Ethics ETH1819-0489: Dr Jessica Jones Nielsen (Medium risk)

Date	19 Nov 2018
Researcher	Dr Jessica Jones Nielsen
	Dr Fran Smith
	Dr Julianna Challenor
Project	A pilot study of brief ACT and brief MBSR-informed group interventions for anxiety in a university setting
School	School of Arts and Social Sciences
Department	Psychology

Ethics application

Risks

R1) Does the project have funding?
No

R2) Does the project involve human participants?
Yes

R3) Will the researcher be located outside of the UK during the conduct of the research?
No

R4) Will any part of the project be carried out under the auspices of an external organisation, involve collaboration between institutions, or involve data collection at an external organisation?
No

R5) Does your project involve access to, or use of, material that could be classified as security sensitive?
No

R6) Does the project involve the use of live animals?
No

R7) Does the project involve the use of animal tissue?
No

R8) Does the project involve accessing obscene materials?
No

R9) Does the project involve access to confidential data (e.g. business sensitive data, employee data, minutes of meetings)?
No

R10) Does the project involve access to personal data (e.g. personnel records or confidential information)?
Yes

R11) Does the project involve deviation from standard or routine clinical practice, outside of current guidelines?
No

R12) Will the project involve the potential for adverse impact on employment, social or financial standing?
No

R13) Will the project involve the potential for psychological distress, anxiety, humiliation or pain greater than that of normal life for the participant?
No

R14) Will the project be conducted or supported by any U.S. federal department or agency?
No

R15) Will the project involve research into illegal or criminal activity where there is a risk that the researcher will be placed in physical danger or in legal jeopardy?
No

R16) Will the project involve engaging individuals that may be involved in illegal or criminal activity?
No

R17) Will the project involve engaging individuals who may be involved in terrorism, radicalisation, extremism or violent activity and other activity that falls within the Counter-Terrorism and Security Act (2015)?
No

Applicant & research team

T1) Principal Applicant

Name
Dr Jessica Jones Nielsen

Provide a summary of the researcher's training and experience that is relevant to this research project.
Dr Jones Nielsen is a qualified and HCPC registered counselling psychologist employed at City, University of London, Department of Psychology. She is a lecturer on the DPsych in counselling psychology training progamme, and supervises DPsych trainees. She has published in both counselling and health related peer-reviewed journals and teaches research methods and analysis lectures within the programme.

T2) Co-Applicant(s) at City

Name

Dr Fran Smith

Provide a summary of the researcher's training and experience that is relevant to this research project.

Dr Smith is a qualified and HCPC registered counselling psychologist employed at City, University of London, Department of Psychology. She is a lecturer on the DPsych in counselling psychology training progamme, and supervises DPsych trainees. She has published in both counselling and health related peer-reviewed journals and teaches the CBT module within the programme. She is also trained in ACT and has experience in supervising clinical practitioners/trainees in this approach.

Name

Dr Julianna Challenor

Provide a summary of the researcher's training and experience that is relevant to this research project.

Dr Challenor is a qualified and HCPC registered counselling psychologist employed at City, University of London, Department of Psychology. She is a lecturer on the DPsych in counselling psychology training progamme, and supervises DPsych trainees. She has published in both counselling and health related peer-reviewed journals and teaches the psychodynamic and other clincal-related training modules within the programme. She is trained in DIT and contributes to the discours around pluralistic qualitative research methods.

T3) External Co-Applicant(s)

T5) Do any of the investigators have direct personal involvement in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

No

T6) Will any of the investigators receive any personal benefits or incentives , including payment above normal salary, from undertaking the research or from the results of the research above those normally associated with scholarly activity?

No

Project details

P1) Project title

A pilot study of brief ACT and brief MBSR-informed group interventions for anxiety in a university setting

P1.1) Short project title

P2) Provide a lay summary of the background and aims of the research, including the research questions (max 400 words).

The aim of this study is to pilot a randomised controlled trial of a brief ACT and brief MBSR-informed group interventions for university students, the procedures for delivering and providing preliminary data for assessing outcomes in ACT and MBSR-informed groups for anxiety in students.

ACCEPTANCE AND COMMITMENT THERAPY (ACT)

One of the most widely practiced and researched of the new CBT treatments, ACT is an empirically derived, time-limited intervention that has been used successfully to treat anxiety disorders. In the approach, ACT aims to increase acceptance and mindfulness processes that are integrated with commitment and behaviour change processes (Eifert, Forsyth, Arch, Espejo, Keller et al., 2009). ACT characterises anxiety disorders as caused by experiential and emotional avoidance (Hayes, Strosahl & Wilson, 1999), and seeks to reduce excessive struggle with anxiety and experiential avoidance with the goal of promoting more flexible ways of relating to anxiety so that individuals can pursue the goals that are important to them. ACT incorporates mindfulness, acceptance and compassion in its therapeutic model in order to facilitate psychological flexibility, a reduction in avoidance, improved emotion regulation and a corresponding reduction in emotional suffering. ACT has been shown to be effective for a range of anxiety disorders and is therefore a treatment for a heterogeneous client population presenting with diverse forms of anxiety. ACT will inform the brief group intervention protocol for this study.

MINDFULNESS-BASED STRESS REDUCTION (MBSR)

In MBSR, participants are taught to develop mindfulness skills through a range of formal and informal mindfulness practices, including, amongst others, the body scan, mindfulness of the breath, movement, sounds, emotions and thoughts. Participants are invited to follow these practices both during their eight weekly classes and as part of the daily homework exercises to encourage mindfulness of everyday activities. Participants are encouraged to develop a sense of equanimity and self-compassion when exploring difficult thoughts, emotions and responses and to develop attentional flexibility and control as a means of managing stress and regulating emotion. A key aspect of the classes is the “enquiry process”, during which participants speak about their experiences of mindfulness practice and the MBSR teacher embodies a kind, non-judgmental, curious and present moment-focused attitude towards these experiences. This is thought to provide participants with a model of how they can relate to their experiences during mindfulness practice. Traditional MBSR runs for eight weeks of two-hour sessions. Given the need for brief group interventions in a university setting, this study will run an adapted version of the traditional MBSR group that has synthesised the main elements, which includes all of the traditional practices and is congruent with the philosophical underpinnings of the original MBSR group. The brief MBSR-informed group will consist of four two-hour weekly sessions and will be guided by the work of Kabat-Zinn (1990) and Segal, Williams and Teasdale (2002) as well as further adapted by Dr Trudi Edginton, an experienced mindfulness teacher.

Given the need for brief group interventions to help university students cope with mental health problems, the main aim of the pilot study is to test the effectiveness between brief ACT and MBSR-informed group interventions. Specifically, we will (a) compare the immediate effects of two group interventions (ACT and MBSR-informed groups) to a waitlist control group in a non-clinical sample of university students, and (b) test whether unique mechanisms of change are common across both approaches. We are further interested in examining both psychological and cognitive manifestations

associated with the outcomes for this study. It is hypothesized that intervention participants in both groups will demonstrate increases in acceptance and mindfulness from pre- to post-intervention and decreases in anxiety in comparison to the waitlist control group and that these differences will vary between groups.

References:

Eifert, Forsyth, Arch, Espejo, Keller et al., 2009). Acceptance and Commitment Therapy for Anxiety Disorders: Three Case Studies Exemplifying a Unified Treatment Protocol. Cognitive and Behavioral Practice, 16(4), pp. 368-385.

Hayes, S. C., Strosahl, K., & Wilson, K. G. (1999). Acceptance and Commitment Therapy: An experiential approach to behavior change. New York: Guilford Press.

Kabat-Zinn J. (1990). Full catastrophe living: How to cope with stress, pain and illness using mindfulness meditation. New York: Dell.

Segal Z. V., Williams J. M. G., & Teasdale J. D. (2002). Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse. New York: Guilford.

P4) Provide a summary and brief explanation of the research design, method, and data analysis.

RESEARCH DESIGN

This pilot study is designed as a randomised controlled trial comparing the effectiveness of two group interventions to a waitlist control (WLC) group: The first group is informed by Acceptance and Commitment Therapy (ACT), and the second group is informed by Mindfulness-Based Stress Reduction (MBSR). Student participants in the intervention groups will take part in either four 2-hour group sessions of ACT or MBSR-informed group interventions. Participants who are placed on the waitlist will be offered either brief ACT or brief MBSR-informed groups after 4 weeks. Both intervention and WLC groups will be administered an assessment battery before the interventions start (baseline), and soon after the intervention (post-intervention). All participants will complete the assessment battery measures at 8 weeks after post-measurement (4-week follow-up). After the completion of the 4-week follow-up measures, participants in the WLC group will be randomly allocated to either intervention groups, followed up by a post-measurement 4 weeks later after the completion of each intervention.

METHODS

Therapeutic interventions: Participants of the intervention groups will be allocated into either a 4-week ACT or MBSR-informed group. Instructions will be offered by the group facilitators, including discussion, reading assignments, as well as training and practice in a variety of acceptance- and mindfulness-based techniques. The ACT and MBSR-informed groups in this study will be facilitated by members of the Department of Psychology.

ACT GROUP

The ACT protocol proposed in this study has been adapted from a manual developed by Flaxman, McIntosh and Oliver (2018) for ACT training in workplace settings. This protocol has been adapted further by the authors in collaboration with Dr Kornilia Givissi and Dr Hana Villar for use in clinical settings and specifically applied to participants struggling with anxiety. This intervention combines psychoeducational and experiential practices to introduce concepts and develop skills in the six core processes of ACT. Participants will attend 4 two-hour weekly sessions of this group. The first five and

last five minutes of each session will be for process measure completion. The focus of each session is detailed in the ACT protocol (Appendix D).

MBSR-INFORMED GROUP

The 4-week MBSR protocol proposed in this study has been adapted from the work of Kabat-Zinn (1990), Segal, Williams, and Teasdale (2002) and has been adapted by Dr Trudi Edginton, an experienced mindfulness teacher. It has synthesised the main elements, includes all of the traditional practices and is congruent with the philosophical underpinning of the original MBSR group. This group consists of 4 two-hour weekly sessions. The first five and last five minutes of each session will be for process measure completion. The focus of each session is detailed in the MBSR-informed protocol (Appendix E).

Waitlist Control (WLC) group: Those assigned to the WLC group will not engage in the group interventions during the course of the intervention period. At the start of the pilot trial, they will be informed of the 4-week waiting period after which they will be randomly allocated into either intervention groups. They will be asked to complete the assessment battery measures at baseline and all follow-up timepoints.

Researcher/Practitioners: The ACT or MBSR-informed protocols in this study will be delivered by qualified and HCPC registered counselling and/or clinical psychology practitioners and are either employed or visiting lecturers in the Department of Psychology. They will all have received training in ACT and/or MBSR, and will undertake weekly clinical peer supervision to ensure fidelity to the intervention models. The research will be evaluated by the named staff members on this application and will not provide interventions but supervision to those delivering the protocols to the study participants.

Evaluation: Evaluation of the study will be conducted by the researchers named within this application. The evaluation will comprise of the assessment battery measures that will be self-administered at the start of the project and collected by the researcher, and therapy process measures that will be completed at the end of each session. To ensure confidentiality, measures will be de-identified and assigned a code. The researcher will remind the participants that they can choose not to complete the measures or answer any of the questions. Any paper-based measures completed by participants will be stored in a locked filing cabinet in the research clinic office until the data have been entered into a computer, after which hard copies will be securely destroyed. Data collected via tablet or other electronic devices will be stored on a City-protected cloud.

MEASURES

All demographic information (including age, gender, education, relationship, and employment status) will be collected at pre-intervention only, whilst process and outcome variables will be measuresd at pre- and post-intervention. The following psychological, cognitive and education-related measures will be included in the assessment battery.

•The Academic Engagement Scale (AES; Brault-Labbé & Dubé, 2008) is a 14-item which measures school engagement and contains thre subscales: (1) school perseverance (e.g., “Despite the difficulties, I persevere in my studies”), (2) enthusiasm towards studies (e.g., “When I perform activities related to school, I’m full of energy”), and (3) positive and negative aspects of school (e.g., “I accept the fact that my studies imply both positive and negative aspects”). These subscales capture the three types of school engagement (behavioral, emotional, and cognitive) described above. Items of the AES were scored on a 6-point Likert-type scale ranging from 1 (strongly

disagree) to 6 (strongly agree). A global AES score was created based on the mean of all 14 items.High scores reflect greater school engagement.

•The Academic Procrastination State Inventory (Schouwenburg, 1995) measures the frequency with which participants engaged in different procrastinatory behaviors during the last week. This measure contains three subscales: (1) the tendency to postpone academic tasks (“Put off the completion of a task”), (2) fear of failure (“Had panicky feelings while studying”), and (3) lack of motivation (“Found the subject manner boring”). Responses were scored on a scale ranging from 1 (not at all) to 5 (all the time) with a higher score reflecting more procrastinatory behaviors.

•The Acceptance and Action Questionnaire–II (AAQ-II; Bond et al., 2011) is a one-factor measure of psychological inflexibility, or experiential avoidance. The scale is scored by adding together the seven items. Higher scores equal greater levels of psychological inflexibility.

• The Comprehensive Assessment of Acceptance and Commitment Therapy (CompACT; Francis, Dawson & Golijani-Moghaddam, 2016) was developed as a general measure of psychological flexibility (and constituent sub-processes) as conceptualized within the ACT model. This 23-item measure has shown initial advantages to the AAQ-II and its inclusion is intended to further test its validity.

•The Cognitive Fusion Questionnaire (CFQ; Gillanders, Bolderston, Bond, Dempster, Flaxman, Campbell et al., 2014) is a 7-item self-report measure of cognitive fusion. Examples of items are: “I over-analyse situations to the point where it’s unhelpful to me” and “I tend to get very entangled in my thoughts.” This questionnaire is answered on a 7-point Likert scale ranging from 1 = never true to 7 = always true. Higher scores reflect higher levels of cognitive fusion.

•The Five Facet of Mindfulness Questionnaire (FFMQ; Bohlmeijer, Ten Klooster, Fledderus,Veehof,& Baer, 2011)is a 39-item measure consisting of five subscales (1. observing, 2. describing, 3. acting with awareness, 4. non-judging of inner experience, and 5. non-reactivity to inner experience).The FFMQ short-version (24 items) will be used to capture four of the psychological flexibility processes, namely contact with the present moment (e.g., “It seems I’m running on automatic without much awareness of what I’m doing”; inverse item), cognitive defusion (e.g., “When I have distressing thoughts or images, I just notice them and let them go), self as context (e.g., “Usually when I have distressing thoughts or images, I can just notice them without reacting”), and acceptance (e.g., “I think some of my emotions are bad or inappropriate and I shouldn’t feel them”; inverse item). Items of the FFMQ were measured on a 5-point Likert-type scale ranging from 1 (never or very rarely true) to 5 (very often or always true). A global FFMQ score are calculated using the mean of all 24 items.

•The Generalised Anxiety Disorder Assessment (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) is a 7-item self-administered instrument that is used to measure or assess the severity of generalised anxiety disorder (GAD). Each item asks the individual to rate the severity of his or her symptoms over the past two weeks. Response options include “not at all”, “several days”, “more than half the days” and “nearly every day” respectively, and then adding together the scores for the seven questions. GAD-7 total score for the seven items ranges from 0 to 21.Scores represent: 0-5 = Mild anxiety, 6-10 = Moderate anxiety, 11-15 = Moderately severe anxiety, and 15-21 = Severe anxiety. When used as a screening tool, further evaluation is recommended when the score is 10 or greater.

•The Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) is a 15-item instrument assessing the frequency with which an individual is openly attentive to, and aware of, present events and experiences. The scale assesses mindfulness of both internal states (e.g., emotions) and overt

behavior (e.g., attention to tasks, social interactions, etc.) on a 6-point Likert scale. Example items of the scale include, “I could be experiencing some emotion and not be conscious of it until some time later” and “It seems I am ‘running on automatic’ without much awareness of what I’m doing.” Higher scores indicate higher mindfulness. The MAAS has demonstrated strong psychometric properties (Brown & Ryan, 2003; Carlson & Brown, 2005).

•The Patient Health Questionnaire-9 (PHQ-9; Kroenke & Spitzer, 2002) is a 9-item self-administered scale used to measure or assess the severity of depression. Each item asks the individual to rate the severity of his or her symptoms over the past two weeks. Response options include “not at all”, “several days”, “more than half the days” and “nearly every day” respectively, and then adding together the scores for the seven questions. Scores represent: 5-9 = mild depression / low mood, 0-14 – moderate depression / low mood, 15-19 – moderately severe depression / low mood, and 20-27 – severe depression/low mood. When used as a screening tool, further evaluation is recommended when the score is 10 or greater.

•The Ruminative Responses Scale (RRS) of the Response Styles Questionnaire (RSQ; Nolen-Hoeksema & Morrow, 1991) is a 22-item measure that assesses the extent to which individuals repeatedly focus on the causes, meanings, and consequences of their negative mood. A factor analysis of the RRS has identified two separate subscales that are differentially related to symptoms of depression. The first, reflection, consists of five questions that assess the degree to which individuals engage in cognitive problem-solving to improve their mood (e.g., Analyze recent events to try to understand why you are depressed), and the second, brooding, consists of five items that assess the degree to which individuals passively focus on the reasons for their distress (e.g., think ‘What am I doing to deserve this?’) (Treynor et al., 2003). Brooding and reflection scores were computed by taking the average of items on each respective scale.

•The Self-Compassion Scale (SCS; Neff, 2003) is a 26-item measure of self-compassion based on an aggregate of responses on three subscales: (1) self-kindness versus self-judgment, (2) common humanity versus isolation, and (3) mindfulness versus overidentification. Example items include, “I try to be loving toward myself when I’m feeling emotional pain” and “When times are really difficult, I tend to be tough on myself” (reversed). Higher scores on the 5-point scale indicate higher self-compassion.

•The Trail Making Test (TMT; Arnett, Seth & Labovitz, 1995) is a neuropsychological test of visual attention and task switching.. The standard TMT comes in two forms: Trails A, where subjects connect a series of 25 numbered circles in ascending order, and Trails B, where subjects connect 25 circles alternating between ascending numbers and letters (e.g., 1-A-2-B, etc.). Completion times on the TMT are used to assess visual attention, speed of processing, mental flexibility, and executive function in patients by comparisons with normative data from appropriate control populations (Tombaugh, 2004).

•The Valuing Questionnaire (VQ; Smout et al., 2014) is a 10-item measure of values, another key sub-process related to psychological inflexibility. The VQ includes two subscales assessing progress in valued living and obstruction to valued living. Each item is rated on a 7-point scale ranging from 0 “not at all true” to 6 completely true.” The VQ is also a relatively new measure, but initial validation results indicate adequate reliability and validity (Smout et al., 2014).

•The WAIS-IV subtest Letter-Number Sequencing (LNS) is a well-validated measure of manipulation WM (Snyder, Miyake, & Hankin, 2015). The participant is read a series of numbers and letters and asked to recall the numbers in ascending order, followed by the letters in alphabetical order.

WEEKLY SESSIONS (Session by Session, SbS)

At the beginning of each group session, participants will be invited to complete the process measures, PHQ-9 and GAD-7 and their mindfulness practice log. In total, clients would be expected to spend approximately 5 minutes completing measures, before and after session. Participants will be instructed to practice according to the manual of the ACT protocol (see Appendix D) and MBSR-informed protocol (see Appendix E) and will be assessed by their facilitator for adherence to the protocol. The Mindfulness Practice Log will be used to have participants record their weekly mindfulness practice for the entire 4-week interventions so as to examine the effects of practice on study outcomes. On these logs,participants will be asked to complete both formal and informal practice at the end of each day. MBSR-informed group participants will indicate the number of minutes sitting meditation, body scan, yoga, and informal mindfulness practice performed that day (see log in Appendix T).

All sessions will be video/audio recorded on a password-protected, encrypted recording device. Video/audio recordings will be used for research purposes to ensure fidelity to the models, and will be analysed using qualitative analytic approaches at a later date. Video/audio recordings are required due to the need to (anonymously) identify individual members when speaking for qualitative analysis methods.

DATA ANALYSIS

Quantitative Analysis: Hypotheses and research questions will be analysed using SPSS. Specifically, Reliable Change Index (RCI) scores will be used to explore changes in the outcomes (Jacobson & Truax, 1991), repeated measures ANOVA will be conducted to measure the change and maintenance of improvements of both intervention groups and through follow-up.

Qualitative Analysis: In-depth qualitative research questions focusing on the content of the group interventions will be analysed using a variety of approaches ie. discursive, thematic and content analysis to name a few.

REFERENCES

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Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. Assessment, 13, 27-45.

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Schouwenburg H. C. (1995). "Academic procrastination: theoretical notions, measurement, and research," in Procrastination and Task Avoidance: Theory, Research, and Treatment eds Ferrari J. R., Johnson J. L., McCown W. G., editors. (New York, NY: Plenum Press;) 71–96.

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Treynor W, Gonzalez R, Nolen-Hoeksema S. (2003). Rumination reconsidered: A psychometric analysis. Cognitive Therapy and Research. 27:247–259.

P5) What do you consider are the ethical issues associated with conducting this research and how do you propose to address them?

