Project Protocol

Piloting an intervention using single case design to reduce uncertainty distress in those with long term health conditions.

Version 1.3 04/02/2022

HRA Protocol Compliance Declaration:

This protocol has regard for the HRA guidance

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

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Name (please print):

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Position:

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Chief Investigator:

Signature: Date:

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Name: (please print):

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PROJECT TIMETABLE

	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	June 2021	July 2021	Aug 2021	Sept 2021	Oct 2021	Nov 2021	Dec 2021	Jan 2022	Feb 2022	Mar 2022	Apr 2022
Preparing research protocol																
Regulatory approval (IRAS, REC, HRA)																
Participant Recruitment																
Conduct Research																
Data Analysis																
Draft Report																
Editing																
Final Report																

1. BACKGROUND

A large amount of people experiencing long term physical health conditions have comorbid anxiety and depression (Naylor et al, 2012). Traditionally they receive support and care for their physical and mental health needs in separate services that are rarely coordinated. This has been identified as ‘’ inconvenient for patients, costly to the NHS, and likely to produce sub-optimal outcomes’’ (National Collaborating Centre for Mental Health, 2018, p 3.) The NHS has recently established long term conditions pathways within existing IAPT services ensuring co-ordinated care for those with comorbid physical and mental health problems.

The National Institute for Health and Clinical Excellence (NICE) recommends Cognitive Behaviour Therapy (CBT) in the treatment of a number of long-term health conditions including Chronic Fatigue, IBS and chronic lower back pain (NICE, 2007, 2008, 2016). CBT applied to health problems focuses on helping people manage symptoms and improve quality of life. Cognitive interventions typically focus on modifying a person’s unhelpful or inaccurate negative thoughts about their illness, symptoms and its impact on daily living. Behavioural interventions focus on teaching pacing skills, reducing maintaining behaviours including monitoring and checking and overcoming avoidance of situations.

It has long been established that uncertainty is a natural component of both acute and chronic illness (Mishel, 1990). Illness uncertainty is defined as ‘’the inability to determine the meaning of illness-related events’’ (Mishel, 1988 p. 225) Sources of uncertainty in chronic illness involves living with ambiguous symptoms,

unpredictability of flare ups, if/when the illness will worsen and whether and how effective treatment will be (McCormick, 2002). Whilst some real-world uncertainty is inevitable in illness, perceived uncertainty can be exacerbated by inconsistent and/or inadequate information given by health professionals on how to manage health conditions. (McCormick, 2002).

Humans typically find states of uncertainty aversive (Carlton, 2012) and research has suggested that they prefer to resolve uncertainty even when the outcome will be unpleasant (Hsee & Ruan, 2016). However, some individuals are better able to cope with uncertainty than others. Intolerance of Uncertainty (IU) has become a widely recognised phenomenon which is thought to be a dispositional trait reflecting negative beliefs about uncertainty and its consequences across situations (Dugas & Robichaud, 2007). It has also been recognised as a situation specific source of distress in emotional disorders (Mahoney & McEvoy, 2012). IU has been identified as a core trans-diagnostic feature underlying multiple emotional disorders (McEvoy et al, 2019). CBT interventions for Generalised Anxiety Disorder specifically targeting IU have been developed (Dugas & Ladoucer, 2000, Dugas & Robichaud, 2007) and demonstrated to be effective in randomised controlled trials (Ladouceur et al., 2000; Dugas et al., 2010) and case series (Hebert & Dugas, 2019). Further research has shown that targeting IU using transdiagnostic CBT treatment may be of benefit in both individual and group therapy. (Tiplady et al., 2017; Mofrad et al., 2020)

In health settings, high IU is associated with increased worry and anxiety about health (Rosen et al, 2010; Taha, Matheson, Cronin & Anisman, 2014). Uncertainty

management interventions have been shown to improve patient's knowledge of their condition, patient-health professional communication, mood and coping skills. (Mishel et al., 2005; Jiang & He, 2012). These interventions have been primarily concerned with reducing perceived illness uncertainty through informational interventions (Zhang, Kwekkeboom, Kim, Loring & Wieben, 2020).

2. RATIONALE

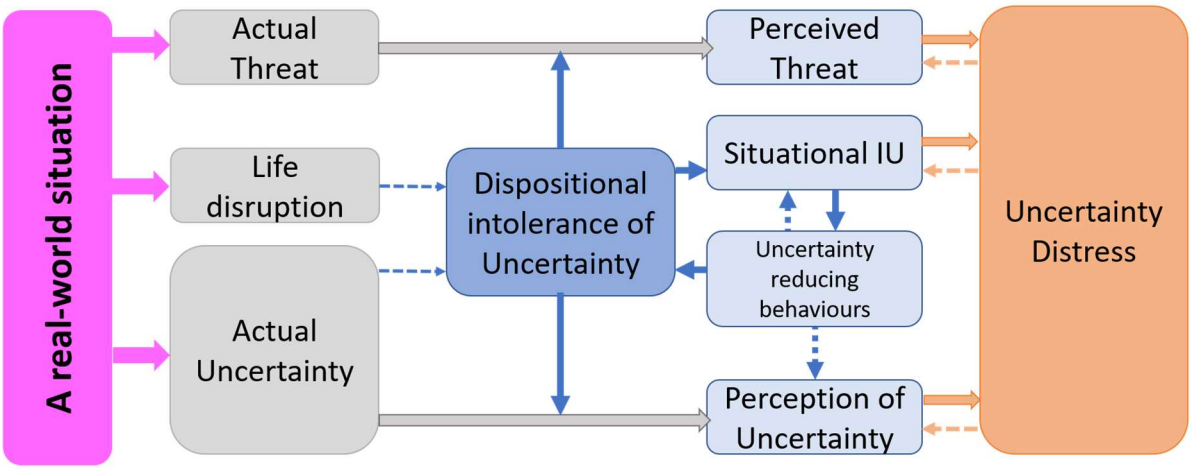
Until recently there has been very little research directly aimed at increasing tolerance of uncertainty in the health population. This is important given the amount of actual uncertainty people with chronic conditions experience. Some recent research has shown promising results in directly targeting IU as one part of a treatment in those recently diagnosed MS to reduce uncertainty distress and improve acceptance of the health condition (Molton et al., 2019).

To date there is no research combining informational interventions to reduce perceived illness uncertainty and interventions improving generic tolerance of uncertainty. The evidence base on these individual approaches would suggest that combining treatment elements targeting both actual and perceived uncertainty would lead to superior treatment outcomes for those with long term health conditions.

Freeston, Tiplady, Mawn, Bottesi and Thwaites (2020) proposed a new theoretically driven model of uncertainty distress grounded in the separate literature bases of threat models of anxiety, illness uncertainty and intolerance of uncertainty. Uncertainty distress is defined as ''the subjective negative emotions experienced in

response to the as yet unknown aspects of a given situation'' (Freeston et al, 2020 p 2)

Figure 1: Model of uncertainty distress (Freeston et al 2020)



The model comprises real world variables of 'Actual Threat' (what is known) and 'Actual Uncertainty' (what is not/cannot yet be known) with psychological factors at a situational and dispositional level. Psychological factors include perceived threat, perceived uncertainty and the ability to tolerate uncertainty.

