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Table of Contents

Abstracts.....9

Systematic Review of the Literature (SRL): Paranoia and appraisals of social comparison: A systematic review of social rank, attractiveness, and belonging.....13

Abstract.....15

Introduction.....16

Method.....20

Results.....24

Discussion.....44

References.....50

Service Improvement Project (SIP): "We don't sleep here": Experiences of sleep problems, factors disrupting sleep, and intervention preferences in an adolescent inpatient service.....59

Abstract.....61

Introduction.....62

Method.....64

Results.....68

Discussion.....78

References.....81

Theory Driven Research Project (TDRP): Advancing the clinical understanding and measurement of negative self-beliefs in young people with paranoia.....86

Abstract.....88

Introduction.....89

Methods.....92

Phase One: Item Generation

Method.....93

Results.....95

Phase Two: Measure Validation

Method.....100

Results.....103

Discussion.....110

References.....114

Executive Summary.....120

Connecting Narrative.....122

Acknowledgements.....126

Appendices

Appendix A SRL: Author guidelines for Psychology and Psychotherapy: Theory, Research and Practice.....127

Appendix B SRL: Search terms.....132

Appendix C SRL: Data extraction headings.....133

Appendix D SRL: Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies (National Institute of Health, 2013).....134

Appendix E SRL: Downs and Black Checklist (Downs & Black, 1998).....141

Appendix F SIP: Interview topic guide.....144

Appendix G SIP: Post-interview checklist of factors disrupting sleep.....150

Appendix H SIP: Supporting quote tables..... 153

H.a Quotes on the impact of poor sleep.....153

H.b Quotes on threat-based appraisals at night.....154

Appendix I SIP: Recommendations for service development.....155

Appendix J SIP: Approval documentation for sponsorship, ethics, and NHS trust research and development....158

J.a Data protection impact assessment confirmation....158

J.b Sponsorship Oxford Health NHS Foundation Trust....166

J.c NHS ethics approval letter....167

J.d Research and development confirmation of capacity and capability....171

Appendix K TDRP: Author submission guidelines - *Behaviour and Cognitive Psychotherapy*....173

Appendix L TDRP: Questionnaire development (Tsang et al., 2017)....177

Appendix M TDRP: Patient and public involvement advertisement....178

Appendix N TDRP: Interview schedule....180

Appendix O TDRP: Phase one screening measure and severity thresholds....183

Appendix P TDRP: Thematic analysis steps (Braun & Clark, 2006; Terry et al., 2017)....185

Appendix Q TDRP: Questionnaire item pools....186

Appendix R TDRP: Phase two measure validation....190

R.a Phase two advertisements....190

R.b Phase two questionnaires....191

R.c Phase two debrief page....198

Appendix S TDRP Sample size determination....201

Appendix T TDRP: Recommended thresholds for good model fit (Hu & Bentler, 1999)....202

Appendix U TDRP: Demographics of online validation sample....203

Appendix V TDRP: Exploratory and confirmatory factor analysis....204

V.a Decisions for the SoS....204

V.b Decisions for the SoS-E.....208

Appendix W TDRP: Correlations of SoS and SoS-E.....211

Appendix X TDRP: Approval documentation for sponsorship, ethics, and NHS trust research and development.....212

X.a University of Oxford sponsorship.....212

X.b NHS ethics approval.....214

X.c Oxford Health NHS Foundation Trust research and development: capacity and capability.....220

X.d Berkshire Healthcare NHS Foundation Trust research and development: capacity and capability.....223

X.e Amendment documentation.....225

References for Appendices.....235

Table of Tables

Systematic Review of the Literature

Table 1.1 Summary of Data from Cross-Sectional Studies....33

Table 1.2 Summary of Data from Experimental Studies....38

Table 1.3 Quality Assessment Observational Cohort and Cross-sectional Studies....41

Table 1.4 Quality Assessment Experimental Studies....42

Service Improvement Project

Table 2.1 Sample Demographics....68

Table 2.2 Sample Characteristics....69

Theory Driven Research Project

Table 3.1 Participant Characteristics....96

Table 3.2 Participant quotes relating to themes and subthemes....97

Table 3.3 Overview of Survey Measures....101

Table 3.4 Descriptive Statistics for the SoS....106

Table 3.5 SoS Final Item Pool....106

Table 3.6 Descriptive Statistics for the SoS-E....107

Table 3.7 SoS-E Final Item Pool....108

Table 3.8 Correlations between the SoS, SoS-E, and other measures....110

Table of Figures

Systematic Review of the Literature

Figure 1.1 PRISMA Flowchart of Search Procedures.....23

Service Improvement Project

Figure 2.1 SIP Final Thematic Map.....70

Theory Driven Research Project

Figure 3.1 Flowchart of Data Cleaning for Online Responses.....104

Abstract

Systematic Review of the Literature: Paranoia and appraisals of social comparison: A systematic review of social rank, attractiveness, and belonging

Purpose: Theoretical models propose a link between paranoia, defined as unfounded threat belief(s) that others intend one harm, and negative evaluations of oneself and one's social standing compared to others (social comparison). This review aims to evaluate evidence for a relationship between paranoia and social comparison, and outline implications for research and clinical practice.

Methods: A systematic search was conducted to identify quantitative studies investigating paranoia and social comparison. General and clinical populations were considered.

Results: Eighteen studies were eligible: thirteen observational, cross-sectional (n=12) and longitudinal (n=1), and five experimental, manipulation (n=4) and clinical intervention (n=1). Eleven observational and three experimental studies reported a significant relationship between paranoia and unfavourable social comparison, with low-to-moderate effect sizes. Studies used validated continuous measures indicative of a dose-response relationship. Methodological limitations included low statistical power, failing to account for confounds, and poorly defined samples. The review identified a potentially fatal flaw of studies that assume a linear relationship, when evidence suggests that individuals who perceive themselves to be at the extremes of the social comparison distribution may be more susceptible to paranoia.

Conclusions: In line with theoretical models, social comparison is indicated as a target for further research in understanding paranoia and may be a meaningful target for clinical intervention. Conclusions on the magnitude of the relationship and causality are limited due to the relatively low methodological rigour of studies. Longitudinal and experimental research is needed to test the putative causal mechanisms of paranoia and delineate which aspects of social comparative processes are involved.

Keywords: Paranoia, social comparison

Abstract

Service Improvement Project: "We don't sleep here": Experiences of sleep problems, factors disrupting sleep, and intervention preferences in an adolescent inpatient service

Objectives: Sleep problems are prevalent in adolescents admitted to psychiatric units but rarely targeted in treatment. This service improvement project investigated inpatient adolescents' experiences of sleep problems, factors disrupting sleep, and intervention preferences.

Design: A qualitative interview design.

Methods: Patients with insomnia symptoms were recruited from one psychiatric unit. Semi-structured interviews with twelve adolescents were analysed using thematic analysis.

Results: Sleep problems were co-occurring and had a reciprocal relationship with daytime impairments. Factors disrupting sleep included an unfamiliar setting and routine, sensory overload, intrusive experiences (e.g., nightmares), intense emotions (associated with anxiety-related hyperarousal, mania, hopelessness, and unhelpful coping strategies), attempts to cope with fatigue (e.g., daytime sleep), and factors specific to eating disorders. Patients described sleep interventions as fundamental to their care, particularly personalised help early in admission. Intervention preferences highlighted the supportive role of staff and peers in settling at night, use of observations, and daytime physical activity.

Conclusions: Findings highlight patients' experiences of too little sleep, fragmented sleep, and shifts in sleep timing. Addressing sleep problems is valued and an important target in inpatient settings, and patients wish for options beyond medication alone. Recommendations are presented.

Keywords: Insomnia, adolescent, inpatient

Abstract

Theory Driven Research Project: Advancing the clinical understanding and measurement of negative self-beliefs in young people with paranoia

Background: Negative self-beliefs are implicated in the causation of paranoia. When we perceive ourselves as inferior, outcast, and hence vulnerable, paranoid ideas flourish. This relationship is pertinent in adolescence, a developmental period of identity formation and expanding social connections. However, little is known about the types of self-cognitions that drive adolescent paranoia.

Aims: We sought to investigate themes of self-beliefs relevant to the experience of paranoia in youth, and develop a precise measurement tool.

Method: This was a mixed methods study. Semi-structured interviews were conducted with 12 young people experiencing paranoia (*age range*=14-23, *M*=19, SD=3.22). Data was analysed using thematic analysis to generate two item pools (self-beliefs, evidence for beliefs). The item pools and measures of self-esteem, paranoia, depression, hallucinations, and grandiosity were completed online by 937 young people (*age range*=14-25, *M*=17.87, SD=2.75) from the general population. Exploratory and confirmatory factor analyses were used to derive the Sense of Self – Youth Scale (SoS) (*n*=1200) and a complementary scale on evidence underlying beliefs (SoS-E) (*n*=1104). Psychometric properties were tested.

Results: The 20-item SoS includes four subscales: *not good enough, bad, broken*, and *an outcast*. Confirmatory factor analyses demonstrated excellent model fit. The SoS demonstrated high internal consistency (α=.941), test-re-test reliability (ICC=.959), convergent and divergent validity. The SoS was significantly associated with paranoia (r=.634, p<.001), depression (r=.699, p<.001), and hallucinations (r=.418, p<.001). The complementary measure, SoS-E, had 18-items with seven subscales, and had a strong correlation with the SoS (r=.817, p<.001).

Conclusions: The SoS and SoS-E are brief, psychometrically robust, self-report measures which may prove helpful for understanding and treating negative self-beliefs relevant to the experience of paranoia in youth.

Keywords: Negative self-beliefs, paranoia, youth

Systematic Review of the Literature

Paranoia and appraisals of social comparison:

A systematic review of social rank, attractiveness, and belonging

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Proposed Journal

Psychology and Psychotherapy: Theory, Research and Practice is an international journal that welcomes papers on the vulnerability to, adjustment to, assessment of, and recovery from psychological disorders, and welcomes submissions of systematic reviews. Previous publications have included research on social and evolutionary perspectives of psychological symptoms and disorders, in line with the topics of this review. Author submission guidelines are presented in Appendix A.

Acknowledgements

This work was supported by the Oxford Institute for Clinical Psychology Training and Research. No funding was sought for this project. A second trainee on the course, Eve Twivy (ET), was involved in the project as a collaborator to perform reliability checks.

Abstract

Purpose: Theoretical models propose a link between paranoia, defined as unfounded threat belief(s) that others intend one harm, and negative evaluations of oneself and one's social standing compared to others (social comparison). This review aims to evaluate evidence for a relationship between paranoia and social comparison, and outline implications for research and clinical practice.

Methods: A systematic search was conducted to identify quantitative studies investigating paranoia and social comparison. General and clinical populations were considered.

Results: Eighteen studies were eligible: thirteen observational, cross-sectional (n=12) and longitudinal (n=1), and five experimental, manipulation (n=4) and clinical intervention (n=1). Eleven observational and three experimental studies reported a significant relationship between paranoia and unfavourable social comparison, with low-to-moderate effect sizes. Studies used validated continuous measures indicative of a dose-response relationship. Methodological limitations included low statistical power, failing to account for confounds, and poorly defined samples. The review identified a potentially fatal flaw of studies that assume a linear relationship, when evidence suggests that individuals who perceive themselves to be at the extremes of the social comparison distribution may be more susceptible to paranoia.

Conclusions: In line with theoretical models, social comparison is indicated as a target for further research in understanding paranoia and may be a meaningful target for clinical intervention. Conclusions on the magnitude of the relationship and causality are limited due to the relatively low methodological rigour of studies. Longitudinal and experimental research is needed to test the putative causal mechanisms of paranoia and delineate which aspects of social comparative processes are involved.

Keywords: Paranoia, social comparison

Paranoia and appraisals of social comparison: A systematic review of social rank, attractiveness, and belonging

Defining paranoia

Paranoia is operationally defined as the unfounded belief that others deliberately intend to cause one harm (Freeman & Garety, 2000). Anxious predictions of harm are current or future-oriented, and may involve the fear of deliberate physical, psychological, or emotional harm (Freeman & Garety, 2000). Paranoia can be specific to social roles, such as the fear of dominant or authority figures, romantic partners, or out-groups and organisations. Research shows that paranoia exists on a continuum in clinical and general population samples, from social evaluative concerns, to ideas of reference and persecution, and at the severe end delusional beliefs about others hostile intent (Bebbington et al., 2013; Freeman et al., 2002; Freeman et al., 2005). Paranoia is measured at a state level; a temporary socio-cognitive process within a specific context, or trait level; a conceptually fixed orientation of one's socio-cognitive processes across contexts (Fridhandler, 1986).

Paranoia is conceptualised as a transdiagnostic process across psychosis-spectrum and common mental health disorders (American Psychiatric Association, 2013), and identified as one of the most distressing psychotic experiences (Garety et al., 1988). When one feels consistently under threat and cannot trust others it becomes difficult to maintain healthy routines and relationships. Over 70% of people experiencing first episode psychosis have a persecutory belief (Coid et al., 2013), half show levels of psychological well-being in the lowest 2% of the general population, and psychiatric admission is a common consequence (Castle et al., 1994; Freeman et al., 2014a). Data from a large nationally-representative UK sample has shown paranoia is associated with suicidality, poor physical and mental health, reduced quality of life and social functioning, and increased clinical service need (Freeman et al., 2011).

Defining social comparison

Wood (1996) defines social comparison (SC) as constituting three major processes: acquiring social information (seeking, encountering, or constructing), evaluating the outcome of comparison in relation to oneself ([dis]similarities, ascertaining meaning or implications of one's relative standing), and reacting to the evaluation via cognitive, affective, and behavioural responses. Accordingly, measures that seek to understand the selection of social information and comparison orientation tap into the first process, measures of evaluative self-other comparisons tap into the second process, and measures of constructs including shame, self-criticism, and submissive behaviours tap into the third process.

It is the second process, cognitive appraisals composed of evaluative self-other comparisons from which we form rank judgements about ourselves in social contexts, that we refer to as SC in this paper. Allan and Gilbert (1995) propose the definition of social comparison as an individual's belief regarding their social standing in comparison to others and report on three salient factors. These include social rank; the comparison of relative power (inferior-superior, incompetent-competent), group fit; how a person judges themselves as fitting in with others (different-same, outsider-insider), and social attractiveness; being wanted or chosen by others (unlikable-likable, unattractive-attractive), with the caveat that constructs are not theoretically distinct. Social comparative appraisals of inferiority, lack of belonging, and low attractiveness (unfavourable social comparisons), when one perceives themselves as occupying a low rank within a social hierarchy, are associated with negative affect and a wide range of psychopathology (Gilbert, 2000; Gilbert et al., 1995).

Paranoia and self-concept

It has long been proposed that paranoia arises in the context of disturbances in self-perception, described in the quote *'paranoia feeds on vulnerability'* (Freeman, 2016, p. 687). Paranoia typically arises in adolescence and early adulthood, a developmental period characterised by heightened sensitivity to social threat (Bird et al., 2019; van Os &

Reininghaus, 2016). Cognitive self-other appraisals during this period help individuals generate meaning, make decisions and adapt to social environments, associated with the development of self-concept and self-esteem (Harter, 2003). Empirical evidence shows that negative beliefs about oneself predict the development and persistence of persecutory beliefs (Fowler et al., 2012; Lincoln et al., 2010). Secondly, trait interpersonal sensitivity (excessive awareness of, and sensitivity to, the behaviour and feelings of others) and beliefs of vulnerability to rejection are significant predictors of paranoia (Freeman et al., 2008; Meisel et al., 2018). Evolutionary theories propose a significant role of unfavourable social comparisons in the causation and maintenance of paranoia, hypothesised to lower one's threshold to the detection of social threats, however this relationship has been relatively overlooked in the literature.

Paranoia and SC

Social groups self-organize into hierarchies, where members vary in level of power, dominance, influence, and skill (Koski et al., 2015). Unfavourable comparisons of low relative power in social contexts, and not fitting in or being wanted in social groups, pose a significant threat to survival (ensuring basic needs are met, reproduction, kinship) and sense of self (self-concept, self-esteem, and judgements of worth). When feeling vulnerable individuals become more attentive to threat signals in the environment, appraise others as more dominant, malevolent, and as competitors, and are more likely to question other's intentions (Raihani & Bell, 2019). When coupled with a history of social adversity and experience of others as hostile, it is easy to see how paranoia might flourish. Paranoia is thus regarded as a defensive process that can be adaptive in certain situations to protect oneself from social threats (Dixon, 1998; Gilbert, 1993). Culturally, political and social contexts may encourage paranoia, and fears of others or particular out-groups can become common and entrenched. Paranoia becomes clinically relevant on an individual level when these processes become exaggerated or unfounded, distressing, and have an impact on functioning.

Types of unfavourable social comparisons

Social rank theory has been proposed to operationalise appraisals of social defeat (SD), defined as the repeated experience of feeling powerless and being excluded, belittled or humiliated by a majority group (Allan & Gilbert, 1995). Theorists propose that exposure to chronic social stressors and adversity, with a perceived failed struggle and loss of rank, leads to a fear of others and paranoid ideation (Selten & Cantor-Graae, 2005; Selten et al., 2013). These studies show that distal and proximal environmental factors predict paranoia, including abuse and trauma in childhood, attachment difficulties, hostile or neglectful parenting styles, high familial expressed emotion, subordination, bullying, discrimination, low socio-economic status, and migration. Similar factors are implicated in the causation of psychosis (Jaya et al., 2017). Notably, the impact of variables such as minority status are ameliorated as ethnic density increases (Bosqui et al., 2014), which may indicate a process of group belonging as important in the reduction of paranoia.

The degree of perceived 'fit' of a member to relevant social groups is essential to meet the need for kinship and a sense of belonging (Bailey et al., 1992). Unfavourable comparisons regarding belonging are proposed to arise from a loss of affiliation, associated with fear of rejection, marginalisation, outsider status and loss of social support (Allan & Gilbert, 1995). The perception of reduced belonging and outsider status is increasingly recognised as a predictor of paranoia (Raine, 2016).

Social attractiveness (the ability to display socially desirable qualities that others find pleasing/rewarding) is implicated in the formation of social connections and hierarchies (Gilbert, 1997). As we perceive oneself as losing attractiveness to others, the experience of feeling devalued and shamed may serve to alert the self and others to a detrimental change in social status (Gilbert, 1997).

Rationale

Systematic reviews comment on, evaluate, extend, or develop theory (Baumeister, 2013). Increasing evidence shows that beliefs of low social rank, social attractiveness, and lack of belonging, predict paranoia (Freeman et al., 2005). Reviews have investigated the relationship between paranoia and self-concept, specifically negative self-appraisals associated with low self-esteem (Atherton et al., 2016; Kesting & Lincoln, 2013; Tiernan, Tracey & Shannon, 2014), and trait interpersonal sensitivity (Meisel et al., 2018). However, to date there has been no review focused on the relationship between paranoia and SC. The aim of this review is to provide insight into current theories on the putative relationship between paranoia and aspects of unfavourable social comparison pertinent in the literature: perceptions of social rank, social attractiveness, and belonging.

Aims

This review aims to:

1. Systematically identify studies investigating the relationship between paranoia and SC.
2. Critically evaluate evidence with a focus on methodology, design, and outcomes.
3. Summarise key findings and present implications for research and clinical practice.

Method

The review protocol was registered with PROSPERO international prospective register of systematic reviews (CRD42021221361).