MEASURES

Participants may experience some boredom, irritation or other negative feelings when completing some of the forms (although, on average, the forms have been rated in pilot studies as more helpful than unhelpful). They may also feel self-conscious when having sessions recorded.

ANONYMITY

There is a danger that participants may be able to identify themselves in case studies that are written once the study is completed and, in a very few of these instances, may experience some feelings of distress. To minimise this as far as possible, no identifying details will be used in case studies, and/or details may be altered to protect the participants' identity.

DISCLOSURE OF STUDENT INFORMATION

To minimise the possibility that participants will be assigned to facilitators who they have personal knowledge of, we will exclude from participation in the study any students or trainees who are on graduate programmes in the Department of Psychology. Participants will also be informed of the name of their allocated assessor prior to assessment session, and informed that they should choose to ask for a different assessor should they have knowledge of this person. The City Counselling Psychology Training and Research Clinic will have no direct access to any student records. Disclosures from the research clinic to the Student Counselling and Mental Health Services will only be in the event of risk or in the case of onward referral if participants report clinically significant issues that are not addressed by significant focus of the interventions.

COERCION

A potential ethical concern may be that students will feel obliged to participate in the study. However, the participant information sheet will give prospective participants full advice on what to expect from the study, and they will be no financial incentive to participate. If, at any point, it is established between participant and facilitator/researcher that the participant would benefit from an alternative psychological interventions, an onward referral will be discussed.

CONFLICT OF INTEREST BETWEEN RESEARCH AND CLINICAL PRACTICE

The research clinic has a dual aim: to develop a greater understanding of psychotherapeutic outcomes and processes; and to help reduce levels of psychological distress in participants. Although the research aim is the principal rationale for establishing the research clinic, the clinical aim will take precedent in instances where there is a potential conflict of interest. An example of this might be where a participant indicates that they find it distressing to complete a particular measure. Here, the researcher would agree with the participant to stop using the measure, even though this may compromise the quality of the dataset.

CONFIDENTIALITY OF DATA

All personal data (signed consent forms) will be stored separately from anonymised data and partially anonymised data in a locked cabinet at City, University of London. Anonymised data (all electronic forms and measures) will be collected and initially stored using cloud technology, with SSL encryption between computers and the cloud server. Text data will be encrypted. When transferred to City, University of London it will be stored in an encrypted portion of an external hard drive that will be locked in a secure cabinet. Any hard copies of anonymised data (e.g., print offs of therapist notes) will be stored in a locked and secure cabinet.

Partially anonymised data (video/audio recordings of sessions) will be stored using the following procedures:

a.) Video/audio files of group sessions are recorded using a password-protected encrypted recording device;

b.) Facilitators finish their recording, naming the file by client code and date (year-month-day).

c.) Video/Audio files are stored locally on the password-protected encrypted recording device.

e.) Video/audio files are downloaded using an appropriate PC or Laptop onto an encrypted container within a USB external drive stored in a locked clinic filing cabinet.

f.) Once downloaded and placed into the encrypted container, video/audio files are wiped from the cloud and recording device.

g.) The USB hard drive is removed and placed back into the locked research clinic filing cabinet.

Data will be retained for a minimum of 5 years.

P6) Project start date

10 Dec 2018

P7) Anticipated project end date

30 Sept 2019

P8) Where will the research take place?

City, University of London campus

P9) If the research is taking place at a time or in a place that could potentially put the researcher at risk (e.g. research taking place in a participant's home) please provide details of the lone working policy you will be following.

City, University of London's

Department of Psychology

Lone Worker Guidelines

When conducting research both on and off site, think about your personal safety when considering times and locations. Try to conduct research in public locations, within office hours as much as possible. If conducting research offsite, the gold standard is to go in pairs – however this may be impractical, so it becomes essential that you consider personal safety.

Procedure for meeting participants offsite

- Record the name of the person or persons you are meeting and the location in a calendar that is shared with team members. Alternatively you may communicate the details of your meeting with your supervisor or a research team member, who should act as your safety contact.

- Ensure that you have provided your mobile number to your safety contact.

- If you are meeting a participant in a non-public location (e.g., their home) call your safety contact before you enter and again when you leave, giving them a rough estimate of how long the meeting should be.

- If you are meeting with a participant in a non-public location, arrange a codeword with your safety contact, which can be used to alert them to high-risk situation and the need for assistance.

- Where possible, arrange the layout of any meeting room so that you have easy access to exits and telecommunications, avoiding obstacles.

-□ Where applicable, know the relevant security numbers for your location. On your phone have these calls on quick dial.

-□ Take a personal alarm with you (these are available in the HSR office).

-□ Always behave in a professional manner (see BPS codes of Conduct).

-□ If you feel that a situation is becoming unsafe, immediately extract yourself. Personal safety is a priority over study data. Remember to then report back to your security contact so this information can be shared and taken into account in future risk assessments.

-□ Unless necessary for the meeting, try to avoid taking expensive equipment or valuables.

-□ Don't advertise laptops by carrying them in a laptop bag -□ use something nondescript.

-□ Remember computer equipment (Laptops, USB Keys, Portable hard Drives) need to meet relevant Data Protection and Encryption levels (further documentation is available).

P10) Is this application or any part of this research project being submitted to another ethics committee, or has it previously been submitted to an ethics committee?
Yes

P10.1) Please give details and justification for going to separate committees, details of the Secretary of the relevant authority/committee, and, if appropriate, attach correspondence and details of the outcome of the application, including any conditions of approval or reasons for rejection.
The protocol which was already approved by City's Department of Psychology Research Ethics Committee in October 2017 (Ref: PSYETH (S/F) 17/18 01) laid out the basic procedures for a counselling psychology training and research clinic, based here at City, University of London. Updates, revisions and additions to this protocol will continue to be submitted for ethics approval over time which includes the modifications to the current study detailed herein. Therefore, we would like to apply for ethical approval for this modified study which entails a change of research design and recruitment plans.

Human participants: information and participation

H1) Will persons from any of the following groups be participating in the project?
None of the above

H2) How many participants will be recruited?
40

H3) Explain how the sample size has been determined.
Given that this is a pilot study, we are investigating the feasibility of the brief psychotherapuetic group interventions in a university setting. Therefore, no sample size is being calculated at this time.

H4) What is the age group of the participants?

Lower	Upper
18	

H5) Please specify inclusion and exclusion criteria.

University Student Participants

We expect to recruit approximately 20-40 participants. Participants may be students at City, University of London, or they may be external to the university.

Exclusion/Inclusion Criteria

Inclusion criteria, as identified at the screening interview, are that individuals:

•Are enrolled students

•At least 18 years of age

•Believe that a psychological intervention may be of benefit to them

•Have a score between 5 -15 on the GAD-7 and <15 on the PHQ-9

Exclusion criteria, as identified at assessment, are:

•Severe and enduring mental health problems, such as such as psychotic disorders, personality disorders or dependent drug use where they are the primary problem and/or may significantly interfere with treatment

•Individuals currently receiving psychological therapy elsewhere

•Students on Masters or Doctoral-level courses in the Department of Psychology at City, University of London. (Undergraduate students in the Department of Psychology will not be seen by academic members of the counselling psychology team).

H6) What are the potential risks and burdens for research participants and how will you minimise them?

1. CLINICAL DETERIORATION

The principal potential risk for students in participating in this study is that the interventions may worsen their psychological health. Research indicates that around 5-10% of clients deteriorate as a result of participating in counselling or psychotherapy (Cooper, 2008). In many cases, it is likely that these changes are due to external life circumstances, rather than the intervention itself. However, if there is deterioration, we will discuss this with the participant concerned and explore additional, or alternative, forms of support. If participants are students at City, University of London, we will also discuss with them additional support from the University's Student Counselling and Mental Health Services for further support.

Guidance on managing suicidal risk in clients will be provided to researchers, which includes procedures for reporting adverse events (Appendix J). If the participant showing risk issues is a student at City, University of London, this information will be shared with the student health services, such that appropriate university measures and procedures can be implemented. Normally, this would be with the participant's full agreement. In addition, this procedure will be made aware to prospective participants in the information sheet, and, for participation in the study, they will need to give signed consent in agreement with it.

Levels of psychological distress in clients will be tracked throughout the therapeutic work (GAD-7 & PHQ-9), and any deterioration will be discussed with the participant and, if necessary, alternative sources of support will be explored.

Facilitators are asked to record instances of risk after every session with participant, including no change in risk status.

Facilitators will also have details of the participants' GPs and will discuss with them the possibility of contacting the GP in the case of severe deterioration (in the case of City, University of London students, this would be through the Student Counselling and Mental Health Services). This would normally be with the participant's consent. However, in exceptional cases where high levels of risk are present (see Clinic Safety Guidelines, Appendix J), the facilitator may contact the GP directly.

2. MEASURES

Participants may experience some boredom, irritation or other negative feelings when completing some of the forms (although, on average, the forms have been rated in pilot studies as more helpful than unhelpful). They may also feel self-conscious when having sessions recorded.

3. ANONYMITY

There is a danger that participants may be able to identify themselves in case studies that are written once the study is completed and, in a very few of these instances, may experience some feelings of distress. To minimise this as far as possible, no identifying details will be used in case studies, and/or details may be altered to protect the participants' identity.

4. DISCLOSURE OF STUDENT INFORMATION

To minimise the possibility that participants will be assigned to facilitators who they have personal knowledge of, we will exclude from participation in the study any students or trainees who are on graduate programmes in the Department of Psychology. Participants will also be informed of the name of their allocated assessor prior to assessment session, and informed that they should choose to ask for a different assessor should they have knowledge of this person. The City Counselling Psychology Training and Research Clinic will have no direct access to any student records. Disclosures from the research clinic to the Student Counselling and Mental Health Services will only be in the event of risk or in the case of onward referral if participants report clinically significant issues that are not addressed by significant focus of the interventions.

5. RISK TO OTHERS

Guidance on identifying and acting on risk to others in the participant's lives is given to facilitators in Appendix J. This also provides facilitators with a disclosure policy to indicate where there is a necessity to disclose information about child abuse and risk. Disclosure policy are as per standard for the counselling and psychotherapy field (they have been adapted from the policies of the Metanoia Institute's long-standing therapeutic clinic) and compliant with relevant legislation. Facilitators are also asked to record any instances of risk to other.

6. COERCION

A potential ethical concern may be that students will feel obliged to participate in the study. However, the participant information sheet will give prospective participants full advice on what to expect from the study, and they will be no financial incentive to participate. If, at any point, it is established between participant and facilitator/researcher that the participant would benefit from an alternative psychological interventions, an onward referral will be discussed.

7. CONFLICT OF INTEREST BETWEEN RESEARCH AND CLINICAL PRACTICE

The research clinic has a dual aim: to develop a greater understanding of psychotherapeutic outcomes and processes; and to help reduce levels of psychological distress in participants. Although the research aim is the principal rationale for establishing the research clinic, the clinical aim will take precedent in instances where there is a potential conflict of interest. An example of this

might be where a participant indicates that they find it distressing to complete a particular measure. Here, the researcher would agree with the participant to stop using the measure, even though this may compromise the quality of the dataset.

8. CONFIDENTIALITY OF DATA

All personal data (signed consent forms) will be stored separately from anonymised data and partially anonymised data in a locked cabinet at City, University of London.

Anonymised data (all electronic forms and measures) will be collected and initially stored using cloud technology, with SSL encryption between computers and the cloud server. Text data will be encrypted. When transferred to City, University of London it will be stored in an encrypted portion of an external hard drive that will be locked in a secure cabinet. Any hard copies of anonymised data (e.g., print offs of therapist notes) will be stored in a locked and secure cabinet.

Partially anonymised data (video/audio recordings of sessions) will be stored using the following procedures:

a.Video/audio files of group sessions are recorded using a password-protected encrypted recording device;

b.Facilitators finish their recording, naming the file by client code and date (year-month-day).

c.Video/Audio files are stored locally on the password-protected encrypted recording device.

e.Video/audio files are downloaded using an appropriate PC or Laptop onto an encrypted container within a USB external drive stored in a locked clinic filing cabinet.

f.Once downloaded and placed into the encrypted container, video/audio files are wiped from the cloud and recording device.

g.The USB hard drive is removed and placed back into the locked research clinic filing cabinet.

Data will be retained for a minimum of 5 years.

H7) Will you specifically recruit pregnant women, women in labour, or women who have had a recent stillbirth or miscarriage (within the last 12 months)?

No

H8) Will you directly recruit any staff and/or students at City?

None of the above

H8.1) If you intend to contact staff/students directly for recruitment purpose, please upload a letter of approval from the respective School(s)/Department(s).

H9) How are participants to be identified, approached and recruited, and by whom?

For the present study, university students will be recruited via referrals made by local student services, an advertisement on the university's website (SONAS), and through printed leaflets, which will be placed at several designated areas around the university campus. Please see recruitment flyer for an example.

Participants will be invited to contact the study lead and receive a Participant Information Sheet via email the email address and, if still interested in participating, will be invited for a screening interview of up to 120 minutes. The protocol for this assessment is provided below. Demographic information

will be collected at the screening interview. The General Anxiety Disorder-7 (GAD-7) and the Patient Health Questionnaire (PHQ-9) measures will be used as screening instruments to determine eligibility for participation in the study. Participants who meet the inclusion criteria and not exclusion criteria will be invited to take part in the study, and randomised into one of the three groups (ACT Group Intervention, MBSR Group Intervention or Waitlist Control) using a random number generator. Participants who do not meet the inclusion criteria will be sign-posted to an appropriate service such as the student counselling service and/or their GP.

The screening interview will be conducted by a qualified counselling or clinical psychologist from the research clinic.

Screening Interview

At the start of the screening interview, the assessor will go over the information sheet with the participant, answer any questions, and invite them to sign a consent form if they are willing to participate in the study. They will then be asked to complete the following forms:

•The Patient Health Questionnaire 9 measure of depression (PHQ-9)

•The Generalised Anxiety Disorder 7 measure of anxiety (GAD-7)

•Demographics Form

If the student is eligible for participation in the study, based on a GAD-7 score between 5-15 and a PHQ-9 score <15, the assessor will then discuss with the participant their reasons for wanting to participate in the study. Prior to completing this screening interview, the participant will also complete a paper version of the Clinic Identity Form

In this screening process, the assessor will also explore with the client their background and reasons for wanting to participate in the study, their psychological/psychiatric history, and any risk factors. On this basis, assessors will assess whether prospective clients meet the eligibility criteria for participation in the study. Where potential participants, at screening, do not meet the eligibility criteria, the assessors (who will all be trained therapists) will discuss this with the prospective participant in a sensitive manner, and explore alternative forms of appropriate care outside the protocol. This may involve suggestions for alternative therapeutic services, or a suggestion that they discuss issues with their GP. See appendix G for screening interview.

During the assessment interview, details of any formal and informal support services and networks that the client draws on should be ascertained for all externally recruited participants.

A risk assessment will be carried out and, where appropriate, resources and strategies to minimize risk that the participant uses will be discussed and documented. A ‘map’ that sets out pathways in the event of a crisis will be set out during the screening interview.

GP details for all participants will be held on record by the research team. Participants will be informed that their GP would be contacted only if a member of the research team becomes concerned about issues of risk of the participant to themselves or others.

H10) Please upload your participant information sheets and consent form.
H11) If appropriate, please upload a copy of the advertisement, including recruitment emails, flyers or letter.
H12) Describe the procedure that will be used when seeking and obtaining consent, including when consent will be obtained.

Yes, informed consent will be collected by the assessor in person at the end of the screening interview. A copy of the form will also be provided to the participant. In addition to receiving an information sheet, participants will have been verbally briefed by the researcher at the screening interview and will be provided a participant information sheet. No written debrief will be provided since all relevant information will be contained in the protocol and the participant information sheet. There will be a duration of a minimum of 2 weeks waiting period between the participants receiving information about the study and conducting the project.

H13) Are there any pressures that may make it difficult for participants to refuse to take part in the project?
No

H14) Is any part of the research being conducted with participants outside the UK?
No

Human participants: method

M1) Will any of the following be involved in the project:
None of the above

M2) Does the project involve any deceptive or covert research practices?
No

M3) Is there a possibility for over-research of participants?
No

M4) Please upload copies of any questionnaires, topic guides for interviews or focus groups, or equivalent research materials.
M5) Will participants be provided with the findings or outcomes of the project?
Yes

M5.1) Explain how this information will be provided.
The study participants will be notified in the breif and debrief of this study to contact the researcher if they would like a summary of the study results. The summary may be emailed or posted to participants for their information.

M6) If the research is intended to benefit the participants, third parties or the local community, please give details.
A potential outcome of this study is to inform current student services providing psychological support to university students as well as HEI leaders on potentially effective psychological programmes to deliver for this population.

M7) Are you offering any incentives for participating?
No

M8) Does the research involve clinical trial/intervention testing that do not require Health Research Authority or MHRA approval?
No

M9) Will the project involve the collection of human tissue or other biological samples that does not fall under the Human Tissue Act (2004) that does not require Health Research Authority Research Ethics Service approval?
No

Data

D1) Indicate which of the following you will be using to collect your data.
Questionnaire
Participant observation
Audio/digital recording interviewees or events
Video recording

D2) How will the the privacy of the participants be protected?
De-identified samples or data

D3) Will the research involve use of direct quotes?
Yes

D5) Where/how do you intend to store your data?
Data to be kept in a locked filing cabinet
Data and identifiers to be kept in separate, locked filing cabinets
Password protected computer files
Storage on encrypted device (e.g. laptop, hard drive, USB
Storage at City

D6) Will personal data collected be shared with other organisations?
No

D7) Will the data be accessed by people other than the named researcher, supervisors or examiners?
Yes

D7.1) Explain by whom and for what purposes.
Data may be accesssed by the research clinic administrator, data manager and research assistant/associates for research, teaching and training purposes only. Where necessary, we will ensure that confidentiality is upheld.

D8) Is the data intended or required (e.g. by funding body) to be published for reuse or to be shared as part of longitudinal research or a different/wider research project now or in the future?
No

D9) Does the funding body or your professional organisation/affiliation place obligations or recommendations on the retention and destruction of research data?
No

D9.1) What are your affiliations/funding and what are the requirements?

D10) How long are you intending to keep the research data generated by the study?
For up to five years.

D11) How long will personal data be stored or accessed after the study has ended?
For up to five years.

D12) How are you intending to destroy the personal data after this period?
Paper documents (ie. informed consent forms) with personal data will be securely destroyed.

Health & safety

HS1) Are there any health and safety risks to the researchers over and above that of their normal working life?
No

HS3) Are there hazards associated with undertaking this project where a formal risk assessment would be required?
No

Attached files

Approved Psychological Therapies Training Research Clinic Ethics Protocol.docx

CPsych Research Clinic participant-information-sheet.doc

CPsych Research Clinic Consent Form.doc

CPsych Research Clinic Advert final.pdf

Research Clinic Ethics Appendices.docx

CITY
UNIVERSITY OF LONDON
EST 1894

Psychological Therapies Research Clinic Ethics Protocol (2017/18)

Department of Psychology

Psychology Department PROTOCOL Ethics Application Form

This form is for the review of research methods or protocols that:

(a) represent more than minimal risk (and therefore require full committee review)
(b) are to be used in more than one research study

Note that even if you receive approval for this protocol you will still need to seek approval for studies that employ this protocol. However, you may refer to the ethics approval code for this protocol in these applications so that they need only be reviewed in relation to the other elements of the study. This means that they may be eligible for light touch review.

This form should be completed in full. Staff should email it to psychology.ethics@city.ac.uk. Students should email it to their supervisor. Where applicable, please ensure you include the accompanying documentation listed in question 13.

Is this project supported by external funding?	**Yes**	**No**
		X
If you answered yes, please provide the name of the funding body and the amount awarded.		

1. Name of applicant(s).
Jessica Jones Nielsen (Study Lead and Supervisor); Fran Smith (Study Supervisor/Therapist); Julianna Challenor (Study Supervisor/Therapist)
2. Email(s).
Jones.Nielsen.1@city.ac.uk Julianna.challenor@city.ac.uk Fran.Smith.1@city.ac.uk
3. Protocol title.
A pilot study of Acceptance and Commitment Therapy (ACT) for anxiety in a university setting
4. Provide a lay summary of the aim of this protocol. (No more than 400 words.)
The aim of this study is to pilot a ten-week protocol, the procedures for delivering and providing preliminary data for assessing outcomes in Acceptance and Commitment Therapy (ACT) for anxiety in clients at the City Counselling Psychology Training and Research Clinic. The protocol is intended to lay out the basic procedures for a counselling psychology training and research clinic, based at City, University of London. It is likely that updates, revisions and additions to this protocol will be submitted for ethics over time. Therefore, we would like to apply for ethical approval for this “base” protocol on which subsequent amendments can be proposed. One of the most widely practiced and researched of the new CBT treatments, ACT is an empirically derived, time-limited intervention that has been used to successfully to treat anxiety disorders. In the approach, ACT aims to increase acceptance and mindfulness processes that are integrated with commitment and behaviour change processes (Eifert, Forsyth, Arch, Espejo, Keller et al., 2009). ACT characterises anxiety disorders as caused by experiential and emotional avoidance (Hayes, Strosahl & Wilson, 1999), and seeks to reduce excessive struggle with anxiety and experiential avoidance with the goal of promoting more

flexible ways of relating to anxiety so that individuals can pursue the goals that are important to them.

