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Official Title: Participant Information Sheet for Assessing the Acceptability and Feasibility of TRUST, a Brief Intervention for Paranoia in Adolescents.

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RESEARCH PROTOCOL

Assessing the acceptability and feasibility of a brief intervention for paranoia in adolescents.

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Contents

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1) RESEARCH TEAM & KEY CONTACTS

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2) INTRODUCTION

Paranoia involves intense fears that others may deliberately intend to cause you harm. This fear of being under threat and unable to trust others can cause significant distress and makes it harder to complete everyday tasks. Paranoia is common in adolescence, occurring in psychosis and other mental health disorders. However, there are currently no specific treatment plans to support adolescents with paranoia. This study aims to address this gap by delivering a new intervention designed to help young people (aged 16-18) who are experiencing paranoia and waiting for mental health care.

Previous research has shown that interventions using values-based approaches (what matters most to a person) and mental imagery (visualising scenarios to change how we think or feel) can help reduce paranoia in adults and general adolescent populations. This study combines these approaches, which have already proven effective, into a six-week intervention for adolescents on a Child and Adolescent Mental Health (CAMHS) waiting list. The participants will complete self-report questionnaires measuring paranoia, social functioning, mental imagery and beliefs about themselves and others before starting the study, after the intervention and again one month later. During the intervention, participants will have six weekly therapy sessions and complete shorter weekly assessments to track changes in paranoia. At the end, we will ask participants about the acceptability of the intervention.

We want to find out how practical the new intervention is to deliver and complete, and how well adolescents will receive and engage with the treatment. We will also assess whether the intervention reduces paranoid thoughts and improve overall well-being. We hypothesise that (1) the intervention will be acceptable and feasible for use with young people who experience paranoia, (2) it will help reduce paranoia and improve their daily functioning and (3) these improvements will be maintained at one-month follow-up.

3) BACKGROUND

Adolescence is a vulnerable period for the development of mental health problems. Their social world becomes more unpredictable and uncertain, so they can be more vigilant of the intentions of others (Blakemore et al., 2018). Therefore, paranoia - the exaggerated fears that others may intend to cause you harm - is a common experience among adolescents (Freeman & Garety, 2014; Freeman 2011). 20-30% report weekly fears and for some will develop into persecutory delusions (Dominguez et al., 2014). Paranoia is transdiagnostic, meaning it occurs across a range of disorders (Freeman et al., 2019a). This means it is reported by help seeking individuals with a range of non psychotic mental health disorders (van Os & Reininghaus, 2016). Recent evidence suggests paranoia is a common presentation

in those attending child and adolescent mental health services (Bird et al., 2021). Approximately 35% of those seeking mental health care show clinical levels of paranoia (Bird, 2022). Other studies show that 1 in 5 adolescents report experiencing weekly paranoid thoughts (Kingston & Parker, 2022).

Research shows how severely paranoia can affect an adolescent's life (Bird et al., 2019). It can make it difficult for them to interact with others, form relationships, and engage in everyday activities, often leading to isolation and distress. If untreated, paranoia can worsen over time, sometimes developing into more severe issues like persecutory delusions (where a person believes others are deliberately trying to harm them) or hallucinations (where a person hears or sees things that are not there) (Bird et al., 2019; Dominguez et al., 2011). Early intervention is key to preventing these symptoms from becoming more persistent and serious.

Despite its prevalence and impact, no specific clinical guidelines exist to address paranoia in adolescents seeking mental health support. This represents a significant gap in care, leaving many young people without support. Current models to address paranoia have focused almost exclusively on research from adults. In adulthood, interventions like values-based approaches and mental imagery have shown promise in reducing paranoia (Parker & Kingston, 2021; Taylor et al., 2020). These interventions work by addressing underlying cognitive processes such as negative self and other beliefs, distressing mental images, and a lack of value-directed behaviour, which are known to maintain paranoia (Garety & Freeman, 2013; Kingston & Ellet, 2014).

This research has the potential to address a critical gap in the mental health care of adolescents by providing:

(A). The research will help determine how to deliver effective, brief treatments for paranoia, informing clinical practices and contributing to future treatment guidelines for adolescents.