The model outlines a trans-diagnostic treatment intervention comprising information management strategies, building safety, addressing overestimation of threat and developing tolerance of uncertainty (Freeston, 2020).

The potential benefits from this research to the NHS are the development of a new, better treatment for those with long term health conditions and associated distress. The treatment can be delivered in a single health care setting which can bridge the gap between physical health and mental health care needs. The impact of this treatment has the potential to reduce disease distress and burden. In addition, it may

have benefits on reduced health care utilisation if patients are managing their health condition, emotional impact of health condition and uncertainty better.

3. RESEARCH QUESTION AND AIMS

The aim of this research is to develop and pilot a treatment intervention which is able to target perceived illness uncertainty (PIU) and intolerance of uncertainty (IU) in individuals experiencing distress in the context of a long-term health condition who are seen by the multi-specialty service within Psychology in Healthcare in Newcastle Upon Tyne Hospitals (NUTH) NHS Foundation Trust.

Hypothesis:

Treatment intervention targeting PIU and IU will effectively reduce uncertainty distress in those with a long-term health condition.

4. STUDY DESIGN/METHODS

4.1 Study Design

A multiple baseline (MBD) single-case experimental design (SCED) will be used. Baselines will be systematically staggered between participants ranging from a minimum of 14 days to a maximum of 28 days. This ensures familiarisation with completing the daily measures and sufficient data points in the baseline phase to establish stability.

Monitoring specific targets prior to introduction of treatment allows for control to reduce the likelihood that any changes can be attributed to factors other than treatment (Morley, 2018, p 66).

Design will be an ABCD design which will be as follows

A- Baseline

B- Novel treatment intervention

C- Monitoring

D- Follow-up.

The methodology will be a within subject design with repeated measures on multiple target variables.

4.2 Measures

4.2.1 Primary Outcome Measure: Daily Diary:

Idiographic target problems will be identified by the participant at the assessment session and prior to the beginning of the baseline phase of the study. Idiosyncratic statements (which may include salient items from standardised measures) will be co-constructed by research therapist and participant which will relate to perceived illness uncertainty, intolerance of uncertainty and health condition symptomatology. Statements will be constructed in line with guidance produced by Freeston and Thwaites (2014). These statements will be rated daily by the participant on a Likert scale and will be referred to as ‘’daily diaries’’.

An example could be ‘’Because I am uncertain how bad my pain will be I find it difficult to decide what I can do today?’’ rated as ‘Strongly Agree’, ‘Agree’, ‘Neutral’, ‘Disagree’ or ‘Strongly Disagree’.

Daily diaries will be completed via ‘Qualtrics’ online survey software. Paper versions will be made available to those who prefer to complete measures in this form. Daily diary measures will be completed each day throughout the study from baseline phase to follow up.

As the design of the study is contingent on the completion of daily diary measures this will be explicitly discussed during the information giving and consent processes to allow participants to make an informed decision as to whether they can commit to completing the diaries. In order to enhance completion daily text message reminders will be sent to participants- for those who are completing the diaries via Qualtrics a link to the Qualtrics programme will be included in the text reminder. The time of the day that the text reminder will be sent will be agreed on an individual basis to ensure maximum likelihood that this prompt will be at a convenient time for the individual to complete the daily diaries.

Previous research studies using daily diaries as target measures in single case experimental design to target intolerance of uncertainty have obtained high levels of data completeness (Tiplady et al., 2017; Bentley, 2020). If individual participants have low completion rates then this will be discussed in the therapy sessions with the participant to ascertain the barriers to completion and where necessary changes made to enhance likelihood of completion –for example change the time that text reminders are sent so it is more convenient for the participant.

4.2.2 Secondary Outcome and Benchmarking measures.

Benchmarking and phase change measures will be completed via 'Qualtrics' or in paper format if requested.

Standardised mood measures will be completed at each session as is routine in psychological therapy services (The National Collaborating Centre for Mental Health, 2020)

These will be:

Patient Health Questionnaire 9 (PHQ-9): a reliable and validated measure of depression severity (Kroenke, Spitzer & Williams, 2001).

Generalised Anxiety Disorder 7 (GAD-7): a reliable and validated measure of generalised anxiety disorder severity (Spitzer, Kroenke, Williams & Lőwe, 2006).

4.2.3 Phase change measures:

Additional measures will be administered at the beginning of each phase and at mid-point in intervention phase (B). These questionnaires relate to the key constructs in the theoretical model.

- Perceived Illness Uncertainty: Mishel Uncertainty in Illness Scale-Community Form (MUIS-C, Mishel and Epstein, 1997)

- Intolerance of Uncertainty: Intolerance of Uncertainty Scale 12 (IUS-12, Carleton, Norton & Asmundson, 2007)
- Intolerance of Uncertainty Behaviours: Intolerance of Uncertainty Behaviours in Everyday Life Questionnaire (IUBEL, Clifford et al., 2015)
- Threat: Brief Pain Inventory (BPI) a validated measure of chronic pain (Tan, Jensen, Thornaby & Shanti, 2004)
- Life Disruption: Measure of the impact of disease on daily functioning

In addition the International Adjustment Disorder Questionnaire (Shevlin et al., 2020) will be used as a pre and post measure.

See Appendix A for copies of measures.

4.3 Treatment Intervention:

Please see Appendix B for overview of treatment phases, interventions within the phase and duration of each phase.

Treatment intervention will be based on uncertainty distress model (Freeston et al, 2020) and will be a semi- standardised manual format. The manual will be developed by the researcher building upon the work of the Newcastle IU Treatment Development Group and the UNcertainty in COronavirus Research Network (UNiCORN), both expert groups of clinicians and researchers.

Treatment sessions will be up to 60 minutes and delivered on an individual basis by qualified therapist(s). Sessions will be delivered either face to face in a hospital setting or video-call through NHS trust approved systems.

Treatment will comprise of 4 modules as based on the treatment model presented in Figure 1 above. These will be:

1. Building Safety (Life Disruption)
2. Managing Information
3. Reducing perceived Threat
4. Reducing intolerance of Uncertainty

Participants will complete between 1 and 4 sessions on each module depending on clinical need guided by their assessment and formulation. Treatment duration will be a maximum of 16 sessions. Therapists will complete a checklist at the end of each session to indicate which parts of the treatment intervention were covered in the session. Please see Appendix C for Treatment Fidelity Checklist developed by Parr et al. (2020) which will be adapted specific for this intervention.

Participants will be asked to consent to the video recording of treatment sessions to be reviewed by members of the research team for the purpose of ensuring quality of treatment and adherence to the treatment protocol. If a participant does not consent to the video recording of sessions then they can still be included in the study. Consent to video-recording will be captured on the consent form.

In addition to being asked to consent to video-recording of the session on the consent form, this will be reviewed at each treatment session. It is made explicit in the PIS that a participant can request that a recording can be stopped at any point and deleted. Ongoing consent to video record sessions will be recorded in the clinical notes along with any requests to stop recording individual sessions. Consent to recording individual sessions or declining the recording of sessions will be recorded on the clinical record of the participant for each session.