ACT incorporates mindfulness, acceptance and compassion in its therapeutic model in order to facilitate psychological flexibility, a reduction in avoidance, improved emotion regulation and a corresponding reduction in emotional suffering. ACT has been shown to be effective for a range of anxiety disorders and is therefore a treatment for a heterogeneous client population presenting with diverse forms of anxiety. A ten-week protocol that has been adapted from Forsyth and Eifert (2016), will be delivered to client participants by qualified and registered counselling and/or clinical psychologists on City, University of London premises. Outcomes and processes will be assessed and if found to be effective, will provide evidence for expanding the study in a second, larger research phase.

5. Provide details of all the methods of data collection you will employ (e.g., questionnaires, reaction times, skin conductance, audio-recorded interviews).

Design: The study will utilize a waist-list cross-over treatment design with participants randomized to the immediate treatment condition or the wait-list condition. Participants who are randomized to the immediate treatment condition will engage in 10 consecutive ACT therapy sessions over 10-weeks lasting 50 minutes each. Following the 10 weeks, the wait-list participants will be crossed to the active intervention arm, and will complete 10 consecutive therapy sessions. Participants in the immediate treatment condition will be assessed at pre-treatment, at 12 weeks (post-treatment), at 6 months and at 9 months. Wait-list participants will alos be assessed at pre-treatment, 12 weeks (following the waiting period), at 6 months (serving as post-treatment assessment following crossover to the immediate treatment condition), and at 9 months.

Therapeutic intervention: The ACT protocol proposed in this study has been adapted from a manual developed by Forsyth and Eifert (2016). Rizert et al (2016) evaluated effectiveness of this ACT self-help workbook with no therapist contact. 503 participants were randomised to immediate workbook or waitlist condition. The workbook group demonstrated significant improvements in being less avoidant, more present, increased self-compassion and accepting of experiences. In addition significant reductions in anxiety, worry and depression were reported. All improvements were maintained at follow ups (12 weeks, 6 months and 9 months)

The therapy will target core processes in the ACT model, with the goal of reducing avoidance of emotional distress, increased self-compassion and acceptance of experiences. In addition, significant reductions in anxiety, worry and depression are expected. There will be 10 sessions each lasting 50 minutes, (the conventional therapeutic intervention duration). The first five and last five minutes of each session will be for measure completion. The focus of each session is detailed in the ACT protocol (Appendix C).

Researcher/Practitioners: The ACT protocol in this study will be delivered by members of the counselling psychology staff who are all qualified and HCPC registered counselling and/or Clinical Psychology practitioners. They will all have received training in ACT, and will undertake weekly clinical and ACT-specific peer supervision to ensure fidelity to the model. The research will be evaluated by the named staff members on this application and will not provide therapy but supervision to those delivering the ACT protocol to the study participants

Evaluation: Evaluation of the protocol will be conducted by the researchers named above. The evaluation will comprise of the outcome measures that will be self-administered at the start of each session and collected by the researcher, and one therapy process measure that will be completed at the end of each session. To ensure confidentiality, questionnaires will be de-identified and assigned a code. The researcher will remind the participants that they can choose not to complete the questionnaires or answer any of the questions. The questionnaires will be stored in a locked filing cabinet in the research clinic office until the data have been entered into a computer, after which hard copies will be securely destroyed.

Measures: The following measures will be employed for outcome data:

1. Client Demographic Form

At pre-measurement, demographic information will be collected, including age, gender, education, relationship, and employment status.

1. Acceptance and action questionnaire–II (AAQ-II)

This is a one-factor measure of psychological inflexibility, or experiential avoidance. The scale is scored by adding together the seven items. Higher scores equal greater levels of psychological inflexibility.

2. Generalised Anxiety Disorder Assessment (GAD-7)

This is a seven item self-administered instrument that is used to measure or assess the severity of generalised anxiety disorder (GAD). Each item asks the individual to rate the severity of his or her symptoms over the past two weeks. Response options include “not at all”, “several days”, “more than half the days” and “nearly every day” respectively, and then adding together the scores for the seven questions. GAD-7 total score for the seven items ranges from 0 to 21.

Scores represent:

- 0-5 = Mild anxiety
- 6-10 = Moderate anxiety
- 11-15 = Moderately severe anxiety
- 15-21 = Severe anxiety

When used as a screening tool, further evaluation is recommended when the score is 10 or greater.

3. Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a nine-item self-administered scale used to measure or assess the severity of depression. Each item asks the individual to rate the severity of his or her symptoms over the past two weeks. Response options include “not at all”, “several days”, “more than half the days” and “nearly every day” respectively, and then adding together the scores for the seven questions.

Scores represent:

- 5-9 = mild depression/low mood
- 10-14 – moderate depression/low mood
- 15-19 – moderately severe depression/low mood
- 20-27 – severe depression/low mood

When used as a screening tool, further evaluation is recommended when the score is 10 or greater.

4. Audio recordings

Audio recordings will be used in supervision to ensure fidelity to the model, and may also be analysed using qualitative analytic approaches at a later date. Partially anonymised data (audio recordings of sessions) will be stored using the following procedures:

a. Audio files of therapy sessions are recorded using a password-protected encrypted recording device
b. Therapists finish their recording, naming the file by client code and date (year-month-day).
c. Audio files are stored locally on the password-protected encrypted recording device.
d. Audio files are downloaded using an appropriate PC or Laptop onto an encrypted container within a USB external drive stored in a locked clinic filing cabinet.
e. Once downloaded and placed into the encrypted container, audio files are wiped from the handheld device.
f. The USB hard drive is removed and placed back into the locked clinic filing cabinet.

5. Follow-up

Follow-up data will be collected at 12 weeks, 6 months and 9 months via a phone call from the therapist and will follow a standard protocol of ratings in which the participant will be asked to rate the level of their struggle with anxiety, their willingness to experience psychological discomfort, their practice of mindful acceptance, and progress in their life goal directed action (Rizert et al., 2016).

References:

Eifert, G.H., Forsyth, J.P., Arch, J., Espejo, E., Keller, M. et al. (2009) Acceptance and Commitment Therapy for Anxiety Disorders: Three case studies exemplifying a unified treatment protocol. *Cognitive and Behavioral Practice* 16, 368 – 385

Fortsyth, J.P. & Eifert, G.H. (2016) *The Mindfulness & Acceptance Workbook for Anxiety*. Oakland: New Harbinger Publications.

Hayes, S.C., Strosahl, K., & Wilson, K.G. (1999) *Acceptance and Commitment Therapy: An experiential approach to behavior change*. New York: Guildford Press

Rizert, T.R., Forsyth, J. P., Sheppard, S. C., Boswell, J. F, Berghoff, C. R & Eifert, G. H (2016). Evaluating the Effectiveness of ACT for Anxiety Disorders in a Self-Help Context: Outcomes from a randomised wait list controlled trial. *Behavior Therapy.*

6. Is there any possibility of a participant disclosing any issues of concern during the course of the research? (e.g. emotional, psychological, health or educational.) Is there any possibility of the researcher identifying such issues? If so, please describe the procedures that are in place for the appropriate referral of the participant.

It is possible that participants may disclose issues of concern during the study, for example in relation to their university course, their relationships and mental health and well-being.

Disclosure of student information

To minimise the possibility that clients will be assigned to therapists who they have personal knowledge of, we will exclude from participation in the study any students or trainees who are on graduate programmes in the Department of Psychology (including all counselling and applied psychology programmes). Clients will also be informed of the name of their allocated assessor prior to assessment, and informed that they should choose to ask for a different

assessor should they have knowledge of this person. The Training & Research Clinic will have no direct access to any student records. In the event of areas of concern relating to education, participants will be advised to contact their tutor and then course director. In cases of risk or where participants report clinically significant issues that are not addressed by significant focus of the intervention, participants will be referred to student services for further on going support.

For health concerns they will be advised to contact their GP. Emotional and psychological concerns will be managed by the therapist as part of the intervention. All of the researchers delivering the protocol will be qualified and experienced counselling or clinical psychologists, registered to practice with the Health and Care Professions Council (HCPC). The researchers will all have the training and experience to work in an appropriate way
with educational, emotional, psychological, health and educational areas of concern. They will follow professional practice guidelines which are to refer to external clinical services in the event that participants disclose issues relating to risk of harm to themselves or others, or a safeguarding issue as defined by the BPS and HCPC.

7. Details of participants (e.g. age, gender, exclusion/inclusion criteria). Please justify any exclusion criteria.

Participants

We expect to recruit approximately 24-36 participants per academic year.

Participants may be students at City, University of London, or they may be external to the University.

Recruitment

Small posters, inviting participants to make contact with the research project will be placed across City, University of London campus. Please see recruitment flyer (Appendix A) for an example. Individuals who make contact will then be sent a Participant Information Sheet (Appendix B) and, if still interested in participating, will be invited for an assessment interview of up to 120 minutes. The protocol for this assessment is given in Appendix C. The aim of the assessment is to identify whether clients are eligible to participate in the study, their goals for therapy. The assessment will be conducted by a qualified counselling or clinical psychologist.

Assessment session

At the start of the assessment session, the assessor will go over the information sheet with the participant, answer any questions, and invite them to sign a consent form (Appendix D) if they are willing to participate in the study. They will then be asked to complete the following forms:

- The Patient Health Questionnaire 9 measure of depression (PHQ-9) (Appendix E)
- The Generalised Anxiety Disorder 7 measure of anxiety (GAD-7) (Appendix F)
- The Acceptance and Action questionnaire (AAQ-II) (Appendix G)
- Client Demographics Form (Appendix H)

If the client is eligible for participation in the study, based on a GAD-7 score of 10 or greater (indicating moderately severe anxiety), the assessor will then discuss with the participant their reasons for wanting to participate in therapy. Prior to completing this initial session, the client will also complete a paper version of the Client Identity Form (Appendix I)

In this assessment process, the assessor will also explore with the client their background and reasons for coming to therapy, their psychological/psychiatric history, and will assess their style of relating. On this basis, assessors will assess whether prospective clients meet the eligibility criteria for participation in the study. Where clients, at assessment, do not meet the eligibility criteria, the assessors (who will all be trained therapists) will discuss this with the prospective client in a sensitive manner, and explore alternative forms of appropriate care outside the protocol. This may involve suggestions for alternative therapeutic services, or a suggestion that they discuss issues with their GP.

Weekly sessions (session by session, SbS)

At the beginning of each counselling session, clients will be invited to complete the PHQ9 and GAD7. Therapists will be instructed to practice according to the manual of the ACT for Anxiety

Protocol (see Appendix C) and will be assessed by their supervisor for adherence to the protocol.

In total, clients would be expected to spend approximately 10 minutes completing measures, before and after session.

All audio sessions will be recorded on a password-protected, encrypted recording device.

Endpoint interview
Within two weeks of completing therapy, participants will be invited back to meet with a researcher and to complete final copies of the outcome (PHQ-9, GAD-7,) and process measure (AAQ-II).

Additional information
The number of sessions offered to clients will be up to a maximum of 10, normally on a weekly basis. This will not be extended, but the psychologists will discuss with clients, towards the end of their therapy, alternative sources of psychological help.
Participants who miss two scheduled appointments without informing the Clinic prior to their absence ('DNAs') will normally be discharged. Sessions that are missed without notification will normally be deducted from the client's overall allocation.
Sessions will normally last 50-60 minutes, with 90 minutes for assessment sessions.
Therapists will be fully qualified counselling or clinical psychologists.
Clients are eligible to withdraw from one or more of the components of research at any point without giving reason for doing so, though they would still have the opportunity to continue with therapy.

Exclusion/Inclusion Criteria
Inclusion criteria, as identified at assessment, are that individuals:

- Are over 18 years of age;
- Have an aspect of their life that they would like to improve;
- Believe that a psychological intervention may be of benefit to them;
- Have a score of 10 or more on the General Anxiety Disorder-7 (GAD-7) at assessment interview.

Exclusion criteria, as identified at assessment, are:

- Severe and enduring mental health problems, such as such as psychotic disorders, personality disorders or dependent drug use where they are the primary problem and/or may significantly interfere with treatment
- Individuals currently receiving psychological therapy elsewhere
- Students on Masters or Doctoral-level courses in the Department of Psychology at City, University of London. (Undergraduate students in the Department of Psychology will not be seen by academic members of the counselling psychology team).

8. How will participants be selected and recruited? Who will select and recruit participants?

Information about the study will be publicised on the City, University of London website and with fliers across the campus. Participants will be invited to contact the study lead and receive an information sheet via their email address. If after reading the information sheet they would like to be screened for inclusion, they will be asked to contact the lead researcher and will be invited to a meeting for screening and to complete the GAD-7 measure. Participants who meet the inclusion criteria and not exclusion criteria and who score above 10 on the GAD-7 will be invited to take part in the study. Participants who do not meet the inclusion criteria will be sign-posted to an appropriate service such as the student counselling service and/or their GP. Once maximum numbers are reached, a waiting list control group will be created as is the convention in psychological therapy outcome studies.

Community-based participants
Non-student clients will be recruited through established community services, rather than through public advertising in newspapers or on the internet, etc. Wherever possible, referral agencies that have 'fall back' and/or crisis management capacity will be preferred over those that are making referrals and then formally closing the service's input to that client.

During the assessment interview, details of any formal and informal support services and networks that the client draws on should be ascertained for all externally recruited clients.

A risk assessment will be carried out and, where appropriate, resources and strategies to minimize risk that the client uses will be discussed and documented. A 'map' that sets out pathways in the event of a crisis will be set out during the assessment.

GP details for all participants will be held on record by the research team. Participants will be informed that their GP would be contacted only if a member of the research team becomes concerned about issues of risk of the participant to themselves or others

In instances where prospective participants miss two or more scheduled assessment appointments without notification, the referral will be terminated and the referring service and prospective participant will be informed. The prospective participant may re-join the waiting list for an assessment appointment at a later date.

9. Will informed consent be obtained from all participants? If not, please provide a justification.

Yes, informed consent (see Appendix D) will be collected in person at the end of the screening session.

10. How will you brief and debrief participants? (Note that where applicable, copies of your information sheet and debrief, or relevant section of these, should be included with your application, see question 13.)

In addition to receiving an information sheet, a written description of the protocol, and information about ACT, participants will have been verbally briefed by the researcher at the screening session. No written debrief will be provided since all relevant information will be contained in the protocol and the participant information sheet. The nature of ACT encourages participant clients to ask questions throughout the sessions as part of the therapeutic process.

11. What potential risks to the participants do you foresee, and how do you propose to deal with these risks? These should include both ethical and health and safety risks.

Clinical deterioration

The principal potential risk for clients in participating in this study is that the therapy may worsen their psychological health. Research indicates that around 5-10% of clients deteriorate as a result of participating in counselling or psychotherapy (Cooper, 2008). In many cases, it is likely that these changes are due to external life circumstances, rather than the intervention itself. However, if there is deterioration, we will discuss this with the participant concerned and explore additional, or alternative, forms of support. If participants are students at City, University of London, we will also discuss with them additional support from the University's Student Counselling and Mental Health Services for further support.

Guidance on managing suicidal risk in clients will be provided to researchers, which includes procedures for reporting adverse events (Appendix J). If the participant showing risk issues is a student at City, University of London, this information will be shared with the student health services, such that appropriate university measures and procedures can be implemented. Normally, this would be with the participant's full agreement. In addition, this procedure will be made aware to prospective participants in the information sheet, and, for participation in the study, they will need to give signed consent in agreement with it.

Levels of psychological distress in clients will be tracked throughout the therapeutic work (GAD-7 & PHQ-9), and any deterioration will be discussed with the client and, if necessary, alternative sources of support will be explored.

Researchers are asked to record instances of risk after every session with clients, including no change in risk status.

Researchers will also have details of the clients' GPs and will discuss with them the possibility of contacting the GP in the case of severe deterioration (in the case of City, University of London students, this would be through the Student Counselling and Mental Health Services). This would normally be with the client's consent. However, in exceptional cases where high levels of risk are present (see Clinic Safety Guidelines, Appendix J), the researcher may contact the GP directly.

Measures
Participants may experience some boredom, irritation or other negative feelings when completing some of the forms (although, on average, the forms have been rated in pilot studies as more helpful than unhelpful). They may also feel self-conscious when having sessions recorded.

Anonymity
There is a danger that participants may be able to identify themselves in case studies that are written once the study is completed and, in a very few of these instances, may experience some feelings of distress. To minimise this as far as possible, no identifying details will be used in case studies, and/or details may be altered to protect the participants' identity.

Disclosure of Student Information
To minimise the possibility that participants will be assigned to researchers who they have personal knowledge of, we will exclude from participation in the study any students or trainees who are on graduate programmes in the Department of Psychology. Participants will also be informed of the name of their allocated assessor prior to assessment, and informed that they should choose to ask for a different assessor should they have knowledge of this person. The City Counselling Psychology Training and Research Clinic will have no direct access to any student records. Disclosures from the clinic to the Student Counselling and Mental Health Services will only be in the event of risk or in the case of onward referral if participants report clinically significant issues that are not addressed by significant focus of the intervention,.

Risk to Other
Guidance on identifying and acting on risk to others in the participant's lives is given to researchers in Appendix J. This also provides researchers with a disclosure policy to indicate where there is a necessity to disclose information about child abuse and risk. Disclosure policy are as per standard for the counselling and psychotherapy field (they have been adapted from the policies of the Metanoia Institute's long-standing therapeutic clinic) and compliant with relevant legislation. Therapists are also asked to record any instances of risk to other.

Coercion
A potential ethical concern may be that students will feel obliged to participate in the clinic protocol. However, the information sheet will give prospective participants full advice on what to expect from the service, and they will be no financial incentive to attend. If, at any point, it is established between participant and researcher that the client would benefit from an alternative therapeutic orientation, an onward referral will be discussed.

Conflict of interest between research and clinical practice
The research clinic has a dual aim: to develop a greater understanding of psychotherapeutic outcomes and processes; and to help reduce levels of psychological distress in participants. Although the research aim is the principal rationale for establishing the clinic, the clinical aim will take precedent in instances where there is a potential conflict of interest. An example of this might be where a client indicates that they find it distressing to complete a particular measure. Here, the researcher would agree with the client to stop using the measure, even though this may compromise the quality of the dataset.

Confidentiality of data
All personal data (signed consent forms) will be stored separately from anonymised data and partially anonymised data in a locked cabinet at City, University of London.

Anonymised data (all electronic forms and measures) will be collected and initially stored using cloud technology, with SSL encryption between computers and the cloud server. Text data will

be encrypted. When transferred to City, University of London it will be stored in an encrypted portion of an external hard drive that will be locked in a secure cabinet. Any hard copies of anonymised data (e.g., print offs of therapist notes) will be stored in a locked and secure cabinet.

Partially anonymised data (audio recordings of sessions) will be stored using the following procedures:

a. Audio files of therapy sessions are recorded using a password-protected handheld device
b. Therapists finish their recording, naming the file by client code and date (year-month-day).
c. Audio files are stored locally on the handheld device.
d. Audio files are automatically encrypted and uploaded to One-Drive, in accordance with University recommendations
e. Audio files are downloaded using an appropriate PC or Laptop onto an encrypted container within a USB external drive stored in a locked clinic filing cabinet.
    - This encrypted container is created, managed, and accessed using Veracrypt and a correct password.
f. Once downloaded and placed into the encrypted container, audio files are wiped from the cloud and handheld device.
g. The USB hard drive is removed and placed back into the locked clinic filing cabinet.

Data will be retained for a minimum of 5 years.

12. What potential risks to the researchers do you foresee, and how do you propose to deal with these risks? These should include both ethical and health and safety risks.

Given the exclusion criteria and the qualified status of the researchers, we do not foresee any significant ethical or health and safety risks to the researchers. We will ensure that the protocol is delivered during working hours. However, we do acknowledge there is a small danger that therapists may be at physical risk from their clients. To ameliorate this, we will follow the University's Lone Worker Policy (Appendix K) and strive to ensure that a therapist is not working alone in the building. In addition, we will provide the therapists with personal alarms should any physical dangers emerge (see Appendix L). Therapists are also provided with guidance on safety procedures for risk to self as well as to clients. University security will be aware whenever clients are in the building

13. Attachments checklist. *Please ensure you have referred to the Psychology Department templates when producing these items. These can be found on the Research Ethics page on Moodle.