(B) Clinical approaches to paranoia is likely to require a tailored approach that acknowledges the unique life-stage issues associated with adolescence (McGorry, 2007). Evidence on age-specific needs and preferences, promoting greater engagement and effectiveness of interventions for adolescents.

(C) A stronger theoretical foundation for understanding the role of diminished value-directed behaviour and distressing mental imagery in the maintenance of paranoia.

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

The principle aim of this research is to determine whether it is feasible and acceptable to deliver a six-session intervention to adolescents who are on a Child and Adolescent Mental Health Service (CAMHS) waiting list and distressed by paranoid worries.

4.2 Secondary Question/Objective:

This study aims to explore whether the intervention provides any preliminary clinical benefits for young people experiencing paranoia. Specifically, we will assess whether the intervention helps to:

- Reduce distressing paranoid thoughts (using the Revised Green Paranoid Thoughts Scale)
- Improve daily functioning in areas like school, social life, and family relationships (using the Work and Social Adjustment Scale for Youth)
- Change negative beliefs about oneself and others (using the Brief Core Schema Scale)
- Reduce distressing mental imagery associated with paranoia (assessed by Negative Mental Imagery Scale)
- Improve Value Based Action (assessed by the CompACT-Y).

5) STUDY DESIGN AND PROTOCOLS

5.1 Participants

Young people aged 16–18 seeking psychological therapy at Westminster Child and Adolescent Mental Health Service (CAMHS) will be invited to participate. A total of 5–8 participants will be recruited, based on the effect replication required for this design and a review of previous single-case experimental design (SCED) studies (e.g., Taylor et al., 2020).

5.2 Study Intervention and/or Procedures

Before starting the intervention, participants will be randomised to different baseline lengths (2, 3, or 4 weeks) via an online randomisation software (Sealed Envelope). During the baseline phase, participants will not receive the intervention but will complete up to four assessments to measure their symptoms and establish a stable starting point.

Participants assigned to a 2-week baseline will complete three assessments (at the start ,middle and end). Those assigned to a 3-week baseline will complete three assessments (weekly). Participants assigned to a 4-week baseline will complete four assessments (at the start, week 1, week 2, and end). The maximum time that it would take participants to complete take a participant to complete questionnaires in one sitting would be approximately 10 minutes. The questionnaires will be completed on Qualtrics. The measures vary in length, but they all consist of rating statements on a Likert scale. The initial

assessment and follow-up questionnaires measure different constructs, including paranoia, functioning, negative self and other beliefs and mental imagery.

After the baseline phase, participants will attend six one-to-one sessions, with each session having a duration of 60 minutes. Participants will also complete one brief weekly questionnaire (RGPTS- Part B) and two single item measures before their session to monitor their symptoms and experiences of paranoia during the intervention.

Session 1: Assessment, formulation and psychoeducation (teaching) about paranoia.
Session 2: Identifying personal values and setting goals based on those values.
Session 3-5: Using mental imagery techniques to challenge negative beliefs about themselves and others.
Session 6: Bringing it all together (e.g., reviewing sessions, plan for implementing strategies, discussing mid and longer term valued goals).

One month after the intervention ends, participants will meet with the CI again and complete the four initial assessment questionnaires (approximately 15 minutes) to measure any lasting effects of the therapy.

The appointments will take place at an NHS Psychological Services base though there is the option for the study to take place on MS Teams if a preference for video therapy is expressed or if required.

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria

- Aged 16-18
- Seeking help from a Child and Adolescent Mental Health Service (CAMHS)
- A score ≥ 11 on the R-GPTS (Scale B)
- Sufficient understanding of English
- Capacity to consent, as assessed during the initial interview
- Wanting support with paranoia
- Low- moderate mental health risks (emotional difficulties that impact functioning, but no immediate risk to safety e.g., no suicidal intent).