Search Strategy

Search procedures adhered to guidelines on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA, Moher et al., 2015; Shamseer et al., 2015). The first reviewer (MK) searched for papers in the PsycINFO, MEDLINE, PubMed, Embase, Web of Science, and Scopus databases on 10 April 2021. The search was rerun on 28 May 2022 to identify new studies since the initial search.

Key terms related to paranoia and SC were used and combined with Boolean operators: [(paranoi* OR persecut* OR psychotic* OR psychosis* OR psychoses* OR ideas of reference OR schizophren* OR delus* OR delud* OR suspicious* OR mistrust*) AND (social comparison OR social position OR social standing OR social rank OR social status OR social judgement OR social defeat OR social appraisal OR social evaluation OR social hierarchy OR power differen* OR sense of belong* OR sense of inferior* or perce* inferior* OR perce* belong*)]. Databases were searched separately to enable the application of Medical Subject Headings (MeSH) and thesaurus options for a comprehensive search (Appendix B), and reference lists of eligible studies were searched for additional papers.

Eligibility criteria

The following criteria were used to determine eligibility: 1) quantitative study design with original data, 2) results presented from a self-report measure of trait or state paranoia, 3) results presented from a self-report measure of SC with one or more appraisal(s) of self in relation to others, 4) study participants include a clinical sample (assessed with a diagnostic tool or recruited as patients), those at ultra-high risk (UHR) of psychosis-spectrum conditions, or a general population sample, 5) full-text is available in English, and 6) is published in a peer-reviewed journal. Studies were excluded based on being non-human studies, full-text not available, or study design (qualitative, case studies/series, reviews, editorials, and theses not published in a peer-reviewed journal). Studies that measured SC or paranoia according to an observer were excluded, as were studies that defined SC as a behavioural or socio-demographic statistic. No limits on date or age were specified.

Selection procedure and data collection

From the initial and second search, 2217 studies were identified. Results were exported into Endnote (version X9.3.2) and duplicates removed (n=980). Studies were screened based on titles and abstracts (n=1237). In total 83 studies were suitable for full-text

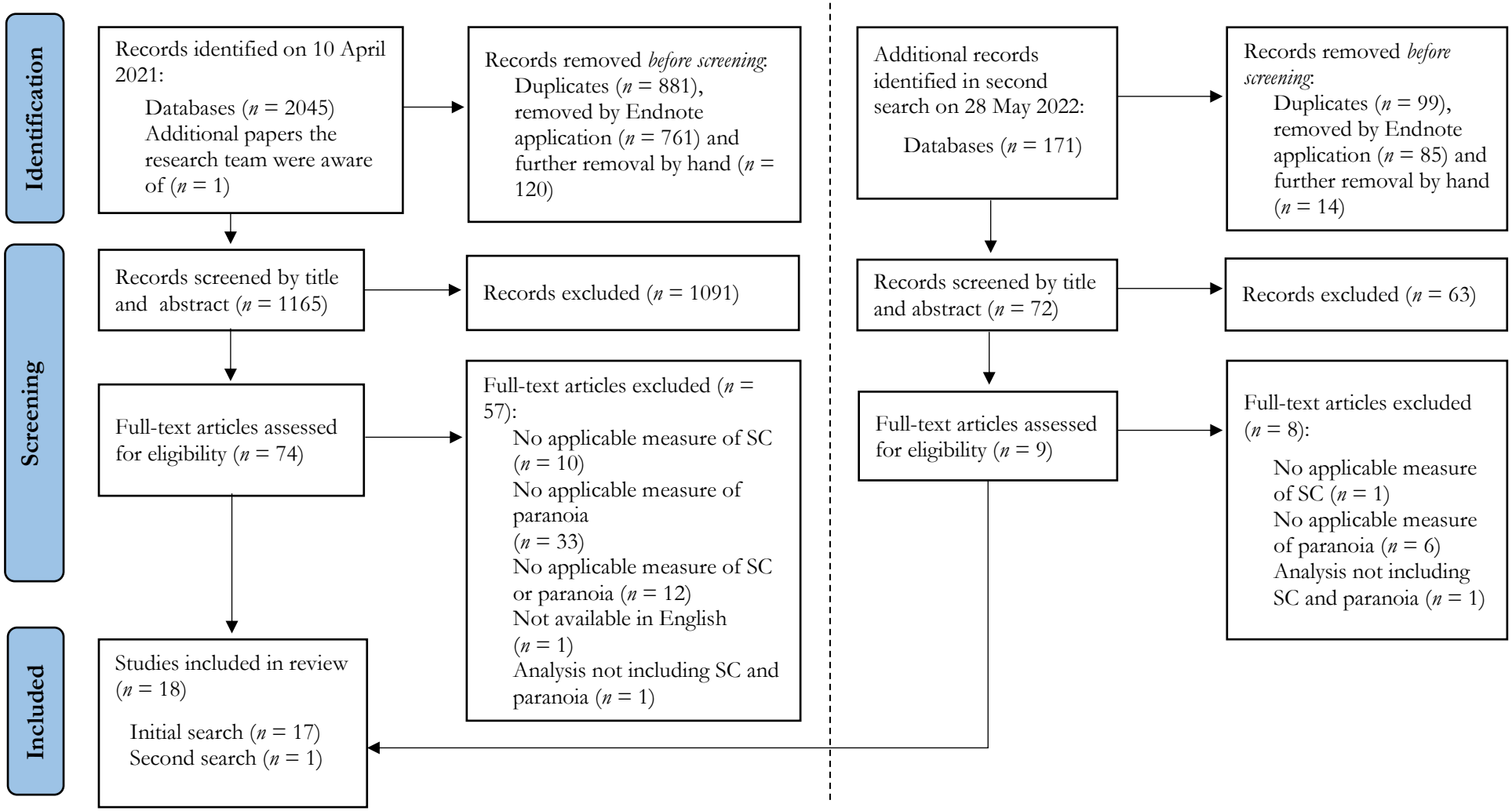
review and 18 were eligible for inclusion. An overview of the search procedures is presented in Figure 1.1.

The second reviewer (ET) independently reviewed a random subset of papers at each stage of the screening process to examine inter-rater reliability. Kappa values ≥.80 were deemed representative of a strong level of agreement (Altman, 1999; McHugh, 2012). When screening a subset of papers by titles and abstracts (20%), kappa was significantly different from zero and indicated a strong level of agreement (κ=.835, p<.001). When screening papers by full-text review (25%), kappa was significantly different from zero and indicated a moderate level of agreement (κ=.648, p=.007). Discrepancies were resolved in consultation with the third reviewer (NC). A second subset of full-text papers (25%) were screened, and results indicated a strong level of agreement (κ=1.000, p<.001).

The first reviewer conducted data collection using an extraction form to promote consistency and reliability (Appendix C). An independent data extraction check was completed by ET on a subset of papers (50%) to minimise risk of errors, and discrepancies resolved in consultation with all reviewers.

Figure 1.1

PRISMA Flowchart of Search Procedures



Analysis and coding of study characteristics

Studies were synthesised qualitatively and grouped according to design. It was deemed that a quantitative synthesis would not provide a meaningful summary due to the predominance of lower quality observational designs and heterogeneity of studies (e.g., diversity of samples, methods, variables of interest in manipulation, and methods of induction). Studies were coded as observational or experimental and as clinical, non-clinical, or mixed population samples.

Quality assessment

The quality of cross-sectional and longitudinal studies was appraised using the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies (National Institute of Health, 2013) (Appendix D). This 14-item tool is specific to observational designs and provides a descriptive measure of quality. Each item and overall quality are rated as good, fair, or poor. ET independently assessed a subset of papers (30%), and reliability was examined for quality ratings of each item. Results show strong agreement between reviewers (κ=.836, p<.001).

The quality of analytic studies with an experimental manipulation or intervention was appraised using the Downs and Black Checklist (Downs & Black, 1998) (Appendix E). This 27-item tool investigates the quality of reporting, external validity, internal validity (confounding, bias), and statistical power. Downs and Black (1998) report high internal consistency (KR-20=.89), inter-rater reliability (r=.75), and test-re-test reliability (r=.88). Scoring guidelines are ambiguous for the item on power and were adjusted to one point if the paper reported and adhered to a power calculation, and zero points if not, in line with previous reviews (Hooper et al., 2008; Morton et al., 2014). It is noted that only randomised controlled trials can reach the maximum score (28). Quality levels were defined as excellent (26-28), good (20-25), fair (15-19), and poor (≤14) (Hooper et al., 2008). ET independently

assessed the quality of a subset of papers (30%) and results indicated strong agreement between reviewers (κ=.828, p<.001).

Results

Overview

Eighteen studies met inclusion criteria, published between 1995 to 2021, with a total of 16,270 participants. The mean participant age ranged from 16.62 to 55.60 years. Studies were predominantly conducted in high-income countries, particularly the UK, and included the US, Germany, Portugal, China, Korea, Pakistan, and Australia. Studies included observational cross-sectional (n=12) and longitudinal (n=1) designs, and experimental manipulation (n=4) and intervention (n=1) designs. Nine studies recruited non-clinical samples, three recruited clinical samples excluding psychosis-spectrum disorders, one recruited a clinical sample with psychosis-spectrum disorders, and five recruited a combined sample of non-clinical and clinical populations (three with psychosis-spectrum diagnoses, one ultra-high-risk of psychosis, and one non-psychosis-spectrum conditions).

Measurement of constructs

Twelve studies used the Social Comparison Scale (SCS; Allan & Gilbert, 1995) to measure self-perceptions of social standing with 11 bipolar constructs. The SCS has high internal consistency (a=.91) and test-re-test reliability (r=.84) (Allan & Gilbert, 1995). Three studies used the MacArthur Scale of Subjective Social Status (SSS; Adler et al., 2000) to assess perceived placement within a social hierarchy. The SSS uses a pictorial ladder with 10 rungs to rank the self within society and local communities, with established validity and reliability (Adler et al., 2000). Two studies used the Defeat Scale (Gilbert & Allan, 1998), and one used the combined Social Entrapment and Defeat Scale (Gilbert & Allan, 1998) to measure appraisals of loss of social rank. Previous research indicates that entrapment and defeat are subscales of the same construct and provide a valid composite score (Taylor et al., 2009). Two studies measured perception of power in relation to others, one using the Social Power

Differential Scale with established validity and reliability (SPD; Birchwood et al., 2000) and one using a single-item visual analogue scale (VAS), however this study does not comment on measure validity (Brown et al., 2020).

Fourteen studies measured trait paranoia. Measures included the Green Paranoid Thoughts Scale (Green et al., 2008), Paranoia Scale (Fenigstein & Vanable, 1992), Persecution and Deservedness Scale (Melo et al., 2009), Psychotic Symptom Rating Scale (Haddock et al., 1999), Symptom-Checklist-90-Revised (Derogatis, 1983), Personality Diagnostic Questionnaire-4+ (Hyler, 1994), Minnesota Multiphasic Personality Inventory-2 (Butcher et al., 1989), and the Schizotypal Personality Questionnaire (Raine, 1991). Good reliability and validity were demonstrated in the respective papers for these measures.

Six studies measured state paranoia. Two used the State Social Paranoia Scale (Freeman et al., 2007) and three used adapted versions of the Paranoia Checklist (Freeman et al., 2005), with evidenced validity and reliability in the respective papers. However, authors do not report on change sensitivity across experimental settings and samples. One study used a two-item VAS and reported high internal consistency (a=.82) (Brown et al., 2020).

Summary of findings from observational studies

For the synthesis of findings papers were split into observational and experimental studies. Summaries of observational cross-sectional and longitudinal studies are presented in Table 1.1 and the quality appraisal in Table 1.3. Twelve of thirteen observational studies reported a significant relationship between paranoia and SC with low-to-moderate effect sizes. These were comprised of samples from non-clinical, clinical, and mixed populations.

Non-clinical samples

In a study by Freeman and Bentall (2017) of the US general population, those who endorsed a conspiracy belief rated themselves as having a significantly lower social rank compared to those who did not endorse a conspiracy belief. In a UK general population sample, Freeman and colleagues (2005) reported significant weak-to-moderate associations

between measures of paranoia (frequency, conviction, and distress) and SCS items; particularly items in the group fit subscale such as '*left out - accepted*'. A mediation study by Wickham and colleagues (2014) in UK undergraduates demonstrated that self-rated low social rank (SCS total) and perceptions that the world is personally unjust fully mediate the relationship between variables of early adversity and paranoia. In an online Australian sample, Sorenson and colleagues (2021) reported moderate positive correlations between paranoia and social defeat (SD), and found paranoia to be a significant independent predictor of SD. Wang and colleagues (2013) studied a sample of Chinese students and reported a trend of lower perceived social rank associated with increased paranoia; however, effect sizes were weak and non-significant. These five studies have an advantage of large sample sizes for sufficient power to detect effects.

Clinical samples

Gilbert and colleagues (2005) studied a group with anxiety and depression, showing that unfavourable comparisons measured by total SCS, perceived social power measured by the SPD (Birchwood et al., 2000), and submissive behaviour measured by the Submissive Behaviour Scale (Gilbert & Allan, 1994), contributed to a significant increase in variance in the prediction of paranoia. However, only perceived social power and submissive behaviours were significant independent predictors of paranoia. A study by Seo and Choi (2018) with a sample of psychiatric patients reported a moderate significant correlation between SD and paranoia. Mediation analyses found that SD was a partial mediator in pathways from measures of early adversity to paranoia in adulthood. Zaffar and Arshad (2020) studied female treatment-seeking patients with social anxiety and found significant moderate correlations between paranoia and measures of SC: total SCS and subscales of social rank, attractiveness, and group fit.

Mixed populations

Allan and Gilbert (1995) investigated cross-sectional relationships between paranoia and measures of SC: SCS total, social rank, attractiveness and group fit. In the non-clinical

group, weak-to-moderate associations between paranoia and two subscales (group fit and attractiveness) were statistically significant. In the clinical group, social attractiveness was significantly associated with paranoia. Total SCS was not found to be significantly associated with paranoia in either group. Berry and colleagues (2018) conducted a longitudinal study across 6-days using an experience sampling method and reported weak significant correlations between total SCS and paranoia within a combined clinical and non-clinical sample.

Collett and colleagues (2016) studied a clinical group with persecutory delusions and high severity of paranoia in comparison to a non-clinical control group with low paranoia, and found a significant group difference on total SCS scores with the clinical group reporting more unfavourable comparisons. Valmaggia and colleagues (2015) used a controlled neutral social environment in virtual reality (VR) to examine the relationship between SC and paranoia cross-sectionally with an ultra-high-risk for psychosis group compared to non-clinical controls. The ultra-high-risk group reported significantly higher levels of unfavourable comparisons (total SCS) and SD compared to controls, and significantly higher paranoia after exposure to the neutral social environment. Analyses found SD to be a significant predictor of paranoia.

Carvalho and colleagues (2018) reported a cross-sectional analysis in a mixed sample of clinical (active and remission phase of schizophrenia-spectrum disorders) and non-clinical groups. A significant association was found between SC and paranoia; however, SC (SCS total) was not found to be a significant predictor of paranoia in a regression analysis that controlled for distal variables (global perception of threat and submission in childhood, parental antipathy and criticism) and proximal variables (shame, submissive behaviours).

Quality assessment of observational studies

The Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies (National Institute of Health, 2013) does not provide an overall score therefore studies were categorised based on quality ratings of individual items. Papers were only rated for applicable

items and categorised as poor, fair, or good with scores 'x < 50%', '50% ≤ x < 75%' and 'x ≥ 75%' respectively. Categories are suggestive of overall quality with four rated as poor (Allen & Gilbert, 1995; Gilbert et al., 2005; Seo et al., 2018; Wang et al., 2013), six fair (Berry et al., 2018; Carvalho et al., 2018, Freeman et al., 2017, Freeman et al., 2005; Sorenson et al., 2021; Wickham et al., 2014), and three good (Collett et al., 2016; Valmaggia et al., 2015; Zaffar et al., 2020). Ratings were inspected for face validity and no changes were made.

Areas of strength included the clarity of research questions and aims, and well-defined exposure and outcome measures with evidenced validity and reliability. Another strength was the use of measures which allow different levels of the exposure to be examined as related to the outcome. Limitations include the lack of detailed sample descriptions, such as omissions for location and time-period of recruitment, and demographics implicated in the relationship between SC and paranoia. This limits conclusions about the generalisability of findings and determining whether there is an interaction with demographic variables. Further, most studies did not report a full account of eligibility criteria. None of the studies commented on statistical power, with the exception of Collett and colleagues (2016). Analyses were typically exploratory in nature and reported estimates of variance in results. This is not considered a fatal flaw of the papers; however, it is difficult to determine whether studies are sufficiently powered to answer the research questions and may result in Type II errors (Columb & Atkinson, 2015). Thirdly, poor adjustment for confounding variables was a significant limitation, such as the omission to control for negative affect or depression, which may increase the risk of false positive results. Five items on the quality appraisal tool, inclusive of questions on the timeline of independent and dependent variables, were not applicable as conclusions on causality cannot be drawn from cross-sectional studies.

Summary of findings from experimental studies

Summaries of manipulation and clinical intervention studies are presented in table 1.2 and the quality appraisal in table 1.4. The experimental manipulation studies recruited non-

clinical samples and two of four reported a significant relationship between paranoia and unfavourable comparisons through manipulations of SC and social threat. One experimental intervention study with a clinical sample was eligible for inclusion.

Non-clinical samples

Freeman and colleagues (2014b) found that by manipulating avatar height (a proxy for SC) in a virtual social environment, paranoia significantly increased when height was reduced (low rank condition), and SC fully mediated the relationship between height and paranoia. One strength of this study is the controlled neutral environment in virtual reality, providing a more accurate measure of paranoia as exaggerated or unfounded threat appraisals rather than a reflection of genuine hostility, which is a weakness of paranoia measurement tools (Freeman et al., 2003). Saalfeld and colleagues (2018) found that individuals reporting particularly low or high subjective rank within society and local communities reported significantly higher paranoia. In this study, social threat was manipulated (and consequently paranoia) in two social game-based scenarios, and results show that pre-existing levels of paranoia predicted harmful intent attributions.

For studies that did not find a significant relationship between SC and paranoia, Brown and colleagues (2020) found that the manipulation of SC through power poses compared to a neutral condition did not have the hypothesised effect on SC, with no subsequent effect on paranoia. Authors comment that power poses may have caused individuals with paranoia to feel more exposed rather than powerful, however, paranoia was not found to moderate results. Ascone and colleagues (2017) designed a manipulation of SC through exposing participants to online profiles of age and gender matched individuals, one group receiving a favourable comparison ('inferior profile') and one receiving an unfavourable comparison ('superior profile'). Authors report that the manipulation predicted SC scores as hypothesised, however no relationship was found between group allocation and paranoia, and paranoia was shown to reduce after profile exposure in both groups. This contradicts the

hypothesised relationship between SC and paranoia. Authors report that participants rated the 'superior profile' as significantly more realistic than the 'inferior profile', thus it is possible that the manipulation was not strong enough to generate an effect on paranoia. The manipulation may also be limited in how representative the effect is in relation to in-vivo social scenarios of self-other comparisons.

Clinical samples

Freeman and colleagues (2014c) used a cognitive-behavioural intervention aimed at improving confidence in individuals with persecutory beliefs, and reported a significant reduction in unfavourable comparisons at the 8-week follow-up compared to individuals with persecutory beliefs in the control group. Improvements were shown in paranoia (moderate reduction) in the intervention group compared with controls, however differences were non-significant at 8 and 12-weeks. The authors report that the intervention was well-received by individuals with high paranoia, and report on high levels of uptake. However, limited conclusions can be drawn from this study on the direct relationship between SC and paranoia.

