



Participant Information Sheet

Title of Study: A Pilot Study of Acceptance and Commitment Therapy (ACT) for Anxiety and Brief Mindfulness Based Stress Reduction-informed groups in a University Setting

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

This study aims to evaluate the effectiveness of an Acceptance and Commitment Therapy (ACT) group and a Mindfulness Based Stress Reduction group for individuals with anxiety. ACT and MBSR have been shown to be effective in helping a range of individuals with anxiety and we want to find out whether it will be useful in a university setting. We can offer you four 2-hour group sessions, which would normally take place once a week. Before the group you will speak with one of the researchers to ensure that it is suitable for you to join the group.

Why have I been invited?

We would like to invite between 8 and 12 people for each of the groups. You have been invited because you have expressed an interest in taking part, are over 18 years of age, have declared that there is an aspect of your life that you would like to improve, believe that a psychological intervention may be of benefit to you.

Do I have to take part?

Participation is voluntary. You can choose not to participate in part or all of the project and you may withdraw from the project at any stage. You do not have to answer questions that you feel are too personal or intrusive. Withdrawing at any time from the project or from any particular part of it will not affect any future treatment and you will not be penalized or disadvantaged in any way. Taking part in the research will not affect your grades. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. However, once the data has been anonymised/published, you will no longer be able to withdraw your data.

What will happen if I take part?

If you decide to take part, you will be:

- invited to a pre-screening interview (which can occur in person or over the phone) which will last approximately 15-20 minutes and will take place in the Rhind Building at City, University of London. The interviewer will check eligibility and obtain informed consent for you to participate in the study, if eligible.*
- asked to complete baseline measurements online which will take approximately 15 minutes to complete. Once you have completed your online measurements you will be invited to complete two cognitive tasks which will last approximately 5 minutes.*
- assigned (randomly) to one of our two intervention groups or a waitlist control group. The intervention groups will occur over 4 consecutive weeks on a Wednesday from 17:00-19:00, a total of about 8 hours for each group. At these group sessions, you will take part in a skills based psychologically informed group. Your group facilitator will work with you on ways to think about, and experience, worries and feelings. Your group facilitator will be a highly qualified psychologist who has been trained to work in therapeutic interventions. If you are allocated to our waitlist group, you will wait until the first set of intervention groups have ended, and you will be randomly allocated to either one of the two intervention groups.*
- asked to complete a set of questions related to your feelings and mood over the preceding week, as well as a questionnaire that asks you about how you have experienced your worries and feelings. At the end of the session you will be asked to rate the meeting to say what you found helpful, and what you found unhelpful.*

At the end of the 4 weeks, all group participants will complete the same set of questionnaires and again at a 4-week follow-up. All sessions will take place in the Rhind Building, at the Northampton Square campus of City, University of London.

What do I have to do?

You will be asked to attend meetings at a certain time and day of each week, and to work with the group facilitator with your worries and feelings. You will also be asked to complete questionnaires each week and sessions will be audio-recorded with a digital audio recorder. You will also be contacted by your facilitator after the sessions have finished, to find out how you have been since the sessions ended.

What are the possible disadvantages and risks of taking part?

There is a chance that you may experience a temporary increase in difficult feelings about anxiety and a heightened awareness of the things that make you worried and upset. This is a normal process in talking therapies and is usually resolved. If you are experiencing distress that you are concerned about, your group facilitator is a fully qualified and experienced counselling or clinical psychologist and therefore will be able to work with you to resolve the difficulty or will know where to refer you if that is your preferred route.

What are the possible benefits of taking part?

We hope that you will experience a reduction in distress related to anxiety, and that your ability to live in a way that is consistent with your values will be enhanced. The study will also contribute to knowledge about the best psychological therapies for university students who are struggling with anxiety.

What will happen when the research study stops?

If the project is abandoned before completion, all data will be destroyed.

Will my taking part in the study be kept confidential?

The researchers will have access to the demographic and questionnaire data before it has been anonymised. After it has been anonymised, the research team will be able to access it, in order to manage it and analyse it. Written data and anonymised recordings of sessions will be uploaded to and stored in secured cloud and an encrypted computer drive. No data will be shared with any staff member of the university other than those in the research team. Your personal information will be kept confidential for a minimum period of ten years in line with University guidelines.

Please note that in the unlikely event that you communicate considerable risk to the researcher, such as plans to harm yourself or another, the researcher would have a duty of care to disclose this to a third party (i.e., the university, your GP). We will take all necessary measures to inform you if it is decided to contact a third party to ensure appropriate levels of support are put in place.

What should I do if I want to take part?

If you would like to take part in this study please email CPsychResearchClinic@city.ac.uk

What will happen to results of the research study?

The results of the study will be written up for a dissertation/thesis and potentially academic and or clinical publications related to psychological therapies. No identifiable personal data will be published.

What will happen if I do not want to carry on with the study?

If you wish to withdraw from the study, you may leave without explanation or penalty, at any time during the study. You may withdraw your data from the study at any point before analysis of the data has begun.

Who has reviewed the study?

This study has been approved by City, University of London Department of Psychology Research Ethics Committee

Further information and contact details

*Dr Jessica Jones Nielsen at Jones.Nielsen.1@city.ac.uk or 0207 040 8755
Dr Julianna Challenor at julianna.challenor@city.ac.uk or 0207 040 0238*

Data Protection Privacy Notice: What are my rights under the data protection legislation?

City, University of London is the data controller for the personal data collected for this research project. Your personal data will be processed for the purposes outlined in this notice. The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

Further, City considers the processing of special category personal data will fall under Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects.

The rights you have under the data protection legislation are listed below, but not all of the rights will be apply to the personal data collected in each research project.

- right to be informed
- right of access
- right to rectification
- right to erasure
- right to restrict processing
- right to object to data processing
- right to data portability
- right to object
- rights in relation to automated decision making and profiling

For more information, please visit www.city.ac.uk/about/city-information/legal

What if I have concerns about how my personal data will be used after I have participated in the research?

In the first instance you should raise any concerns with the research team, but if you are dissatisfied with the response, you may contact the Information Compliance Team at dataprotection@city.ac.uk or phone 0207 040 4000, who will liaise with City's Data Protection Officer Dr William Jordan to answer your query. If you are dissatisfied with City's response you may also complain to the Information Commissioner's Office at www.ico.org.uk

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is: A Pilot Study of Acceptance and Commitment Therapy (ACT) for Anxiety and Brief Mindfulness Based Stress Reduction-informed groups in a University Setting.

You could also write to the Secretary at:

Anna Ramberg
Research Integrity Manager
Research & Enterprise
City, University of London
Northampton Square
London
EC1V 0HB
Email: Anna.Ramberg.1@city.ac.uk

City holds insurance policies which apply to this study. If you feel you have been harmed or injured by taking part in this study you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Thank you for taking the time to read this information sheet.

25/01/2019 Version 2