A proportion of the recorded treatment sessions will be watched and rated by a member of the research team using the treatment fidelity checklist (Appendix C). The therapist and raters' checklists will then be compared to establish fidelity to treatment model. All recordings will be deleted at the end of the study.

To evaluate the treatment's credibility and satisfaction, participants will be given a feedback questionnaire to complete. This will be based on those used in previous programmatic Intolerance of Uncertainty research projects (Bentley et al 2020) Please See Appendix D.

4.4 Data Analysis:

Data analysis on primary outcome measures will use visual analysis which is traditional for quantitative single-case methodology (Morley, 2018, p 88). Tau-U will be used to measure data non overlap between the phases using an online calculator

at http://www.singlecaseresearch.org/calculators/tau-u (Parker, Vannest, Davis and Sauber, 2011).

4.4.1 Primary Outcomes:

Data from daily diary measures will be plotted on a graph with the horizontal axis representing duration in days and the vertical axis representing numerical score on Likert scale. Phases will be clearly labelled separated from the next on the horizontal axis and indicated by a vertical line on the graph.

The graph will be examined for level, trend, variability, immediacy of effect, overlap and consistency of pattern within phase which are considered to be the key features used to assess within- and between-phase data patterns (Kratochwill et al., 2010).

Visual analysis will be initially carried out by the research team and then subsequent independent analysis carried out by a second rater.

4.4.2 Benchmarking and phase change measures:

These measures will be analysed for reliable and clinically significant change (Jacobson & Truax, 1991).

Reliable change criteria are used to assess whether an individual's scores on specific psychometric questionnaires between two time points (in this case pre and post treatment) change significantly more than would be expected due to measurement error of the questionnaire alone. A Reliable Change Index (RCI) is

computed by dividing the difference between the pre-treatment and posttreatment scores by the standard error of the difference between the two scores. (Jacobson and Truax 1991)

Clinically significant change criteria are used to measure whether changes on specific psychometric questionnaires from pre-treatment to post-treatment are large enough to be considered to be clinically meaningful. It represents a change in scores which moves the person from the 'clinical group' (scores above the clinical cut off for a particular measure) to the 'non-clinical group' (scores below the clinical cut off for the measure. (Jacobson and Truax 1991)

5. SAMPLE AND RECRUITMENT

5.1 Sample Size

Replication will be sought across three to six participants. Three replications are the conventional minimum number to establish an effect (Morley, 2018 p 158). Recruiting up to six participants allows for attrition and to still meet the minimum number of 3 at the same time as ensuring as few participants as necessary are exposed to the novel treatment intervention.

The number of participants will be determined by:

a) pragmatic constraints including time available following ethical approval

b) participant recruitment

c) number of therapists implementing the treatment protocol.

5.2 Recruitment

Participants will be initially recruited from the Rheumatology Department within Newcastle Upon Tyne Hospital Foundation NHS Trust. If the sample size is not reached within the Rheumatology Department, then recruitment will commence in the Gastroenterology Department. Participants will be those experiencing distress associated with the adjustment to their long-term health condition and those who would be referred to the Psychology in Healthcare Department for psychological intervention (treatment as usual). The healthcare team will be briefed of the purpose of the study and inclusion/exclusion criteria in order to identify potential participants. The healthcare team will then identify any potential participants in their routine consultations and introduce the research study and seeking expressions of interest to find out more about participating in the research. Verbal consent will be obtained to pass contact details to the research team and this will be recorded in the participants' electronic medical record. Expressions of interest will be passed to the research team and potential participants will then be contacted and given verbal and written information (Participant information sheet) about the study.

Participants will be screened by the research therapist(s) through a short interview process in line with eligibility criteria and using standardised questionnaires. Those who are screened who are not suitable for participation in the research trial will be

offered alternative psychological therapy for their difficulties via the multi-speciality psychology in health care team. This is 'treatment as usual' for patients experiencing difficulties adjusting to health problems.

5.3 Consent

Participants will be required to voluntarily give fully informed consent. They will be informed about the research through the participant information sheet (PIS) and will be given at least 48 hours to consider their participation and to discuss this will significant others. Potential participants will be given the opportunity to discuss with any queries they may have or obtain clarity on any matter. Once they are satisfied that they are fully informed about the study the written consent form will be completed with the participant by the chief investigator. If participants have expressed a wish for remote delivery of treatment then an electronic consent form will be completed via Qualtrics.

Participants will be informed that they can withdraw from the study at any point without having to give a reason.

Consent to continue participation in the research study will be reviewed at each contact with the participant and documented on the session summary sheet and in clinical records.

5.4 Eligibility Criteria

5.4.1 Inclusion criteria

- Age 18- 65
- Diagnosed long term health condition (Rheumatoid Arthritis, IBS/IBD)
- Minimum of 12 months since diagnosis of physical health condition
- Difficulties adjusting to long term health problems.
- Willingness to engage with psychological treatment to manage distress associated with their health condition.
- Fluent English speaking

5.4.2 Exclusion criteria

- Under 18 or over 65
- Multiple long term health conditions
- Progressive long term health conditions
- Experiencing mental health difficulties which may affect ability to engage with time-limited psychological therapy including diagnoses of Major Depressive Episode and/or severe and enduring mental health problems, comorbid substance misuse and suicidality.
- Diagnosis of Autism Spectrum Disorders (ASD)
- Non-English speaking

5.5 Clinical Considerations

Participants accessing treatment through the trial are those who would wait to access treatment through the Psychology in Healthcare department in the acute hospital setting or access treatment for their distress separately through mental health services. Participants will be informed that whilst this treatment is based on

empirical evidence and an extension of previous treatment models targeting IU this specific treatment model is new. Participants will be informed that if they chose to withdraw at any time there will be an arrangement in place so that they can access their original place on the waiting list without penalty to receive usual care or be referred to access alternative treatment if they were not already on the waiting list.

6. ETHICAL AND REGULATORY COMPLIANCE

6.1 Regulatory Review

An application will be made for Health Research Authority (HRA) and Research Ethics Committee (REC) approval involving submission of the protocol and all research documentation.

6.2 Scientific Review

The scientific quality of the project has been reviewed by an independent panel at Newcastle University.

It has also been reviewed by experienced members of the research team and the project research supervisor.

See Appendix E and F for the Ethics Grid and Diversity Grid required for approval by University.

6.3 Potential risks and Burdens

6.3.1 Distress:

As with any psychological therapy intervention there is the potential for it to be distressing to the participant when discussing their problems. However, this is no

greater than the potential for this to happen in alternative psychological treatment they would receive as usual. Participants will be advised of this in the participant information sheet. The research therapists conducting the treatment are qualified CBT therapists with skills and experience working with people in distress and will help manage the distress in the session. The hope is that as with other psychological therapies, distress will reduce through the course of therapy.

If distress does not reduce and mental health deteriorates during the course of therapy therapists will seek appropriate supervision and options would be discussed explicitly with the participant including withdrawal from the research and referral for additional/alternative support and treatment.