Quality assessment of experimental studies

Hypotheses, sample characteristics, manipulations, measurement tools, and results were well-defined within the five experimental studies, and estimates of random variability were reported consistently. Several limitations are important to note, including the absence of follow-up data in four of five studies meaning that effects were not examined over time. Most studies used a self-selected, opportunistic sample which introduces self-selection bias and the possible distortion of findings. Self-selecting participants may be more confident in social situations and hold higher perceptions of social rank compared to a representative sample of the population, which has significant implications for studies measuring social constructs.

Blinding of subjects and researchers was problematic for three of five studies. Knowledge of group assignment may introduce bias in participant behaviour or researchers

recording of outcomes according to expectations. Only one of five studies adhered to a power calculation, making it unclear whether studies were sufficiently powered to detect effects.

Table 1.1

Summary of Data from Cross-Sectional Studies

Author (year)	Design	*N*	Participant characteristics	Country	Non-clinical control group	Paranoia measure	SC measure	Summary of findings
Allan et al., (1995)	Cross-sectional, correlation and measure development	a) 263 b) 32	a) Non-clinical university undergraduates and postgraduates (99M, 164F, M^{age}=23.4). b) Clinical group with depression or anxiety disorders attending a day hospital (16M, 16F, M^{age}=38.9). Clinical group scored higher on paranoia (1.63, SD=.96) than the non-clinical group (0.60, SD=.61). No report on ethnicity or country of origin.	England, UK	No	SCL-90-R Paranoid ideation subscale (trait paranoia)	SCS: total, rank, group fit, social attractive-ness	a) Non-clinical group: SC subscales group fit (r = -.19, p <.05) and attractiveness (r = -.17, p <.05) were significantly correlated with paranoia. Total SC (r = -.12) and rank (r = -.06) were not shown to significantly correlate with paranoia. b) Clinical group: SC subscale attractiveness (r = -.48, p <.01) was significantly correlated with paranoia, total SC (r = -.32), rank (r = -.29) and group fit (r = .02) were not significantly correlated with paranoia.
Berry et al., (2018)	Longitudinal 6-day period, correlational, experience sampling method	a) 19 b) 25	a) Clinical group with psychotic diagnoses in secondary care (7M, 12F, M^{age} = 33.7), 18 White-British (95%), 1 Asian-British (4%), findings excluded participants with bipolar disorder (n=6). b) Non-clinical group with self-report of no current mental health problems (11M and 14F, M^{age} = 35.4), 21 White-British (84%), 2 White-other (8%), 1 Asian-British (4%), 1 Mixed Race (4%).	England, UK	No	PS (trait paranoia)	SCS total	Higher perceived social rank (SCS total) on social media negatively predicted paranoia (β = -.0780, SE = .0105, p <.001), 95% CI [-.10, .06] and negative affect, and positively predicted positive affect and self-esteem (effects are unstandardised coefficients).

Carvalho et al., (2018)	Cross-sectional, correlation and group comparison	187	Four samples: patients with active schizophrenia (Azores islands, 20M, 11F, M^{age} = 41.5; Madeira islands 30F, M^{age} = 46.5), patients in remission (Azores islands, 24M, 6F, M^{age}=43.5), first-degree relatives (8M, 24F, M^{age}=55.6), and a general population sample (43M, 21F, M^{age}=45.2). Analysis two compares a) patients active, and b) general population. No report on ethnicity or country of origin.	Azores and Madeira, Portugal	No	PC: frequency, conviction, distress	SCS total	Statistically significant weak-modest correlations between paranoia and SCS in total sample. Paranoia conviction and SCS total (r = -.26, p <.001). SC not a significant predictor of paranoia in the regression controlling for perception of threat and childhood submission, memories of parental antipathy, criticism, shame, and submissive behaviour, paranoia frequency (β = .11, t = 1.65, p =.101), paranoia conviction (β = .05, t = .11, p = .101), paranoia distress (β = .02, t = .30, p = .765). In comparison of clinical (n = 61) and non-clinical (n = 64) groups, SC was not a significant predictor of paranoia frequency, clinical (β = .19, t = 1.75, p = .086) and non-clinical sample (β = .05, t = .41, p = .684).
Collett et al., (2016)	Cross-sectional, between-groups	a) 21 b) 21	a) Clinical group: patients with persecutory delusions (M^{age} = 45.6), b) non-clinical group with no history of mental health problems (M^{age} = 41.9). Gender balance equal in both groups (10M, 11F). No report on ethnicity or country of origin.	England, UK	Yes	PSYRATS, PaDS	SCS	Significant group differences on SCS: Clinical = 608.37 (SD = 323.84), non-clinical=1147.48 (SD = 337.40), t = -5.14 (df = 38), 95% CI [-751.30, -326.91], p <.001, d = 1.78.
Freeman et al., (2017)	Cross-sectional psychiatric survey	5692	Adults from the general population, 1618 (26.7%) endorsed conspiracy belief (862F, 756M, M^{age} = 45.8). In this sample 997 (22.2%) non-Latino White, 316 (41.5%) African American, 128 (37.8%) Mexican, 68 (38.2%) Other, 67 (37.3%) Other Hispanic, 27 (28.3%) Other Asian, 15 (35.1%) Afro-Caribbean. 4027 (73.3%) did not endorse a conspiracy belief (2417F, 1610M, M^{age} = 44.7). In this sample 3149 (77.8%) non-Latino White, 357 (58.5%) African American, 216 (62.2%) Mexican, 116 (61.8%) Other, 112	US	No	Single-item in NCS-R. Endorsed conspiracy belief: "I am convinced there is a conspiracy behind many things in the world".	SSS	Those who endorsed a conspiracy belief rated themselves lower on the US ladder (M = 5.66, SE = .70) than those who did not endorse the conspiracy item (M = 6.23, SE = .05), t = 7.91, df = 42.00, p < .001. Individuals with a belief in conspiracy (M = 6.14, SE = .08) also rated themselves lower in their communities than individuals who did not endorse the conspiracy item (M = 6.64, SE = .05), t = 6.58, df = 42.00, p <.001.

			(62.7%) Other Hispanic, 55 (71.7%) Other Asian, 22 (64.9%) Afro-Caribbean.					
Freeman et al., (2005)	Cross-sectional, correlational	1202	General population sample recruited online (821F, 371M, M^{age}=23), ethnicity reported as White (*n*=1001), Asian (*n*=98), Other (n=70), African-Caribbean (*n*=9), Black African (*n*=9).	England, UK	No	PC	SCS	Significant associations between paranoia and SC, particularly SC 'left out' subscale. Association of paranoia frequency with: SC total (r = -.27, p <.001), SC inferior-superior (r = -.15, p <.001), SC less competent-more competent (r = -.12, p = .001), SC less likable-likable (r = -.04, p = .251), SC more reserved-less reserved (r = -.09, p = .005), SC left out-accepted (r = -.37, p <.001). Association paranoia conviction with: SC total (r = -.19, p <.001), SC inferior-superior (r = -.09, p = .005), SC less competent-more competent (r = -.08, p = .005), SC less likable-likable (r = -.05, p = .001), SC more reserved-less reserved (r = -.06, p = .074), SC left out-accepted (r = -.27, p <.001). Association paranoia distress with: SC total (r = -.27, p <.001), SC inferior-superior (r = -.18, p <.001), SC less competent-more competent (r = -.19, p = .001), SC less likable-likable (r = -.01, p = .763), SC more reserved-less reserved (r = -.08, p = .013), SC left out-accepted (r = -.33, p <.001).
Gilbert et al., (2005)	Cross-sectional, correlational	71	Non-psychotic clinical group (mixed anxiety and depression, 36M, 35F, M^{age} = 40.9, mean paranoia score = 54.74). No report on ethnicity or country of origin.	England, UK	No	PS	SCS, SPD	Association between paranoia and SCS (r = -.23), and paranoia and SPD (r = .06) both non-significant. In the regression, after controlling for depression, social rank variables SCS, SPD, and submissive behaviour contributed to a significant increase in variance in the prediction of paranoia (F = 6.61, p = .001). SPD was a significant negative contributor (self as more powerful contributed to paranoia), (β = -.28, *semi partial correlation* = -.18, p <.05) and SCS alone was non-significant (β = -.18, *semi partial correlation* = -.13).
Seo et al., (2018)	Cross-sectional, correlational mediation	199	Non-psychotic psychiatric patients (110M, 89F, M^{age} = 33.98). No report on ethnicity or country of origin.	Seoul, Korea	No	MMPI-2: Clinical Scale 6 (trait paranoia)	DS (adapted to Korean, 12 items)	A significant correlation was found between SD and paranoia (r = .44, p <.001). SD was a partial mediator from childhood trauma to paranoia.

Sorenson et al., (2021)	Cross-sectional, regression	a) 934 b) 720	Both samples are adults from the general population, a) M^{age} = 31.07, 67.75% female, 76.08% country of birth Australia, b) M^{age} = 29.49, 75% female, 80.62% country of birth Australia.	Australia	No	SPQ	DS	Positive Pearson's moment correlations were found between the SPQ-Suspiciousness/ paranoid ideation subscale and SD in sample a) r = .45 , and b) r = .46, both significant (p <.001). In the regression analyses, SPQ-S was shown to be a significant predictor of SD in sample a) (β = .23, *semi partial correlation* = .19, p <.01), and in sample b) (β = .19, *semi partial correlation* = .18, p <.01)
Valmaggia et al., (2015)	Cross-sectional, comparison regression	a) 64 b) 43	a) UHR psychosis identified using the CAARMS, aged 18 to 35, M^{age} = 22.55, 38M, 26F. Ethnicity: 19 (29.7%) Black, 23 (35.9%) White-British, 11 (17.2%) White-Other, 11 (17.2%) Other. b) Healthy volunteers matched at group level for age, ethnicity, and gender. M^{age} = 24.02, 20M, 23F. Ethnicity: 10 (23.3%) Black, 16 (37.2%) White-British, 7 (16.3%) White-Other, 10 (23.3%) Other. Score on PQ of 18 or higher required to control for at-risk mental states.	England, UK	Yes	SSPS (state paranoia)	SCS, SEDS, both measures added to form SD composite	At baseline, UHR subjects reported significantly higher levels of social defeat than controls (OR = .96, 95% CI [.94, .97], p <.001). Following exposure to the VR social environment, the UHR group reported significantly more paranoid appraisals than the controls (p <.001). UHR sample: level of social defeat predicted paranoia (OR = 1.02, 95% CI [1.00, 1.05]), Wald $\chi 2(1) = 4.50$, p = .034.
Wang et al., (2013)	Cross-sectional	3552	Chinese high school students, 1790M, 1762F, M^{age} = 16.62, 92.5% Han Chinese ethnicity, 7.5% ethnic minorities.	China	No	PDQ-4+ (paranoid PD subscale)	SSSy	Students scoring lower on perceived SR scored higher on paranoia measure, effect size is weak and non-significant. SC in society: d = .06, F = 3.22, low (2.75 ± 1.94), high (2.64 ± 1.89). SC in school community: d = 0.11, F = 9.27, low (2.85 ± 2.01), high (2.63 ± 1.87).
Wickham et al., (2014)	Cross-sectional, mediation	683	Undergraduates, 156M, 527F. Liverpool University M^{age} = 21.03, University of East London M^{age} = 26.64, Liverpool Hope University M^{age} = 24.10. No report on ethnicity or country of origin.	England, UK	No	PaDS	SCS	The standardized indirect effect through social rank was statistically significant for paranoid ideation (β =- .07, *SE* = .01, p = .01). Standardised direct effect between SR and paranoia reported as β = -.28, no further statistics reported on this relationship.

Zaffar et al., (2020)	Cross-sectional, correlational	100	Female, adult treatment-seeking patients with social anxiety (M^{age} =25.21). No report on ethnicity or country of origin.	Lahore, Punjab, Pakistan	No	PS (trait paranoia)	SCS	Associations of paranoia and SC variables were all statistically significant: SC total (r = -.67, p <.01), SC rank (r = -.66, p <.01), SC attractiveness (r = -.60, p <.01), SC group fit (r = -.56, p <.01).

Note. SCS = Social Comparison Scale (Allan, & Gilbert, 1995), SPD = Social Power Differential Scale (Birchwood et al., 2000), SSS = The MacArthur Scale of Subjective Social Status; and SSSy = The MacArthur Scale of Subjective Social Status in Youth (Adler et al., 2000), SEDS = Social Entrapment and Defeat Scale (Taylor et al., 2009), DS = The Defeat Scale (Gilbert, & Allan, 1998), GPTS = Green Paranoid Thoughts Scale (Green et al., 2008), SSPS = State Social Paranoia Scale (Freeman et al., 2007), SCL-90-R = Symptom Checklist-90-Revised (Derogatis, 1983), PS = Paranoia Scale (Fenigstein, & Vanable, 1992), PC = Paranoia Checklist (Freeman et al., 2005), PDQ-4+ = The Personality Questionnaire-4+ (Hyler, 1994), PaDS = Persecution and Deservedness Scale (Melo et al., 2009), PSYRATS = Psychotic Symptom Rating Scale (Haddock et al., 1999), MMPI-2 = Minnesota Multiphasic Personality Inventory-2 (Butcher et al., 1989), SPQ = Schizotypal Personality Questionnaire (SPQ; Raine, 1991), the CAARMS = Comprehensive Assessment of At Risk Mental States, UHR = Ultra-high-risk.

Table 1.2

Summary of Data from Experimental Studies

Author (year)	Design	*N*	Participant characteristics	Country	Manipulation / intervention	Control group?	Moderators/ mediators?	Paranoia measure	SC measure	Summary of findings
Ascone et al., (2017)	Experimental manipulation, independent groups, two conditions	172	Female students, majority psychology undergraduates, no past or present mental health diagnoses, aged 18 to 25. No report on ethnicity or country of origin.	Germany	Social rank manipulation, exposure to high 'unfavourable comparison' vs low 'favourable comparison' rank online profile of same-aged female student	No	Negative affect and anxiety/ insecure striving (did not perform mediation analysis due to non-significance)	PC adapted to 11-item version (state paranoia)	SCS (total), instructions adapted: 'Please indicate how you feel in comparison to other female fellow students of your cohort at the moment'.	Large effect of manipulation on social rank (p <.001, ηp^2 = .19). No significant effect of manipulation on anxiety and paranoia (p >.38), significant for negative affect (p <.016, ηp^2 = .03). Paranoia decreased from pre to post experiment in both conditions, significant time effect (F (1, 170) = 149, p <.001, ηp^2 = .47). Mediation not analysed in detail due to non-significant findings.
Brown et al., (2020)	Randomized controlled experimental manipulation, between-groups (two groups each randomised into two conditions)	a) 100 b) 50	General population: a) paranoia group with scores 22+ on GPTS-B (power condition: 21M, 29F, M^{age} = 31.3, 36 White-British/Irish, 14 Other), (neutral condition: 22M, 28F, M^{age} =35.1, 37 White-British/Irish, 13 Other). b) Non-paranoia group (power condition: 13M, 12F, M^{age} =37, 17 White British/Irish, 8 Other), (neutral condition: 9M, 16F, M^{age} = 38.4, 16 White British/Irish, 9 Other).	England, UK	Manipulation of power appraisal: randomised to power pose or neutral pose within each group, all exposed to neutral VR social environment	Yes	Appraisal of power planned as mediator in analysis, not conducted due to non-significance	Baseline GPTS-B (trait paranoia), two VAS (state paranoia) instructed: 'Please mark on the line how vulnerable you felt during the VR scenario' and 'Please mark on the line below how much	Self-reported power appraisal using VAS	Randomisation and analyses separate for paranoia and non-paranoia group. Paranoia group: no differences in paranoia between power and control condition during either the first or second VR scenario (group difference at final time point = -.23, 95% CI [-1.17, .72], p=.634). Non-paranoia group: no difference in paranoia between the power and control groups during either the first or second VR scenario (group difference at final time point = -.71, 95% CI [-2.16, .74], p = .338). Mediation not performed due to lack of change in paranoia.

Freeman et al., (2014b)	Experimental manipulation, randomised two condition two-period crossove trial	60	Female general population, adults 18 years or above (M^{age} = 31.5), no history of severe mental illness (15 with history of mild-moderate mental illness, majority depression). Paranoid thinking evident in past month (17 or above on GTPS-B). Ethnicity: 47 White, 4 Black African, 2 Indian, 2 Pakistani, 1 Chinese, 4 Other.	England, UK	Manipulation of height in VR as proxy for SR: normal vs lowered height condition and both groups exposed to neutral VR social environment twice.	Yes – crossover trial	SC	Baseline GPTS-B (trait paranoia), SSPS (state paranoia)	SCS	VR order of height presentation predicted change in SC scores (coefficient = -7.83, 95% CI [-10.08, -5.99], *SE* = 1.12, *t* = -6.99, *p* <.001) and change in paranoia scores (coefficient = 2.0, 95% CI [.36, 3.65], *SE* =.82, *t* = 2.44, *p* = .018). VR order of height presentation was not a significant predictor of change in paranoia when SC scores entered (coefficient = .12, 95% CI [-2.00, 2.25], *SE* = 1.06, *t* = .12, *p* = .907). SC fully mediated relationship between height and paranoia.
Freeman et al., (2014c)	Early phase II randomised controlled trial	30	Patients with current persecutory delusion (score 3+ on conviction scale of PSYRATS, persisted for 3+ months, diagnoses of non-affective psychosis). Treatment group (*n*=15): 11M, 4F, M^{age} =41.9, ethnicity reported as 15 White and 0 Other. Control group (*n*=15): 9M, 6F, M^{age} =41.5, ethnicity reported as 13 White and 2 Other.	England, UK	Six session CBT intervention across eight weeks aimed at improving self-confidence, vs control condition (standard care)	Yes		GPTS and PSYRATS (trait paranoia)	SCS	Significant differences between groups in SCS at 8-weeks (*t* = 2.32, *p* = .028) effect size = .88, no significant different at 12-weeks (*t* = .84, *p* = .411). Improvements seen in paranoia and persecutory beliefs but did not reach significance. Non-significant differences between groups in paranoia (GPTS) at 8-weeks (*t* = -1.68, *p* = .105), effect size = .59, and 12-weeks (*t* = -.50, *p* = .624). Non-significant differences between groups in paranoia (PSYRATS) at 8-weeks (*t* = -1.64, *p* = .113), effect size = .91, and 12-weeks (*t* = -.68, *p* = .502).

Saalfeld et al., (2018)	Cross-sectional correlation and experimental manipulation	2030	Adult general population, 1175F, 851M and 4 unknown, M^{age} = 35.9. No report on ethnicity or country of origin.	US	Two conditions: social status task and political affiliation task. Social threat exposure to induct paranoia.	No	GPTS (trait paranoia)	SSS	SS had a negative effect on paranoia (estimate = -.26, 95% CI [-.45, -.06]). After controlling for effects of SS on pre-existing paranoia, participants who self-reported being on rung 9 or 10 (highest scores) of the social ladder reported higher paranoia than those with lower SSS scores (estimate = 1.31, 95% CI [.67, 1.95]).