Please place an 'X' in all appropriate spaces

	Attached	Not applicable
***Text for study advertisement**	X	
***Participant information sheet**	X	
***Participant consent form**	X	
Questionnaires to be employed	X	
Debrief		X
Others (please see contents of all documents below) APPENDIX A: Study Flyer APPENDIX B: Participant Information Sheet APPENDIX C: ACT for Anxiety Protocol APPENDIX D: Consent Form APPENDIX E: PHQ-9 Measure APPENDIX F: GAD-7 Measure APPENDIX G: AAQ-II Measure APPENDIX H: Client Demographic Form APPENDIX I: Client Identity Form APPENDIX J: City Counselling Psychology Training & Research Clinic Safety and Disclosure Guidelines APPENDIX K: Lone Worker Guidelines	X	

APPENDIX L: Personal Alarm Procedure		

14. Declarations by applicant(s)

Please confirm each of the statements below by placing an 'X' in the appropriate space

I certify that to the best of my knowledge the information given above, together with accompanying information, is complete and correct.	**X**
I accept the responsibility for the conduct of the procedures set out in the attached application.	**X**
I have attempted to identify all risks related to the research that may arise in conducting the project.	**X**
I understand that **no** research work involving human participants or data can commence until ethical approval has been given.	**X**

	Signature (Please type name)	**Date**
First applicant		**20/07/2017**
Supervisor *(For PhD students and Research Assistants only. Please ensure the supervisor submits the form.)*		

Reviewer Feedback Form

Name of reviewer(s).
Ethics committee (lead reviewer: Kielan Yarrow)
Email(s).
Does this application require any revisions or further information?

Please place an 'X' the appropriate space

No Reviewer(s) should sign the application and return to psychology.ethics@city.ac.uk		**Yes** Reviewer(s) should provide further details below and email directly to the applicant, ccing to psychology.ethics@city.ac.uk	X

Revisions / further information required
To be completed by the reviewer(s)

(1) The committee recommends that you consider whether using a waitlist control group is optimal (please note, this is NOT a requirement for ethical approval). Could you test the therapy more rigorously by comparing it to another intervention? For example, could you compare your proposed 'talking' version of ACT to the ACT self-help workbook mentioned in the application? If you decide to proceed with the original design, more detail is needed for what happens to the waitlist group – which measure will be given and when?

(2) The issue of audio recording of sessions was also discussed in detail. It was felt that participants should be made aware, in the information sheet, that audio recordings of session may be used for future research purposes. Unless this is explained, they are likely to assume it is purely for the purposes of their own therapy. A statement about this needs to be added to the consent form too.

(3) Section 11: Members of the committee were also concerned about the proposed use of an unspecified, password-protected cloud server to store audio data. The university recommends using OneDrive. See: https://www.city.ac.uk/research/about-our-research/research-integrity/research-data-management/preserve-and-store

(4) Some clarification is needed about who is doing what – who are the therapists (students?) and who are the researchers?

(5) The advert should probably mention all exclusion criteria

(6) We recommend that data are retained for a minimum, rather than maximum, of five years. Again, see: https://www.city.ac.uk/research/about-our-research/research-integrity/research-data-management/preserve-and-store

(7) Section 6: The committee were unsure about the proposed letter at discharge to student health services. What is the purpose of this? Is it really necessary?

(8) Another issues raised was the use of the acronym ACT in the advert information sheet – this is likely to be quite meaningless to potential participants. Perhaps you could just include one mention of Acceptance and Commitment Therapy and then refer to 'therapy' or 'talking therapy' rather than 'ACT' in the remainder of the documents.

Minor points

> Section 5 – between-group design (intervention vs. wait-list control) or, arguably, mixed 2x2 (group x pre/post).

> What is “fewer”? (Something that the intervention will reduce, apparently?)

> Section 7 outwith = outside?

> Information – remove “if applicable” from expenses & payments. Rephrase “Participants will be informed that their GP would be contacted only if a member of the research team becomes concerned about issues of risk of the client to themselves or others.” to be client facing.

> Consent – there are some directives to insert details (from the template) that need to be completed, e.g. [*outline steps to be taken*]

> Consent form needs editing to remove “videotaped” as this is not mentioned elsewhere in the application

Applicant response to reviewer comments

To be completed by the applicant. Please address the points raised above and explain how you have done this in the space below. You should then email the entire application (including attachments), with tracked changes directly back to the reviewer(s), ccing to psychology.ethics@city.ac.uk

Please see tracked changes and wording in red throughout the document and side comments addressing the points raised above.

Reviewer signature(s)

To be completed upon FINAL approval of all materials.

	Signature (Please type name)	**Date**
First reviewer	**Ethics Committee**	**4th October 2017**
Second reviewer *(If applicable.)*		

Appendix A: Ethics Approval Letter

Psychology Research Ethics Committee
School of Arts and Social Sciences
City University London
London EC1R 0JD

26 October, 2018

Dear Jessica Jones Nielsen, Fran Smith, Julianna Challenor:

Reference: PSYETH (S/F) 17/18 01
Project title: A pilot study of Acceptance and Commitment Therapy (ACT) for anxiety in a university setting

I am writing to confirm that the research proposal detailed above has been granted approval by the City University London Psychology Department Research Ethics Committee.

Period of approval
Approval is valid for a period of three years from the date of this letter. If data collection runs beyond this period you will need to apply for an extension using the Amendments Form.

Project amendments
You will also need to submit an Amendments Form if you want to make any of the following changes to your research:

(a) Recruit a new category of participants
(b) Change, or add to, the research method employed
(c) Collect additional types of data
(d) Change the researchers involved in the project

Adverse events
You will need to submit an Adverse Events Form, copied to the Secretary of the Senate Research Ethics Committee (anna.ramberg.1@city.ac.uk), in the event of any of the following:

(a) Adverse events
(b) Breaches of confidentiality
(c) Safeguarding issues relating to children and vulnerable adults
(d) Incidents that affect the personal safety of a participant or researcher

Issues (a) and (b) should be reported as soon as possible and no later than 5 days after the event. Issues (c) and (d) should be reported immediately. Where appropriate the researcher should also report adverse events to other relevant institutions such as the police or social services.

Should you have any further queries then please do not hesitate to get in touch.

Kind regards

Trinity Armstrong
Ethics committee Secretary
Email: psychology.ethics@city.ac.uk

Sophie Lind
Chair
Email:Sophie.Lind.2@city.ac.uk

Appendix B: Study Flyer

Department of Psychology
City, University of London

PARTICIPANTS NEEDED FOR RESEARCH IN A STUDY ON ACCEPTANCE AND COMMITMENT THERAPY FOR ANXIETY

Do you feel stress a lot of the time? Are you searching for meaning and purpose in your life? If you think you might be interested in participating in psychological counselling, as part of a project exploring the value of this talking therapy which is a new approach to working with anxiety, we are looking for volunteers to take part in our study.

Participants should be over 18 years of age; have an aspect of their life that they would like to improve; and believe that a psychological intervention may be of benefit to them.

Your participation would involve attending up to 10 therapy sessions free of charge, each of which is approximately 50 minutes, completing a range of questionnaires as part of the counselling experience and having sessions audio-recorded. The therapy will based in the Rhind Building, Northampton Square Campus, City, University of London with experienced practitioners.

- You will not be invited to participate in this study if you:
  - Have a diagnosis of a severe and enduring mental health problem, such as such as psychotic disorders, personality disorders or dependent drug use where they are the primary problem and/or may significantly interfere with treatment
  - Are currently receiving psychological therapy elsewhere
  - Are studying on Masters or Doctoral-level course in the Department of Psychology at City, University of London.

For more information about this study, or to take part, please contact:
Dr Jessica Jones Nielsen or Dr Julianna Challenor

Department of Psychology
at
020 7040 8755 or
Email: jones.nielsen.1@city.ac.uk or julianna.challenor.1@city.ac.uk

This study has been reviewed by, and received ethics clearance through the *[insert committee name here]* Research Ethics Committee, City University London [*insert ethics approval code here*].

If you would like to complain about any aspect of the study, please contact the Secretary to the University's Senate Research Ethics Committee on 020 7040 3040 or via email: Anna.Ramberg.1@city.ac.uk

Appendix C: Participant Information Sheet

Title of Study: A Pilot Study of Acceptance and Commitment Therapy (ACT) for Anxiety 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 Acceptance and Commitment Therapy (ACT) - a psychological therapy - for individuals with anxiety. ACT has 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 a maximum of 10 sessions, which would normally take place once a week. Your first, 'assessment' session will be up to 90 minutes, and the subsequent sessions are 50 minutes each.

Why have I been invited?
We would like to invite between 8 and 12 people for each ten-week block of ACT sessions. 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, and have a score of 10 or more on the General Anxiety Disorder-7 (GAD-7) at assessment interview.

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.

What will happen if I take part?
If you decide to take part, you will be involved for up to 11 weeks, and a total of about 11.5 hours. The first meeting with the researcher/therapist will be an assessment session lasting up to 90 minutes. After that, you will meet the researcher/therapist for one hour once a week, for ten weeks. At these meetings, you will take part in a psychological therapy session, where your researcher/therapist will be using a therapy called ACT. This will last for 50 minutes. Your researcher/therapist will work with you on ways to think about, and experience, worries and feelings. Your researcher/therapist will be a highly qualified psychologist who has been trained to work in therapeutic interventions.

At the start and end of each session you will be asked to complete some questionnaires 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 session to say what you found helpful, and what you found unhelpful.
At the end of the 11 weeks, the results from the questionnaires will be analysed to find out whether there has been a change in the way participants experience their worries and feelings.
All meetings will take place in the Rhind Building, at the Northampton Square campus of City, University of London.

Expenses and Payments
You will not have to pay for participating in the therapy (and you will not be paid for your participation).

What do I have to do?
You will be asked to attend sessions at a certain time and day of each week, and to work with the researcher/ therapist 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 researcher/therapist after the sessions have finished, to find out how you have been since the therapy 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 therapist 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.

Will my taking part in the study be kept confidential?
Only the researcher who is your therapist 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 OneDrive and an encrypted computer drive that is kept in a locked cabinet.
No data will be shared with any staff member of the university other than those in the research team.

Your GP details will be held on record by the research team. Your GP will be contacted only if a member of the research team becomes concerned about issues of risk to you or others.

After anonymising, audio will be accessed by the researcher who is your therapist, and members of the research team. It may be used in future research projects. You will have the option of agreeing to this separately.
Your personal information will be kept confidential for a minimum period of 5 years according to the data protection act.
If the project is abandoned before completion, all data will be destroyed.

What will happen to the results of the research study?
The results of the study will be written up for publication in journals and may be presented at academic conferences. Anonymity will be maintained at all times.

What will happen if I don't 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.

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 the University 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: *[insert project title here]*

You could also write to the Secretary at:
Anna Ramberg
Secretary to Senate Research Ethics Committee
Research Office, E214
City University London
Northampton Square
London
EC1V 0HB
Email: Anna.Ramberg.1@city.ac.uk

City University London 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.

Who has reviewed the study?
This study has been approved by City University London *[insert which committee here]* Research Ethics Committee, [*insert ethics approval code here*].

Further information and contact details
Dr Jessica Jones Nielsen Jones.Nielsen.1@city.ac.uk 0207 040 8755
Dr Julianna Challenor julianna.challenor@city.ac.uk 0207 040 0238

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

Appendix D: ACT for Anxiety Protocol

Assessment Session	
WEEK 1	• Introduction to ACT • Choose a new approach to get a different outcome o Evaluating effectiveness of anxiety management techniques to date • Understanding anxiety and its disorders • Confronting the core problem: living to avoid fear and anxiety is no way to live

WEEK 2	• Letting go of old myths opens up new opportunities
	  o Tracking experience of getting tangled up in anxiety and judgements about it
	  o Learn to observe your experience (mind watching exercise)
	  o Stay and ride out the storm (riding the storm out exercise)
	• Facing the costs to take charge of your life
	  o Costs of anxiety management (anxiety management cost-benefit analysis)
	  o Weakening the blocking power of barriers exercise

WEEK 3	• What matters more to you: managing anxiety or living a good life?
	  o Looking at values (Funeral meditation exercise).
	  o Enhance your life with LIFE worksheet
	• Ending your struggle with anxiety is the solution
	  o Ending the tug of war with anxiety
	  o When control works and when it doesn't work
	  o Holding anxiety gently exercise

WEEK 4	• You control your choices, actions and destiny
	  o Control over choices and actions
	  o Finding new alternatives to familiar feelings and impulses exercise
	  o Letting go of struggle for control
	  o Willingness (the willingness switch exercise)
	• Getting into your life with mindful acceptance
	  o Acceptance and what it can do for you
	  o Qualities of mindful acceptance
	  o Mindful acceptance practice (Acceptance of thoughts and feelings exercise)

WEEK 5	• Taking the observer perspective: You are much more than your problems
	  o Curious observer perspective (the silent observer self exercise)
	  o The constant observer exercise

	• Taking control of your life
	  o What are my values?
	  o Difficulty with identifying values

WEEK 6	• Finding your values
	  o Valued direction worksheet
	  o Building your life compass exercise

WEEK 7	• Breaking free from anxiety with mindful acceptance
	  o Driving your life bus exercise
	  o Changing radio stations exercise
	  o Worry, anxiety, fear surfing
	  o Acceptance of anxiety exercise

WEEK 8	• Bringing compassion to your anxiety
	  o Travelling with my anxiety child
	  o Practicing acts of kindness and tender loving care
	  o Loving kindness mediation exercise
	• Developing comfort in your own skin
	  o FEEL exercises (Being willingly out of breath/ dizzy aerobic)
	  o Staying with intense bodily discomfort exercise

WEEK 9	• Developing comfort with your judgemental mind
	  o Unhooking your judgemental mind exercise
	  o FEEL l exercises to unhook your judgemental mind]
	  o FEEL exercises to respond to cut and run urges
	  o Leaves on a stream exercise
	• Making peace with a difficult past
	  o Defusing from a difficult past
	  o The many stories of you
	  o Grounding in the now exercise
	  o Being kind with your old wounds exercise
	  o Candle of forgiveness exercise

WEEK 10	• Moving toward a valued life
	  o Setting and achieving goals
	  o Value and goal worksheet
	  o Anticipating barriers exercise
	• Staying the course and living your values
	  o How to keep on moving
	  o Getting back on track
	  o Using emotional discomfort to teach you

Note. Adapted from Forsyth, J. P & Eifert, G, H. (2016). The mindfulness and acceptance workbook for anxiety: A guide to breaking free from Anxiety, phobias and worry using Acceptance and Commitment Therapy. New Harbinger: Oakland CA

Appendix E: Consent Form

Title of Study: *A Pilot Study of Acceptance and Commitment Therapy (ACT) for Anxiety in a University Setting*

Ethics approval code: [*Insert code here*]

Please initial box

1.	I agree to take part in the above City, University of London research project. I have had the project explained to me, and I have read the participant information sheet, which I may keep for my records. I understand this will involve: • being interviewed by the researcher • allowing the interview to be audiotaped • completing questionnaires asking me about emotions, anxiety and depression • making myself available for a further sessions should that be required	
2.	This information will be held and processed for the following purpose(s): *To answer the research questions*. I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation.	
3.	I consent to the audiotapes (in which I am not identifiable) being listened by other researchers and interested professionals and to be used in future research projects.	
4.	I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalized or disadvantaged in any way.	
5.	I agree to City, University of London recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in this statement and my consent is conditional on the University complying with its duties and obligations under the Data Protection Act 1998.	
6.	I agree to take part in the above study.	

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of Researcher	Signature	Date

When completed, 1 copy for participant; 1 copy for researcher file.

CITY
UNIVERSITY OF LONDON
EST 1894

Appendix F: PHQ-9 Measure

PATIENT HEALTH QUESTIO NNAIRE-9

72883

THIS SECTION FOR USE BY STUDY PERSONNEL ONLY.

Were data collected? **No** *(provide reason in comments)*

If **Yes**, data collected on visit date ☐ **or** specify date: _____ DD-Mon-YYYY

Comments: ☐

Only the patient (subject) should enter information onto this questionnaire.

Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

SCORING FOR USE BY STUDY PERSONNEL ONLY

0 +_____+_____+ _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc.

EPI0905.PHQ9P

I confirm this information is accurate.	Patient's/Subject's initials:	Date:

Appendix G: GAD-7 Measure

GAD-7

	Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1	Feeling nervous, anxious or on edge	0	1	2	3
2	Not being able to stop or control worrying	0	1	2	3
3	Worrying too much about different things	0	1	2	3
4	Trouble relaxing	0	1	2	3
5	Being so restless that it is hard to sit still	0	1	2	3
6	Becoming easily annoyed or irritable	0	1	2	3
7	Feeling afraid as if something awful might happen	0	1	2	3

A12 – GAD7 total score

Appendix H: AAQ-II Measure

Below you will find a list of statements. Please rate how true each statement is for you by circling a number next to it. Use the scale below to make your choice.

1 =	2 =	3 =	4 =	5 =	6 =	7 =
never true	very seldom true	seldom true	sometimes true	frequently true	almost always true	always true

1.	My painful experiences and memories make it difficult for me to live a life that I would value.	1	2	3	4	5	6	7
2.	I'm afraid of my feelings.	1	2	3	4	5	6	7
3.	I worry about not being able to control my worries and feelings.	1	2	3	4	5	6	7
4.	My painful memories prevent me from having a fulfilling life.	1	2	3	4	5	6	7
5.	Emotions cause problems in my life.	1	2	3	4	5	6	7
6.	It seems like most people are handling their lives better than I am.	1	2	3	4	5	6	7
7.	Worries get in the way of my success.	1	2	3	4	5	6	7

Note. This is a one-factor measure of psychological inflexibility, or experiential avoidance. Score the scale by summing the seven items. Higher scores equal greater levels of psychological inflexibility.

Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., Waltz, T., & Zettle, R. D. (in press). Preliminary psychometric properties of the Acceptance and Action Questionnaire – II: A revised measure of psychological inflexibility and experiential avoidance. *Behavior Therapy.*

Appendix I: Client Demographic Form

1. What is your age?

Day..... Month..... Year.....

2. What is your gender?

Male ☐ Female ☐ Other (please describe)

3. What is your ethnic group? (please tick one answer)

White

1. English/Welsh/Scottish/Northern Irish/British [ ]
2. Irish [ ]
3. Gypsy or Irish Traveller [ ]
4. Any other White background, please describe.....

Mixed/Multiple ethnic groups

5. White and Black Caribbean [ ]
6. White and Black African [ ]
7. White and Asian [ ]
8. Any other Mixed/Multiple ethnic background, please describe.....

Asian/Asian British

9. Indian [ ]
10. Pakistani [ ]
11. Bangladeshi [ ]
12. Chinese [ ]
13. Any other Asian background, please describe.....

Black/ African/Caribbean/Black British

14. African [ ]
15. Caribbean [ ]
16. Any other Black/African/Caribbean background, please describe [ ]

Other ethnic group

17. Arab [ ]
18. Any other ethnic group, please describe.....

4 Do you have a disability?

Yes ☐ No ☐

If yes, please specify.....

5 What is your relationship status?

1. Single [ ]
2. In a relationship [ ]
3. Married/Registered [ ]
4. Divorced/Separated [ ]
5. Any other relationship status, please describe..... [ ]

6 What is your employment status?

1. Full-time [ ]
2. Part-time [ ]
3. Not employed [ ]

Appendix J: Client Identity Form

Client code:

Date of first contact: Date of assessment:

Client Name: Preferred client name: Preferred pronoun:

Date of birth:

Address: Tel No: Email:

GP details and contact:

Assessor:

Referred To: Therapist: Date/time:

Appendix K City Counselling Psychology Training & Research Clinic Safety and Disclosure Guidelines

These safety guidelines should be followed in the initial assessment and whenever clients present with risk. They should be used alongside City, University of London's Safeguarding Policy, Risk Management Policy, and Student Mental Health Policy**.**

Supervisors should check that all supervisees are aware of these procedures and that trainees are provided with any additional training that may be required.

The City Counselling Psychology Training & Research Clinic Placement Manager should ensure that a clinician to whom any new client is being referred has an understanding of these guidelines and has regular supervision.

Risk Assessment
Assessing risk/safeguarding and its management with clients is good practice (Care Act 2014).

Risk of significant harm in the clinical setting can be defined as the likelihood of a harmful event occurring. It includes self-harm, self-neglect, neglect/harm of children/dependents, and accidental harm. It also covers issues related to the personal safety of staff. In assessing risk, the following should be considered:

- Self-reporting by the person on interview
- Past history of the person including social issues, substance misuse, offending and medication
- Observation of the behaviour and mental state of the person
- Discrepancies between what is reported and what is seen
- Psychological tests/questionnaires
- Statistics derived from studies of related cases
- Indicators of risk derived from research; local and national recommendations
- Recent or ongoing events which resulted in:
    - Harm or exploitation from others
    - Harm to others or to property
    - Deliberate self-harm
    - Harm to self through neglect
    - Significant risks to self through substance misuse
    - Risks to physical health
- Whether there is regular contact with children under 18

The following questions can be explored with clients:

- What helps you to stay well and stable on a day-to-day basis?
- What are the experiences that upset you and you find stressful?
- Do you have a plan for how to avoid or cope with these events or experiences?
- What have you learned as indicators that may mean you are becoming unwell?
- What works best for you and how others can others respond helpfully?
- When you are unwell or in a crisis, what makes you feel safe?
- What makes you feel unsafe or make things worse?
- What is important to you and needs to be taken care of in your personal life?
- Who are the people you want contacted when you are in crisis?
- Who are the people you do not want contacted when you are in crisis?

A risk assessment checklist where suicidal thoughts/threats are presented is provided at the end of this document. This should be used in all cases of suicidal risk.