6.3.2 Burden

The main burden for participants is the time involved in participation in the research. From the start of baseline monitoring to follow up will be up to 25 weeks. During active treatment participants will be required to commit one hour per week for therapy sessions for up to 16 weeks, however this is no different from standard psychological therapy. Standardised questionnaire measures will be completed at various points during the treatment however this is standard practice for psychological therapies. The additional burden arises as a result the time taken to complete daily diaries which are specific to the research project. Participants will be required to complete daily diaries for a maximum of 175 days of which these measures take approximately 5 minutes daily. Participants will be informed of the likely time commitment required within the Participant Information Sheet (PIS) and will be able to make an informed decision whether they want to participate. They will be compensated for this time using a Wage Payment Model (Dickert & Grady, 1999)

reimbursing them for the time taken to complete measures in the form of vouchers - see section 6.4 Incentives and rewards below.

6.3.3 Disclosures and discovery of information that may need acting upon:

Whilst it is not anticipated there is a small chance that disclosure of information to or discovery of information by the therapist may need acting upon such as risks to self-and/or others. In the case of this occurring the research therapists will follow standard service protocols. Participants will be explicitly advised at the start of the treatment intervention that if this were to occur that confidentiality would be broken. If it is safe to do so the participant will be advised that the information will be shared and with whom. The researcher will have access to contact details for participants GP, local Crisis Team, local social care duty teams. Support and advice will be sought from the clinical supervisor attached to the research project. Research therapists are qualified CBT therapist who are skilled and experienced with dealing with such disclosures and discovery of information in their everyday roles.

6.4 Incentives and Payment

Potential benefits to participants from being part of the research is the opportunity to contribute to the development of a new treatment to help reduce distress associated with uncertainty of long-term health conditions.

In order to mitigate the burden and time cost of completing daily diary measures, participants will be reimbursed for their time in vouchers. The amount will be calculated on a wage payment model (Dickert & Grady) based on the current minimum wage for the UK. Please see Appendix G for details.

It is estimated that completion of daily diaries will be around 5 minutes per day throughout the duration of the study (Up to 175 days). The study design is contingent on the completion of the daily diary entries and it is hoped that participants will complete them all. If completion of diaries is less than 100% the participant will be reimbursed the amount relevant to the time the participant has taken to complete the proportionate amount of diaries.

Participants will be reimbursed in the form of e-vouchers at the end of the end of their participation in the study. In order to pay the e-vouchers, Newcastle University will require personal details (name and email address). This will be made clear in the PIS and this information will be treated in accordance with GDPR and Newcastle University policies and will be kept separate from other information provided for the research.

All payment monies have been agreed to be paid by Newcastle University, School of Psychology. Participants can donate wage-payment to charity if they wish.

6.5 Confidentiality:

Personal identifiable data and sensitive clinical data will be recorded on the host NHS trust's electronic record keeping system in line with NHS information governance policy including Data Protection Act (DPA) and The General Data Protection Regulation (GDPR).

Video recordings will be stored securely on Trust Approved Systems and will be accessed only by named members of the research team and will not be transferred. They will be watched for the purpose of supervision and ensuring quality of treatment and assessing treatment fidelity to the model. All videos will be deleted at the end of the research project.

Data transferred from the NHS setting to the University will be done so anonymously using a unique participant identifier and stored on the University's secure server. Daily diaries and phase changes measures will be completed via 'Qualtrics' a survey software package where each participant will be sent a link which they can access from their smart phone. No personal identifiable data will be held on Qualtrics. The research team will be able to access the responses from the Qualtrics programme.

Personal identifiable information held by the University will be a contact telephone number to arrange appointments and send daily text reminders and an email address of the participant for the purpose of payment of voucher reimbursement for their participation. An email address or postal address will be held if the participant requests a summary of research findings. Participants will be informed that these details will be held by the University for these specific purposes only.

All participants will be asked to choose a pseudonym for the purpose of writing up and disseminating results. Care will be taken that they will not be identifiable through

the combination of key demographic information – if there is a risk of this demographic data will be presented in broad categories or omitted.

7. STUDY SAFETY REPORTING (ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS)

All adverse events will be reported to the Principle Investigator who will then assess each event for causality, seriousness and expectedness. Adverse events that are not assessed as serious (AE's) will be recorded in the participant's electronic clinical record and documented in the investigator site file. Adverse events that are assessed as serious will be reported to the Chief Investigator immediately or within 24 hours of the Principle Investigator becoming aware of the event. The Principle Investigator will complete the Serious Adverse Events form and send via email to the Sponsor as soon as possible after being made aware of the event. The Principle Investigator will also report serious adverse event through the Host NHS Trust's internal incident reporting system. Safety reporting will be completed in line with the Sponsor NHS Trusts Standard Operating Procedure for Safety reporting of Adverse Events and Serious Adverse Events.

8. RESEARCH COSTS

Costs incurred in this project will be the wage-payment vouchers as compensation for time completing daily measures and text message reminder service. All costs will be covered by the Doctorate in Clinical Psychology and have already been agreed.

See Appendix H for costing grid.

9. DISSEMINATION POLICY

This research will be disseminated within the University of Newcastle as part of the requirements for the award of Doctorate in Clinical Psychology. The research will be presented at an appropriate research conference and written up for publication in a peer reviewed journal.

9. REFERENCES

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8. APPENDICIES

Appendix A- Measures

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	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

FOR OFFICE CODING 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. No permission required to reproduce, translate, display or distribute.

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✓" to indicate your answer)*	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

(For office coding: Total Score T____ = ____ + ____ + ____)

STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #:_____

Brief Pain Inventory (Short Form) - Experimental

Date: ____/____/____ Time: _____

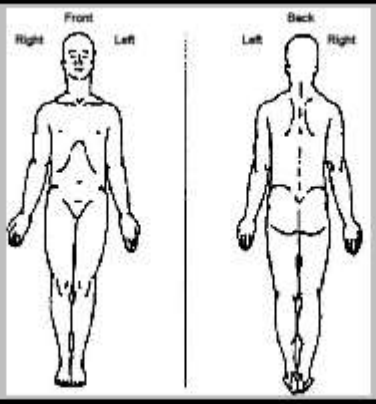
Name: _____ _____ _____

Last First Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

Page 1 of 2

BPI-SF English – School Work – January 2010

Phase	Overview of Intervention	Duration
Assessment session	Assessment and formulation of difficulties. Identification of treatment targets – establishment of daily diary measures. Completion of standardised questionnaires.	1 session
Baseline (A)	Completion of daily diaries.	2-4 weeks
Treatment Intervention (B)	Psychological therapy intervention to reduce uncertainty distress. Comprised of 4 modules 1. Managing information 2. Building safety 3. Addressing over-estimation of threat 4. Tolerating Uncertainty Each module will be between 1-4 sessions based on individual need.	Maximum 16 weeks
Monitoring (C)	No treatment Continued completion of daily diaries Participant consolidates strategies learnt.	4 weeks
Follow Up (D)	Relapse prevention session Treatment evaluation questionnaire Completion of standardised (phase change) measures	Single session

Appendix B- Overview of treatment phases including interventions and duration

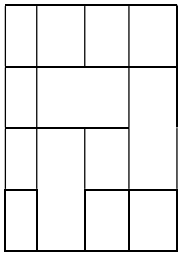
Appendix C- Treatment Fidelity Checklist

Personalised Anxiety Treatment – Autism (PAT-A)

Session Recording Form

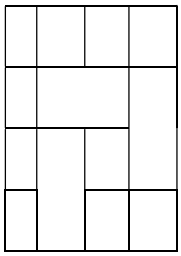
Participant ID:	**Therapist:**
Date:	**Session:**
Initial Treatment Plan:	
Current Treatment Plan:	
SUPERVISION:	
Has this case been discussed since the last session? **YES NO**	
Were changes to the treatment plan discussed? **YES NO**	
What was the main conclusion from Supervision?	
Continue with current plan	
Adjust current plan	*Specify:*
	Specify:

Change treatment plan	
Additional information/supervision notes:	

Session Recording Form Continued…	
Participant ID:	**Therapist:**
Date:	**Session:**
Research Information:	
Did the participant attend the session?	
YES NO 	*If No please detail the reasons for this if know*

Did the participant consent to ongoing inclusion within the PAT-A trial?