Note. SCS = Social Comparison Scale (Allan, & Gilbert, 1995), SPD = Social Power Differential Scale (Birchwood et al., 2000), SSS = The MacArthur Scale of Subjective Social Status; and SSSy = The MacArthur Scale of Subjective Social Status in Youth (Adler et al., 2000), SEDS = Social Entrapment and Defeat Scale (Taylor et al., 2009), DS = The Defeat Scale (Gilbert, & Allan, 1998), GPTS = Green Paranoid Thoughts Scale (Green et al., 2008), SSPS = State Social Paranoia Scale (Freeman et al., 2007), SCL-90-R = Symptom Checklist-90-Revised (Derogatis, 1983), PS = Paranoia Scale (Fenigstein, & Vanable, 1992), PC = Paranoia Checklist (Freeman et al., 2005), PDQ-4+ = The Personality Questionnaire-4+ (Hyler, 1994), PaDS = Persecution and Deservedness Scale (Melo et al., 2009), PSYRATS = Psychotic Symptom Rating Scale (Haddock et al., 1999), MMPI-2 = Minnesota Multiphasic Personality Inventory-2 (Butcher et al., 1989), SPQ = Schizotypal Personality Questionnaire (SPQ; Raine, 1991).

Table 1.3

Quality Assessment of Observational Cohort and Cross-sectional Studies (National Institute of Health, 2013)

	Allan et al. (1995)	Berry et al. (2018)	Carvalho et al. (2018)	Collett et al. (2016)	Freeman et al. (2017)	Freeman et al. (2005)	Gilbert et al. (2005)	Seo et al. (2018)	Valmaggia et al. (2015)	Wang et al. (2013)	Wickham et al. (2014)	Zaffar et al. (2020)	Sorenson et al. (2021)
1. Research question and objective(s) clearly stated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Study population clearly specified and defined?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Participation rate of eligible persons at least 50%?	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y	NR	Y	NR
4. Subjects recruited from similar populations? Eligibility criteria prespecified and uniform?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
5. Was a sample size justification, power description, or variance and effect estimates provided?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6. Were exposure(s) of interest measured prior to outcome(s)?	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	Y	N/A	N/A	N/A	N/A
7. Timeframe sufficient to expect to see an association between exposure and outcome if it existed?	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	Y	N/A	N/A	N/A	N/A
8. Different levels of exposure examined as related to outcome?	Y	Y	Y	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y
9. Exposure measure(s) clearly defined, valid, reliable, and implemented consistently?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
10. Exposure(s) assessed more than once over time?	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11. Outcome measures clearly defined, valid, reliable, and implemented consistently?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
12. Outcome assessors blinded to the exposure status?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13. Loss to follow-up after baseline 20% or less?	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	Y	N/A	N/A	N/A	N/A
14. Potential confounding variables measured and adjusted for?	N	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N
Overall Quality Rating	Poor	Fair	Fair	Good	Fair	Fair	Poor	Poor	Good	Poor	Fair	Good	Fair

Note. Y = criterion met; N = criterion not met; NR = not reported; N/A = not applicable; Colour Green = quality rating good; Yellow = quality rating fair; Orange = quality rating poor; Red = N criterion not met; Grey = quality rating NR or N/A

Table 1.4

Quality assessment of experimental studies using the Downs and Black Checklist (1998)

	Ascone et al. (2017)	Brown et al. (2020)	Freeman et al. (2014b)	Freeman et al. (2014c)	Saalfeld et al. (2018)
Overall evaluation					
Total score for quality rating (maximum 28)	17 (fair)	22 (good)	19 (fair)	22 (good)	15 (fair)
Reporting					
1. Hypothesis/ aim/ objective(s) clearly described?	1	1	1	1	1
2. Main outcomes clearly described in the Introduction or Methods?	1	1	1	1	1
3. Sample characteristics clearly described?	1	1	1	1	1
4. Intervention/ manipulation(s) of interest clearly described?	1	1	1	1	1
5. Distributions of principal confounders in each group clearly described?	1	1	1	2	0
6. Main findings clearly described?	1	1	1	1	1
7. Estimates given of the random variability in the data for main outcomes?	1	1	1	1	1
8. Adverse events that may be a consequence of the intervention reported?	0	0	0	1	0
9. Characteristics of those lost to follow-up described?	N/a	N/a	N/a	0	0
10. Probability values reported in full except where value is < 0.001?	1	1	1	1	0
External validity					
11. Subjects invited representative of the population?	0 (UtD)	0 (UtD)	0 (UtD)	0 (UtD)	0 (UtD)
12. Subjects prepared to participate representative of the population?	0 (UtD)	0 (UtD)	0 (UtD)	0 (UtD)	0 (UtD)
13. Manipulation environment or intervention representative of real-world scenario or treatment? †	0	1	1	1	1

	Ascone et al. (2017)	Brown et al. (2020)	Freeman et al. (2014b)	Freeman et al. (2014c)	Saalfeld et al. (2018)
Internal validity – bias					
14. Attempt made to blind subjects to manipulation or intervention? †	0 (UtD)	1	1	0	0
15. Attempt made to blind those measuring the main outcomes?	0 (UtD)	1	0	1	0
16. If any results were based on "data dredging", was this made clear?	1	1	1	1	1
17. Time between manipulation or intervention and outcome consistent? †	1	1	1	1	1
18. Statistical tests appropriate?	1	1	1	1	1
19. Compliance with the manipulation or intervention reliable? †	1	1	1	1	1
20. Main outcome measures used accurate (valid and reliable)?	1	1	1	1	1
Internal validity - confounding (selection bias)					
21. Patients in different groups recruited from the same population?	1	1	1	1	1
22. Subjects in different groups recruited over the same period of time?	0 (UtD)	0 (UtD)	0 (UtD)	1	1
23. Subjects randomised to intervention groups?	1	1	1	1	0
24. Randomised assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	0 (UtD)	1	0	0	0
25. Adequate adjustment for confounding?	1	0	1	1	1
26. Losses of patients to follow-up taken into account?	N/a	N/a	N/a	1	0
Power					
27. Did the study report and adhere to a power calculation?	0	1	0	0	0

Note. N/a = Not applicable; UtD = Unable to determine; † = Items adapted to incorporate manipulation studies

Discussion

This review aimed to systematically identify and critique studies that investigate the relationship between SC and paranoia. Findings across methodologies suggest a weak-to-moderate positive association between unfavourable social comparisons and paranoia in clinical and general populations. The literature to date is strengthened by innovative experimental studies with more robust designs to draw conclusions, and observational studies with sufficient statistical power to provide confidence in the results.

These findings support the theory that unfavourable social comparisons of low social rank, social attractiveness, and lack of belonging engender a sense of personal vulnerability in social contexts (Freeman, 2016). This may pose a significant threat to survival and sense of self, increasing one's attention to signals of social threat, appraisals of others as more dominant and malevolent, and subsequent increase in paranoid thoughts (Gilbert, 1993; Raihani & Bell, 2019).

Saalfeld and colleagues (2018) report evidence consistent with the theory that paranoia lowers one's threshold to the detection of social threats, and that paranoid appraisals scale in a defensive manner consistent in those with higher and lower baseline paranoia when exposed to social threats. This study analysed data by looking at differences between those on the extremes of the SC distribution, finding that paranoia was significantly higher in those who reported particularly low (unfavourable) or high (favourable) SCs. This result is relatively novel as research to date suggests that paranoia is associated with low subjective social rank. One explanation is that it may be the perception of oneself as different which underlies the relationship, consistent with an evolutionary perspective that those who perceive themselves at the bottom of the hierarchy fear exploitation from those above, and those who perceive themselves at the top fear being targeted by those below (Kramer & Gavrieli, 2005). In line with this, Gilbert and colleagues (2005) report that perceptions of high social power predict paranoia. If this hypothesis is valid, studies using statistical analyses that assume linearity

potentially overshadow this finding and correlations between SC and paranoia will appear flattened. It is unclear whether studies in this review sampled participants along a distribution of subjective social status or whether studies were adequately powered to consider this effect.

For types of SC, several studies suggest a stronger relationship between paranoia and perceptions of low social attractiveness for clinical groups, and paranoia with perceptions of low group fit for non-clinical groups, compared to social rank and overall scores on the SCS measure (Allan & Gilbert, 1995; Freeman et al., 2005). Studies also indicate that social defeat may be a stronger predictor of paranoia than SC as measured by the SCS (Gilbert et al., 2005; Seo & Choi, 2018, Valmaggia et al., 2015). Studies that consider SC and paranoia in the framework of social defeat theory report a mediation effect of defeat in the relationship between early adversity and paranoia (Seo & Choi, 2018; Wickham et al., 2014). Wickham and colleagues (2014) find evidence for a second mediator, appraisals about a just world, which may capture a global process of comparing the fairness of one's circumstances in relation to others. This supports the theory that exposure to chronic social stressors engenders a perceived loss of rank, contributing to a heightened threat detection system and subsequent paranoia (Selten & Cantor-Graae, 2005; Selten et al., 2013). However, defeat scales capture a variety of constructs with a lack of specificity, including self-other appraisals (*'I have lost my standing'*), appraisals of one's circumstances (*'life has treated me like a punch bag'*), and reactive components (*'I feel down and out'*).

Results from this review should be interpreted with caution. Studies vary in quality with the most common quality rating being fair. A lack of follow-up data and inadequate control of confounds are two significant areas of concern. For example, negative affect and perceptual anomalies are important variables implicated in SC appraisals and are shown to differentiate between paranoia and other forms of anxiety (Freeman et al., 2008). Evidence would be strengthened by longitudinal studies with repeated measurements to delineate the nature of SC and paranoia relationships in naturalistic social environments.

Observational studies cannot establish causal effects. Few studies investigate SC and paranoia with an experimental design, and of those studies, very few can be considered as investigating SC as a predictor of paranoia in real-world social interactions. Freeman and colleagues (2014b) induced unfavourable comparisons in virtual reality by manipulating height as a marker of social rank, leading to increased paranoia when subjects interacted with taller avatars. However, in a study where subjects were asked to compare themselves with high or low status profiles, results suggested a clear impact on perceived social rank and no effect on paranoia (Ascone et al., 2017). It is challenging to assess real-time appraisals, and at present, evidence points to the utility and validity of simulated environments, with studies showing paranoia in real-world contexts to be highly associated with paranoia in virtual environments (Veling et al., 2014).

Clinical implications are tentative given the limited body of literature and small effect sizes. Cognitive-behavioural interventions for paranoia may usefully incorporate questions and self-monitoring tasks on time spent comparing the self to others, sources of information, types of unfavourable comparisons (inferior rank-related cognitions) and the impact of comparisons. Psychosocial interventions may be tailored to help individuals attend to personal strengths and build confidence in social situations, with experiential learning of a felt sense of value and inclusion in social groups (evidence for re-appraising unfavourable SC of social attractiveness and belonging).

Limitations

Search strategy

There may be an effect of publication bias for studies with a significant result. As a socio-cognitive construct, SC has numerous definitions in the literature and search terms may not fully represent the construct. Measures of SC may be included in studies of self-esteem or interpersonal sensitivity; however, these are separate constructs to the variables of interest in this review. Reference list searches of included studies may help mitigate this limitation.

Another limitation of the search strategy was the proportion of agreement between reviewers in full-text screening which fell below .81. This was due to disagreements on SC measures; whether papers should be included if they report on comparisons in relation to hallucinations, and papers which measured meta-cognitive beliefs about judgements of self-worth. These instances were discussed with the third reviewer and deemed ineligible according to the definition of social comparison (Wood, 1996) and study protocol. A second subset of full-text papers were reviewed to ensure data collected are correct representations of the variables of interest.

Studies including participants with psychosis were frequently ineligible due to low specificity in measurement of paranoia, and could not be included due to grouping paranoia with hallucinations, conceptual disorganisation, grandiosity, excitement, and hostility into one positive symptom subscale. An advantage of investigating paranoia as a single-symptom approach is that it isolates a consistent element of psychopathology for study (providing validity that the same construct is being measured within and across samples) and avoids misclassification which troubles studies based on diagnostic categories such as schizophrenia (Freeman & Garety, 2000).

Sample characteristics

Studies frequently neglect to report sample characteristics such as ethnicity and socio-economic status, and those that do are weighted towards Caucasian females in higher education. This is a significant problem as research in psychotic disorders suggests that both variables of interest (unfavourable SC and paranoia) may have a higher incidence in minority populations, especially individuals living in low ethnic density neighbourhoods (Bosqui et al., 2014). Discrimination, victimisation, and low perceived belonging are hypothesized to play a significant role in unfavourable comparisons and are shown to predict a lowered threshold to the detection of threat, and consequently paranoia (Thomas et al., 2017). Studies with larger samples that measure demographic factors in detail are needed to establish the relationship

between SC and paranoia in minority populations where risk of unfavourable comparisons and paranoia is reputedly high.

Quality assessment

The quality appraisal tool for observational studies was limited by item applicability and was descriptive rather than numerical. It is recognised in the literature that tools for examining the quality of cross-sectional studies are limited and those providing numerical scores have questionable reliability (Moskalewicz & Oremus, 2020). The Downs and Black (1998) tool for experimental studies also had limitations. The value of a total score is questionable as items are given equal weighting, however some items were more pertinent to different study designs.

Measures

An inherent limitation of self-report measures in this review is the influence of biases such as social desirability and the introspective ability of subjects. For SC, studies using single-item measures risk not fully capturing the construct of interest (low content validity) and have fewer points of discrimination (sensitivity). Most studies in this review use a more comprehensive measure; the SCS (Allan & Gilbert, 1995). This provides an indication of self-evaluations according to global constructs of rank (e.g., inferior-superior), group-fit (e.g., different-same) and social attractiveness (e.g., undesirable-desirable). One limitation is the lack of information on whether subjects consider these variables (e.g., similarity to others) as negative and important to their self-concept. Variables of importance may change within and between samples according to factors such as developmental life-stage and cultural relevance. Returning to the definition of SC (Wood, 1996), it is important for future research to consider other aspects of SC not included in this review, such as the relationship between acquisition of social information and paranoia (information sought, frequency, and comparison direction).

Conclusion

Research on the relationship between appraisals of social comparison and paranoia is scarce and methodological issues of current studies limit conclusions. Measuring both constructs with ecological validity requires careful designs that simulate the cognitive, affective, and behavioural processes associated with self-other comparisons. These processes occur continuously in social interactions and result from the evolution of specialised socio-cognitive abilities shaped by humans living within complex social hierarchies. A tentative interpretation of current evidence is that appraisals of difference and social attractiveness, with extremely negative or positive self-other perceptions, may predict a lowered threshold to the detection of social threat and subsequent paranoia. Most studies are designed to focus on the detection of linear associations between SC and paranoia, and recruit convenience samples which may not provide a true representation of the distribution of SC and paranoia in more diverse populations.

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Service Improvement Project

"We don't sleep here": Experiences of sleep problems, factors disrupting sleep, and intervention preferences in an adolescent inpatient service

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Proposed Journal

Psychology and Psychotherapy: Theory, Research and Practice is an international journal that welcomes papers on the vulnerability to, adjustment to, assessment of, and recovery from psychological disorders, and welcomes submissions of qualitative research studies. Author submissions guidelines are presented in Appendix A.

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Abstract

Objectives: Sleep problems are prevalent in adolescents admitted to psychiatric units but rarely targeted in treatment. This service improvement project investigated inpatient adolescents' experiences of sleep problems, factors disrupting sleep, and intervention preferences.

Design: A qualitative interview design.

Methods: Patients with insomnia symptoms were recruited from one psychiatric unit. Semi-structured interviews with twelve adolescents were analysed using thematic analysis.

Results: Sleep problems were co-occurring and had a reciprocal relationship with daytime impairments. Factors disrupting sleep included an unfamiliar setting and routine, sensory overload, intrusive experiences (e.g., nightmares), intense emotions (associated with anxiety-related hyperarousal, mania, hopelessness, and unhelpful coping strategies), attempts to cope with fatigue (e.g., daytime sleep), and factors specific to eating disorders. Patients described sleep interventions as fundamental to their care, particularly personalised help early in admission. Intervention preferences highlighted the supportive role of staff and peers in settling at night, use of observations, and daytime physical activity.

Conclusions: Findings highlight patients' experiences of too little sleep, fragmented sleep, and shifts in sleep timing. Addressing sleep problems is valued and an important target in inpatient settings, and patients wish for options beyond medication alone.

Keywords: Insomnia, Adolescent, Inpatient

"We don't sleep here": Experiences of sleep problems, factors disrupting sleep, and intervention preferences in an adolescent inpatient service

Adolescents admitted to child and adolescent mental health (CAMHS) units are reported to have some of the poorest sleep relative to community adolescent samples (Boafo et al., 2019; Kaplan et al., 2014). Insomnia is the most prevalent sleep disorder during adolescence with estimates of 13.7-18.5% (Hysing et al., 2013), defined as a significant disturbance in sleep initiation, maintenance, quality and/or early waking (American Psychiatric Association, 2013). A recent empirical study found half of 100 CAMHS inpatients screened positive for insomnia (Johnsen et al., in prep). Epidemiological studies suggest adolescent insomnia is chronic (Roberts et al., 2009), associated with poorer outcomes and more severe psychopathology (Åslund, 2020; Roberts et al., 2009; Shochat et al., 2014; Thompson et al., 2020).

Historically, sleep problems were viewed as a symptom or consequence when co-occurring with psychiatric disorders and disregarded in treatment (Freeman et al., 2020). However, it is now well-evidenced that poor sleep and mental health conditions exacerbate one another, with a stronger pathway of sleep problems as causal in the development of mental health conditions (Freeman et al., 2020; Pigeon et al., 2017). For example, poor sleep is shown to increase negative affect, hallucinations, and paranoia (Hennig et al., 2020; Reeve et al., 2015). In CAMHS inpatients, moderate-to-large associations are reported separately between insomnia severity and depression, anxiety, psychosis, and conduct problems (Johnsen et al., in prep). Of great concern is the association of sleep problems with risk behaviours, especially when considering discharge. A meta-analysis of cross-sectional studies found that adolescents reporting poor sleep had a 135% higher risk of suicidal ideation compared to those without sleep problems (Liu et al., 2019). Prospective studies indicate that sleep problems are a robust predictor of self-harm and suicidal ideation, independent of depression (Wong & Brower, 2012; Wong et al., 2011).

The sleep of adolescent inpatients is likely influenced by environmental factors, psychological processes, and changes to the biological processes driving sleep. Puberty onset corresponds with a biologically-driven delay in the sleep-wake cycle: the homeostatic drive accumulates more slowly, and melatonin secretion (a marker for circadian rhythmicity) is delayed, predisposing adolescents to later sleep (Borbély, 1982; Carskadon et al., 1993; Taylor et al., 2005). Hyperarousal, associated with elevated cortisol and hypothalamic-pituitary-adrenal dysregulation, further disrupts sleep (Riemann et al., 2010).

Studies highlight how physiological and psychological factors interact, such as night-time worry increasing hyperarousal (Blake et al., 2017; Sheaves et al., 2018a). Cognitive and behavioural factors associated with insomnia include exaggerated beliefs about the consequences of sleep disruption and unhelpful sleep habits (Blake et al., 2017; Chiu et al., 2015). Environmental factors likely disrupt sleep; however research is sparse. On an adult unit, reports highlight disturbances due to night-time observations (Sheaves et al., 2018a).