6.2 Exclusion Criteria

- Severe comorbid diagnoses apparent at the initial assessment (e.g., a primary alcohol or substance dependence issue)

- The presence of a developmental disability or cognitive impairment that would interfere with participation.
- Concurrent participation in another psychological therapy
- High levels of current risk (e.g., significant and immediate concerns about the young person's safety, such as suicidal intent)

6.3. Recruitment

Potential participants will be identified through two main routes:

(A) New Referrals: Westminster CAMHS holds a weekly intake meeting where newly referred cases are reviewed. Professionals in attendance will identify young people who may be suitable for the study and notify the clinician conducting their Initial Assessment (IA). If, at the end of the IA, the young person is still deemed appropriate for the study, the clinician will introduce the study and ask the young person if they consent to their contact details being shared with the Chief Investigator (CI). If the young person expresses interest, verbal consent will be obtained for their contact details to be shared with the Chief Investigator (CI). The CI will then invite them to an initial meeting, talk them through the study, ask them to complete the screening questionnaire and assess eligibility, and then invite them to take part and gain consent (see below).

(B) Existing Waiting List: An administrator or Assistant Psychologist at Westminster CAMHS will also review the waiting list to identify young people who have already had their IA and are awaiting treatment. The young person's case manager or an assistant psychologist will contact them to discuss potential participation in the study. If the young person agrees, their contact details will be passed to the CI for further discussion and formal consent.

Potential participants may become aware of the study through posters displayed in the Westminster CAMHS reception area. These posters will provide basic information about the study, including its purpose, eligibility criteria, and how to express interest.

To enhance recruitment, information about the study will be shared through multiple channels, such as the Monthly Business Meetings at Westminster CAMHS, Weekly sub-team meetings and Posters in the reception area, where young people attending their IA may see the study and express interest.

6.4 Randomisation

Participants will be randomised to different baseline lengths (2, 3, 4) weekly assessment via an online randomisation software (Sealed Envelope).

6.5 Participants who withdraw consent [or lose capacity to consent]:
Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. Should the participant lose capacity to consent during the study then they will be withdrawn but any data already collected will be retained and used in the study. This will be outlined on the consent form and information sheet.

If there are concerns regarding mental capacity by either the research team or the participants' clinical care team then the clinical care team will undertake a Mental Capacity Act assessment. This would be completed and recorded in clinical records per their standard local procedure. The results of this would be passed to the research team via email.

7) OUTCOME MEASURES

The primary outcome for the study is feasibility of the intervention and as such, this will measure using the following metrics:

Regarding the number of:
- Individuals approached regarding the study
- Individuals recruited for the study
- Sessions attended
- Individuals who drop-out and at which point in the programme

Acceptability will be measured using the results from the Client Satisfaction Questionnaire (CSQ; Larsen et al., 1979). This is completed after session 6 of the intervention.
Any preliminary potential clinical benefits will be determined using the following outcome measures; changes in outcome measure scores from first baseline to end of therapy assessment will be calculated. The suitability of outcome measures will also be measured (determined by % completion).

- Paranoia: The Revised Green Paranoid Thoughts Scale (R-GPTS; Freeman et al., 2019).
- Functioning: The Work and Social Adjustment Scale for Youth (WSAS-Y; Jassi et al., 2020)
- Negative self and Other Beliefs: The Brief Core Schema Scales (BCSS; Fowler et al., 2006)
- Mental Imagery: The Negative Mental Imagery Scale (Oaie et al., 2024)
- Values: Compact (ACT-Y) – (Morey et al., 2024)

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

The research team will not have access to personal identifiable data prior to verbal consent from the potential participant. The researchers will liase with the mental health care team via secure NHS email and details of contact information will only be shared in the NHS site. The use of personal contact details will be limited to contacting participants once they had met inclusion criteria and expressed interest in participating in the study; this would be to arrange screening and appointments. Data will be pseudonymised during the course of the research. An ID will be assigned to each participant to ensure that outcome measure data can be linked together throughout the process of the research. Pseudonymisation is used to protect participant confidentiality because only those with access to the key are able to link the data to the individual; access to the key will be strictly limited to the chief investigator and their supervisors.