Clinical Considerations
It is generally recognised that a person who is determined to end their life will do so despite the best efforts of counsellors and other professionals. However, there is a great deal that we can do to minimise that as an option for our clients. In working with suicidal clients you will discover that:

- Asking your client about suicide does not increase the risk. Your client can only get appropriate help from you if they talk openly about their suicidal intentions and actions.

- Accepting and affirming the client's suicidal feelings is NOT the same as approving the act itself. An empathic understanding of their situation may enable you to assess the extent to which they really intend to harm themselves.
- It is useful to distinguish between suicidal ideas as an indicator of the intensity of feelings, and as a statement of intent to self-harm or neglect or to complete suicide.

The aim of suicide can be to solve a problem or to escape an unbearable emotion, whereas the aim of self-harm may be to relieve tension among many other reasons. Self-harm for example, is common where there has been trauma and is often used by clients who are cut off or dissociated as a way of reconnecting; where there is blood for example it may give concrete expression to cut -off pain. Sometimes it is done to evoke responses from others. Your client may be ambivalent about self-harm but sometimes it is the only way they can find relief from unbearable pain. Reflecting that ambivalence; helping client put feelings into words help to build an alliance with the part of the client that seeks help rather than harm.

Factors that are known to indicate a heightened risk of suicide include:

- Recent disruption/loss of relationships; recent discharge from psychiatric hospital
- Physical illness (esp. diagnosed, chronic and/or painful)
- Social withdrawal: breaking off contact (emotional or otherwise) with others.
- Sudden change in presentation (whether positive or negative)
- Severe hopelessness
- Depressive turmoil, panic attacks, severe mood cycling
- Global insomnia

Background factors that may be linked with a risk of suicide include:

- A history of psychiatric treatment
- Sociopathic or criminal behavior
- Alcohol problems or drug dependence
- Low socio economic status or unemployment
- The absence of close support such as a partner or a parent
- A history of abuse or trauma which has eroded coping mechanisms
- A family pattern of none communication of emotion

Client profiles with a higher statistical risk of suicide:

- Male, over 40, recently separated or single, living alone and abusing substances
- Individuals over 60 with chronic, debilitating or terminal illness or medical problems
- Clients diagnosed with a major depression with psychotic features
- Young men between ages 18-25
- Males accused or arrested for pedophilia, sexual abuse or other socially perceived shameful behavior

Recording Risk: General Guidelines

Failures in care where serious incidents occur are complex and multifaceted. However, there are very significant lessons from serious case reviews.

First, clinicians often do a thorough job in risk assessing but forget to record in a timely manner. If something goes wrong unfortunately even when this is not associated with clinician error there is little evidence of this good work.

Of more concern is when clinicians do not have sufficient training or knowledge but also do not have regular supervision and/or sharing of information does not occur, particularly with key external agencies or referrers. Working together and sharing information in a timely manner is an essential component of risk assessment treatment and prevention of harm to self and others. Keep accurate records of all contacts with your clients and of consultations with third parties concerning your clients after each session in the clinical notes with a clear heading of risk assessment/safeguarding if any new information arises.

Where risk occurs, the clinician should record periods of notable risk in the Therapist Note Form, including details of:

- Context: where, how, why, with whom, and what is the source and reliability of this information
- Precipitating factors and triggers: what preceded this event or experience?

- Outcome: what happened as a consequence of this event or experience?
- Protective factors?
- Client perspective: what does the person have to say about these?

Keep a record after every session of your risk assessment, even if this is a brief entry, for example, 'No change in risk noted in today's session.'

Therapists should also record levels of client risk (none/low/medium/high), including type of risk, on the Profile page of Pragmatic Tracker.

All records should be factual, and you should be mindful of the need to share information with clients. There may also be exceptional circumstances: for example, where a serious crime or harm to children has occurred and you need to call the police or social services as discussed below.

Keep your supervisor and placement manager informed of any clients about whom you are concerned.

Send a standard letter to client and referrer/GP after any absence with clients who are considered at high risk.

Risks to Therapist in Session
Attempt to diffuse the situation if you have assessed risk to yourself in the session. Do not engage in confrontation at this time. Make sure that your body posture is not threatening, your voice is calm and that you are not blocking the exit (although you need to be close to it).

Ensure that you always have access to your personal alarm and are familiar with procedures for using it.

Ensure that you have signed your client in, so that security is aware that you and your client are on the premises.

Ensure that you have indicated times when you will be meeting with clients in the schedule, so that your placement manager is aware of where you are.

Ensure that you have emergency contact details for the placement manager, and a code word for indicating that you are under duress.

Dealing with Disclosures of Child Abuse/Safeguarding
In the course of counselling and psychotherapy clients may disclose child abuse:
- they experienced in the recent past
- historical abuse they are aware of
- current and immediate risk of abuse to children

The City Counselling Psychology Training & Research Clinic is not a statutory agency and it does not have a role in administering adult or child protection legislation. However, the service is committed to ensuring good practice and safety and reporting guidelines, and we accept that 'safeguarding is everybody's business' (Care Act 2014).

Under s.47 of the Children Act 1989, amended 2004, the local authority has a statutory duty to investigate situations where a child under 18 is suffering, or is likely to suffer 'significant harm', whether physical, emotional or psychological in nature and in cases of neglect.

The nature of counselling and psychotherapy requires trust and confidentiality. In most cases, best practice requires the practitioner to seek to empower the client in addressing the situation. Where a disclosure by practitioner is required, it is important to seek the consent for any disclosure of personally sensitive information.

If there is a risk of harm to children by a third party, the client must be given adequate information and time to make a considered decision, where a child is not at immediate risk of harm. If the child is at risk of immediate harm and/or a crime has been committed, then trainees must discuss this immediately with their supervisor. Exceptional circumstances which pertain to

safeguarding matters where action may need to be taken in spite of the client's wishes may occur at any time during assessment or treatment.

If you are concerned about excessive radicalisation or influence upon a young person you are seeing, discuss this in your next supervision session, unless there is an immediate risk to the person or others. Adhere to university safeguarding policy and guidance on radicalisation

Procedure for dealing with allegations of child abuse and/or serious risk to an adult, or where a crime may have been committed, are as follows:

- Report the incident immediately to the City Counselling Psychology Training & Research Clinic Placement Manager. Discuss the circumstances and options for dealing with the incident, referring to the counselling agreement and other clinic/university procedures.
- Report the incident to your primary supervisor and discuss in relation to professional codes of ethics and advice about clinical strategies.
- Consider consulting your insurance legal helpline and obtain legal advice about the best course of action as well if you have this in place.
- In cases where you need to report child abuse and risk you should contact either the local social services or a specialist agency can be contacted anonymously. NSPCC has a recognised statutory role and legal authority in this field. NSPCC Child Protection Helpline (24 hours): Tel: 0808 800 5000
- In emergencies you can contact the police on 999

Risk Assessment Checklist where Suicidal Ideation/Threats are Present

YES	NO	SUICIDE THREATS	ACTION (if any YES ticked)
1☐	☐	Expresses wanting to be dead	1-3 DISCUSS IN SUPERVISION CONTINUE TO ASSESS SEE 4-6 below
2☐	☐	Discloses suicide ideation	FOLLOW PLAN AGREED WITH CLIENT IN ASSESSMENT /RECORD / ASSESS
3☐	☐	Suicide ideation is realistic/ Has researched means of suicide with intention to employ means	ASSESS RISK RECORD ASSESEMENT AND DISCUSS IN SUPERVISION **3 /4**EXPLAIN TO CLIENT THAT YOU NEED TO TELL THE APPROPRIATE PERSON (E.G. GP AND IF CAPACITY IS AN ISSUE AT TIME OF DISCLOSURE SIGNIFICANT OTHER /AND /OR EMERGENCY SERVICES) **5/TRAINEES:** **CONSULT WITH QUALIFIED THERAPIST BEFORE CLIENT LEAVES CLINIC AND CALL SUPERVISOR AFTER SESSION**
4☐	☐	Has made suicide plan but denies immediate plan to carry it out	
5☐	☐	Has the means (tablets, rope etc.) assess -was this recently acquired? What are protective factors -e.g. fulfilling work, family/ children	
6☐	☐	Makes credible threats of suicide (expressing intention)	6-10 CALL GP / **<u>BEFORE</u>** CLIENT LEAVES IF REFERRED THROUGH RU COUNSELLING SERVICE, ALERT THEM. DISCUSS IMMEDIATE ACTION PLAN WITH GP, RU COUNSELLING SERVICE AND/ QUALIFIED THERAPIST/SUPERVISOR BEFORE ALLOWING CLIENT TO LEAVE CLINIC MAKE DECISIONS IN CONSULTATION WITH EVERYONE INVOLVED. IF IN DOUBT, ARRANGE TRANSPORT TO A&E IF A&E, ASK IF CLIENT AGREES FOR NEXT OF KIN TO BE CALLED.WHAT IS DOCUMENTED IN THE SAFETY PLAN IF CLIENT EXPRESSES INTENTION OF IMMEDIATE SUICIDE AND TRIES TO LEAVE, CALL AMBULANCE/POLICE
7☐	☐	Has had a ‘dry run’ (e.g. visited location; tried out rope)	
8☐	☐	Is preparing for death (giving away things, settling debts, writing suicide note)	
9☐	☐	Makes constant indirect references to own death and is preoccupied with death	
10☐	☐	Has made precautions against discovery	

Adverse Events

An adverse event (AE) is defined as any negative psychological, emotional or behavioural occurrence, or sustained deterioration in a research participant. These include:

Significant deterioration in behaviour, including threatening violence, exhibiting violent behaviour or serious injury to another person; or exposure to violence or abuse
Significant increase in emotional difficulties
Self-harm (if not a presenting issue), or escalating self-harm (when it is a presenting issue)
A complaint made against the therapist, or an issue with the therapist, resulting in discontinuation of therapy
Suicidal intent
Hospitalization due to drugs or alcohol, or for psychiatric reasons (including, in-patient hospitalization, or significant disability/incapacity)
Death, including suicide

Therapists should record in their Therapist Note Form any AEs experienced by their clients. They should also consider whether participation in the Pluralistic Therapy for Depression study may have played a causal role in evoking this AE. In the event that it is deemed to have had, or when there is judged to be any possibility that it may have had, this should be reported to the Chief Investigators (CI), Jessica Jones Nielsen, immediately, and no later than two working days of becoming aware of the event.

A serious AE (SAE) is defined as any AE that is life-threatening, or results in death. AEs assessed by the therapist as serious should be reported to the CI immediately (irrespective of attribution of causality), and no later than two working days of becoming aware of the event.

The CI will review the assessments of causality/seriousness attributed to the AE/SAE reported and assign their own judgment. To do this, the CI may need to hold a meeting with the professional who reported the AE/SAE, and potentially other members of the City Counselling Psychology Training & Research Clinic Team.

Where the AE/SAE is assessed by the CI as serious, or where there is the possibility that it was caused by participation in the ACT for Anxiety study, the CI will report this to Head of Department and Chair of the Departmental Ethics Committee.

The overall safety of participants is the responsibility of the CI. However, in practice the CI must rely on the research team to ensure that AEs are identified and addressed in an appropriate and timely manner. Thus, safety is a shared responsibility.

Appendix L: Lone Worker Guidelines

City University Psychology Department
Lone Worker Guidelines

When conducting research both on and off site, think about your personal safety when considering times and locations. Try to conduct research in public locations, within office hours as much as possible. If conducting research offsite, the gold standard is to go in pairs – however this may be impractical, so it becomes essential that you consider personal safety.

Procedure for meeting participants offsite

--- Record the name of the person or persons you are meeting and the location in a calendar that is shared with team members. Alternatively you may communicate the details of your meeting with your supervisor or a research team member, who should act as your safety contact.

--- Ensure that you have provided your mobile number to your safety contact.

- If you are meeting a participant in a non-public location (e.g., their home) call your safety contact before you enter *and again* when you leave, giving them a rough estimate of how long the meeting should be.

- If you are meeting with a participant in a non-public location, arrange a codeword with your safety contact, which can be used to alert them to high-risk situation and the need for assistance.

--- Where possible, arrange the layout of any meeting room so that you have easy access to exits and telecommunications, avoiding obstacles.

--- Where applicable, know the relevant security numbers for your location. On your phone have these calls on quick dial.

--- Take a personal alarm with you (these are available in the HSR office).

--- Always behave in a professional manner (see BPS codes of Conduct).

--- If you feel that a situation is becoming unsafe, immediately extract yourself. Personal safety is a priority over study data. Remember to then report back to your security contact so this information can be shared and taken into account in future risk assessments.

--- Unless necessary for the meeting, try to avoid taking expensive equipment or valuables.

--- Don't advertise laptops by carrying them in a laptop bag --- use something nondescript.

--- Remember computer equipment (Laptops, USB Keys, Portable hard Drives) need to meet relevant Data Protection and Encryption levels (further documentation is available).

--- Don’t advertise valuables (e.g. keep them in deep pockets).

--- If you need to take a cab, use a registered company such as CABWISE.

Working late or at weekends

--- Consider if it is absolutely necessary to work at the office past your usual times or at weekends. Can this work be completed at home?

--- If you need to be in the office please ensure the security office know that you are in the building and which room you are in.

--- If you are working at weekends ensure that you sign in and out at the entrance.

--- Carry a personal alarm with you at all times.

Important Contact Details

Richard Mansfield City University Security Services Manager 0207 040 8045 07812 671 916 Richard.Mansfield.1@city.ac.uk

Mohammad Torabi City University Safety Manager 020 7040 8009 07970831247 Mohammad.Torabi.1@city.ac.uk

If you are worried about someone who is acting suspiciously, ring the main security desk on ext. 3333 or University Duty Manager ext. 1011

For further security advice contact the Security Office on ext. 8045 or the main Security Office on ext. 5581.

REPORT ANY ASSAULT TO THE POLICE --- CALL 999 and if near to the University, speak to the University Security Staff who will provide assistance.

Appendix M: Personal Alarm Procedure

USING THE ALARMS

There will be a therapy room, which can be found in the 3rd drawer of the filing cabinet.

Alarms to be charged before the sessions.

Press the centre button for security assistance. Hold the centre button for 3-6 seconds and the red light will flash constantly.

Each device is GSM linked so it can give the operator a fix on our location, which is relayed to security when there is a call informing them that an alarm has been pressed.

After about 30 seconds the operator will open a conversation if and when he or she feels it is safe to do so. The operator has a university pre-set protocol to follow which involves security and police.

If a crisis situation occurs out-of-hours, a Residential Warden will be available to assist using the university's security number below.

MRS REDFORD

"Mrs Redford" is a local arrangement only within the university and has no relationship with the Skyguard alarms. The term should only be used when requesting security assistance by phone and it is felt overtly requesting security may fuel an awkward/threatening situation. Instead of asking for security assistance directly, asking for "Mrs Redford to proceed to room DXXX in Rhind" disguises the need for security as a way of avoiding a hostile situation from occurring.

CONTACT NUMBERS

Security Emergency Number – 0207 040 XXXX
Jessica Jones Nielsen – 0207 040 8755 / 0780 588 8896
Julianna Challenor – 0207 040 0238 / 07549 499 591

Appendix N: Roles and Responsibilities

Training & Research Clinic Advisory Group (monthly meetings, all clinic members plus external stakeholders) (see membership below)

- Discussion and advising on all aspects of clinic procedures
- Coordination across protocols
- Liaison with, and input from wider university

Therapist (trainees and staff members)

- Delivering intervention to clients, as per protocol
- Responsible for ensuring data is collected from clients, as per protocol

Research Administrator

- Managing storage of data and clinic equipment
- Maintaining database of clients
- Coordinating recruitment of clients
    - Liaising with university health and wellbeing service
    - Taking initial referral
    - Assigning client codes
    - Allocating client to counsellor
- Clinic management:
    - Handling of clinic email account and telephone
    - Assessing client and therapist availability
    - Arranging assessment, interview and therapy appointments
    - Emailing clients of all appointments including reminders and missed sessions
    - Managing clinic calendar and room booking system - liaising with Paul Bretherton and wider university
    - Liaising with health and wellbeing service when appropriate
- Minuting Clinic Management Group meetings and distributing minutes

Clinic Placement Manager

- Coordinating recruitment of trainee therapists
    - Liaising with course directors
    - Sending recruitment information to courses
    - Arranging interviews
    - Coordinating interview process and decision-making
- Maintaining a database of trainee counsellors
- Writing placement coordinator section of reports for trainees
- Regular meetings with trainees to review progress
- Induction of trainees – ensuring trainees are aware of protocols, measures, etc

Clinic Director (Jessica Jones Nielsen and Julianna Challenor)

- Chair of Clinic Advisory Group
- Coordinating activities of student researchers
    - Maintaining records of research being conducted
    - Allocating duties to student researchers
- Emergency contact

Protocol leads (ACT for Anxiety – Fran Smith)

- Overall responsibility for individual research protocols
- Responsible to the Head of the Department of Psychology (Emmanuel Pathos)

Data Manager

- Management of electronic data
- Liaising with Pragmatic Tracker team
- Managing iPads
- Supporting trainees to collect data as per protocols

Research Facilitator

- Managing clinic finances including managing new acquisitions and furnishings

Student Counselling and Mental Health Service?

- Referral of clients to the research clinic?
- Advice and guidance on clinic procedures?

Clinic Supervisor

- Providing supervision to clinic research therapists

Annex A: CPsychR Clinic Advisory Group membership

- X (Data Manager, Researcher)
- Midge Seymour-Roots (Student Counselling and Mental Health Service)
- Lydia Pell (Student Counselling and Mental Health Service)
- X (Placement Manager)
- Ohemaa Nkansa-Dwamena (Consultant)
- X (Psychiatry Clinical Advisor)
- X (Research Facilitator)
- Fran Smith (Supervisor)
- Emmanuel Pathos (Head of Department)
- X (Researcher)
- Tina Forster (Centre for Psychological Wellbeing & Neuroscience)
- Dr Corinna Haenschel (Centre for Psychological Wellbeing & Neuroscience)
- Dr Paul Flaxman (Centre for Psychological Wellbeing & Neuroscience)
- Cornelia Givissi (Therapist)
- Deborah Rafalin (Supervisor)
- Trudi Edginton (DPsych Counselling)
- Jessica Jones Nielsen (Co-Research Director)
- Julianna Challenor (Co-Research Director
- X (Estates and Campus Services)
- X (Security Services)
- X (Researcher)
- X (External Supervisor)
- X (Consultant Psychiatrist)
- X (Administrator)
- Hannah Villlar (Hackney MIND)

Appendix S: Weekly Time Schedule for the Training and Research Clinic

	Monday	Tuesday	Wednesday	Thursday	Friday
Time	DG20	DG20	Location2	Location2	DG20
8:00-9:00	Set up	Set up	TBC	TBC	Set up
9:00-10:00	Client Participant 1	Client Participant 1	TBC	TBC	Client Participant 1
10:00-10:30	*Break*	*Break*	*Break*	*Break*	*Break*
10:30-11:30	Client Participant 2	Client Participant 2	TBC	TBC	Client Participant 2
11:30-12:00	*Break*	*Break*	*Break*	*Break*	*Break*
12:00-13:00	Supervision	Supervision	TBC	TBC	Supervision
13:00-13:30	*Break*	*Break*	*Break*	*Break*	*Break*
13:30-14:30	Client Participant 3	Client Participant 3	TBC	TBC	Client Participant 3
14:30-15:00	*Break*	*Break*	*Break*	*Break*	*Break*
15:00-16:00	Client Participant 4	Client Participant 4	TBC	TBC	Client Participant 4
16:00-16:30	*Break*	*Break*	*Break*	*Break*	*Break*
16:30-17:30	Client Participant 5	Client Participant 5	TBC	TBC	Client Participant 5
17:30-18:00	*Break*	*Break*	*Break*	*Break*	*Break*

Appendix C: 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 assessors 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, and have a score between 5 -15 on the GAD-7 and less than 15 on the PHQ-9 at the screening interview.

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 involved for up to 10 weeks, and a total of about 10 hours. After the initial screening conversation which can occur in person or over the phone, you will meet the facilitator in a group for two hours a week for four weeks. At these sessions, you will take part in a skills based psychologically informed group, where your group facilitator will be using a therapy called ACT or MBSR. 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 an ACT or MBSR group.

At the start of the project you will be asked to complete a set of questionnaires related to psychological, emotional and cognitive functioning. When you are attending groups, you will be 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 video/audio-recorded with a digital video/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 that is kept in a locked cabinet.
No data will be shared with any staff member of the university other than those in the research team.

Your GP details will be held on record by the research team. Your GP will be contacted only if a member of the research team becomes concerned about issues of risk to you or others.

After anonymising, video/audio files will be accessed by the researcher who is your group facilitator, and members of the research team. It may be used in future research projects. You will have the option of agreeing to this separately.

Your personal information will be kept confidential for a minimum period of 5 years according to the data protection act.

What should I do if I want to take part?

Provide information about how a participant can participate in the research. If separate tasks are required, please list them all.

What will happen to results of the research study?
Details of what sort of publications, including possible future publications as well as the current thesis/report, might arise from the research and whether anonymity will be maintained. If the participants will receive a copy of the publication/summary of the results, include details of what they need to do in order to receive it.