Reports suggest that polypharmacy for sleep has risen significantly over the last 20 years, including melatonin, antipsychotics, and benzodiazepines (Lenhart & Buysse, 2001; Rios et al., 2019). However, pharmacotherapy is insufficient in treating insomnia for most (Blake et al., 2017) and there are no specific treatment guidelines in the UK for adolescent insomnia. Cognitive-behavioural therapy is the recommended first-line treatment for insomnia (CBTi) in adulthood, with an emerging evidence base for adolescent insomnia (American Psychiatric Association, 2013; National Institute for Health and Care Excellence, 2022; Wilson et al., 2019). CBTi includes sleep restriction, stimulus control, cognitive work, and sleep hygiene (Moore & Hartman, 2021). Meta-analyses of adolescent CBTi show moderate effect size improvements in insomnia (Blake et al., 2017) and a "halo effect" with wide-ranging clinical benefits (Freeman et al., 2020; Manber et al., 2008). CBTi shows promising results on an adult psychiatric unit, with a large effect size reduction in insomnia (Sheaves et al., 2018). Sleep treatments were popular; however this is yet to be tested in a CAMHS inpatient setting.

Interventions on psychiatric units aim to reduce acute distress and clinical symptoms, mitigate risk, and shorten length of stay (NHS England, 2018). In this service improvement project, the participating unit identified sleep disturbance as a significant clinical concern. Prior to potential service adaptations, an in-depth understanding of patient perspectives was identified as a priority to refine theory, promote engagement, and maximise clinical benefit (Skivington et al., 2021).

Aims

Study aims on the unit were:

1. To explore patient experiences of sleep problems
2. To explore patient perceptions of what disrupts sleep and what maintains sleep problems
3. To explore patient preferences for sleep interventions

Methods

Design

A qualitative interview study. Approval was received from an NHS Research Ethics Committee (Ref: 21/SC/0186).

Research team

The study team included clinicians with expertise in sleep disorders, CAMHS, and inpatient care. This ensured multiple perspectives were obtained for study credibility and dependability (Guest et al., 2012). Materials including information, consent forms, and the interview schedule were developed with the study team and three experts by experience (CAMHS inpatients).

Data collection and analysis was performed by MK (trainee clinical psychologist). MK had prior experience working with adolescents with severe mental health problems and

personal experience of sleep disturbance. MK came with an appreciation that reflecting on prior assumptions with the study team was crucial to attend to different accounts of sleep on the unit, and kept a reflexive log.

Service Context

The Highfield is an 18-bed inpatient unit providing multi-disciplinary care, assessment and treatment for adolescents aged 11-18 with acute mental health needs across Oxfordshire, Buckinghamshire and Wiltshire. Common diagnoses include severe presentations of anxiety, depression, and eating disorders. Presenting difficulties are typically emotion dysregulation, self-harm, and suicidal ideation. It is recognised that a large proportion present with neurodevelopmental disorders and trauma histories, and are admitted due to significant risk to self or others (e.g., following a suicide attempt, severely under-weight). Psychological treatments include dialectical behaviour therapy (DBT), CBT and family therapy. The clinical team identified sleep disturbance as a significant concern for many patients, and had documented an increasing demand for sleep medications with limited success in supporting sleep initiation and maintenance.

Participants

Participants were sought from an inpatient unit in Oxford Health NHS Foundation Trust (Highfield Unit). Inclusion criteria were aged 11-18 and a self-reported problem with sleep initiation, maintenance, or early waking. Exclusion criteria were insufficient English for interviews; moderate-to-severe learning disability; clinical concerns related to risk; and lack of capacity to consent. Clinicians introduced the study to all patients weekly at morning meetings and were asked to consider caseloads. With verbal consent, individual meetings were arranged with MK, who provided information and determined suitability. Criteria were checked with the referring clinician at referral and before interviews. Of the fourteen adolescents referred, two were transferred to other services before eligibility was determined, and twelve participated. Six were aged 16-18 and gave written informed consent. Six were aged 13-15 and

gave written assent, with prior consent from a parent or guardian. The interviewer had no pre-existing relationship with participants. Due to the study being introduced at weekly meetings, it is not known for certain how many were invited to participate and rate of uptake.

The researchers attempted purposive sampling for variation in demographics and diagnoses. This was limited by the patient group admitted during the recruitment window: 01 October 2021 to 01 April 2022. With consent, descriptive data were obtained from electronic records.

Procedure

The Sleep Condition Indicator (SCI; Espie et al., 2014), an 8-item insomnia screening tool, was administered prior to interviews to describe the sample. Questions are rated over the previous month on a 5-point scale (0-4) on sleep continuity, consequences of poor sleep, frequency and duration of problems, and sleep satisfaction. The SCI is valid and reliable in youth samples (Wong et al., 2017). Lower total scores indicate greater symptom severity (0-32), and scores ≤16 reliably indicate insomnia in adults (Espie et al., 2014). The SCI was chosen over other measures (e.g., Insomnia Severity Index) as a brief screening tool that was familiar to unit clinicians as a routine outcome measure at admission and discharge. The simple phrasing (e.g., '*how long does it take you to fall asleep*?') and anchor points in time were applicable to the setting and minimised cognitive demands for an acutely unwell adolescent population.

Semi-structured interviews (29-68 minutes, M=49.8) were conducted by MK at the unit. The topic guide (Appendix F) included open-ended questions about sleep on the unit, factors disrupting sleep, and intervention preferences. A brief description of CBTi was read to elicit views on psychological treatment described in this way. Follow-up questions were used to promote engagement. Steps were taken to minimise potential power imbalances between interviewer and participant by emphasising that participant views were paramount and that the

researchers aimed to learn from them, reminding participants that they did not have to answer questions. Interviews were audio-recorded, transcribed verbatim and anonymised (MK).

Participants completed a post-interview checklist of factors disrupting or maintaining sleep problems (Appendix G), adapted from an adult inpatient checklist (Sheaves et al., 2018b). The checklist was created to support future sleep assessment and interventions such as CBTi, allowing clinicians to tailor the treatment approach to individual presentations. By having an easy to administer checklist, this can inform efficient sleep-focused formulations and the selection of environmental adaptations or psychological techniques. Piloting the checklist with the current sample enabled a greater understanding of maintenance factors specific to this population and setting. Participants were invited to add items.

Each participant received a £10 voucher as a token of thanks for participation.

Analysis

Thematic analysis was conducted and NVivo 12 Software used for data management. This method acknowledges the ways individuals make meaning of experience, and the ways that broader social contexts impinge on meanings (Terry et al., 2017). An abductive approach (Tavory & Timmermans, 2014) included deductive methods to draw on theoretical frameworks and inductive methods to develop ideas based on new observations.

Initial interviews were reviewed and themes identified were incorporated into the interview schedule (Bazeley, 2013). For example, after three interviews it was evident that fatigue and daytime rest was important in reports of sleep disturbance. Prompts were added to elicit additional information. Six phases of analysis were followed (Terry et al., 2017). Transcripts were read and re-read by MK to become familiar and immersed in the data. Regular supervision (BS, JB) was used to develop themes (generation, refinement, and classification) and perform credibility checks. A preliminary coding framework which incorporated multiple perspectives on the data was agreed, corresponding to overarching interview topics.

Results

Demographic information

Participant demographics and characteristics are presented (Table 2.1 and 2.2). Twelve participants were recruited (M^{age}=15.4). Psychiatric diagnoses included anorexia nervosa, separation anxiety, obsessive compulsive disorder, depression, emotionally unstable personality, bipolar, and attachment disorder. Four participants had autism. Duration of stay at interview varied from 12 to 193 days (M=53.4). During the recruitment window, 52 patients were admitted to the unit (48 female, 47 White-British).

Overview of themes

Themes were organised according to study aims and expanded with subthemes. The final thematic map is presented (Figure 2.1).

Table 2.1

Sample Demographics (n=12)

Demographics	Frequency
Age (years)	
13	1
14	2
15	3
16	3
17	3
Gender	
Female	10
Gender neutral	2
Ethnicity	
White-British	9
White (other white background)	3

Table 2.2

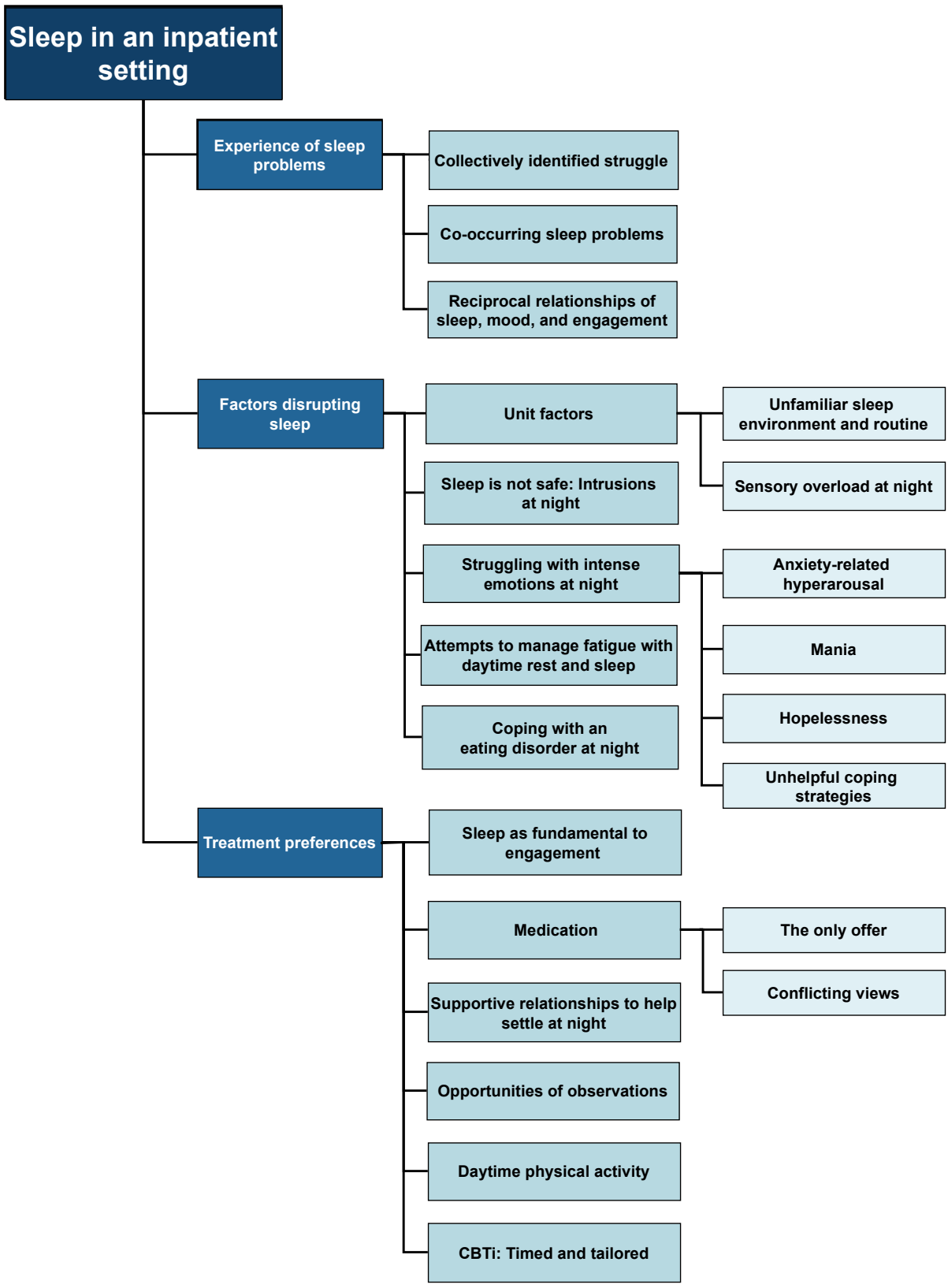
Sample Characteristics

Participant	Diagnoses	Admission duration (days)	Previous intervention for sleep?	SCI total score
1	AN, SA	84	No	14
2	BD, Autism	29	Yes – Melatonin	15
3	AN	19	No	12
4	AN, Autism	23	No	10
5	AN, DP	70	No	11
6	DP	48	Yes – Sleep hygiene	4
7	DP, Autism	11	Yes – Melatonin	6
8	AN	84	No	13
9	OCD, Atypical AN	193	No	10
10	AN, Autism	26	Yes – Melatonin	8
11	Atypical AN	12	No	21
12	EUPD, AD	42	Yes – Melatonin, Zopiclone	8

Note. SCI; Sleep Condition Indicator, AN; anorexia nervosa, SA; separation anxiety, OCD; obsessive compulsive disorder, DP; depression, EUPD; emotionally unstable personality disorder, BD; bipolar disorder, AD; attachment disorder.

Figure 2.1

Final Thematic Map



Theme 1: Experience of sleep problems

Collectively identified struggle

When asked about their sleep on the unit, participants gave a resounding response that they noticed themselves and their peers struggling with similar problems. *'In the mornings we ask each other have you slept well, most say no'* (P4), *'I don't think I've had a good night's sleep since I've been here... it's the same for others'* (P10), *'We don't sleep here' (P12).*

Co-occurring sleep problems

Problems were co-occurring, including poor sleep initiation, maintenance, early morning waking, and wakings associated with parasomnias. Participants reported that these difficulties led to shorter sleep durations: *'I'm not sleeping... two hours if I'm lucky'* (P7). Drowsiness in the morning and not the evening was common: '*not feeling tired at night... it's frustrating, I went to bed at a reasonable time but couldn't sleep, now I have to wake up, but can't because I'm so tired*' (P2).

Most reported having sleep problems before the unit, particularly poor sleep initiation, and most described a deterioration in sleep maintenance once on the unit: *'I didn't wake up in the night at home, it was getting to sleep that was difficult...now I wake five times a night*' (P5), '*Since being here... I'm a light sleeper, easily woken up... I struggle to get back to sleep after*' (P3).

Reciprocal relationships of sleep, mood, and engagement

Sleep disruption had a negative impact on energy levels, mood, relationships, cognitive processes, and engagement in daytime therapeutic tasks. A reciprocal relationship was evident in descriptions of sleep disruption leading to difficulties in the day, which interfered with sleep the following night (Appendix H.a).

Theme 2: Factors disrupting sleep

Unit factors

Unit factors were divided into two sub-themes: unfamiliar environment and routine, and sensory overload.

Unfamiliar environment and routine

Participants reported challenges in acclimatising to a new sleep setting and bedtime triggering thoughts about life outside the unit. '*It's strange... I don't think anyone walks into their room and is like 'ahh, home sweet home' and falls asleep'* (P1). *'There's lots of rules and routine, it was scary [...] I would lay in bed and think about how different everything was... being in a different place to my family'* (P4). Many described spending hours at night planning the next day, triggered by a fear of uncertainty about the unit: *'the unknowns... I plan everything before going to sleep, it makes me feel prepared... on a unit things day-to-day are unknown*' (P10).

The routine half hourly night observations were reported to be disruptive due to light and noise. Whilst environmental factors triggered awakenings, psychological processes (e.g., anxiety-related hyperarousal) exacerbated sleep disruption: *'In the middle of the night... when it's noises, or someone upset, that scares me a lot, it brings up memories from before I came here...'* (P8).

Participants described the morning being an abrupt start and feeling anxious about the consequences of poor sleep: *'if I wake up too much in the night, I might sleep through when I'm supposed to prep breakfast... that's worrying, if you wake up late, they [staff] do it for you... you feel like you have gone backwards'* (P5). Mornings appeared particularly anxiety-provoking for those with eating disorders due to 6am weigh-ins twice weekly (due to nurse availability): *'people go to weigh-ins and have a lot of trouble sleeping before and after... and wake early, because they're stressed or thinking a lot'* (P1).

Sensory overload at night

The busy environment and experiences of sensory overload caused problems with sleep initiation. *'I would have sensory overloads a lot, because it's loads of slamming, bright lights, it's not nice, sometimes you can hear talking really loudly when you're trying to sleep'* (P1). This was particularly evident for autistic adolescents at night.

Sleep is not safe: Intrusions at night

Four participants reported hyperarousal at night and wakings due to trauma-related re-experiencing and nightmares. Participants described anxiety due to predictions that sleep

would be a distressing or unsafe place, which appeared to further maintain the experience of nightmares: '*I wake a lot because of nightmares... increasingly worse since I've been here, it's made me anxious before bed because I think this is likely to happen. That in turn makes the nightmares more frequent, if I'm anxious going to bed'* (P6). *'Things I don't want to think about come back in my dreams and put me off sleep... it's not a good place'* (P7).

Three participants described a negative impact on sleep from idiopathic nightmares and three described dissociation and sleepwalking post nightmares: *'...it's a pretty terrifying place... I'll have dreams about different incidents but circumstances change. I'll wake up and be somewhere else like the bathroom floor...'* (P7). Behavioural responses to threat served to maintain sleep problems. For example, participants reported avoidance of sleep: '*If I have a nightmare, I try and not go back to sleep... that makes me more tired, ... sets me up to fail, because I'm already really anxious, and then I've had more time awake to think...'* (P7).

Struggling with intense emotions at night

Participants reported disrupted sleep due to intense emotions at night. Four subthemes emerged: Anxiety-related hyperarousal, mania, hopelessness, and unhelpful coping strategies.

Anxiety-related hyperarousal

All participants reported that anxious thoughts thrived at night, increasing sleep latency and length of awakenings. A heightened physiological alertness to stimuli appeared to be driven by threat-based appraisals, which may maintain wakefulness despite sleep pressure and aligned circadian timing: *'...it took me a lot longer to fall asleep because I would lay in bed and think about all the stuff that I was scared about'* (P4).

Intensity of affect at night was particularly notable: *'I won't be able to focus on anything but that emotion, it distracts me from getting to sleep... feeling overwhelmed and anxious'* (P4), *'when I feel anxious [in bed] my heart beats faster and I feel sick'* (P12). Threat-based appraisals included those specific to mental health presentations (Appendix H.b), negative interpretations and

significance attributed to poor sleep: *'I feel not great that I've been so unable to sleep or wake up normally, something's gone wrong again'* (P6), and self-evaluative concerns related to peer inclusion: *'what I'm going to wear, that anxiety... whether people are going to judge me'* (P3), *'...whether or not I was likeable'* (P6).

Mania

Two participants were similarly hyperaroused at night and reported an overactive mind preventing sleep initiation, however, this was associated with restlessness and interest in things other than sleep: *'My mind is too active, I wanna go out and do more and more instead of sleeping... it's hard to get out of that mood... I stay awake for so long'* (P2). Participants related these experiences to mania as part of their mental health condition.

Hopelessness

One difficulty leading to disengagement from unit structure and subsequent sleep disturbance was a sense of hopelessness about mental health difficulties or treatment: '*I find it hard to sleep... because I will be overthinking and feel really low. What's the point in trying to get better, it's not going to get better'* (P12). For many, sleep was used to escape demands of the unit and internal experiences. Participants reported sleeping earlier or retreating to bed in the day: *'when I've had a rubbish day I get into bed, usually an hour early, to end my day as soon as possible...'* (P9), *'...it's overwhelming in the day... which leads me back to laying in bed... if I can sleep through the day then I do'* (P10).

Participants reported disrupted sleep patterns due to staying in bed in the morning, which can result in bedtimes misaligned to circadian rhythms, or sub-optimal homeostatic sleep pressure. Early mornings were a particular time for hopelessness: *'having the pressure of the day ahead makes it hard to get out of bed, hopelessness comes in, ...makes you feel physically tired'* (P9).

Unhelpful coping strategies

Participants reported frustration with a lack of strategies to cope with anxiety processes at night. It seemed that an accumulation of homeostatic sleep pressure led to

eventual sleep: *'I haven't got a way to stop ruminating...I just get exhausted from being awake for so long that I drop off'* (P6). Participants described unsuccessful strategies such as thought suppression: *'...you try and not think about something, and it just makes it worse for sleep'* (P7). Three reported that they would like help at night but wished to avoid disturbing staff: *'I wouldn't say anything to them because that would make me feel really bad'* (P4).

