over the next module. Participants will also be able to send questions to their assigned therapist throughout the programme if they are having difficulty with a specific exercise.

The guided intervention will be supported by qualified clinicians, typically clinical psychologists or psychological wellbeing practitioners, who have received specific training in the rumination-focused CBT approach. Template responses to each module have been compiled, providing the coach with clear examples of possible feedback which they can then tailor to individual clients.

Coaches will be provided with ongoing supervision. Supervision meetings will involve a brief overview of all clients and a more in-depth discussion of cases deemed to be more complex or where there is risk or non-response to treatment. All responses from both client and coach are automatically saved by the online platform. The coachs responses to clients will be regularly discussed in supervision to ensure they are on-task and to allow for any editing prior to the message being sent.

The unguided version of the therapy contains the same six modules, with almost identical content, adapted for self-help, including some conditional feedback on common difficulties with exercises. Participants are able to move freely from one module to the next, but are advised to spend 1-2 weeks on each to allow time for practice. Participants in the unguided version will be made aware that there is no coach monitoring their responses. However, they will be told that their questionnaires scores will be monitored on a weekly basis to check for any risk reported.

Control condition
A no treatment control condition will be used. Participants in the control condition will be informed that they have been allocated to carry on as usual. In order to ensure participants welfare, participants are permitted to access any other treatments throughout the course of the study, as necessary. They will also be able to access the unguided i-RFCBT at the end of the study if they so wish.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Onset of a major depressive episode and/or generalized anxiety disorder over a 12-month period, assessed with Structured Clinical Interview for Diagnosis 3 months (post-intervention), 6 months, and 15 months after randomisation.

Secondary outcome measures
Secondary outcomes will be collected on:
1. Symptoms of depression and anxiety; levels of worry and rumination, measured at baseline, 3, 6, and 15 months post-randomisation
2. Feasibility and acceptability of data collection procedures, levels of attrition, effect size and acceptability of the unguided internet RFCBT intervention.

Overall study start date
14/11/2013

Overall study end date
28/02/2016

Eligibility

Participant inclusion criteria
1. Aged 18-24
2. Elevated worry/rumination, defined as scoring above the 75th percentile on at least one of two standard questionnaire measures of worry/rumination
3. Able to understand written English to engage with the intervention
4. Private internet access to ensure confidentiality
5. In line with standard practice, participants currently receiving antidepressant medication will be eligible, provided the dosage has been stable for at least the previous month

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
24 Years

Sex
Both

Target number of participants
237

Total final enrolment
235

Participant exclusion criteria
1. Meeting diagnostic criteria for a current (within past month) major depressive episode
2. Current and significant substance abuse or dependence
3. Current symptoms of psychosis or bipolar disorder
4. Current psychological therapy
5. Active suicide risk

Recruitment start date
14/11/2013

Recruitment end date
28/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
University/education

Funder Name
University of Exeter, UK, through a matched funded PhD studentship to a successful Wellcome Trust Capital Bid.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/01/2016		Yes	No
Results article	results	13/05/2019	17/05/2019	Yes	No