YES NO



If No please detail the reasons for this in the PAT-A site file and clinical notes

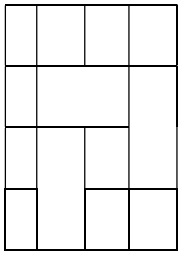
How long did the session last? *(approximate in minutes)*

…… *Minutes*

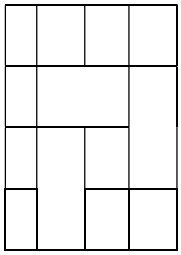
Please provide additional information if the session duration was longer/shorter than expected or did not last approximately 50-60 minutes:

Have any adverse events occurred since the previous session? *(Adverse events are defined here as all negative events that occur in parallel to treatment in relation to the patient)*

YES NO



If Yes please provide details using the Unwanted Events Checklist. If countermeasures are required please follow the Unwanted Events Standard Operating Procedure.

Has the participant received/started any therapies away from PAT-A since the previous session? *(Therapies are defined here as formal psychological interventions, psychoeducational counselling, support groups or medication)*	
YES NO 	*If Yes please provide a summary here*

Session Recording Form Continued…	
Participant ID:	**Therapist:**
Date:	**Session:**
General Structural Features of CBT	
YES NO	*If No, why not?*
Review/Check In	

Agenda Setting	
Review Homework	
Feedback	
Homework Setting	

Assessment				
Participant ID:	**Therapist:**			
Date:	**Session:**			
Essential Elements:				
	Not at all	**Touched on**	**Sometime spent**	**Main focus**
MINI diagnostic interview				

Psychometrics				
What is IU (definition)				
Identifying uncertainty in everyday life				
Risk assessment				
Daily Diary development				
Exploring safety behaviours				
Interventions/strategies from another module: *E.g. description of strategy/name of module*				
1.				
2.				
3.				
Other Interventions/strategies utilised:				

Socialisation to Intolerance of Uncertainty	
Participant ID:	**Therapist:**
Date:	**Session:**

Possible Elements:

	Not at all	Touched on	Sometime spent	Main focus
What is IU (definition, purpose)				
Evolutionary advantage of IU				
Identifying uncertainty in everyday life				
Recognising responses to uncertainty				
Recognising impact of uncertainty				
Idea of uncertainty in the absence of threat Feeling unsafe in the absence of safety signals, threat vs uncertainty				
Physiological response to IU				
Reviewing the Uncertainty Cycle/formulation				
Identifying barriers & current coping strategies				
Cost Certainty Balance				
Positive outcomes from uncertain situations				

Sitting with Uncertainty				
Risk monitoring				
Daily Diary monitoring				
Interventions/strategies from another module: *E.g. description of strategy/name of module*				
1.				
2.				
3.				
Other Interventions/strategies utilised:				

Low stakes exposure to Uncertainty Module	
Participant ID:	**Therapist:**

Date:	**Session:**

Possible Elements:

	Not at all	Touched on	Sometime spent	Main focus
Developing non-threat based experiments with low likelihood of consequence of any value				
Reviewing previous low stakes experiment				
Cost-benefit analysis				
Daily diary monitoring				
Risk monitoring				
Interventions/strategies from another module: *E.g. description of strategy/name of module*				
1.				
2.				
3.				
Other Interventions/strategies utilised:				

High stakes exposure to Uncertainty Module				
Participant ID:	**Therapist:**			
Date:	**Session:**			
Possible Elements:				
	Not at all	**Touched on**	**Sometime spent**	**Main focus**
Engage in non-threat based experiments with higher potential consequence of value				
Daily Diary monitoring				
Risk monitoring				
Interventions/strategies from another module:				

E.g. description of strategy/name of module				
1.				
2.				
Other Interventions/strategies utilised:				

Consolidation/end of treatment				
Participant ID:	**Therapist:**			
Date:	**Session:**			
Possible Elements:				
	Not at all	**Touched on**	**Sometime spent**	**Main focus**
Discussed transferable learning of how this might apply to anxiety (threat based situations)				
Troubleshooting				

Daily Diary monitoring				
Risk monitoring				
Interventions/strategies from another module: *E.g. description of strategy/name of module*				
1.				
2.				
Other Interventions/strategies utilised:				

Session Engagement	
Participant ID:	**Therapist:**
Date:	**Session:**
How verbally communicative was the participant during the therapy session *(e.g. responding to the therapists questions)?*	

Disengaged *(Participant rarely responds)*	**Limited Response** *(Participant provides minimal information; e.g. Yes/No)*	**Contributes** *(Participant provides information when required)*	**Additional Contribution** *(Participant provides additional information that is not requested)*
Is the participant able to remain attentive/on-task during the therapy session?			
Frequently Off-task *(Struggles to remain on task throughout and difficult to re-engage)*	**Occasionally On-task** *(Participant remains on task for some exercises but difficult to re-engage)*	**Frequently On-task** *(Participant remains on task for most exercises. Attention can be regained easily)*	**Remains On-task** *(Participant is highly engaged and attentive throughout the session)*
How often do the participant and therapist reach agreement?			
No Agreement *(Participant/therapist rarely agree)*	**Limited Agreement** *(Agreement is reached on occasions but with great difficulty)*	**Some Agreement** *(Agreement reached on some matters without difficulty)*	**Frequent Agreement** *(Participant and therapist agree on most matters discussed)*
Is there evidence that the participant understands the content discussed within the session?			
Does Not Understand *(Unable to demonstrate any understanding even with scaffolding)*	**Minimal Understanding** *(Understanding only demonstrated when significant prompting/ scaffolding given)*	**Frequent Understanding** *(Understanding demonstrated with minimal prompting/ scaffolding)*	**High level of Understanding** *(Participant is able to demonstrate high levels of understanding without prompting/scaffolding)*
Does the participant get stuck on particular content within the session?			
Frequently *(For considerable periods/every time new material is introduced. Significantly impacts upon session)*	**Sometimes** *(Participant becomes stuck on several occasions or for a significant period of time. Some impact on session)*	**Rarely** *(Participant becomes stuck on one or two aspects. Does not significantly interfere with session)*	**Not at all** *(Participant devotes appropriate time/effort on content throughout)*