Despite the policy of no smartphones, most participants used devices at night as a distraction technique to cope with intense emotions, with plausibly unhelpful effects for sleep by weakening sleep-bed associations: *'In bed I'll watch something...listen to a podcast. [...] it's not really helpful for sleep, it's a distraction to... take you out of your head'* (P8).

Attempts to manage fatigue with daytime rest and sleep

Most participants reported persistent fatigue, related to their daytime schedule, and confusion at their lack of ability to sleep: *'Its incessant, breakfast takes so much energy, then straight to school. Complying... engaging, doing the minimum is so much effort...'* (P10), *'most of the time I want to lay down, I'm exhausted... but then wouldn't be able to sleep when I try... but I was tired'* (P4). Participants attempted to manage fatigue by sleeping or laying in bed during the day, which may weaken sleep-bed associations and disrupt circadian zeitgebers: '*...so tired during the day I've been falling asleep in the classroom, slept in, missed breakfast [...] then I can't sleep in bed*' (P10).

Coping with an eating disorder at night

Three participants reported pain and hunger at night, relating this to their eating disorder and attempts to manage rules they had set themselves around eating. *'I drink water rather than eating. Then I'd get up lots during the night to go to the toilet. I used to feel really dizzy... I thought it would help if I drink lots of water just before I go to sleep'* (P4). *'[Sleep] was a bit disrupted because of physical pains, to do with my eating disorder'* (P5).

Theme 3: Intervention preferences

Sleep as fundamental to engagement

All participants spoke about the cumulative benefits of better sleep, having an impact on mood, cognitive abilities, and engagement. *'You're not ever going to feel good if you don't sleep, you're going to be tired and not able to engage... sleep is very important'* (P12). *'I can manage my emotions better... I feel more capable... internally it improves my mood. [...] I'm more interactive with people... participating better'* (P3). Participants also reported a positive impact on their perceived ability to cope in the day: *'it alleviates anxiety because I go to school slightly less stressed, thinking 'okay you've got energy for the day', feeling reassured'* (P4).

Medication

Two themes emerged from accounts of help for sleep on the unit: medication being the only offer, and conflicting views on medication.

The only offer

When asked about help for sleep on the unit, nearly all reported that they had not received help other than medication. '*I started to say can something be changed, and people said we can give you that medication [Melatonin]. I haven't got any other help'* (P10). Participants reported that they were unsure what else could be done besides medication: '*they can't really help much with sleep [...] just try medication I guess* (P11).

Conflicting views

Views on medication for sleep, and impact of other psychotropic medications on sleep, were highly varied. This is likely due to the heterogeneity in prescribed medications. Of four participants prescribed melatonin, two reported benefits early on: *'it made me tired and fall asleep really quickly, it didn't help me stay asleep though'* (P2), and two reported no effect. Most participants were on anti-psychotic medications and reported a daytime sedative effect: *'taking it in the morning made me really tired'* (P11), *'I asked for it to be taken off, I've noticed I'm less drowsy, I can get on...'* (P3). One participant was on a mood stabiliser, Lithium, and reported an indirect

positive impact on sleep: *'...it stabilises my mood ... I'm not restless or manic, I can sleep a lot easier'* (P2). One participant on fluoxetine reported a negative impact on sleep: *'the main side-effect was finding it harder to sleep... it made it a lot worse'* (P6).

Supportive relationships to help settle at night

Despite reports of medication being the only offer, interviews highlighted that clinicians and adolescents were creative in developing individual strategies for sleep. Intensive nurse support (INS) in the evening was helpful for generating ideas to settle at night. This included soothing boxes, weighted blankets, and sleep hygiene such as less screen time in bed. Participants appreciated having someone who knew about their difficulties and offered encouragement: *'sometimes... it's just a nice friendly face saying don't worry, it's gonna be alright, I'm gonna help you get into your room, and we'll talk about it tomorrow'* (P1). Participants also reported staff helping to introduce routines such as calling parents in the evening: *'it makes it seem normal, to say goodnight'* (P8).

Participants spoke about adapting the timing of support and scheduling anxiety-provoking or cognitively demanding conversations for the daytime: *'staff trying a therapy session at 2am... I don't want to talk about my problems then, they can be during the day'* (P1).

Opportunities of observations

Six participants reported that bi-hourly staff observations were helpful and offered opportunities for comfort and coping strategies. *'Checks can be useful, if I have nightmares and go into that [dissociative] state, staff checking alleviates anxiety going to bed, ... they bring me back'* (P6), *'I know that nothing bad could happen... because someone makes sure I'm alright'* (P1). Observations also appeared to reduce barriers to help-seeking: *'They're necessary... I don't have to approach staff; they see that I'm struggling, and they'll help'* (P12).

Daytime physical activity

Three participants talked about the importance of movement to improve sleep quality and duration. *'Walks are helpful, they alleviate anxiety and make you feel alright, if I've had a bad meeting,*

I walk to process things... by the time it gets to bed, that thing happened but I've finished with it, ... I can sleep easier. I still wake up but usually sleep longer, and feel better the next morning' (P6).

CBTi: Timed and tailored

In response to information on CBTi participants said they would find this helpful, specifically focused on anxiety at night: *'It sounds helpful to work on thought patterns, a lot of my problems are not being able to quieten my mind...'* (P2), *'I want to work on sleep... I'd be less anxious in the day and night, knowing that sleep isn't so much of an issue'* (P6). Participants spoke about the importance of different interventions to target sleep problems in inpatient settings: *'definitely it should happen whilst you're an inpatient because certain difficulties with sleep only happen when you're an inpatient...it really would make an impact'* (P1), *'we need more options, if we're going to tackle problems here, we might as well tackle the common one, sleep'* (P2).

Participants spoke about the need to tailor treatment for individuals and had a preference for individual work: *'I think individually, when people are in a group here they wouldn't talk or engage... it's too hard to talk in front of people'* (P10). All participants endorsed a preference for short and regular input with help early in admission: '*rather than tackle it when it is really bad, it's more helpful sooner rather than later, you should prevent the problem'* (P1).

Discussion

This service improvement project explored CAMHS inpatients' experiences of sleep disturbance, factors disrupting sleep, and intervention preferences. Given the paucity of research into sleep problems for adolescent inpatients with severe mental health presentations, this study offers important insights into the nature of sleep problems for this population and setting. Results show a collectively identified struggle with sleep and co-occurrence of sleep problems: too little sleep, fragmented sleep, and shifts in sleep timing (e.g., daytime sleep). Parasomnias led to frequent night wakings and hyperarousal, implicating them as an important treatment target. Lack of tiredness at night and difficulty rising in the morning was common.

Accounts suggest a reduced sleep pressure at the desired time for sleep onset associated with daytime sleep.

Participant accounts of sleep fragmentation highlighted unit factors, such as problems adjusting to the environment, and light and noise at night. Unit factors were similar to those identified as disrupting sleep in adult psychiatric units (Sheaves et al., 2018a), however, highlighted specific developmental factors such as separation from attachment figures, and preferences for 1:1 support with familiar staff in the evenings. Surprisingly, half of the participants described night-time observations as supportive for sleep in overcoming barriers to accessing support. Consistent with the literature on insomnia, accounts highlighted psychological factors that may maintain sleep disruption. In particular, the role of intense affect and hyperarousal in increased sleep onset latency and prolonged night-wakings (Blake et al., 2017; Sheaves et al., 2018a). In terms of interventions, accounts highlighted the lack of available options to support sleep and that patients want personalised help early in admission. Participants spoke about the range of positive effects that targeting sleep might have on energy, relationships, engagement, ability to think clearly, and regulating mood.

Strikingly, the study sample included eight participants with anorexia nervosa. This fits with emerging but limited literature on the comorbidity of sleep problems and anorexia in adolescence (Bat-Pitault et al., 2021), and may have led to the relatively novel findings on the role of fatigue, somatic symptoms, and unhelpful behavioural responses in disrupted sleep.

Limitations

Purposive sampling in one unit during the recruitment window gave a sample of predominantly female White-British adolescents. This limits the generalisability of findings, but is not necessarily a weakness for service improvement projects with the intention to make recommendations based on the experience and preferences of a specific population. The lack of male participants will likely have shaped the findings. Risk factors for adolescent insomnia include later stages of adolescence in association with late and post-puberty, and female sex

(Johnson et al., 2006, Zhang et al., 2016). Teenage girls with insomnia are shown to report associated emotional and relational difficulties, perhaps reflected in the themes identified in this study (e.g., intense emotions at night), and teenage boys with insomnia report maladaptive lifestyles (e.g., smoking, drug use), which has implications for adapting treatments to address specific maintenance factors (Zhang et al., 2016).

Given existing theories and the presence of a well-established insomnia treatment (CBTi) which is not currently tested in adolescent inpatient settings, the research team had pre-specified ideas which participants were encouraged to consider. The pros of this approach are specific for treatment development (e.g., understanding preferences), however a study into wider narratives on sleep in CAMHS inpatients could prove fruitful. The views of other stake-holders such as clinicians were not sought due to feasibility and previous exploration (Johnsen et al., in prep).

Recommendations for clinical practice

Results will be presented to the service to develop a greater understanding and provision of sleep interventions for CAMHS inpatients. Potential recommendations for service development were made (Appendix I).

Conclusions

A common area of concern for CAMHS inpatients is sleep disturbance. Co-occurring sleep problems appear both pre-existing and setting specific. From patient accounts we learn that addressing sleep problems is valued and an important target in inpatient care, with a need for different types of intervention, and a preference for personalised help early in admission. Findings on environmental and psychological factors can be used to develop interventions and optimise engagement.

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Theory Driven Research Project

Advancing the clinical understanding and measurement of negative self-beliefs in young people with paranoia

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Proposed Journal

Behavioural and Cognitive Psychotherapy is a journal is aimed at members of the helping and teaching professions, and focuses on both experimental and clinical work contributing to the theory, practice, and evolution of cognitive and behaviour therapy. These aims are in line with the research paper below in the development of a precise assessment tool of negative self-beliefs relevant for clinical practice. Author submission guidelines are presented in Appendix K.

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Transcription for study phase one qualitative interviews was completed with participant consent by the candidate (MK) and Becca Thompkins (BT) (Psychology student, Berkshire Early Intervention in Psychosis Service).

Abstract

Background: Negative self-beliefs are implicated in the causation of paranoia. When we perceive ourselves as inferior, outcast, and hence vulnerable, paranoid ideas flourish. This relationship is pertinent in adolescence, a developmental period of identity formation and expanding social connections. However, little is known about the types of self-cognitions that drive adolescent paranoia.

Aims: We sought to investigate themes of self-beliefs relevant to the experience of paranoia in youth, and develop a precise measurement tool.

Method: This was a mixed methods study. Semi-structured interviews were conducted with 12 young people experiencing paranoia (*age range*=14-23, *M*=19, SD=3.22). Data was analysed using thematic analysis to generate two item pools (self-beliefs, evidence for beliefs). The item pools and measures of self-esteem, paranoia, depression, hallucinations, and grandiosity were completed online by 937 young people (*age range*=14-25, *M*=17.87, SD=2.75) from the general population. Exploratory and confirmatory factor analyses were used to derive the Sense of Self – Youth Scale (SoS) (*n*=1200) and a complementary scale on evidence underlying beliefs (SoS-E) (*n*=1104). Psychometric properties were tested.

Results: The 20-item SoS includes four subscales: *not good enough, bad, broken*, and *an outcast*. Confirmatory factor analyses demonstrated excellent model fit. The SoS demonstrated high internal consistency (α=.941), test-re-test reliability (ICC=.959), convergent and divergent validity. The SoS was significantly associated with paranoia (*r*=.634, *p*<.001), depression (*r*=.699, *p*<.001), and hallucinations (*r*=.418, *p*<.001). The complementary measure, SoS-E, had 18-items with seven subscales, and had a strong correlation with the SoS (*r*=.817, *p*<.001).

Conclusions: The SoS and SoS-E are brief, psychometrically robust, self-report measures which may prove helpful for understanding and treating negative self-beliefs relevant to the experience of paranoia in youth.

Keywords: Negative self-beliefs, paranoia, youth

Advancing the clinical understanding and measurement of negative self-beliefs in young people with paranoia

Paranoia is the unfounded threat belief that others deliberately intend to cause one social, psychological, or physical harm (Freeman & Garety, 2000). Research shows that paranoia exists on a continuum from common experiences of mistrust (social evaluative concerns), to ideas of reference (ideas of being watched, followed or discussed), persecutory ideation, and at the severe end persecutory delusions (Bebbington et al., 2013). The pervasiveness of paranoia has been established in adults (Freeman et al., 2005) and adolescents (Bird et al., 2019), shown to be transdiagnostic across psychosis-spectrum and common mental health conditions including depression, social anxiety, and personality disorders (American Psychiatric Association, 2013; Fenigstein, 2001).

The developmental context

Paranoia may be particularly important in youth (defined as aged 14-25) (United Nations, 2017), a developmental stage when beliefs about the self and others become more established, serving as a basis for screening, categorizing, and interpreting experiences (e.g., *'I am no good', 'others are out to get me'*). Accounts of youth paranoia are rooted in prior adverse experiences, difficult peer interactions, and becoming aware of dangers (Bird et al., 2022). Experiences of out-group coalitional threat increase and avoidance of social exclusion becomes a primary motivator of behaviour, priming individuals to engage in self-evaluative thinking and become sensitive to others' intentions (Blakemore, 2018; Raihani & Bell, 2019). In the general population, a quarter of adolescents report frequent (weekly) paranoid thoughts (Bird et al., 2019; Ronald et al., 2014; Wigman et al., 2011), in comparison to adult studies which report approximately one third have weekly mild paranoid thoughts (Freeman et al., 2005). However, it is difficult to make comparisons between age groups due to use of different measures. Paranoia is more severe and disabling for youth accessing child and

adolescent mental health services (CAMHS) compared to non-clinical samples, and is pervasive across affective and neurodevelopmental disorders (Bird et al., 2020).

The contributory causal role of self-beliefs

Two models of paranoia and self-esteem have been proposed. Bentall and colleagues (2001) suggest that paranoia is a defence against unconscious low self-esteem by blaming disappointment on malevolent others. Freeman and colleagues theorise that paranoia is a direct reflection of conscious low self-esteem, and that threat-based appraisals build on a sense-of-self as vulnerable, activated by negative self-cognitions (Freeman, 2016; Freeman et al., 2002).

Systematic reviews show those with paranoia typically have low self-esteem and compare themselves unfavourably to others (Kesting & Lincoln, 2013; Tiernan et al., 2014). Negative self-beliefs are shown to significantly increase paranoid ideation when experimentally induced (Atherton et al., 2016; Freeman et al., 2014a), and predict paranoia over time (Fowler et al., 2012). Brief, targeted interventions for patients with persecutory beliefs have demonstrated that reductions in negative self-cognitions led to reductions in paranoia (Forkert et al., 2022; Freeman et al., 2014b). Importantly, individuals with paranoia want treatments for negative self-cognitions to regain confidence (Freeman et al., 2019).

Negative self-beliefs in those aged 11-16 predict the persistence of paranoia and associated distress (Bird et al., 2017). Stronger correlations are shown with paranoia and perceptions of low social rank compared to global self-esteem (Gilbert et al., 2005; Lincoln et al., 2010). In adolescence, dysfunctional self-concepts may relate to social comparisons of achievement (e.g., sense of worthlessness due to getting lower grades than peers), appearance, and a developing sense of one's standards and conduct (e.g. right/wrong, good/bad) (Blakemore, 2018).

Measuring self-beliefs

A widely used measure of global self-esteem is the Rosenberg Self-Esteem Scale (Rosenberg, 1965). However, this scale does not have the specificity to capture differences in themes of self-beliefs. The Brief Core Schema Scale (Fowler et al., 2006) was developed to measure specific negative and positive self-beliefs in psychosis. Items were developed for adults in a top-down method. Self-beliefs in youth with paranoia may not be adequately captured, as content specific to social comparison (e.g. inferiority, belonging) and appearance are absent.

Rationale

"Attention to phenomenology helps identify fruitful therapy targets" (Clark, 2004, p. 1092). Negative self-cognitions are implicated in the causation of paranoia, are plausible mechanistically, are present in a large proportion of individuals with paranoia, and the causal role has been tested in experimental and intervention studies. Negative self-cognitions may be particularly important in adolescent paranoia, a developmental period characterised by social threats and the development of identity. To develop treatments that are specific to the phenomenology, we must understand what self-cognitions are pertinent and have tools to measure these. Early recognition and measurement of negative self-cognitions may lead to shorter, tailored psychological interventions, potentially improving mental health trajectories and treatment costs.

The aim of this project is to explore and catalogue negative self-cognitions relevant to youth with paranoia, using a bottom-up approach to generate a representative and clinically useful measure.

Research Questions

1. What are the negative self-beliefs relevant to youth with paranoia?
2. How can these be assessed in a concise measurement tool?
3. Does the measure demonstrate validity and reliability?

Hypotheses

Item Generation

- Themes of negative self-beliefs will include inferiority and negative evaluations of difference.

Measure Validation

The new measure will have high:

- Internal consistency.
- Convergent validity with established measures of self-esteem, negative-self-schema, and self-cognitions related to social rank.
- Divergent validity with theoretically distinct constructs: age, and with measures of opposing constructs: positive-self-schema and grandiosity.
- Test-re-test reliability.

Methods

Study design

Steps for questionnaire development were followed as outlined by Tsang and colleagues (2017) (Appendix L). A mixed methods design was used with two phases: item generation and measure validation. Approval was obtained from an NHS Research Ethics Committee (Ref: 21/SW/0100).

Patient and public involvement

Experts by experience (five members of the McPin Young People's Advisory Group who had experiences of paranoia and low self-confidence) were involved in a focus group and provided feedback on the studies design, methods, and materials (Appendix M).

Research team

The study team included clinicians and researchers with expertise in youth paranoia, CAMHS, and early intervention in psychosis (EIP) services. This ensured different

perspectives were obtained throughout the research process, increasing credibility and dependability (Guest et al., 2012).

Selection of Population

Mental health services

Paranoia is transdiagnostic and the research team noted that clinically paranoia is observed in CAMHS, reflected by an emerging evidence-base suggesting paranoia is prevalent and frequently overlooked in services for young people (Bird et al., 2020). Paranoia is also conceptualised as a symptom of psychosis and EIP services are commissioned in the UK for the ages of 14 to 65 (Jones, 2013).

Age range

Adolescence and early adulthood are shown as an age range particularly susceptible to mental health problems. Reports suggest that approximately 75% of mental health conditions begin by the age of 25 (Kim-Cohen et al., 2003) and the most common age of onset for paranoia and psychotic symptoms is aged 15 to 30 (Jones, 2013). In terms of health research, 'youth' is defined by the World Health Organisation and United Nations as aged 15 to 24. The current study age range of 14-25 was selected in line with this definition, and to represent the lower age range for EIP services.

Phase one: Item generation

Methods

Design

A qualitative study employing semi-structured interviews. Item generation consisted of a bottom-up data driven approach to ensure themes and language were reflective of accounts from youth with paranoia.