Following Royal Holloway, University of London Standard Operating Procedures pertaining to 'taking recordings of participants for research projects' and 'information security classification, ownership and secure information handling', personal data in physical form will not be left unattended and files will be transferred to the secure NHS and university servers as soon as possible. Audio and/or video recordings of sessions will be stored in a secure cloud platform which can be accessed by the chief investigator and co-investigators on private computers in secure environments. Video recordings provide additional detail in regard to non-verbal cues for supervision; audio recordings will be an alternative option. Audio and/or video recordings will be destroyed after a three-month period. The recordings is for checking intervention protocol adherence as opposed to gathering any data for the research.

Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information.

The data generated will be analysed in a private residence of, and by, the Chief Investigator. Data transferred will be completely anonymised on an NHS computer prior to transfer. Data will not be transferred outside of the UK.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

A statistical review was not deemed necessary for this research study as only frequencies and associations will be assessed.

Descriptive statistics will be used to evaluate the characteristics of the sample population.

Descriptive statistics will be utilised to evaluate the feasibility of the intervention. Participant recruitment, attendance and retention will be described using frequency statistics and percentages.

The feasibility and acceptability criteria follow a three-level 'traffic light' approach (Avery et al., 2017) to determine whether a future trial is feasible with the current design (GREEN), feasible with modifications (AMBER), or not feasible due to significant issues (RED). Our target sample size is 5 to 8 participants.

1. Recruitment:
    - GREEN: 5 or more participants recruited
    - AMBER: 3 to 4 participants recruited
    - RED: 2 or fewer participants recruited
2. Retention:
    - GREEN: 5 or more participants complete the end-of-therapy assessment
    - AMBER: 3 to 4 participants complete the end-of-therapy assessment
    - RED: 2 or fewer participants complete the end-of-therapy assessment
3. Adherence:
    - GREEN: 5 or more participants attend at least 3 therapy sessions
    - AMBER: 3 to 4 participants attend at least 3 therapy sessions
    - RED: 2 or fewer participants attend at least 3 therapy sessions

Therapy acceptability will also be evaluated through participant feedback using a therapy process feedback questionnaire and an adverse effects questionnaire, administered upon therapy completion or withdrawal.

We will proceed with to a full trial if all criteria are classified as GREEN. If any criteria are AMBER, we will consider adjustments to the intervention and study design to address the

issues and reassess feasibility. If that is possible, we will progress to a full trial. If any criteria are RED, we will not progress unless substantial amendments can make further testing feasible.

Outcome measure scores pre- and post-intervention will be analysed using SPSS statistical software to determine effect sizes and descriptive statistics (M, SD, % change) will also be reported. Individual graphs will be plotted for each participant to visually display the changes in outcome measures over the course of the study. Reliable (Morley & Dowzer., 2014) and clinically significant change (Jacobson & Truax., 1992) will be calculated using the Leeds Reliable Change Index calculator from baseline to end of treatment.

9.2 Sample Size

As the primary objective of the study is to complete a single case experimental design to determine feasibility of an intervention, a power calculation is not required, rather the target is based on consideration of logistics, resources and time per guidance from the Pilot and Feasibility Studies Working Group (https://pilotandfeasibilitystudies.qmul.ac.uk/resources/).

10) DATA MONITORING AND QUALITY ASSURANCE

The study will be subject to the audit and monitoring regime of Royal Holloway, University of London.

Due to the research study being a proof of concept and feasibility single case experimental designs, we will not be using a Data Monitoring Committee. The Chief Investigator is a trainee clinical psychologist and the co-investigators are qualified clinical psychologists, along with the research and intervention taking place in an NHS secondary care setting, it is anticipated that the setting of the research, training and experience of the researchers will allow for safety to be monitored closely. Clinical supervision will be utilised regularly by the Chief Investigator and other members of the participant's care team (Care Coordinators in secondary care services, General Practitioner) who are responsible for risk will be appraised of any concerns regarding distress or safety. There are detailed safeguarding procedures in place.