Is the participant able to process information in a timely manner?			
Rarely *(Evidence of significant processing difficulties for the majority of the session)*	**Sometimes** *(Participant demonstrates processing difficulties on several occasions)*	**Frequently** *(Participant able to process most information although possible difficulties observed)*	**Timely Processing** *(No evidence of processing difficulties)*

Did the participant engage and complete the homework task set?				
Not Attempted	**Attempted but Abandoned**	**Partially Completed**	**Completed**	**Extra Homework Completed**

Any other observation? *(please describe)*

UE Class	Present (description)	Context	Relation	Severity
Lack of clear treatment results				
Prolongation of treatment				
Non-compliance of the participant				
Emergence of new symptoms				
Deterioration of symptoms				
Negative wellbeing of the participant				
Strains in the Participant-therapist relationship				
Very good Participant-therapist relationship				
Strains in family relations				
Change in family relations				
Strains in work relations				
Changes in the work situation				

Sick leave of the patient				
Problems in the extended social net				
Any changes in life circumstances				
Stigmatization				

Glossary of Ratings:		
Context	**Relation to Treatment**	**Severity**
1. Assessment	1. Unrelated	1. Mild, without consequences
2. Randomisation	2. Probably unrelated	2. Moderate, distressing
3. Treatment	3. Possibly related	**3. Severe, in need of countermeasures ***
4. Treatment As Usual	4. Probably related	**4. Very severe, lasting negative consequences**
5. Participant-therapist relationship	5. Related	**5. Extremely severe, hospitalization required or life threatening**
6. End Of Treatment		

**** If severity is rated as 3 or above please follow Unexpected Events Standard Operating Procedure***

Checklist taken from: Linden, M. (2013). How to define, find and classify side effects in psychotherapy: from unwanted events to adverse treatment reactions. Clinical psychology & psychotherapy, 20(4), 286-296.

Appendix D- Alice Bentley's (2020) Treatment Evaluation Form

Intolerance of Uncertainty Research Therapy Evaluation Form

The following are some questions about your experience of the Intolerance of Uncertainty therapy. Please use this opportunity to be as honest as you can about your experience so we can use it to develop the therapy and help others in future. It may be that we discuss some of these questions further during our last session together.

What was your main reason for volunteering to participate in the sessions?

How would you like to describe your experiences of participating in the sessions?

Did the explanation of Intolerance of Uncertainty as a common factor in a range of difficulties make sense to you? If not, what would have helped?

What was the best thing about engaging in the sessions?

What was the most difficult part of engaging in the sessions?

Is there anything that you think should have been done differently?

How did you find the pace of the sessions?

Too slow Just right Too Fast

How did you find the content of the sessions?

Not enough information Just right Too hard to understand

How did you find the complexity of the sessions?

Too simple for me Just right Too hard to understand

Have the sessions helped you achieve the goals that you had for therapy?

Not at all Partially Completely

How would you rate the following aspects of the sessions in terms of how helpful they were? (Using the scale from 1 to 5)	1 (Not at all helpful)	2	3	4	5 (Extremely Helpful)
Having the chance to talk about my feelings					
Taking some time out to think about myself					
Completing tasks outside of the session					
Talking to my family/friends about things we discussed in sessions					
Using daily diaries to track my feelings, thoughts and behaviours					
Talking about how avoiding uncertainty may have played a role in the development of my difficulties					
Using maps/diagrams to understand the role that uncertainty may have played in the development of my difficulties					
Talking about how avoiding uncertainty may have played a role in keeping my difficulties going (maintenance)					
Using maps/diagrams to understand the role that uncertainty may have played in keeping my difficulties going					
Understanding the types of things I do to avoid uncertainty in my everyday life (e.g. planning, routines, reading reviews)					
Understanding the types of things that I do to avoid uncertainty in situations that cause me anxiety (e.g. checking behaviours, googling symptoms)					
Changing some of the things I do in response to uncertainty in everyday life					
Changing some of the things I do to avoid uncertainty in situations that cause me anxiety					
Reflecting on the impact of doing things differently in my everyday life					
Reflecting on the impact of doing things differently in situations that cause me anxiety					

Appendix E – Ethics Grid

NEWCASTLE UNIVERSITY
DOCTORATE IN CLINICAL PSYCHOLOGY

Research Course: Ethical Issues Reflection Grid for Research Projects

Trainee name:	**Sarah Kay**	**Date:**	15/06/2020
Project title: Piloting an intervention using single case design to reduce uncertainty distress in those with long term health conditions and associated anxiety.			
Where will ethical approval be sought for this project? Ethical approval will be sought from the National Research Ethics Service.			

	Not applicable	**Issue is considered to be of no or minimal concern**	**Issue is considered to raise moderate concerns**	**Issue is considered raise high levels of concern**	**For issues raising moderate or high levels of concern, indicate how will they be managed** **Note: It would be good practice to explain why a specific issue is of no or minimal concern, rather than simply tick the box.**
Issues arising from the study design					
Specific issues in obtaining informed consent (age, capacity, etc.)	☐		☒	☐	Participants will be given clear written information about the aims of the study and what is required in the Participant Information Sheet (PIS) prior to the beginning of the study. Participants will be given at least 48 hours to consider participation. Written consent forms will be signed and participants will be given the opportunity to ask questions to clarify any details. For those wishing to have remote therapy , electronic Consent forms will be signed via Qualrics, survey software. Participation will be on a voluntary basis and the researcher will check the participants understanding of the requirements of the study to ensure they are making an informed choice as whether they wish to be part of the study.

	Not applicable	Issue is considered to be of no or minimal concern	Issue is considered to raise moderate concerns	Issue is considered raise high levels of concern	For issues raising moderate or high levels of concern, indicate how will they be managed Note: It would be good practice to explain why a specific issue is of no or minimal concern, rather than simply tick the box.
Written consent will <u>not</u> be obtained	☒		☐	☐	Written consent will be obtained through a consent form. For those wishing to have remote treatment intervention this will be done via an electronic version of the consent form accessed through a link to Qualtrics survey software.
Consent will be obtained online	☒	☐	☐	☐	Consent will be obtained in person or via link accessed through a smart phone to electronic form via Qualtrics.
Impact of excluding participants from the research	☐	☒	☐	☐	As this is a feasibility treatment study the inclusion and exclusion criteria have been tightly defined. No potential participant will be disadvantaged by being excluded from the study as they will remain on the waiting list to access treatment as usual from the health psychology department.
Collection of intrusive or sensitive data raising specific issues of storage, etc.	☐		☐	☐	Clinical data will be recorded on the host NHS trust's electronic record keeping system which is password protected and recorded on an encrypted system in line with NHS information governance policy. Any additional 'research' data will be recorded on the University's secure server but will not include any personal identifiable information. Participants will complete daily diaries via 'Qualtrics' which will be accessed via a password and not include any identifiable information.
Deception	☒		☐	☐	The aims of the study will be transparent to the participant.
Intended provision of advice	☐		☒	☐	If the participant asks for any advice outside of the treatment protocol they will be signposted back to their physical health team for this.