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

Data Protection Privacy Notice: What are my rights under the data protection legislation?
Please note that City will not usually rely on consent as a lawful basis for processing of personal data for research purposes, only for special category data (previously known as sensitive data) unless the research is relates to health/social care. However, you may need to seek consent for collection of personal data for ethical or professional reasons. If you have any concerns about which lawful basis to use for your research, please contact the Information Compliance Team at dataprotection@city.ac.uk

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.

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.

20/11/2018 Version 1

CONSENT FORM

Title of the Study: A pilot study of brief ACT and brief MBSR-informed group interventions for anxiety in a university setting

Please initial box

1	I confirm that I have had the project explained to me, and I have read the participant information sheet, which I may keep for my records.	
	I understand this will involve:	
	• being interviewed by the researcher	
	• allowing the interview to be videotaped/audiotaped	
	• completing questionnaires asking me about emotions, anxiety and depression	
	• making myself available for a further interview should that be required	
2	This information will be held by City as data controller and processed for the following purpose(s): To answer the research questions. Public Task: 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.	
3	I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation.	
	I understand that confidentiality cannot be guaranteed for information which I may disclose in the focus group(s)/group interviews(s).	
	I consent to the videotapes being shown to other researchers and interested professionals.	
4	I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.	
5	I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in this statement and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).	
6.	I agree to the arrangements for data storage, archiving, sharing.	
7	I agree to the use of anonymised quotes in publication.	
8	I agree to take part in the above study.	

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of Researcher	Signature	Date

When completed, 1 copy for participant; 1 copy for researcher file.

Do you feel stress a lot of the time?

Are you searching for meaning and purpose in your life?

PARTICIPANTS NEEDED FOR RESEARCH IN A STUDY ON PSYCHOLOGY-BASED GROUP THERAPIES FOR ANXIETY

Department of Psychology City, University of London

If you think you might be interested in participating in a psychologically informed, mindfulness skills based group as part of a project exploring the value of two forms of mindfulness based groups and their approach to working with anxiety, we are looking for volunteers to take part in our study. Participants should be over 18 years of age; have an aspect of their life that they would like to improve; and believe that a psychological intervention may be of benefit to them.

Your participation would involve attending up to 10 therapy sessions free of charge, each of which is approximately 50 minutes, completing a range of questionnaires as part of the counselling experience and having sessions audio-recorded. The therapy will based in the Rhind Building, Northampton Square Campus, City, University of London with experienced practitioners.

You will not be invited to participate in this study if you:

- ✓ Have a diagnosis of a severe and enduring mental health problem, such as such as psychotic disorders, personality disorders or dependent drug use where they are the primary problem and/or may significantly interfere with treatment
- ✓ Are currently receiving psychological therapy elsewhere
- ✓ Are studying on Masters or Doctoral-level course in the Department of Psychology at City, University of London

For more information about this study, or to take part, please contact the **CPsych Research Clinic** at CPsychResearchClinic@city.ac.uk or 020 7040 8755.

This study has been reviewed by, and received ethics clearance through the Department of Psychology Research Ethics Committee, City University London [insert ethics approval code here]. If you would like to complain about any aspect of the study, please contact the Secretary to the University's Senate Research Ethics Committee on 020 7040 3040 or via email: Anna.Ramberg.1@city.ac.uk

Research Clinic Ethics Appendices

Appendix A: ACT for Anxiety Brief 4 Week Group Intervention Protocol

ACT IN GROUPS SUMMARY OVERVIEW OF A FOUR SESSION PROGRAMME

Developed by: Dr. Paul Flaxman, Ross McIntosh & Dr. Joe Oliver (2018)

Overview of Session 1

Welcome, introductions and warm-up	Trainer intro; 2 activities intros for group Basic nature and content of the training; confidentiality; self-care 3 column framework
Introduction to mindfulness	**Raisin exercise and enquiry** Then identify one routine activity to perform more mindfully over the next week (use reminder stickers)
	Mindfulness message A form of mental training Waking from the autopilot Gathering the "scattered mind" 3 main ways to practice Gentle selling (by summarizing some top-line evidence) Persistence and practice required
	Body and breath meditation + enquiry Draw similarity to physical fitness training for the body
Introduction to values- based action	**Values/ valuing psychoeducation** Values in words – "the personal qualities we most want to express in our daily behaviour" Benefits of valuing (counter-cultural message!) – taking consistent steps towards expressing values in action can increase our sense of meaning, purpose, and life direction
	Values card sort and enquiry Turning an abstract personal value into concrete action: Identifying 'towards moves' Useful message - size of the action is unimportant!
Discussion of internal barriers to values- based action	Not as easy as it sounds! We humans can often get 'hooked' or 'hijacked' by our own inner experiences; noticing this is central to this training What shows upside *inside* of us that can interfere with our tendency to move towards expressing these personal qualities? Passengers on the bus metaphor Large part of this training is noticing the internal stuff that interferes with us moving towards expressing personally valued qualities Link to Session 2 (enticing people to return!)
Summary of home practice	Noticing exercises: Noticing experience during routine activity; noticing body and mind during guided practice; noticing at least one 'towards' move each day

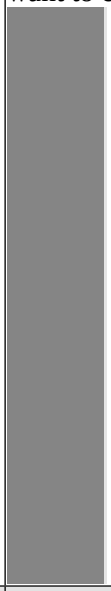
Summary of training purpose	Two sheets of paper – message 1: Communicating that the purpose of the training is to make personal values a more prominent guide to action

Overview of Session 2

Welcome back	Intro to session; reminder of what the training is about (3 columns)
Mindfulness practice and enquiry	Body and breath practice Mindfulness message: Distinction between *Thinking* and *Sensing* modes of mind
Home practice review	Group discussion of the noticing exercises Personal reflection over the past few days (ACT matrix exercise)
Values card sort	Repeat the card sort and gather experiences Action identification around another value (ideally working with different value to session 1) Identify small towards moves Consider a challenging event or situation coming up over the next week – which personal quality (or qualities) do you most want to express in that situation?
Defusion segment: Relating skilfully to "unhelpful" thoughts	Defusion psychoeducation – "what the mind is designed to do" (normalising negative thought content) Experiencing such thoughts is not the problem – issue is how we *relate to* them, or respond when they show up; whether nor not we get caught up in them/ let them dictate our behaviour All starts with heightened awareness Note down some of the everyday thoughts that can have an unhelpful (and perhaps subtle) influence over your ability to engage in personally valued action Using POTB cartoon handout with speech bubbles Trainer demonstrates this exercise first, revealing his or her own "unhelpful" thought content
	Three steps: 1) become aware of it, and write it down "out there" on the page; 2) giving the mind a playful label or nickname for when it is offering an unhelpful script; 3) cultivating distance ("I'm having the thought that...; I notice that I'm having the thought that.....")
Summary of home practice	Noticing exercises: Noticing experience during routine activity; noticing body and mind during guided practice; noticing at least one 'towards' move and one 'away' move each day
Reconnecting with training purpose	Two sheets of paper – message 2. Communicating potential *coexistence* of towards moves and unhelpful thoughts, feelings, and urges. They don't have to operate in opposition!

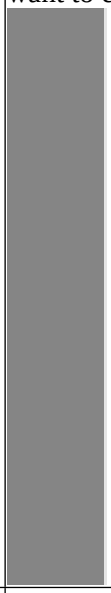
Overview of Session 3

Welcome back	Intro to session; reminder of what the training is about (3 columns)
Mindfulness practice and enquiry	Body and breath practice Mindfulness message: The body as a "refuge" and "radar"; the doorway into the sensing mode of mind
Home practice review	Group discussion of the noticing exercises Personal reflection over the past few days (ACT matrix exercise)

Relating skilfully to unhelpful or difficult mood and emotion	Reintroduce POTB metaphor – not just thoughts that can interfere with our values-based choices; behaviour also often hijacked by emotion or mood Bringing a difficulty to the workbench Physicalizing exercise + enquiry; noticing what shows up in the body Rumi's Guest House poem
ACT matrix: Life areas	Choose one life area; write about the personal qualities you most want to express in this area of life 
Reconnecting with training purpose	Two sheets of paper – message 3: Communicating that the key skill is about learning to engage in towards moves even while experiencing unhelpful thoughts, feelings, and urges. Message can be bolder here – raising the possibility of moving towards what matters *knowing* it will bring up some difficult internal stuff
Summary of home practice before next session	Noticing exercises: Noticing experience during routine activity; noticing body and mind during guided practice; noticing at least one 'towards' move and one 'away' move each day; noticing what shows up inside and gets in the way.
3 step exercise to end	Practice then describe: hour glass figure; bringing the longer practices into daily life; useful for regular mindful "check-ins"; all about getting better at 'noticing'.

Overview of Session 4

Welcome back	Intro to session; reminder of what the training is about (3 columns)
Mindfulness practice and enquiry	Body and breath practice Review of mindfulness messages from the previous sessions: Waking from the autopilot; gathering the scattered mind (session 1); thinking vs. sensing modes of mind (session 2); and making good use of the body for enhancing psychological well-being (session 3)
Home practice review	Group discussion of the noticing exercises Personal reflection over the past few days (ACT matrix exercise)

ACT matrix: Life areas	Choose another life area; write about the personal qualities you most want to express in this area of life 
Link into passengers on the bus	Valuing might sound straightforward, but as we've seen, we humans are often "hijacked" by our unhelpful internal experiences (thoughts, emotions, moods, urges etc). There are different ways of responding to the unhelpful stuff - we can demonstrate by *acting out* the passengers on the bus (see separate instructions)
Passengers on the bus role play	Self-care example (what thoughts might show up and hijack driver's behaviour?) Trainer is the driver (the person); participants are the passengers (various thoughts); one participant to hold the value in a corner of the room Give lots of clear direction to the group Four ways of responding: (1) compromising/ appeasing (just doing what they say to keep them quiet); (2) fighting/ struggling (an exhausting and unwinnable battle); (3) acceptance/ acknowledgement; (4) acceptance + steps towards the value Key questions during each demonstration: where is the driver (the person) investing his/ her energy? What was the passengers' experience? What was the value's experience? Is the bus moving? What did the rest of the group observe?
Review of programme/ keeping things going	Review of three columns (bringing it all together) Review of the Matrix perspective Share in pairs/ small group: What will you take away from the training? Which exercises and/ or messages resonated most with you? In which area(s) of life would you most like to practice using this point of view? Highlight resources and books
End with poem	

Appendix B: MBSR Informed Brief 4 Week Group Intervention Protocol

The Modified Mindfulness Course

A shortened mindfulness course will be delivered by a trained mindfulness teacher and Clinical Psychologist across four 2-hour sessions. The course will be accompanied by audios and a booklet designed by Dr Trudi Edginton highlighting the main themes within each session using visually engaging pictures to help enhance understanding, encoding and recollection.

There will be one session per week for 4 consecutive weeks, at the same time each week. The details of each session are described below:

Week 1:
Introduction to the topic.
Guided mindful eating. Focus on being 'in the moment' and appreciating the task the participant doing at each point in time.
Mindful eating will take form via eating a raisin – studying the raisin in detail (colour, sensations such as smell and texture) and focusing in detail on the process involved in eating the raisin.
The aim of this session will be to teach participants to focus on each task that they are doing in detail, with the goal to be able to give full attention to each task, without thinking about the next task.
Homework given in the form of a practice exercise.

Week 2:
Recap of the previous week's topic.
Guided mindful breathing exercise, focus on the breath and being 'in the moment'.
Guided mindful body-scan. Focus on different parts of the body and its sensations via a guided body scan exercise.
Emphasis on observing sensations rather than judging sensations. Focus on being 'in the moment', focusing at one thing at a time, and also training the ability to focus attention and awareness to different parts of the body at will.
Homework given in the form of a practice exercise.

Week 3:
Recap of the previous week's topic.
Guided session mindful coping and dealing with difficulties.
The aim of the session will be to become mindfully aware of whatever is most predominant in the participant's moment by moment experience, and for participants to uncover how they are relating to feelings and thoughts are arising, and approach them in an accepting way.
Exercise practiced during the session: The Three Step Breathing Space – creating an imaginary space around ourselves by imaging our breath expanding beyond our body into the space around us.
Homework given in the form of a practice exercise.

Week 4:
Recap of the previous week's topic.
Guided session on mindful choices and looking after own self.

Exercises involve (a) focusing on what the participant finds nourishing and depleting in their daily activities and (b) a guided Mountain exercise whereby participants imagine themselves as being a mountain which stands tall despite the ever-changing environment around them. Recap of topics covered will be included at the end, and suggestion for how to continue the practice beyond the course will be provided.

Appendix C: Screening Questionnaire

Title	First Name	Surname
Address		
Tel: home: work: mobile:		E-mail
Name and contact details of your next of kin:		
Age:		
Do you have previous experience of mindfulness or meditation?		
Have you had any mental ill-health within the last few years, such as anxiety or depression? If yes, please provide further details		
Have you experienced any major life events such as bereavement or trauma in the last few years? If yes, please provide further details		
Are you seeing or have you recently seen a therapist, counsellor or psychiatrist?		
Do you have any physical illness or limitations you think I should be aware of?		
Are you on any medication? If yes, please describe what and why.		
Signature		Date

Appendix D: PHQ-9 Measure

PATIENT HEALTH QUESTIO NNAIRE-9 72883

THIS SECTION FOR USE BY STUDY PERSONNEL ONLY.
Were data collected? **No** *(provide reason in comments)*
If **Yes**, data collected on visit date **or** specify date: ____
DD-Mon-YYYY

☐

Comments: ☐

Only the patient (subject) should enter information onto this questionnaire.

Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

SCORING FOR USE BY STUDY PERSONNEL ONLY
0 +_____+_____+ _____
=Total Score: ____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc.
 EPI0905.PHQ9P

I confirm this information is accurate.	Patient's/Subject's initials:	Date:

Appendix E: GAD-7 Measure

GAD-7

	Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1	Feeling nervous, anxious or on edge	0	1	2	3
2	Not being able to stop or control worrying	0	1	2	3
3	Worrying too much about different things	0	1	2	3
4	Trouble relaxing	0	1	2	3
5	Being so restless that it is hard to sit still	0	1	2	3
6	Becoming easily annoyed or irritable	0	1	2	3
7	Feeling afraid as if something awful might happen	0	1	2	3

A12 – GAD7 total score

Appendix F: Participant Identity Form

Participant code:

Date of first contact:

Date of assessment:

Participant Name:

Preferred name:

Preferred pronoun:

Date of birth:

Address:

Tel No:

Email:

GP details and contact:

Assessor:

Allocated To:

Group Facilitator:

Date/time:

Appendix G: AAQ-II Measure

Below you will find a list of statements. Please rate how true each statement is for you by circling a number next to it. Use the scale below to make your choice.

1 =	**2 =**	**3 =**	**4 =**	**5 =**	**6 =**	**7 =**
never true	**very seldom true**	**seldom true**	**sometimes true**	**frequently true**	**almost always true**	**always true**

My painful experiences and memories make it difficult for me to live a life that I would value.	1	2	3	4	5	6	7
I'm afraid of my feelings.	1	2	3	4	5	6	7
I worry about not being able to control my worries and feelings.	1	2	3	4	5	6	7
My painful memories prevent me from having a fulfilling life.	1	2	3	4	5	6	7
Emotions cause problems in my life.	1	2	3	4	5	6	7
It seems like most people are handling their lives better than I am.	1	2	3	4	5	6	7
Worries get in the way of my success.	1	2	3	4	5	6	7

Note. This is a one-factor measure of psychological inflexibility, or experiential avoidance. Score the scale by summing the seven items. Higher scores equal greater levels of psychological inflexibility.

Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., Waltz, T., & Zettle, R. D. (in press). Preliminary psychometric properties of the Acceptance and Action Questionnaire – II: A revised measure of psychological inflexibility and experiential avoidance. *Behavior Therapy*.

Appendix H: Cognitive Fusion Questionnaire

CFQ

Below you will find a list of statements. Please rate how true each statement is for you by circling a number next to it. Use the scale below to make your choice.

1	2	3	4	5	6	7
never true	very seldom true	seldom true	sometimes true	frequently true	almost always true	always true

1.	My thoughts cause me distress or emotional pain	1	2	3	4	5	6	7
2.	I get so caught up in my thoughts that I am unable to do the things that I most want to do	1	2	3	4	5	6	7
3.	I over-analyse situations to the point where it's unhelpful to me	1	2	3	4	5	6	7
4.	I struggle with my thoughts	1	2	3	4	5	6	7
5.	I get upset with myself for having certain thoughts	1	2	3	4	5	6	7
6.	I tend to get very entangled in my thoughts	1	2	3	4	5	6	7
7.	It's such a struggle to let go of upsetting thoughts even when I know that letting go would be helpful	1	2	3	4	5	6	7

Thank you for completing this questionnaire

Smout, M., Davies, M., Burns, N., & Christie, A. (2014). Development of the Valuing Questionnaire (VQ). *Journal of Contextual Behavioral Science, 3*(3), 164–172. doi:10.1016/j.jcbs.2014.06.001

Appendix K: CompACT Questionnaire

CompACT

Name:	Date:

Please rate the following 23 statements using the scale below:

0	1	2	3	4	5	6
Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree

1. I can identify the things that really matter to me in life and pursue them	0	1	2	3	4	5	6
2. One of my big goals is to be free from painful emotions	0	1	2	3	4	5	6
3. I rush through meaningful activities without being really attentive to them	0	1	2	3	4	5	6
4. I try to stay busy to keep thoughts or feelings from coming	0	1	2	3	4	5	6
5. I act in ways that are consistent with how I wish to live my life	0	1	2	3	4	5	6
6. I get so caught up in my thoughts that I am unable to do the things that I most want to do	0	1	2	3	4	5	6
7. I make choices based on what is important to me, even if it is stressful	0	1	2	3	4	5	6
8. I tell myself that I shouldn't have certain thoughts	0	1	2	3	4	5	6
9. I find it difficult to stay focused on what's happening in the present	0	1	2	3	4	5	6
10. I behave in line with my personal values	0	1	2	3	4	5	6
11. I go out of my way to avoid situations that might bring difficult thoughts, feelings, or sensations	0	1	2	3	4	5	6
12. Even when doing the things that matter to me, I find myself doing them without paying attention	0	1	2	3	4	5	6
13. I am willing to fully experience whatever thoughts, feelings and sensations come up for me, without trying to change or defend against them	0	1	2	3	4	5	6
14. I undertake things that are meaningful to me, even when I find it hard to do so	0	1	2	3	4	5	6
15. I work hard to keep out upsetting feelings	0	1	2	3	4	5	6
16. I do jobs or tasks automatically, without being aware of what I'm doing	0	1	2	3	4	5	6
17. I am able to follow my long terms plans including times when progress is slow	0	1	2	3	4	5	6
18. Even when something is important to me, I'll rarely do it if there is a chance it will upset me	0	1	2	3	4	5	6
19. It seems I am "running on automatic" without much awareness of what I'm doing	0	1	2	3	4	5	6
20. Thoughts are just thoughts – they don't control what I do	0	1	2	3	4	5	6
21. My values are really reflected in my behaviour	0	1	2	3	4	5	6
22. I can take thoughts and feelings as they come, without attempting to control or avoid them	0	1	2	3	4	5	6
23. I can keep going with something when it's important to me	0	1	2	3	4	5	6

Name:	Date:

Appendix O: Demographic Form

What is your age?

Day…… Month…….. Year……..

What is your gender?

Male ☐ Female ☐ Other (please describe)

3. What is your ethnic group? (please tick one answer)

White
1. English/Welsh/Scottish/Northern Irish/British [ ]
2. Irish [ ]
3. Gypsy or Irish Traveller [ ]
4. Any other White background, please describe……

Mixed/Multiple ethnic groups
5. White and Black Caribbean [ ]
6. White and Black African [ ]
7. White and Asian [ ]
8. Any other Mixed/Multiple ethnic background, please describe……

Asian/Asian British
9. Indian [ ]
10. Pakistani [ ]
11. Bangladeshi [ ]
12. Chinese [ ]
13. Any other Asian background, please describe……

Black/ African/Caribbean/Black British
14. African [ ]
15. Caribbean [ ]
16. Any other Black/African/Caribbean background, please describe [ ]

Other ethnic group
17. Arab [ ]
18. Any other ethnic group, please describe……

4 Do you have a disability?

Yes ☐ No ☐

If yes, please specify……

5 What is your relationship status?
1. Single [ ]
2. In a relationship [ ]
3. Married/Registered [ ]
4. Divorced/Separated [ ]
5. Any other relationship status, please describe…… [ ]

6 What is your employment status?
1. Full-time [ ]
2. Part-time [ ]
3. Not employed [ ]

Appendix L: Five Facet Mindfulness Questionnaire

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes <u>your own opinion</u> of what is <u>generally true for you</u>.