Participants

Inclusion criteria for qualitative interviews were aged 14–25, receiving assessment and/or treatment in CAMHS or EIP across Oxford and Berkshire Health NHS Foundation

Trusts (OHFT, BHFT), and meeting a clinical cut-off for elevated paranoia (score ≥23 on the Bird Checklist of Adolescent Paranoia, see Appendix O). Exclusion criteria were insufficient English for interviews; moderate-to-severe learning disability; clinical concerns related to risk; lack of capacity to consent; and declined recording of the research interview. CAMHS and EIP services were approached to be participating sites, and clinicians were asked to consider patients on their caseload. With verbal consent, individual meetings were arranged with MK, who provided information and screened for suitability. Of the fifteen referred, two did not meet the clinical cut-off for paranoia, one declined, and twelve agreed to participate. Ten were aged 16-25 and gave written informed consent. Two were aged 14-15 and gave written assent, with prior consent from a parent/guardian.

Procedure

An interview schedule (Appendix N) was developed in collaboration with experts; those with lived, clinical, and/or research experience. Six open-ended questions were designed to elicit inner experiences (self-cognitions) by asking how individuals might describe themselves, exploring examples when they had perceived things were going well or badly for them. Participants were asked to support statements with examples and follow-up questions were used to ensure credibility (Korstjens & Moser, 2018). Several interview questions were designed to elicit positive self-perceptions to settle participants into the interview and acknowledge both positive and negative self-beliefs. These are viewed as distinct constructs and attention was drawn in interviews to understanding negative self-perceptions for measure development. Semi-structured interviews (28-64 minutes, M=41) were conducted by MK at NHS clinics, home visits, or online. Participants received a £10 'Love2Shop' voucher as a token of thanks. Interviews were audio-recorded and transcribed verbatim (MK, BT). Recruitment was from 15 November 2021 to 19 February 2022.

Analysis

Thematic analysis was conducted (Braun & Clark, 2012; Terry et al., 2017) using NVivo12 for data management. Six phases of analysis were followed as defined by Terry and colleagues (2017) (Appendix P). This method acknowledges the ways individuals make meaning of experience, and, in turn, the ways that social contexts impinge on meanings. Themes identified from qualitative interviews were used to generate initial items, and expanded by consultation with experts from the research team (n=3) to create the final item pools.

Results

Demographics

Demographics of participants from qualitative interviews are presented in table 3.1. Age ranged from 14-23 (M=19, SD=3.22).

Overview of themes

Two major themes were identified: 1) negative self-beliefs, 2) evidence supporting beliefs. For negative self-beliefs, six subthemes were identified: *worthless, not capable, bad, broken, excluded,* and *unlucky*. For evidence supporting beliefs, seven subthemes were identified: *thought processes, ability to achieve, negative impact on others, disliked/ rejected by others, avoidance of others, reliance on others,* and *change to fit in.* Quotes are presented in table 3.2. Subthemes were used as the framework for item generation. The researchers met to review items according to subthemes, incorporating language from participant accounts, and from reviewing existing measures. This resulted in two item pools: 72 negative self-beliefs labelled the Sense of Self–Youth Scale (SoS), and 41-items describing evidence supporting beliefs, labelled the Sense of Self–Evidence (SoS-E) (Appendix Q).

Table 3.1

Participant Characteristics (n=12)

P	Age	Gender	Ethnicity	Clinical Team	Presenting Problems[a]	Paranoia Score[b]
1	23	F	British Asian - Pakistani	Adult EIP	FEP	40 (Moderate)
2	22	M	White - British	Adult EIP	FEP	23 (Mild)
3	20	M	Asian - Cantonese, Nepalese	Adult EIP	Mixed depression and anxiety	27 (Mild)
4	21	F	White - British	Adult EIP	Anxiety, ARMS	46 (Moderate)
5	22	M	British Asian - Indian	Adult EIP	FEP, depression and anxiety	41 (Moderate)
6	23	F	British Asian - Pakistani	Adult EIP	Depression with psychotic features	25 (Mild)
7	15	F	British Asian - Indian	CAMHS EIP	FEP	24 (Mild)
8	17	F	White - British	CAMHS	GAD, AN	51 (Moderate)
9	17	F	British Caribbean	CAMHS	ARMS, emotional dysregulation	56 (High)
10	18	M	Mixed White - Black African	CAMHS EIP	FEP, depression and anxiety	57 (High)
11	14	F	White - British	CAMHS EIP	ARMS	70 (High)
12	16	F	Mixed British European-Indian	CAMHS EIP	FEP	24 (Mild)

Note. P; Participant number, Adult EIP; Early intervention in psychosis service, CAMHS; Child and adolescent mental health service, CAMHS EIP; EIP team specific to CAMHS population (aged 14-18), FEP; First episode of psychosis, ARMS; At risk mental state for psychosis, GAD; Generalised anxiety disorder, AN; Anorexia nervosa.

[a]Presenting problems as reported by the referring clinician in CAMHS or EIP.

[b]Paranoia score as measured by the Bird Checklist of Adolescent Paranoia (B-CAP).

Table 3.2

Participant quotes relating to themes and subthemes

Theme	Subtheme	Participant Quotes
Negative self-beliefs	1. Worthless	P5: 'I don't like myself, I'm just not good enough. I think... physically you're not tall enough... not strong enough... ugly... not that sociable. It's the whole primal thing of social structure, you want other people to value you and you want to be at the top of the social hierarchy. It's a desire to be valid, worthwhile'.
		P6: 'I'm clearly inadequate and I'm not much use in society or as an individual... as a sister, or daughter… I think to myself, you're clearly not good enough for those roles'.
		P6: 'I'm lacking... and if I'm lacking, I'm easily replaceable. I'm worth nothing, it's probably feeling worthless'.
		P11: 'I deserve nothing... worthless, I feel really insecure about myself, my personality, my body... like I'm dirty. Nobody could love me'.
	2. Not capable	P3: 'Thoughts like '*I could do better*', I'm not as hard working as I think I am, or compared to others. Yeah, I feel inadequate... not good enough to be something that I want to be'.
		P9: 'I feel really rubbish about myself, and that I can't do anything, because I'm not clever enough to do anything. I'll be watching like TV... I'll look at people doing well and think, I'll never do this because I'm too this or too that.'
		P10: 'I'm useless, weak. I'd definitely say I'm weak, because I can't handle situations as well as other people can, and I get very emotional'.
		P12: 'I just don't like who I am, feeling useless... I thought I'm a bit dumb, too slow, I could never finish the work'.
	3. Bad	P1: 'I thought to myself, what have you done, you are bad. I was bringing shame to myself, I feel so guilty'.
		P2: '... viewing myself as toxic... it's feeling like robbers and thieves... viewing myself as part of that group of bad people. I thought of myself as almost fundamentally a bad person, and I remember journaling one day and I actually wrote that exact line, that I am a fundamentally bad person. In society what do we do with bad people, we put them in prison'.
		P8: '... maybe I am horrible... I think I'm quite mean, judge people quickly, feel suspicious, I don't think that's a good person'.

		P9: 'I worry that I am dangerous... volatile and nasty, that I won't be able to control myself. I'm more of a bad person than I am a good person. I just feel like a really horrible person'.
	4. Broken	P4: 'Feeling damaged, I just wouldn't be able to think properly, wouldn't be able to think about my own emotions'. P6: 'I'm not as I should be, maybe it's how I was raised, something went wrong with me and I can't fix it'. P9: '... something's broken, I'm blasé to everything and don't have much feeling... some people say I'm quite empty'.
	5. Excluded	P1: 'They walk past and think she is weird... maybe I am, I get very lonely'. P6: 'I'm clearly not good enough to be with people like that... people see me as different, an outcast. You need to change something about yourself to be accepted'. P7: 'I don't fit in with groups at school... just in how I come across to people. In tests too... recently, it was a simple question, I can't even do that. If you don't get the answers right, that makes you different from other people in class'.
	6. Unlucky	P2: 'It's been a theme over the past year really, I've felt unlucky, or unfortunate'.
Evidence supporting negative self-beliefs	1. Thought processes	P4: 'I struggle to think about my own thoughts, my own emotions... a fear of it carrying on and not being able to think, fear of losing a bit of control of your thoughts'. P9: 'Doubting myself... that I won't be able to control myself because I don't have any of my own thoughts left in my head. It's not me that's thinking...'. P12: 'I can't think properly. I'm trying to control my thoughts and have less of them, and have good thoughts, I try to not allow anything bad to come into my mind. It's hard'.
	2. Ability to achieve	P3: 'An example when I was dieting... I was not following through, I would eat too much, and the portions would be not right... I could have done better... always disappointed... I didn't accomplish my goals'. P7: [what runs through your mind:] 'redo the work, and... this isn't correct... give up... just angry with myself, you could have done better, or you can't do it, you're not good enough'.
	3. Negative impact on others	P9: 'I feel bad cos it is quite hard to be my best friend, I feel they aren't messaging me or going to leave, so I block them first on social media. I could hurt someone, I don't think I'm in the wrong at the time, then afterwards I realise and get sad'.

		P11: 'I can be awful... and feel really guilty about it and other times don't care because it's easier. Don't care about anyone, I've said some nasty stuff'.
4.	Disliked/ rejected by others	P1: '... they stared at me and said look at yourself, they thought you are dumb and bad, just look at yourself'. P6: '... they'll see me negatively and I'll be judged as weird, a bit of freak'. P10: 'I'm still not accepted by people... the way I dress, the way I come across... my sexuality, skin colour'. P11: '... they thought I was an awful person, just cause of where I lived. So, I wasn't allowed to see that mate outside of school. ...The stuff I've been through as well, people didn't like me for it... judged me'.
5.	Avoidance of others	P2: 'I viewed myself as someone that people might not want to spend much time with... so I would be quite anti-social in terms of just keeping to myself... being apart'. P6: 'I would sit right at the back so I can be away from others… who would want to sit near me'. P9: 'If you tell somebody then you're going to get hurt, so, I stay away, by myself, just wait until the dust is settled and I feel better about myself. It's not great'.
6.	Reliance on others	P2: 'I am weak-willed, an example would be... there's this website I use to find answers, I use it way too often, or get my friend to help, I wish I could solve problems myself'. P6: '... not being able to rely on my own senses makes me very uncomfortable, having to rely on other people's senses, making you feel inadequate... less independent'.
7.	Change to fit in	P6: 'You need to change something about yourself to get… to be accepted and not abandoned, so you're welcome and safe basically'. 'I change my thoughts and I'm not thinking how I want to think'. P11: 'It's like a coping mechanism, I can change myself around others... so it's fine'.

Phase two: Measure validation

Methods

Design

Cross-sectional survey data was collected online to determine the measures psychometric properties and associations with other measures.

Participants

Inclusion criteria were aged 14–25 and currently living in the UK. Exclusion criteria were inability to understand and complete questionnaires in English.

Procedure

Participants were recruited from the general population via social media adverts (Facebook, Instagram, Twitter) and from the University of Reading, Berkshire. Participants from phase one were also invited to complete the questionnaire. For 14-15-year-olds a parent/guardian was required to review an information and consent form before the young person could access the youth information and assent form. If 16+ years, individuals followed a direct link to provide consent. The survey was hosted on Qualtrics, and questionnaires were in order of those in table 3. Participants were invited to provide an email address to complete the new measures one week later, and were presented with a debrief page. Survey advertisements, measures, and debrief page are presented in Appendix R.

Measures

Questionnaires were selected based on similarity to the construct of interest (negative self-beliefs) for validity tests. Given that the new measures were developed with and for use in adolescents with paranoia, it was important to include a validated measure of adolescent paranoia. Negative self-beliefs have a significant clinical overlap with the construct of depression, therefore a measure of depressive symptomology was included.

Table 3.3

Overview of Survey Measures

Construct	Measure Description
Demographics	A standardised self-report form was created to collect information on age, gender, ethnicity, accessing assessment and/or treatment from mental health services, and mental health diagnoses.
Paranoia	*The Bird Checklist of Adolescent Paranoia (B-CAP) (Bird et al., 2020).* The B-CAP, composed of 18-items, measures the frequency of paranoid thoughts over the past two weeks (e.g., 'People are collecting my information or photos to use against me'). Items are rated on a 6-point scale (0=Never, 5=All the time) and total scores range from 0-90. Higher scores indicate greater severity of paranoia. The B-CAP is shown to be valid and reliable in adolescent clinical and non-clinical samples (Bird et al., 2020), and is a valid tool for identifying excessive and unfounded fears of harm from others that are evidenced as being distinct from recent experiences of victimisation (Bird et al., 2020). For severity ranges and cut-off scores see Appendix O. Internal consistency in the current sample was excellent (α=.94).
Schema: Self and others	*The Brief Core Schema Scale (BCSS) (Fowler et al., 2006).* The BCSS is a 24-item measure of schemata about the self and others, developed for adults with psychosis (e.g., 'I am unloved', 'Other people are accepting'). Items are rated on a 5-point rating scale (0-4) and give four summatory scores: negative-self, positive-self, negative-others, positive-others. The BCSS has been shown to be valid and reliable in adolescent CAMHS samples (Bird et al., 2017; Noone et al., 2015). Internal consistency in the current sample was good for all subscales: positive-self (α=.87), positive-other (α=.88), negative-self (α=.89) and negative-other (α=.92).
Self-esteem	*The Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965).* The RSES is a 10-item measure of global self-esteem (e.g., 'On the whole, I am satisfied with myself'). Items are rated on a scale of 0-3 (0=Strongly disagree, 3=Strongly agree). Scores range from 0 to 30 with higher scores indicating greater self-esteem. This measure has been applied to adolescents with paranoia (Bird et al., 2017; Raes & Van Gucht, 2009). Internal consistency in the current sample was good (α=.89).
Social comparison	*The Social Comparison Scale (SCS) (Allan & Gilbert, 1995).* The SCS is comprised of 11-items to measure global judgements concerning one's rank, social attractiveness and group fit in comparison to others (e.g., 'In relationship to others I feel inferior - superior'). The measure uses a sematic differential methodology with bipolar constructs rated on a scale of 1 to 10. Lower scores indicate greater negative comparisons of inferiority and low rank self-perceptions. The scale had good internal consistency in the current sample (α=.89).
Depression	*The Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001).* The PHQ is a 9-item measure of symptoms indicative of major depression (e.g., 'Little interest or pleasure in doing things') and rated on a 4-point Likert scale (0=Not at all, 3=Nearly every day). Items are rated according to severity of symptoms over the past two weeks and total scores range from 0-27 (0-4 none, 5-9 mild, 15-19 moderately severe, 20-27 severe). Research shows that the PHQ-9 has

	excellent validity and reliability (Kroenke et al., 2001). Internal consistency in the current sample was excellent (α=.90).
Hallucinations and grandiosity	*The Specific Psychotic Experiences Questionnaire (SPEQ) (Ronald et al., 2014).* The SPEQ is a self-report measure of psychotic experiences in adolescence comprised of six subscales with evidenced validity and reliability (Ronald et al., 2014). Two subscales were used in this study. The hallucinations subscale: SPEQ-H, composed of 9-items (e.g., 'Hear noises or sounds when there is nothing about to explain them?') and rated on a 6-point Likert scale (0=Not at all, 5=Daily). Secondly, the grandiosity subscale: SPEQ-G, composed of 8-items (e.g., 'Everyone is going to know about me because of my greatness') and rated on a 4-point Likert scale over the past month (0=Not at all, 3=Completely). Higher scores indicate higher frequency of hallucinatory experiences and higher endorsement of grandiose beliefs. Internal consistency in the current sample was excellent for the SPEQ-H (α=.90), and good for the SPEQ-G (α=.86).

Analysis

It is recommended for factor analyses that the subject-to-item ratio is used to determine sample size with a minimum ratio of 5:1 (Bryant & Yarnold, 1995; Suhr, 2006). Therefore, minimum sample size required for EFA and CFA was 720 for the SoS, and 410 for the SoS-E. A power calculation was conducted to determine minimum sample size for test-re-test (Appendix S). Statistical analyses were conducted in JASP (V0.16.1), and R (RStudio, 2022.02.2) using the 'lavaan' package (Rosseel, 2012). A forced-choice response format was selected to reduce missing data.

Exploratory and confirmatory factor analyses (EFA and CFA) were used to derive final items for the SoS and SoS-E. Completed SoS datasets (n=1200) were randomly divided into two equal groups: a derivation sample (EFA) and validation sample (CFA). SoS-E datasets (n=1104) were divided in the same manner. Items were inspected and those poorly correlated (<.3 with other items) or highly correlated (≥.8 indicating multicollinearity) were deleted. Parallel analysis and inspection of scree plots were used to determine the number of factors to extract, ensuring to retain factors with eigenvalues >1.

EFA was estimated using principal axis factoring and oblique rotation as factors were expected to correlate. Items were considered for deletion based on factor loadings (did not

load onto factors above .40, high cross-loadings on multiple factors) and content (theoretically inconsistent or redundant). To assess model fit, CFA was conducted using the MLR robust maximum-likelihood estimator to account for skewness of the data. Good model fit was determined using Hu and Bentler's (1999) recommended thresholds (Appendix T). A higher order factor model was examined to identify the existence of a global latent factor for each scale (negative sense-of-self, and evidence for negative-self).

Inspection of the distribution plot and normality tests (Shapiro-Wilk) suggested a deviation from normality (W=.985, p<.001). Spearman's correlations were used to examine convergent and divergent validity, and associations between measures of self-concept, paranoia, depression, hallucinations, and grandiosity. Test-re-test was run by investigating intra-class correlation coefficients (ICC) between results taken at two time-points, one week apart.