	Not applicable	Issue is considered to be of no or minimal concern	Issue is considered to raise moderate concerns	Issue is considered raise high levels of concern	For issues raising moderate or high levels of concern, indicate how will they be managed Note: It would be good practice to explain why a specific issue is of no or minimal concern, rather than simply tick the box.
Incentives	☐	☐	☒	☐	As a reimbursement for time spent completing the daily diaries and other outcome measures the participants will be offered shopping vouchers. The amount will be determined using a wage payment model (Dikert & Grady 1999). All costs covered by Newcastle University school of Psychology
Debriefing	☐	☒	☐	☐	Participants will be offered a debriefing session however this is not likely to raise ethical issues as the participants will be aware of the purpose of the research from the beginning. They will be given the opportunity to provide feedback on the treatment intervention.
Use of gatekeepers	☐	☐	☒	☐	Gatekeepers within the host NHS Trust will facilitate access to potentially suitable participants. They will be briefed as to the aims of the study and inclusion/exclusion criteria to aid them in doing so.
Data collected outside EU/ EEA	☒	☐	☐	☐	Data is only to be collected within the EU
Data exported outside EU/ EEA	☒		☐	☐	Data will not be exported outside of the EU
Online collection of data	☐	☐	☒	☐	Some data (daily diaries) will be collected through Qualtrics. This will be accessed by the participant using a unique password known only to them and then retrieved by the researcher.
Use of social media for data collection	☒	☐	☐	☐	Data will not be collected via Social Media.

	Not applicable	Issue is considered to be of no or minimal concern	Issue is considered to raise moderate concerns	Issue is considered raise high levels of concern	For issues raising moderate or high levels of concern, indicate how will they be managed Note: It would be good practice to explain why a specific issue is of no or minimal concern, rather than simply tick the box.
Burden to participants	☐	☐	☒	☐	Participants will be advised that will all psychological therapies there is a potential for distress when discussing their difficulties however this is no different from the treatment they will be on the waiting list to receive. The main burden is time taken to complete daily diaries and other outcome measures. Participants will be informed of the likely time commitment required within the Participant Information Sheet (PIS) and will be re compensated for this time using a Wage Payment Model.
Use of personal material in dissemination of research (e.g. quotations)	☒		☐	☐	Personal quotes will not be included in the dissemination of the research.
Descriptions of specific participants in dissemination of research	☐		☒	☐	Participants will be referred to by pseudonyms. Care will be taken that combination of demographics (age, gender, and ethnicity) will not make a person identifiable. Some background information will be included to provide context of the participants but non-essential information will be omitted or changed to maintain anonymity.
Other:	☐	☐	☒	☐	Please specify: Right to Withdrawn As in any other psychological therapy participants will be given the right to withdraw during the study without having to provide an explanation. They can return to their prior place on the waiting list to access treatment as usual. If participants withdraw they will be asked for permission to still use their data however this is entirely optional and they can decline.

Issue	Issue is considered to be of no or minimal concern	Issue is considered to raise moderate concerns	Issue is considered to raise high levels of concern	Likelihood of the issue arising	Please provide brief explanatory comment as necessary (issues raising moderate/high levels of concern and/or with medium/high likelihood of arising require further justification). Table will expand as you write into each box. Note: It would be good practice to explain why a specific issue is of no or minimal concern, rather than simply tick the box.
Issues arising in the conduct of the study					
Stress to participants	☐	☒	☐	V low ☐ Low ☐ Mediu ☒ m ☐ High	As with any psychological therapy intervention there is the potential for it to be distressing to the participant when discussing their problems. However this is no greater than the potential for this to happen in treatment they would receive as usual. Participants will be advised of this in the participant information sheet.
Harm to participants	☐	☒	☐	V low ☐ Low ☒ Mediu ☐ m ☐ High	As with any psychological therapy there is a potential for mental health to deteriorate during treatment. If this were to happen supervision would be sought and options would be discussed explicitly with the participant as to whether they wanted to be referred for additional support and treatment.
Disclosure by participants of information that my need acting on	☐	☒	☐	V low ☐ Low ☐ Mediu ☒ m ☐ High	During the research study a participant may disclose something that needs acting upon such as risks to self and/or others. Participants will be explicitly advised at the start of the treatment intervention that if this were to occur that confidentiality would be broken. If it is safe to do so the participant will be advised that the information will be shared and with whom. The researcher will have access to contact details for participants GP, local Crisis Team, local social care duty teams. Support and advice will be sought from the clinical supervisor attached to the research project.
Discovery of information that my need acting on	☐	☒	☐	V low ☐ Low ☐ Mediu ☒ m ☐ High	During the research study discovery of information that needs acting on may be made. Participants will be explicitly advised at the start of the treatment intervention that if this were to occur that confidentiality would be broken. If it is safe to do so the participant will be advised that the information will be shared and with whom. The researcher will have access to contact details for participants GP, local Crisis Team, local social care duty teams. Support and advice will be sought from the clinical supervisor attached to the research project.

Issue	Issue is considered to be of no or minimal concern	Issue is considered to raise moderate concerns	Issue is considered to raise high levels of concern	Likelihood of the issue arising	Please provide brief explanatory comment as necessary (issues raising moderate/high levels of concern and/or with medium/high likelihood of arising require further justification). Table will expand as you write into each box. Note: It would be good practice to explain why a specific issue is of no or minimal concern, rather than simply tick the box.
Participants seeking advice	☐	☒	☐	V low ☐ Low ☐ Medium ☒ High ☐	If a participant seeks advice outside of the treatment protocol the participant will be signposted to the relevant person involved with their care to answer that.
Other:	☐	☐	☐	V low ☐ Low ☐ Medium ☐ High ☐	Please specify:

Have people with lived experience of the issue been involved in:	No, not appropriate	This would have been desirable	Yes	If yes, to what extent	Please provide brief explanatory comment as to your decision to consult or not, and if so, in which aspects were people with lived experience involved. Table will expand as you write into each box.
Participation of people with lived experience in the research process					
Planning	☐	☐	☒	A little ☒ On key issues ☐ A lot ☐	Please specify: Feedback from participants from prior programmatic research into intolerance of uncertainty interventions will be taken into account when designing this treatment protocol

Have people with lived experience of the issue been involved in:	No, not appropriate	This would have been desirable	Yes	If yes, to what extent	Please provide brief explanatory comment as to your decision to consult or not, and if so, in which aspects were people with lived experience involved. Table will expand as you write into each box.
Design/review	☒	☐	☒	A little ☐ On key issues ☐ A lot ☐	Please specify:
Oversight	☒	☐	☐	A little ☐ On key issues ☐ A lot ☐	Please specify:
Analysis/ write up	☒	☐	☐	A little ☐ On key issues ☐ A lot ☐	Please specify:
Other	☐	☐	☒	A little ☐ On key issues ☐ A lot ☒	Please specify: The treatment protocol is co-constructed with each participant and they play an active part in their treatment.