1	2	3	4	5
never or very rarely true	**rarely true**	**sometimes true**	**often true**	**very often or always true**

_____ 1. When I'm walking, I deliberately notice the sensations of my body moving.
_____ 2. I'm good at finding words to describe my feelings.
_____ 3. I criticize myself for having irrational or inappropriate emotions.
_____ 4. I perceive my feelings and emotions without having to react to them.
_____ 5. When I do things, my mind wanders off and I'm easily distracted.
_____ 6. When I take a shower or bath, I stay alert to the sensations of water on my body.
_____ 7. I can easily put my beliefs, opinions, and expectations into words.
_____ 8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.
_____ 9. I watch my feelings without getting lost in them.
_____ 10. I tell myself I shouldn't be feeling the way I'm feeling.
_____ 11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.
_____ 12. It's hard for me to find the words to describe what I'm thinking.
_____ 13. I am easily distracted.
_____ 14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.
_____ 15. I pay attention to sensations, such as the wind in my hair or sun on my face.
_____ 16. I have trouble thinking of the right words to express how I feel about things
_____ 17. I make judgments about whether my thoughts are good or bad.
_____ 18. I find it difficult to stay focused on what's happening in the present.
_____ 19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.
_____ 20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.
_____ 21. In difficult situations, I can pause without immediately reacting.
_____ 22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.

PLEASE TURN OVER ÷

1	2	3	4	5
never or very rarely true	**rarely true**	**sometimes true**	**often true**	**very often or always true**

_____ 23. It seems I am “running on automatic” without much awareness of what I’m doing.
_____24. When I have distressing thoughts or images, I feel calm soon after.
_____ 25. I tell myself that I shouldn’t be thinking the way I’m thinking.
_____ 26. I notice the smells and aromas of things.
_____ 27. Even when I’m feeling terribly upset, I can find a way to put it into words.
_____ 28. I rush through activities without being really attentive to them.
_____ 29. When I have distressing thoughts or images I am able just to notice them without reacting.
_____ 30. I think some of my emotions are bad or inappropriate and I shouldn’t feel them.
_____ 31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.
_____ 32. My natural tendency is to put my experiences into words.
_____ 33. When I have distressing thoughts or images, I just notice them and let them go.
_____ 34. I do jobs or tasks automatically without being aware of what I’m doing.
_____ 35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.
_____ 36. I pay attention to how my emotions affect my thoughts and behavior.
_____ 37. I can usually describe how I feel at the moment in considerable detail.
_____ 38. I find myself doing things without paying attention.
_____ 39. I disapprove of myself when I have irrational ideas.

Appendix M: The Mindful Attention Awareness Scale (MAAS)

The trait MAAS is a 15-item scale designed to assess a core characteristic of mindfulness, namely, a receptive state of mind in which attention, informed by a sensitive awareness of what is occurring in the present, simply observes what is taking place.

Brown, K.W. & Ryan, R.M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology, 84,* 822-848.

Carlson, L.E. & Brown, K.W. (2005). Validation of the Mindful Attention Awareness Scale in a cancer population. *Journal of Psychosomatic Research, 58,* 29-33.

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
almost always	very frequently	somewhat frequently	somewhat infrequently	very infrequently	almost never

_____1. I could be experiencing some emotion and not be conscious of it until some time later.
_____2. I break or spill things because of carelessness, not paying attention, or thinking of something else.
_____3. I find it difficult to stay focused on what's happening in the present.
_____4. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.
_____5. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.
_____6. I forget a person's name almost as soon as I've been told it for the first time.
_____7. It seems I am "running on automatic," without much awareness of what I'm doing.
_____8. I rush through activities without being really attentive to them.
_____9. I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.
_____10. I do jobs or tasks automatically, without being aware of what I'm doing.
_____11. I find myself listening to someone with one ear, doing something else at the same time.
_____12. I drive places on 'automatic pilot' and then wonder why I went there.
_____13. I find myself preoccupied with the future or the past.
_____14. I find myself doing things without paying attention.
_____15. I snack without being aware that I'm eating.

Scoring: To score the scale, simply compute a mean (average) of the 15 items.

Appendix O: Mindfulness Practice log

Initials: *Week No: 1-2* *Date:* *Part No:*

Weekly Mindfulness Practice Log

FORMAL MINDFULNESS PRACTICES

Please indicate how long you engaged in ***formal practices*** over the past week (formal exercises are meditative practices you learn during training **-** and for which you will use the **audio recordings to guide you**)**:**

Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday
❑ 0 min	❑ 0 min	❑ 0 min	❑ 0 min	❑ 0 min	❑ 0 min	❑ 0 min
❑ 1-5 min	❑ 1-5 min	❑ 1-5 min	❑ 1-5 min	❑ 1-5 min	❑ 1-5 min	❑ 1-5 min
❑ 5-10 min	❑ 5-10 min	❑ 5-10 min	❑ 5-10 min	❑ 5-10 min	❑ 5-10 min	❑ 5-10 min
❑ 10-15 min	❑ 10-15 min	❑ 10-15 min	❑ 10-15 min	❑ 10-15 min	❑ 10-15 min	❑ 10-15 min
❑ 15-20 min	❑ 15-20 min	❑ 15-20 min	❑ 15-20 min	❑ 15-20 min	❑ 15-20 min	❑ 15-20 min
❑ 20-25 min	❑ 20-25 min	❑ 20-25 min	❑ 20-25 min	❑ 20-25 min	❑ 20-25 min	❑ 20-25 min
❑ 25-30 min	❑ 25-30 min	❑ 25-30 min	❑ 25-30 min	❑ 25-30 min	❑ 25-30 min	❑ 25-30 min
❑ 30-35 min	❑ 30-35 min	❑ 30-35 min	❑ 30-35 min	❑ 30-35 min	❑ 30-35 min	❑ 30-35 min
❑ 40-45 min	❑ 40-45 min	❑ 40-45 min	❑ 40-45 min	❑ 40-45 min	❑ 40-45 min	❑ 40-45 min
❑ 45 min +	❑ 45 min +	❑ 45 min +	❑ 45 min +	❑ 45 min +	❑ 45 min +	❑ 45 min +

Now please indicate which of the **FORMAL EXERCISES** you practiced on each day (please tick all exercises you practiced on each day)**:**

Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday
❑ Body scan	❑ Body scan	❑ Body scan	❑ Body scan	❑ Body scan	❑ Body scan	❑ Body scan
❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)	❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)	❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)	❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)	❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)	❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)	❑ 4-stage sitting meditation (body, breathing, thoughts, sounds)
❑ Breath & Body Meditation	❑ Breath & Body Meditation	❑ Breath & Body Meditation	❑ Breath & Body Meditation	❑ Breath & Body Meditation	❑ Breath & Body Meditation	❑ Breath & Body Meditation
❑ Mindful movement (stretch& breath)	❑ Mindful movement (stretch& breath)	❑ Mindful movement (stretch& breath)	❑ Mindful movement (stretch& breath)	❑ Mindful movement (stretch& breath)	❑ Mindful movement (stretch& breath)	❑ Mindful movement (stretch& breath)
❑ Mindful walking/movemnt	❑ Mindful walking/movemnt	❑ Mindful walking/movemnt	❑ Mindful walking/movemnt	❑ Mindful walking/movemnt	❑ Mindful walking/movemnt	❑ Mindful walking/movemnt
❑ 3-Stage breathing med.	❑ 3-Stage breathing med.	❑ 3-Stage breathing med.	❑ 3-Stage breathing med.	❑ 3-Stage breathing med.	❑ 3-Stage breathing med.	❑ 3-Stage breathing med.

Appendix P: The Rumination Scale

People think and do many different things when they feel depressed. Please read each of the items below and indicate whether you almost never, sometimes, often, or almost always think or do each one when you feel down, sad, or depressed. Please indicate what you generally do, not what you think you should do.

1 almost never 2 sometimes 3 often 4 almost always

1. think about how alone you feel

2. think “I won’t be able to do my job if I don’t snap out of this”

3. think about your feelings of fatigue and achiness

4. think about how hard it is to concentrate

5. think “What am I doing to deserve this?”

6. think about how passive and unmotivated you feel.

7. analyze recent events to try to understand why you are depressed

8. think about how you don’t seem to feel anything anymore

9. think “Why can’t I get going?”

10. think “Why do I always react this way?”

11. go away by yourself and think about why you feel this way

12. write down what you are thinking about and analyze it

13. think about a recent situation, wishing it had gone better

14. think “I won’t be able to concentrate if I keep feeling this way.”

15. think “Why do I have problems other people don’t have?”

16. think “Why can’t I handle things better?”

17. think about how sad you feel.

18. think about all your shortcomings, failings, faults, mistakes

19. think about how you don’t feel up to doing anything

20. analyze your personality to try to understand why you are depressed

21.go someplace alone to think about your feelings

22. think about how angry you are with yourself

Appendix Q: The Self Compassion Scale

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never				Almost always
1	2	3	4	5

_____ 1. I'm disapproving and judgmental about my own flaws and inadequacies.
_____ 2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.
_____ 3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.
_____ 4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.
_____ 5. I try to be loving towards myself when I'm feeling emotional pain.
_____ 6. When I fail at something important to me I become consumed by feelings of inadequacy.
_____ 7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am.
_____ 8. When times are really difficult, I tend to be tough on myself.
_____ 9. When something upsets me I try to keep my emotions in balance.
_____ 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.
_____ 11. I'm intolerant and impatient towards those aspects of my personality I don't like.
_____ 12. When I'm going through a very hard time, I give myself the caring and tenderness I need.
_____ 13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.
_____ 14. When something painful happens I try to take a balanced view of the situation.
_____ 15. I try to see my failings as part of the human condition.
_____ 16. When I see aspects of myself that I don't like, I get down on myself.
_____ 17. When I fail at something important to me I try to keep things in perspective.
_____ 18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.
_____ 19. I'm kind to myself when I'm experiencing suffering.
_____ 20. When something upsets me I get carried away with my feelings.
_____ 21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.
_____ 22. When I'm feeling down I try to approach my feelings with curiosity and openness.
_____ 23. I'm tolerant of my own flaws and inadequacies.

_____ 24. When something painful happens I tend to blow the incident out of proportion.
_____ 25. When I fail at something that's important to me, I tend to feel alone in my failure.
_____ 26. I try to be understanding and patient towards those aspects of my personality I don't like.

Appendix R: The Trail Making Test (TMT) Parts A & B

Both parts of the Trail Making Test consist of 25 circles distributed over a sheet of paper. In Part A, the circles are numbered 1 – 25, and the patient should draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 – 13) and letters (A – L); as in Part A, the patient draws lines to connect the circles in an ascending pattern, but with the added task of alternating between the numbers and letters (i.e., 1-A-2-B-3-C, etc.). The patient should be instructed to connect the circles as quickly as possible, without lifting the pen or pencil from the paper. Time the patient as he or she connects the "trail." If the patient makes an error, point it out immediately and allow the patient to correct it. Errors affect the patient's score only in that the correction of errors is included in the completion time for the task. It is unnecessary to continue the test if the patient has not completed both parts after five minutes have elapsed.

Step 1: Give the patient a copy of the Trail Making Test Part A worksheet and a pen or pencil.

Step 2: Demonstrate the test to the patient using the sample sheet (Trail Making Part A –*SAMPLE*).

Step 3: Time the patient as he or she follows the “trail” made by the numbers on the test.

Step 4: Record the time.

Step 5: Repeat the procedure for Trail Making Test Part B.

Scoring:

Results for both TMT A and B are reported as the number of seconds required to complete the task; therefore, higher scores reveal greater impairment.

	Average	**Deficient**	**Rule of Thumb**
Trail A	29 seconds	> 78 seconds	Most in 90 seconds
Trail B	75 seconds	> 273 seconds	Most in 3 minutes

Sources:

Corrigan JD, Hinkeldey MS. Relationships between parts A and B of the Trail Making Test. *J Clin Psychol*. 1987;43(4):402–409.

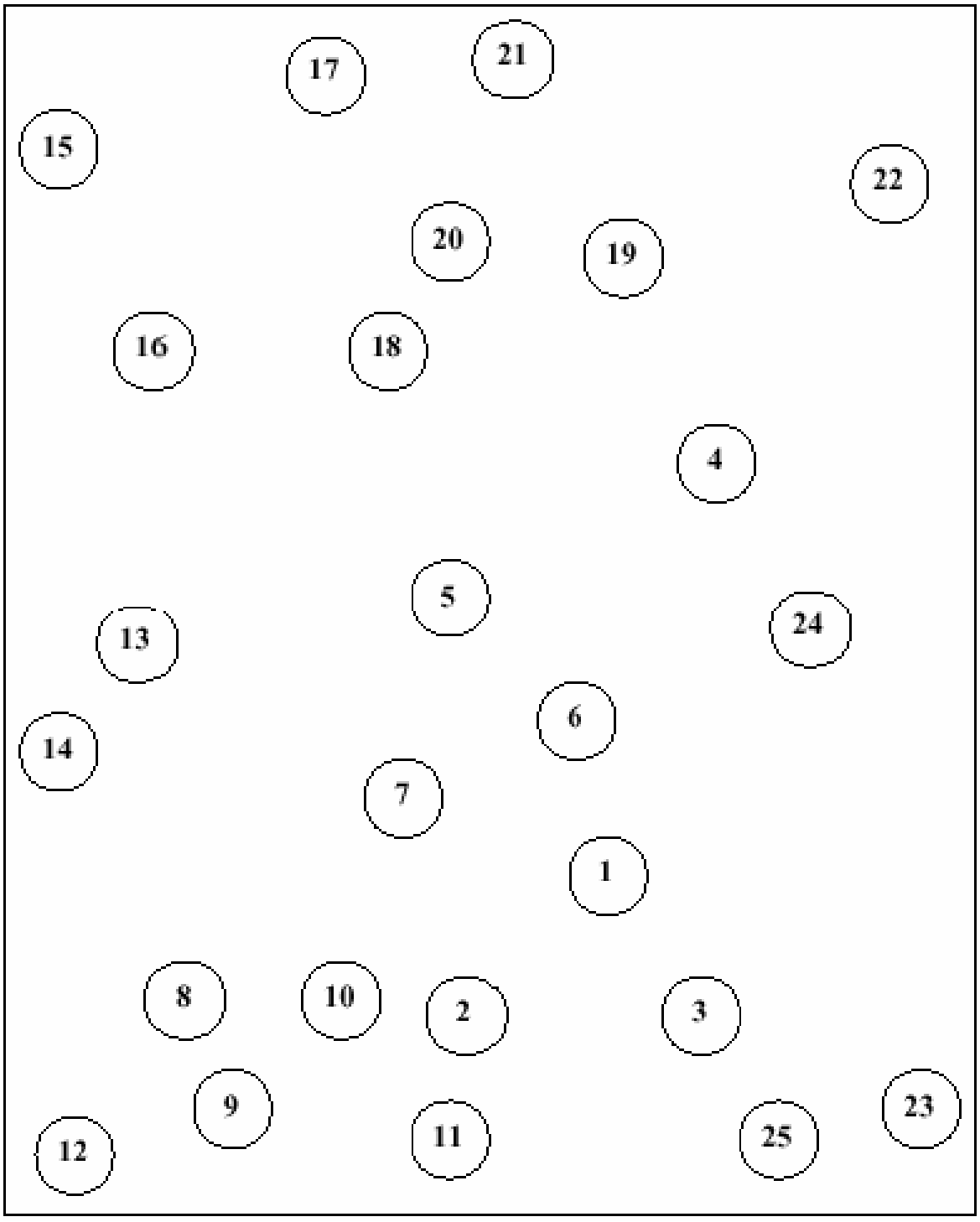
Gaudino EA, Geisler MW, Squires NK. Construct validity in the Trail Making Test: what makes Part B harder? *J Clin Exp Neuropsychol*. 1995;17(4):529-535.

Lezak MD, Howieson DB, Loring DW. *Neuropsychological Assessment*. 4th ed. New York: Oxford University Press; 2004.

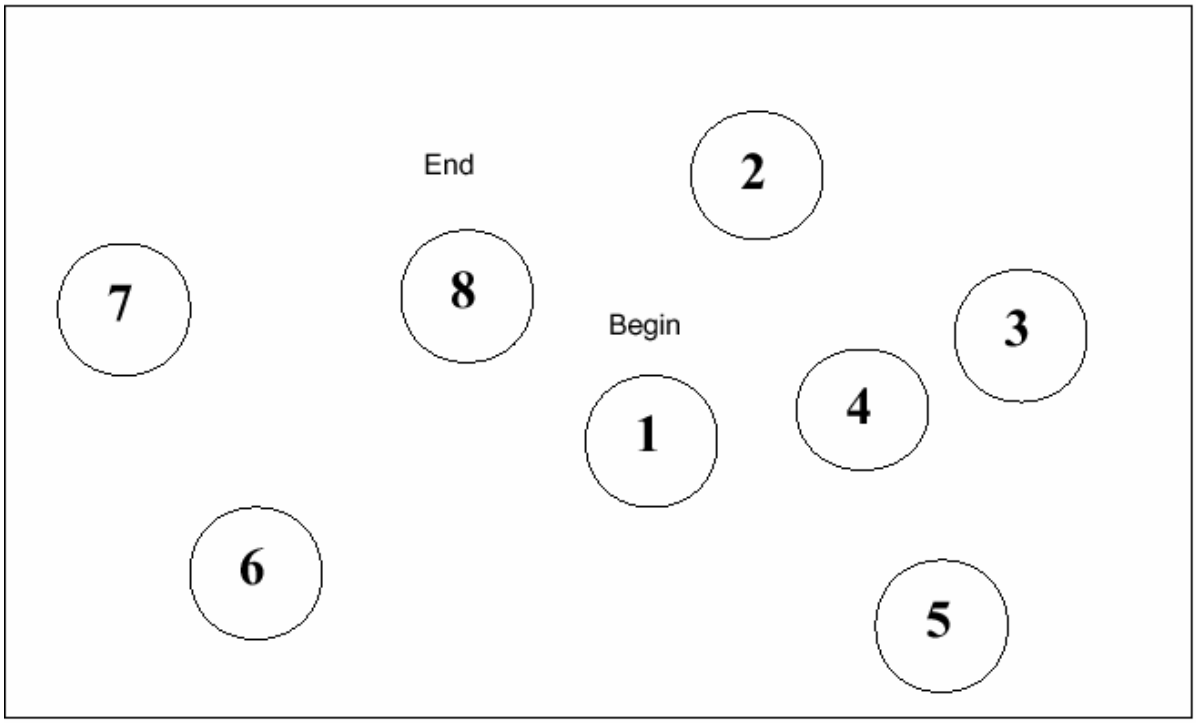
Reitan RM. Validity of the Trail Making test as an indicator of organic brain damage. *Percept Mot Skills*. 1958;8:271-276.