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

As with all psychological interventions, there is the potential that young people will discuss things that they find upsetting (e.g., paranoia related worries). To address this, sessions will

take place in a safe and confidential NHS psychology service, where additional support can be accessed if needed. Following safeguarding procedures of the service will guide the researcher in managing adverse events or disclosures that occur if sessions are online. Participants will also receive written information on how to contact crisis services between sessions if more regular support is needed.

12) PEER REVIEW

The research was written into a detailed proposal document and reviewed by the Royal Holloway University of London Clinical Psychology Doctorate Course research sub-committee. The proposal included information on the project summary, background and aims, plan of investigation (including sample, setting, measures, design, analysis), ethical considerations, service user involvement, practical considerations and dissemination. The criteria used by the committee included validity, feasibility and methodological soundness of the project.

The first review of the full proposal took place on 18/10/2024 and feedback was provided to the trainee clinical psychologist by the committee. Their comments were answered and conditions responded to on 13/25/2025. The proposal was approved on 10/01/2025.

13) ETHICAL and REGULATORY CONSIDERSATIONS

13.1 Approvals

NHS Research Ethics Committee and HRA approval will be obtained from Health and Social Care Research Ethics Committee REC A (HSC REC A) before commencing research.

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

13.2 Risks

Talking about paranoia and mental health may bring up difficult emotions or memories for participants. In some cases, the intervention could make paranoid thoughts worse, increase distress, or lead to more mistrust. To manage this, the Chief Investigator (CI) will regularly check for signs of distress or worsening paranoia. Participants safety will be prioritised when carrying out the therapy. If they become distressed, they will be invited to take a break, and made aware that the session can be discontinued. If needed, the CI will work with their supervisors to decide if it's safe to continue sessions. A distress protocol will be in place to guide the CI in handling any adverse events. The sessions will take place in a safe, confidential CAMHS setting with support available if necessary.

Participants might worry about being labelled with paranoia, especially if they have previously been told their experiences were more related to common adolescent worries, like social anxiety. This could lead to feelings of shame. To reduce this risk, only participants with significant paranoia will be included, using a specific assessment tool (RGPTS Scale B). The study will take a supportive approach, reassuring participants that their participation is voluntary and that any symptoms will be explored in a non-judgmental way.

The study requires a screening call, six sessions, and a one-month follow up, which may feel like a burden for some participants, especially if they are struggling with low motivation. The CI will work to schedule sessions at convenient times and will send reminders for appointments and questionnaires. The weekly questionnaires will be brief (about 10-15 minutes), and the CI will keep the process as easy as possible for participants to reduce their burden.

Previous research suggests that adults and a general population of adolescents have already benefited from the components of this research. However, we do not yet know whether the outcomes will be the same for this client group. This is therefore a risk. However, there is no evidence to suggest that any harm will come through participation. Moreover, as this is a new intervention, there may be unexpected outcomes, such as lack of interest or difficulty engaging with the content. The CI will regularly assess participant feedback and the effectiveness of the intervention, adjusting as needed to ensure the participant's well-being.

Participants may be concerned about sharing personal information with the CI as they are not part of their direct care team. To address this, the researcher will clearly explain that any information shared will remain confidential and only be used for the study. Participants will also be reassured that their personal information will not be shared with anyone outside the research team unless required by law or safety concern. Participants will be made aware of the risk of confidentiality being broken, if there is concern about risk to themselves or others. The benefit of this is that the participants and those around them are kept safe. If this disturbs the therapeutic relationship, steps will be taken for trust and rapport to rebuild, with assistance from supervisors.

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-

negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING and RESOURCES

The study has not received any external funding. Royal Holloway, University of London Doctorate in Clinical Psychology programme provides a small budget, which will be used to work with Experts by Experience (EbEs) for dissemination of results.

16) PUBLICATION POLICY

The findings from the study will form the basis of part of a doctoral thesis on the Doctorate in Clinical Psychology at Royal Holloway. The findings from the study will be disseminated via social media, a lay summary will be provided to participants and summaries will be provided to the care service from which participants were recruited. The researchers also aim to disseminate the results of the research through peer-reviewed scientific journals and conference presentation.

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