Data Management	Not yet	Yes	What are/will be key data management issues (e.g. pseudonymization/anonymization of data, keeping in contact with participants, sharing of data, transfer of data, etc.)? How will this be managed
Data management			
Have you developed a data management plan	☒	☐	Please specify:

Data Management	Not yet	Yes	What are/will be key data management issues (e.g. pseudonymization/anonymization of data, keeping in contact with participants, sharing of data, transfer of data, etc.)? How will this be managed
Does it conform to GDPR 2018?	☐	☒	Please specify: Personal data will be held within the host NHS Trust and therefore will comply with NHS information governance which includes GDPR. No personal data will be on the University server- scores will be held under Pseudonyms.

Mark Freeston 2020

Appendix F –Diversity Grid

NEWCASTLE UNIVERSITY DOCTORATE IN CLINICAL PSYCHOLOGY

Research Course: Social Diversity Reflection Grid for Research Projects

Dimension (from Burnham, 1993)	1. Focus of study to some degree	2. Part of selection, or measured/ assessed, or controlled for	3. Considered unlikely to interact with other variables and so not measured	4. Considered when selecting or designing measures or developing guidelines, instructions or procedures	Does this dimension raise potential ethical issues in your proposed study?	**Trainee name:** **Sarah Kay** **Date:** **15/06/2020** **Project title:** **Please provide brief explanatory comment as necessary. Table will expand as you write into each box.**
1. Gender	☐	☒	☒	☐	☐	Gender is not selected but will be included in descriptors of participants to provide contextual information.
2. Geography	☐	☐	☐	☒	☐	Geographical location considered – participants will be made aware of where the study (treatment intervention) is to take place. As the participants will be recruited from a regional hospital and no reimbursement for travel costs will be available this may impact upon who chooses to participate.
3. Race	☐	☒	☐	☐	☐	Not selected for but will be included in descriptors of participants to provide contextual information.

4. Religion	☐	☐	☒	☐	☐	Not seen as to interact with other variables in this study and therefore not asked.
5. Age	☐	☒	☐	☐	☐	Selection criteria is over 18. Age will be reported to provide contextual information but not selected for.
6. Ability	☐	☒	☐	☒	☐	Participants will be selected with a reading age of 15 and basic GCSE level English. This will ensure that they will be able to understand the main theoretical concepts of the study (intolerance of uncertainty) and utilise written materials provided. This is a feasibility study which means that any additional adaptations of concepts and materials are beyond the remit of this study.
7. Appearance	☐	☐	☒	☐	☐	Not considered to interact with other variables in this study.
8. Class	☐	☐	☐	☒	☐	Not selected for or used as a descriptor. Considered in terms of its influencing factor on who may access health care provisions and psychological therapy provisions.
9. Culture	☐	☒	☐	☒	☐	Not selected for but will be included in descriptors of participants to provide contextual information. May come into treatment interventions particularly those which are co-constructed. This will only be the case if the participant brings it into the treatment interventions.
10. Ethnicity	☐	☒	☐	☒	☐	Not selected for but will be included in descriptors of participants to provide contextual information. May come into treatment interventions particularly those which are co-constructed. This will only be the case if the participant brings it into the treatment interventions.
11. Education	☐	☒	☐	☒	☐	Participants will be selected with a reading age of 15 and basic GCSE level English. This will ensure that they will be able to understand the main theoretical concepts of the study (intolerance of uncertainty) and utilise written materials provided. This is a feasibility study which means that any additional adaptations of concepts and materials are beyond the remit of this study.

12. Employment	☐	☐	☐	☒	☐	Participants' employment status may impact on their ability to attend regular treatment intervention sessions within the times the researchers are able to commit to.
13. Sexuality	☐	☐	☒	☐	☐	Not considered to interact with other variables and therefore will not be asked.
14. Sexual orientation	☐	☐	☒	☐	☐	Not considered to interact with other variables and therefore will not be asked.
15. Spirituality	☐	☐	☒	☐	☐	Not considered to interact with other variables and therefore will not be asked.
Other 1	☒	☐	☐	☒	☐	HEALTH: Participants will be selected on the basis of having a long term health condition as this is the population of interest for the study.
Other 2	☐	☐	☐	☐	☐	
Other 3	☐	☐	☐	☐	☐	

Mark Freeston, May, 2018.

References:

Burnham, J. (1993). Systemic supervision. The evolution of reflexivity in the context of the supervisory relationship. Human Systems, 4, 349-381.

Burnham, J. (2013). Developments in Social GGRRAAACCEEESSS: visible-invisible, voiced-unvoiced. In I. Krause (Ed.), *Cultural Reflexivity*. London: Karnac.

Appendix G – Participant Reimbursement

The national minimum wage in the UK as of April 2020 is £8.20 per hour for those aged 21-24 and £8.72 for those over 25. (Obtained from https://www.gov.uk/national-minimum-wage-rates)

A payment of £9 per hour will be given to research participants pro rata for the completion of daily diaries. It is estimated that the daily diaries will take 5 minutes each day and therefore it is estimated that participants will spend 35 minutes completing diaries each week.

Baselines will vary between participants and also the number of interventions will also vary depending on clinical need of each participant. Below is the calculation for the maximum amount of reimbursement based on baseline of 4 weeks and completion of all 16 sessions in the treatment phase.

Phase	**Time (minutes) spent completing Diaries**	**Total Payment**
Baseline (4 weeks)	140	£21
Intervention (16 weeks)	560	£84
Monitoring (4 weeks)	140	£21
Follow up	35	£5.25
		£131.25

Appendix H- Costing Grid

Trainee Name: Sarah Kay Cohort: 2019-2022

Costs of under £200 to be paid by either by the University or Employer will normally be approved. If the total to be paid by either the University or the Employer exceeds £200, a detailed justification signed by the trainee[s] and supervisor must be attached. In both cases the Panel Chair will indicate whether the costs appear justified. The final decision is made at a cohort level given the budget envelope is for the entire cohort, this will be reviewed by the Research Director in consultation with the School Administrator.

EXPENSE TYPE	DESCRIPTION	COST
Travel		0
Photocopying		£0
Materials		£0
Participants	Participant reimbursment based on wage payment model - maximum £131.25 per participant x 6	£788
Postage		
Other	Text message reminder service for daily diaries (Textlocal- 1200 text messages required)	£70.56
	Total University Costs:	£858.06

Date 15/06/2020

Participant costs MUST be approved by the School Administrator prior to data collection commencing.
You must provide as much detail as possible on number of participants, type of participation and level of remuneration requested. Participation in research will normally be rewarded with Amazon e-vouchers either in the form of a token of appreciation to all participants (normally £5) or entry to a prize draw (voucher of £20-£25 per XXX participants).
Please note that any requests for participant costs outside of normal boundaries must be provided with a full justification and confirmation from supervisor.

EMPLOYER COSTS Note, in most cases employer will cover travel costs.

EXPENSE TYPE	DESCRIPTION	COST
Travel		
Photocopying		
Materials		
Participants		
Postage		
Other		
	Total Employer Costs:	£0.00

Date

OTHER ORGANISATION NHS Host Trust (Newcastle Hopsital Trust)

EXPENSE TYPE	DESCRIPTION	COST
Travel		
Photocopying		
Materials		
Participants		
Postage		
Other		
	Total Other Costs:	£0.00

Approved (Name)

Signature

Date