Trail Making Test Part A

Patient's Name:_____ Date: _____

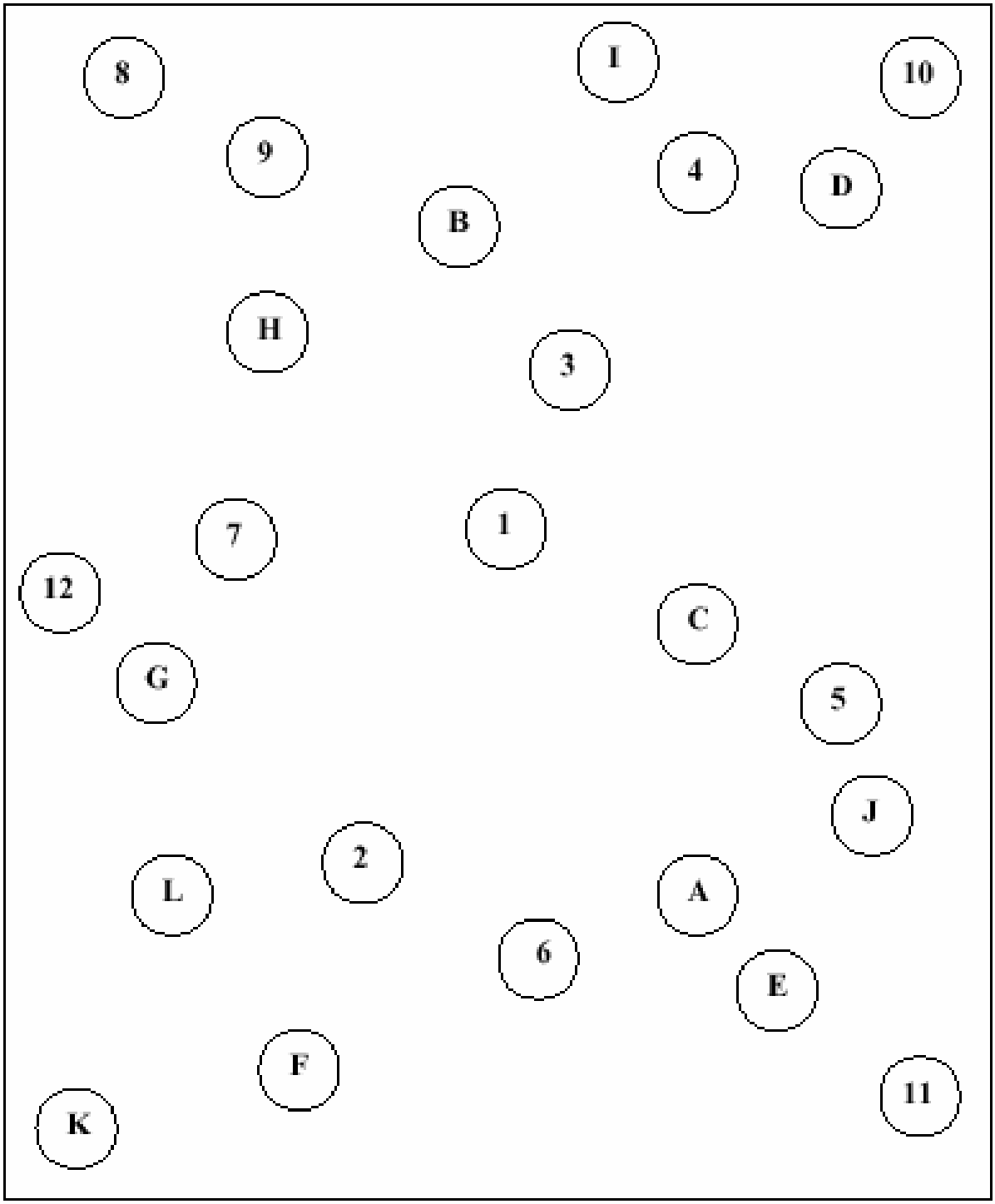


Trail Making Test Part A – *SAMPLE*

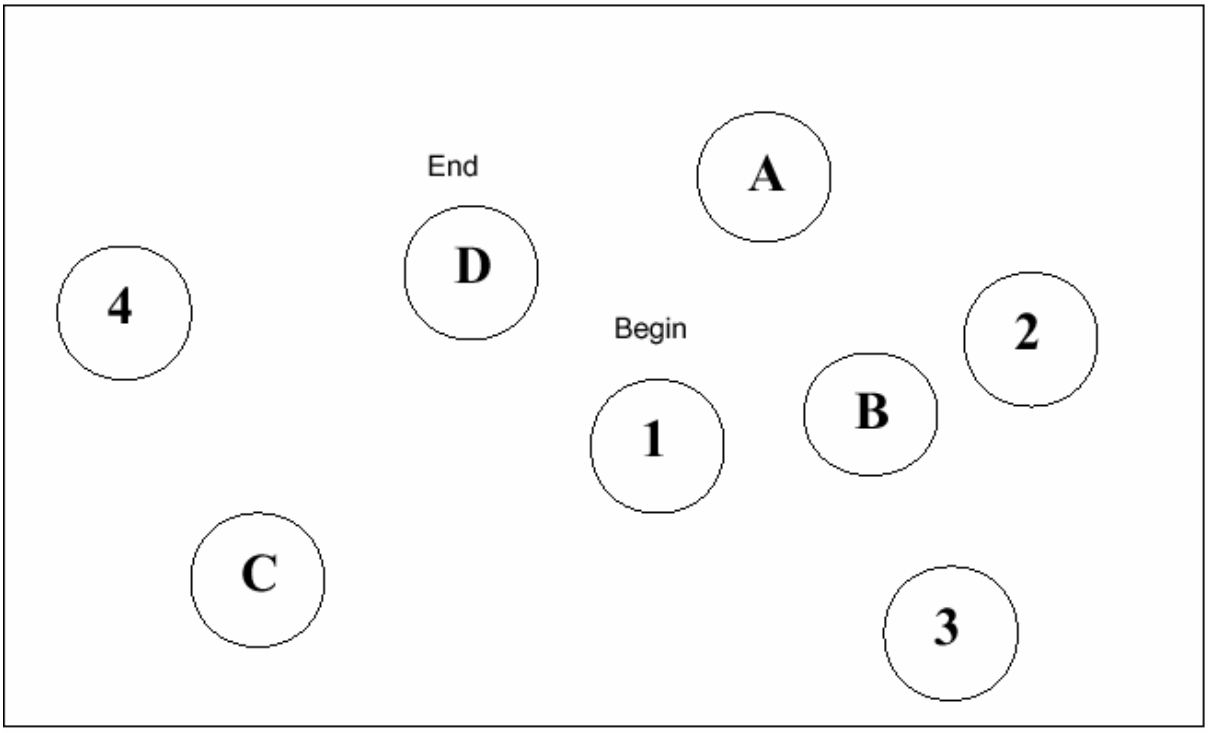


Trail Making Test Part B

Patient's Name:_____ Date: _____



Trail Making Test Part B – *SAMPLE*



Appendix S: Valuing Questionnaire

Name _____ Date:_____

VALUING QUESTIONNAIRE

Please read each statement carefully and then circle the number which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0 Not at all true 1 2 3 4 5 6 Completely true

1) I spent a lot of time thinking about the past or future, rather than being engaged in activities that mattered to me	0	1	2	3	4	5	6		____
2) I was basically on "auto-pilot" most of the time	0	1	2	3	4	5	6		____
3) I worked toward my goals even if I didn't feel motivated to	0	1	2	3	4	5	6	____	
4) I was proud about how I lived my life	0	1	2	3	4	5	6	____	
5) I made progress in the areas of my life I care most about	0	1	2	3	4	5	6	____	
6) Difficult thoughts, feelings or memories got in the way of what I really wanted to do	0	1	2	3	4	5	6		____
7) I continued to get better at being the kind of person I want to be	0	1	2	3	4	5	6	____	
8) When things didn't go according to plan, I gave up easily	0	1	2	3	4	5	6		____
9) I felt like I had a purpose in life	0	1	2	3	4	5	6	____	
10) It seemed like I was just 'going through the motions', rather than focusing on what was important to me	0	1	2	3	4	5	6		____
							Progress:	____	
							Obstruction:		____

Appendix T: City Counselling Psychology Training & Research Clinic Safety and Disclosure Guidelines

These safety guidelines should be followed in the initial assessment and whenever participants present with risk. They should be used alongside City, University of London's Safeguarding Policy, Risk Management Policy, and Student Mental Health Policy.

Supervisors should check that all supervisees are aware of these procedures and that trainees are provided with any additional training that may be required.

The City Counselling Psychology Training & Research Clinic Placement Manager should ensure that a clinician to whom any new participant is being referred has an understanding of these guidelines and has regular supervision.

Risk Assessment
Assessing risk/safeguarding and its management with participants is good practice (Care Act 2014).

Risk of significant harm in the clinical setting can be defined as the likelihood of a harmful event occurring. It includes self-harm, self-neglect, neglect/harm of children/dependents, and accidental harm. It also covers issues related to the personal safety of staff. In assessing risk, the following should be considered:
Self-reporting by the person on interview
Past history of the person including social issues, substance misuse, offending and medication
Observation of the behaviour and mental state of the person
Discrepancies between what is reported and what is seen
Psychological tests/questionnaires
Statistics derived from studies of related cases
Indicators of risk derived from research; local and national recommendations
Recent or ongoing events which resulted in:
Harm or exploitation from others
Harm to others or to property
Deliberate self-harm
Harm to self through neglect
Significant risks to self through substance misuse
Risks to physical health
Whether there is regular contact with children under 18

The following questions can be explored with participants:
What helps you to stay well and stable on a day-to-day basis?
What are the experiences that upset you and you find stressful?
Do you have a plan for how to avoid or cope with these events or experiences?
What have you learned as indicators that may mean you are becoming unwell?
What works best for you and how others can others respond helpfully?
When you are unwell or in a crisis, what makes you feel safe?
What makes you feel unsafe or make things worse?
What is important to you and needs to be taken care of in your personal life?
Who are the people you want contacted when you are in crisis?
Who are the people you do not want contacted when you are in crisis?

A risk assessment checklist where suicidal thoughts/threats are presented is provided at the end of this document. This should be used in all cases of suicidal risk.

Clinical Considerations
It is generally recognised that a person who is determined to end their life will do so despite the best efforts of counsellors and other professionals. However, there is a great deal that we can do to minimise that as an option for our participants. In working with suicidal participants you will discover that:

Asking your participant about suicide does not increase the risk. Your participant can only get appropriate help from you if they talk openly about their suicidal intentions and actions.
Accepting and affirming the participant's suicidal feelings is NOT the same as approving the act itself. An empathic understanding of their situation may enable you to assess the extent to which they really intend to harm themselves.
It is useful to distinguish between suicidal ideas as an indicator of the intensity of feelings, and as a statement of intent to self-harm or neglect or to complete suicide.

The aim of suicide can be to solve a problem or to escape an unbearable emotion, whereas the aim of self-harm may be to relieve tension among many other reasons. Self-harm for example, is common where there has been trauma and is often used by participants who are cut off or dissociated as a way of reconnecting; where there is blood for example it may give concrete expression to cut -off pain. Sometimes it is done to evoke responses from others. Your participant may be ambivalent about self-harm but sometimes it is the only way they can find relief from unbearable pain. Reflecting that ambivalence; helping participant put feelings into words help to build an alliance with the part of the participant that seeks help rather than harm.

Factors that are known to indicate a heightened risk of suicide include:
Recent disruption/loss of relationships; recent discharge from psychiatric hospital
Physical illness (esp. diagnosed, chronic and/or painful)
Social withdrawal: breaking off contact (emotional or otherwise) with others.
Sudden change in presentation (whether positive or negative)
Severe hopelessness
Depressive turmoil, panic attacks, severe mood cycling
Global insomnia

Background factors that may be linked with a risk of suicide include:
A history of psychiatric treatment
Sociopathic or criminal behavior
Alcohol problems or drug dependence
Low socio economic status or unemployment
The absence of close support such as a partner or a parent
A history of abuse or trauma which has eroded coping mechanisms
A family pattern of none communication of emotion

Participant profiles with a higher statistical risk of suicide:
Male, over 40, recently separated or single, living alone and abusing substances
Individuals over 60 with chronic, debilitating or terminal illness or medical problems
Participants diagnosed with a major depression with psychotic features
Young men between ages 18-25
Males accused or arrested for pedophilia, sexual abuse or other socially perceived shameful behavior

Recording Risk: General Guidelines
Failures in care where serious incidents occur are complex and multifaceted. However, there are very significant lessons from serious case reviews.

First, clinicians often do a thorough job in risk assessing but forget to record in a timely manner. If something goes wrong unfortunately even when this is not associated with clinician error there is little evidence of this good work.

Of more concern is when clinicians do not have sufficient training or knowledge but also do not have regular supervision and/or sharing of information does not occur, particularly with key external agencies or referrers. Working together and sharing information in a timely manner is an essential component of risk assessment treatment and prevention of harm to self and others. Keep accurate records of all contacts with your participants and of consultations with third parties concerning your participants after each session in the clinical notes with a clear heading of risk assessment/safeguarding if any new information arises.

Where risk occurs, the clinician should record periods of notable risk in the Therapist Note Form, including details of:
Context: where, how, why, with whom, and what is the source and reliability of this information
Precipitating factors and triggers: what preceded this event or experience?
Outcome: what happened as a consequence of this event or experience?
Protective factors?
Participant perspective: what does the person have to say about these?

Keep a record after every session of your risk assessment, even if this is a brief entry, for example, 'No change in risk noted in today's session.'

Therapists should also record levels of participant risk (none/low/medium/high), including type of risk, on the Profile page of Pragmatic Tracker.

All records should be factual, and you should be mindful of the need to share information with participants. There may also be exceptional circumstances: for example, where a serious crime or harm to children has occurred and you need to call the police or social services as discussed below.

Keep your supervisor and placement manager informed of any participants about whom you are concerned.

Send a standard letter to participant and referrer/GP after any absence with participants who are considered at high risk.

Risks to Therapist in Session
Attempt to diffuse the situation if you have assessed risk to yourself in the session. Do not engage in confrontation at this time. Make sure that your body posture is not threatening, your voice is calm and that you are not blocking the exit (although you need to be close to it).

Ensure that you always have access to your personal alarm and are familiar with procedures for using it.

Ensure that you have signed your participant in, so that security is aware that you and your participant are on the premises.

Ensure that you have indicated times when you will be meeting with participants in the schedule, so that your placement manager is aware of where you are.

Ensure that you have emergency contact details for the placement manager, and a code word for indicating that you are under duress.

Dealing with Disclosures of Child Abuse/Safeguarding
In the course of counselling and psychotherapy participants may disclose child abuse:
they experienced in the recent past
historical abuse they are aware of
current and immediate risk of abuse to children

The City Counselling Psychology Training & Research Clinic is not a statutory agency and it does not have a role in administering adult or child protection legislation. However, the service is committed to ensuring good practice and safety and reporting guidelines, and we accept that 'safeguarding is everybody's business' (Care Act 2014).

Under s.47 of the Children Act 1989, amended 2004, the local authority has a statutory duty to investigate situations where a child under 18 is suffering, or is likely to suffer 'significant harm', whether physical, emotional or psychological in nature and in cases of neglect.

The nature of counselling and psychotherapy requires trust and confidentiality. In most cases, best practice requires the practitioner to seek to empower the participant in addressing the situation. Where a disclosure by practitioner is required, it is important to seek the consent for any disclosure of personally sensitive information.

If there is a risk of harm to children by a third party, the participant must be given adequate information and time to make a considered decision, where a child is not at immediate risk of harm. If the child is at risk of immediate harm and/or a crime has been committed, then trainees must discuss this immediately with their supervisor. Exceptional circumstances which pertain to safeguarding matters where action may need to be taken in spite of the participant's wishes may occur at any time during assessment or treatment.

If you are concerned about excessive radicalisation or influence upon a young person you are seeing, discuss this in your next supervision session, unless there is an immediate risk to the person or others. Adhere to university safeguarding policy and guidance on radicalisation

Procedure for dealing with allegations of child abuse and/or serious risk to an adult, or where a crime may have been committed, are as follows:
Report the incident immediately to the City Counselling Psychology Training & Research Clinic Placement Manager. Discuss the circumstances and options for dealing with the incident, referring to the counselling agreement and other clinic/university procedures.
Report the incident to your primary supervisor and discuss in relation to professional codes of ethics and advice about clinical strategies.
Consider consulting your insurance legal helpline and obtain legal advice about the best course of action as well if you have this in place.
In cases where you need to report child abuse and risk you should contact either the local social services or a specialist agency can be contacted anonymously. NSPCC has a recognised statutory role and legal authority in this field. NSPCC Child Protection Helpline (24 hours): Tel: 0808 800 5000
In emergencies you can contact the police on 999
Risk Assessment Checklist where Suicidal Ideation/Threats are Present

YES NO SUICIDE THREATS ACTION (if any YES ticked)
10
0
Expresses wanting to be dead 1-3
DISCUSS IN SUPERVISION
CONTINUE TO ASSESS SEE 4-6 below

FOLLOW PLAN AGREED WITH PARTICIPANT IN ASSESSMENT /RECORD / ASSESS
20
0
Discloses suicide ideation
30
0
Suicide ideation is realistic/
Has researched means of suicide with intention to employ means ASSESS RISK RECORD ASSESEMENT AND DISCUSS IN SUPERVISION

3 /4EXPLAIN TO PARTICIPANT THAT YOU NEED TO TELL THE APPROPRIATE PERSON (E.G. GP AND IF CAPACITY IS AN ISSUE AT TIME OF DISCLOSURE SIGNIFICANT OTHER /AND /OR EMERGENCY SERVICES)

5/TRAINEES:
CONSULT WITH QUALIFIED THERAPIST BEFORE PARTICIPANT LEAVES CLINIC AND CALL SUPERVISOR AFTER SESSION

40
0
Has made suicide plan but denies immediate plan to carry it out
50
0
Has the means (tablets, rope etc.) assess -was this recently acquired?
What are protective factors -e.g. fulfilling work, family/ children
60
0
Makes credible threats of suicide (expressing intention) 6-10
CALL GP / BEFORE PARTICIPANT LEAVES
IF REFERRED THROUGH RU COUNSELLING SERVICE, ALERT THEM.
DISCUSS IMMEDIATE ACTION PLAN WITH GP, RU COUNSELLING SERVICE AND/ QUALIFIED THERAPIST/SUPERVISOR BEFORE ALLOWING PARTICIPANT TO LEAVE CLINIC
MAKE DECISIONS IN CONSULTATION WITH EVERYONE INVOLVED. IF IN DOUBT, ARRANGE TRANSPORT TO A&E
IF A&E, ASK IF PARTICIPANT AGREES FOR NEXT OF KIN TO BE CALLED.WHAT IS DOCUMENTED IN THE SAFETY PLAN
IF PARTICIPANT EXPRESSES INTENTION OF IMMEDIATE SUICIDE AND TRIES TO LEAVE, CALL AMBULANCE/POLICE
70
0
Has had a ‘dry run’ (e.g. visited location; tried out rope)
80
0
Is preparing for death (giving away things, settling debts, writing suicide note)
90
0
Makes constant indirect references to own death and is preoccupied with death
100
0
Has made precautions against discovery

Adverse Events
An adverse event (AE) is defined as any negative psychological, emotional or behavioural occurrence, or sustained deterioration in a research participant. These include:

Significant deterioration in behaviour, including threatening violence, exhibiting violent behaviour or serious injury to another person; or exposure to violence or abuse
Significant increase in emotional difficulties
Self-harm (if not a presenting issue), or escalating self-harm (when it is a presenting issue)
A complaint made against the therapist, or an issue with the therapist, resulting in discontinuation of therapy
Suicidal intent
Hospitalization due to drugs or alcohol, or for psychiatric reasons (including, in-patient hospitalization, or significant disability/incapacity)
Death, including suicide

Therapists should record in their Therapist Note Form any AEs experienced by their participants. They should also consider whether participation in the Pluralistic Therapy for Depression study may have played a causal role in evoking this AE. In the event that it is deemed to have had, or when there is judged to be any possibility that it may have had, this should be reported to the Chief Investigators (CI), Jessica Jones Nielsen, immediately, and no later than two working days of becoming aware of the event.

A serious AE (SAE) is defined as any AE that is life-threatening, or results in death. AEs assessed by the therapist as serious should be reported to the CI immediately (irrespective of attribution of causality), and no later than two working days of becoming aware of the event.

The CI will review the assessments of causality/seriousness attributed to the AE/SAE reported and assign their own judgment. To do this, the CI may need to hold a meeting with the professional who reported the AE/SAE, and potentially other members of the City Counselling Psychology Training & Research Clinic Team.

Where the AE/SAE is assessed by the CI as serious, or where there is the possibility that it was caused by participation in the ACT for Anxiety study, the CI will report this to Head of Department and Chair of the Departmental Ethics Committee.

The overall safety of participants is the responsibility of the CI. However, in practice the CI must rely on the research team to ensure that AEs are identified and addressed in an appropriate and timely manner. Thus, safety is a shared responsibility.

Appendix U: Lone Worker Guidelines

City University Psychology Department
Lone Worker Guidelines

When conducting research both on and off site, think about your personal safety when considering times and locations. Try to conduct research in public locations, within office hours as much as possible. If conducting research offsite, the gold standard is to go in pairs – however this may be impractical, so it becomes essential that you consider personal safety.

Procedure for meeting participants offsite
-- Record the name of the person or persons you are meeting and the location in a calendar that is shared with team members. Alternatively you may communicate the details of your meeting with your supervisor or a research team member, who should act as your safety contact.
-- Ensure that you have provided your mobile number to your safety contact.
-- If you are meeting a participant in a non--public location (e.g., their home) call your safety contact before you enter and again when you leave, giving them a rough estimate of how long the meeting should be.
-- If you are meeting with a participant in a non--public location, arrange a code word with your safety contact, which can be used to alert them to high--risk situation and the need for assistance.
-- Where possible, arrange the layout of any meeting room so that you have easy access to exits and telecommunications, avoiding obstacles.
-- Where applicable, know the relevant security numbers for your location. On your phone have these calls on quick dial.
-- Take a personal alarm with you (these are available in the HSR office).
-- Always behave in a professional manner (see BPS codes of Conduct).
-- If you feel that a situation is becoming unsafe, immediately extract yourself. Personal safety is a priority over study data. Remember to then report back to your security contact so this information can be shared and taken into account in future risk assessments.
-- Unless necessary for the meeting, try to avoid taking expensive equipment or valuables.
-- Don't advertise laptops by carrying them in a laptop bag -- use something nondescript.
-- Remember computer equipment (Laptops, USB Keys, Portable hard Drives) need to meet relevant Data Protection and Encryption levels (further documentation is available).

-- Don’t advertise valuables (e.g. keep them in deep pockets).
-- If you need to take a cab, use a registered company such as CABWISE.

Working late or at weekends
-- Consider if it is absolutely necessary to work at the office past your usual times or at weekends. Can this work be completed at home?
-- If you need to be in the office please ensure the security office know that you are in the building and which room you are in.
-- If you are working at weekends ensure that you sign in and out at the entrance.
-- Carry a personal alarm with you at all times.

Important Contact Details
Richard Mansfield City University Security Services Manager 0207 040 8045 07812 671 916
Richard.Mansfield.1@city.ac.uk
Mohammad Torabi City University Safety Manager 020 7040 8009 07970831247
Mohammad.Torabi.1@city.ac.uk
If you are worried about someone who is acting suspiciously, ring the main security desk on ext. 3333 or University Duty Manager ext. 1011
For further security advice contact the Security Office on ext. 8045 or the main Security Office on ext. 5581.
REPORT ANY ASSAULT TO THE POLICE -- CALL 999 and if near to the
University, speak to the University Security Staff who will provide assistance.