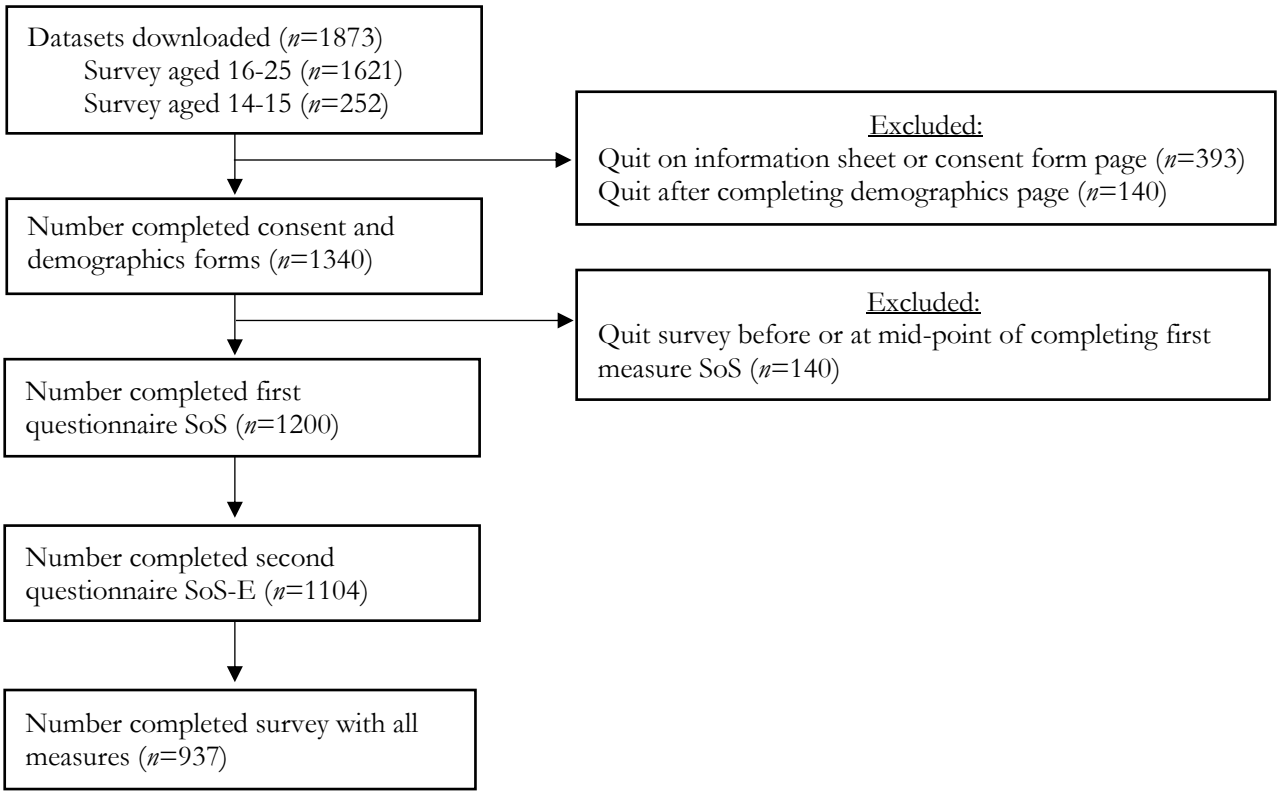
Results

Demographics

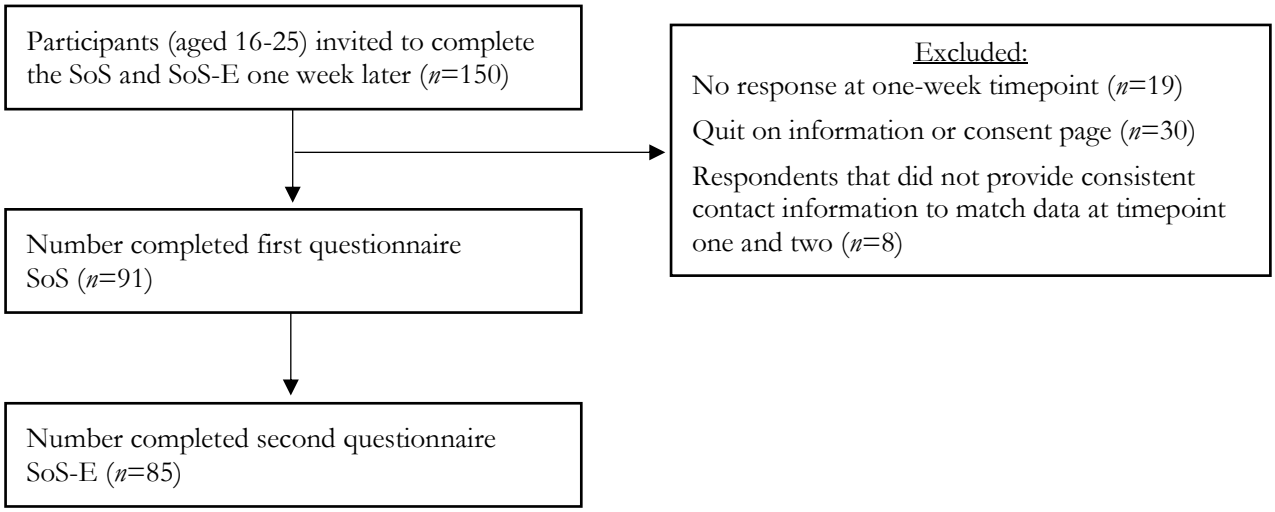
In total, 1200 participants completed the 72-item SoS, 1104 completed the 41-item SoS-E, and 937 completed all measures. Of those who completed all measures, the majority were female (n=646, 68.94%) and White-British (n=624, 67.0%). Age ranged from 14-25 (M=17.87, SD=2.75). Almost a third (n=277, 29.56%) reported being seen by mental health services at the time of participation. Over a third (n=358, 38.21%) reported a diagnosed mental health condition, mostly frequently anxiety. Survey completion times were varied due to non-continuous sessions (Mdn=16 min, M=41 min). Further information is presented in Appendix U. For test-re-test, 91 participants completed the SoS and 85 completed the SoS-E. Data was checked for random error and anomalous responses, and none were identified for removal. Data cleaning processes are outlined in Figure 3.1.

Figure 3.1

Flowchart of data cleaning for online responses



Test-re-test



Exploratory and Confirmatory Factor Analyses

The SoS

The Kaiser-Meyer-Olkin measure of sampling adequacy was .98, Bartlett's test of sphericity was significant ($\chi^2(2556.00)=34471.40$, $p<.001$), and communalities for all items were ≥.30. With these conditions satisfied, adequate common variance was assumed, and factor analysis considered appropriate. EFA in the derivation sample ($n=600$) resulted in a 20-item measure with a 4-factor structure. This was supported by examination of the scree plot and explained 64.8% of the model variance (further information in Appendix V.a). On examination of items compared to the initial prediction, items relating to the themes of '*worthless*' and '*not capable*' loaded onto one factor (re-labelled '*not good enough*') which was deemed theoretically consistent. The sixth theme ('*unlucky*') did not emerge as a factor, which may have been due to high cross-loadings with other factors meaning this was not distinct. Factors were examined and labelled according to themes: '*not good enough', 'bad', 'broken'*, and '*an outcast'*.

CFA in the validation sample ($n=600$) indicated an excellent model fit for the 4-factor structure (robust $\chi^2=377.859$, $df=164$, $p<.001$, CFI=.967, TLI=.962, RMSEA=.050, SRMR=.040). Factor scores were each found to have strong correlations with the total score (Appendix W) and a higher order factor model was examined to identify the existence of a global latent factor (negative sense-of-self). This indicated an excellent model fit (robust $\chi^2=380.978$, $df=166$, $p<.001$, CFI=.967, TLI=.962, RMSEA=.050, SRMR=.041) and suggested it is representative of the primary factors. A total score, calculated by summing all items, was used for subsequent validity analyses. Descriptives and item loadings for the final item pool are shown in Table 3.4 and 3.5.

Table 3.4

Descriptive Statistics for the SoS (n=937)

SoS	Score ranges	Mean (SD)
Total	0-80	37.82 (18.19)
Subscale: *Not Good Enough*	0-32	17.14 (8.87)
Subscale: *Bad*	0-16	4.98 (3.87)
Subscale: *Broken*	0-16	7.88 (4.87)
Subscale: *An outcast*	0-16	7.83 (4.49)

Table 3.5

SoS Final Item Pool

Items	EFA loadings	CFA loadings
Self as: *Not good enough*		
1. I believe that I am... Less than others	0.733	0.707
2. I believe that I am... A failure	0.754	0.840
3. I believe that I am... Pathetic	0.752	0.807
4. I believe that I am... Ugly	0.895	0.704
5. I believe that I am... Inadequate	0.878	0.821
6. I believe that I am... Undesirable	0.793	0.756
7. I believe that I am... Useless	0.791	0.861
8. I believe that I am... Worthless	0.791	0.865
Self as: *Bad*		
1. I believe that I am... A villain	0.965	0.810
2. I believe that I am... Bad	0.755	0.873
3. I believe that I am... Dangerous	0.587	0.544
4. I believe that I am... Toxic	0.594	0.647
Self as: *Broken*		
1. I believe that I am... Wounded	0.823	0.763
2. I believe that I am... Damaged	0.876	0.875
3. I believe that I am... Hurt	0.768	0.768
4. I believe that I am... Broken	0.861	0.869
Self as: *An outcast*		
1. I believe that I am... Too different to others	0.733	0.745
2. I believe that I am... Singled out	0.519	0.663
3. I believe that I am... The odd one out	0.914	0.813
4. I believe that I am... An outcast	0.811	0.844

Note. CFA factor loadings are standardised.

SoS-E

EFA in the derivation sample (*n*=552) resulted in an 18-item measure with a 7-factor structure. This was supported by examination of the scree plot and parallel analysis, and explained 56.8% of the model variance (further information in Appendix V.b). Factors were consistent with the number and content of themes identified from the qualitative interviews. Five factors had two-items. Although preferable to have greater than two-items per factor, it is acceptable to retain two-item factors when factor loadings in EFA are high and between factor correlations are moderate (Worthington & Whittaker, 2006; Yong & Pearce, 2013).

CFA in the validation sample (*n*=552) indicated an excellent model fit for the 7-factor structure (robust χ^2=249.886, *df*=114, *p*<.001, CFI=.960, TLI=.946, RMSEA=.048, SRMR=.038). Factor scores were each found to have moderate-to-strong correlations with the total score (Appendix W) and a higher order factor model was examined to identify the existence of a global latent factor (evidence for negative sense-of-self). This indicated an adequate model fit (robust χ^2=316.284, *df*=128, *p*<.001, CFI=.944, TLI=.933, RMSEA=.054, SRMR=.049) and suggested it is representative of the primary factors. A total score, calculated by summing all items, was used for subsequent analyses. Descriptives and item loadings are presented in table 3.6 and 3.7.

Table 3.6

Descriptive Statistics for the SoS-E (n=937)

SoS-E	Score ranges	Mean (SD)
Total	0-72	41.52 (11.74)
Subscale: *Thought processes*	0-20	14.72 (3.80)
Subscale: *Ability to achieve*	0-8	4.66 (2.09)
Subscale: *Negative impact on others*	0-8	3.68 (1.81)
Subscale: *Disliked/ Rejected by others*	0-12	5.49 (3.14)
Subscale: *Avoidance of others*	0-8	4.89 (2.4)
Subscale: *Reliance on others*	0-8	3.21 (2.15)
Subscale: *Change self to fit*	0-8	4.89 (2.17)

Table 3.7

SoS-E Final Item Pool

Items	EFA loadings	CFA loadings
Subscale: *Thought processes*		
1. I have bad thoughts	0.607	0.697
2. I think too much	0.764	0.552
3. I can't keep up with my changing thoughts and feelings	0.620	0.772
4. I doubt myself	0.668	0.615
5. I can't think clearly	0.550	0.734
Subscale: *Ability to achieve*		
1. I give up on things too easily	0.943	0.767
2. I fail at things I set out to do	0.706	0.866
Subscale: *Negative impact on others*		
1. I make other people feel bad	0.728	0.728
2. I say or do bad things	0.928	0.857
Subscale: *Disliked/ Rejected by others*		
1. I get called names by other people	0.904	0.698
2. I hear that other people dislike me (e.g., my appearance, sexuality, race, religion)	0.729	0.689
3. I find that other people leave me	0.491	0.679
Subscale: *Avoidance of others*		
1. I say too little to other people	0.703	0.833
2. I try to keep away from other people	0.754	0.624
Subscale: *Reliance on others*		
1. Other people often have to look after me	0.777	0.752
2. I rely on other people to solve my problems	0.680	0.726
Subscale: *Change to fit in*		
1. I have to change what I think around other people	1.044	0.824
2. I have to change who I am around other people	0.631	0.837

Note. CFA factor loadings are standardised.

Measure Validation

Internal Consistency

Correlations between the SoS total and subscales, and SoS-E total and subscales, are in Appendix W. The four SoS subscales significantly correlated with each other and had strong positive correlations (Mukaka, 2012). Cronbach's alpha was high for the SoS total scale

(α=.941) and subscales: *not good enough* (α=.936), *bad* (α=.819), *broken* (α=.896), *an outcast* (α=.854), indicating good to excellent internal consistency (Cronbach, 1951). For the SoS-E, Cronbach's alpha indicated good internal consistency for the total scale (α=.878) and subscales: *thought processes* (α=.800), *ability to achieve* (α=.803), and acceptable consistency for: *negative impact* (α=.777), *disliked/ rejected* (α=.735), *avoidance* (α=.651), *reliance* (α=.695), *change to fit in* (α=.787). As a rule of thumb, values between .65 to .80 are considered acceptable, sufficient, or moderate in questionnaire development papers (Taber, 2018; Vaske et al., 2017). These estimates are unsurprising given the low item number of subscales and impact on the value of Cronbach's alpha (Vaske et al., 2017).

Convergent Validity

Non-parametric analyses (Spearman's rho) were used to investigate the relationship between total scores of the SoS, SoS-E and measures of similar constructs. Both measures demonstrated concurrent validity with self-report measures of global self-esteem and negative-self-schema (table 3.8). The SoS and SoS-E had negative correlations with self-evaluations of high social rank (SCS). Overall, convergent validity was deemed to be good.

Correlations with other mental health outcomes

The SoS and SoS-E had moderate-to-strong positive correlations with self-report measures of depression, paranoia, hallucinations, and negative-other-schema, and a negative correlation with positive-other-schema.

Divergent Validity

A non-parametric analysis of correlations between the new measures and opposing constructs of positive-self-schema and grandiosity, and age as a theoretically unrelated concept, were used to demonstrate divergent validity. The SoS and SoS-E had moderate-to-strong negative correlations with positive-self-schema, and weak negative correlations with grandiosity (table 3.8). Correlations between the new measures and age were statistically

significant (p<.001) but weak as expected, showing a trend of reduced negative self-beliefs with increased age (SoS: r=-.211, SoS-E: r=-.264). Divergent validity of the scales was deemed to be adequate.

Table 3.8

Correlations (Spearman's rho) between the SoS, SoS-E and other measures (n=937)

Construct	Scale	Mean (SD)	*Correlations (r)*	
			SoS	***SoS-E***
Evidence underlying negative self-beliefs	SoS-E	41.52 (11.74)	.817***	-
Global self-esteem	RSES	24.03 (6.01)	.764***	.700***
Negative-self schema	BCSS negative - self	10.60 (6.41)	.868***	.750***
Negative-other schema	BCSS negative - other	9.58 (5.96)	.465***	.482***
Positive-self schema	BCSS positive - self	7.51 (5.11)	-.619***	-.583***
Positive-other schema	BCSS positive - other	9.04 (4.68)	-.345***	-.356***
Perceptions of social rank	SCS	42.81 (16.75)	-.591***	-.556***
Depression	PHQ-9	16.33 (7.18)	.699***	.708***
Paranoia	B-CAP	25.02 (19.78)	.634***	.673***
Hallucinations	SPEQ-H	11.89 (10.78)	.418***	.476***
Grandiosity	SPEQ-G	4.33 (4.81)	-.119***	-.125***

Note. *** p<.001

Test-re-test reliability

Test-re-test reliability was excellent for total scores of the SoS (n=91, ICC=.959, 95% CI=.942-.971) and SoS-E (n=85, ICC=.950, 95% CI=.928-.965).

Discussion

The SoS is a single factor, 20-item self-report questionnaire measuring negative self-beliefs with four subscales: *not good enough, bad, broken, an outcast*. The measure has excellent psychometric properties and is highly correlated with measures of self-schema and self-esteem, in addition to measures of related psychological difficulties including paranoia, depression, and hallucinations. The measure was developed based on qualitative interviews

with young people in mental health services experiencing paranoia, thus is likely to have high face validity and utility in clinical practice. The researchers had not set out to create two questionnaires, however interviews highlighted beliefs and specific evidence underlying beliefs, which may complement each other – hence the development of the second scale (SoS-E). Factor analyses demonstrated an excellent model fit for the subscales of both questionnaires, and each had a general latent factor, whereby total scores could be used to make the scales easy to understand and administer.

The single overarching factor of the SoS was consistent with a global negative sense-of-self as vulnerable, and extended initial predictions of self-beliefs as inferior and different. In the qualitative interviews, participants talked about an increasing a sense of vulnerability as they went out alone or with peers, increased awareness of dangers, and experiencing a lack of safety related to characteristics perceived as making them a target of others hostility (e.g., race, gender, sexuality, ability, socio-economic status). This is consistent with qualitative research on adolescent paranoia (Bird et al., 2022) and may reflect risks and cultural dialogues in society (Pain, 2001; Taylor & Shrive, 2021). When individuals believe they belong to stigmatised groups, and believe negative stereotypes apply to themselves, this can lead to internalised shame (Wood et al., 2017) and may account for specific negative self-beliefs identified (e.g., self as *bad, broken*).

Given that paranoia is common, persistent, and predictive of greater psychological problems for youth in CAMHS (Bird et al., 2021) it is imperative that we address this in developmentally tailored interventions. Targeting negative self-cognitions is a treatment component for paranoia in the context of psychosis (Chadwick et al., 1996; Freeman et al., 2021). Therapeutic work to identify and re-evaluate beliefs presents challenges such as eliciting beliefs in a normalising and non-stigmatising way. The SoS with common themes for youth with paranoia may help facilitate these conversations early in therapy and inform intervention planning around specific beliefs to maximise clinical benefits.

Limitations

The decision to recruit a broad sample with different ages and mental health conditions in the qualitative interviews reflected the diversity of young people with paranoia presenting to services. The non-clinical population in this study had a large proportion of White-British females recruited through social media, which may be problematic given the evidence for higher levels of paranoia in marginalised groups. Self-selection bias may have occurred whereby participants took part due to personal relevance of the topic. To mitigate the impact of non-response bias, recruitment was varied through different social platforms, educational institution, and methods (e.g., adverts, websites, and email invitation). The decision to use a forced-choice format may also have limitations. For example, it is unclear whether participants found the response-options or specific items difficult to answer.

In development of the SoS, a theme identified in one interview was self-evaluations of being unlucky/unfortunate, however this did not emerge as a distinct factor in EFA. Less common self-beliefs relevant to youth with paranoia may have been excluded by these methods, and clinical assessment remains essential to explore specific beliefs alongside self-report measures. The SoS-E contained several factors with two items. Subscales had adequate internal consistency and could be strengthened by further development and inclusion of multi-item factors. Items were theoretically driven, and subscales demonstrated high test-re-test reliability.

Both scales require validation in clinical samples to understand the model fit with youth reporting high levels of paranoia, and experimental studies may elucidate the potential causal role of specific beliefs.

Conclusions

This study describes the development and validation of a new measure of negative self-beliefs and complementary measure of evidence underlying negative self-beliefs, relevant to youth experiencing paranoia. The SoS and SoS-E could provide information useful for

targeted interventions designed to support young people in developing a positive and adaptive sense-of-self, around others and in their communities. These precise assessment tools may help drive forward clinical practice.

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Executive Summary

Advancing the clinical understanding and measurement of negative self-beliefs in young people with paranoia

Research has shown that paranoia is a common experience for young people, defined as a difficulty trusting others due to having distressing and unfounded beliefs that others deliberately intend one harm. This may include worry about social, psychological, or physical harm from others. At mild levels, mistrust of others may be adaptive to cope with social threats, but as severity increases, paranoia is associated with numerous negative outcomes (e.g., poorer relationships, development of mental health difficulties, increase in need for support from health services, and increased suicidality). We know that one of the mechanisms that contributes to the development of paranoia are negative self-beliefs. When we feel vulnerable, paranoia flourishes and can lead to chronically low confidence. If the negative self-beliefs underlying paranoia can be better understood and measured, this will inform more targeted interventions specific to young people's experiences.

Traditionally, measures of self-beliefs consider broad questions about global self-esteem (e.g. *on the whole, I am satisfied with myself*), and whether young people rate themselves as a success or failure in different areas. We suspect that for young people experiencing paranoia, self-beliefs that hold importance may directly relate to social relationships and identity, such as a lack of belonging, thoughts about being an outsider or being different, and beliefs about personal vulnerability. There are currently no measures that capture the self-cognitions of young people experiencing paranoia that tap into underlying self-beliefs. This study aims to address this gap, and provide a clinically useful measure. Study aims were to identify self-beliefs associated with paranoia in young people, develop a precise measurement tool, and to test the tools psychometric properties (how valid and reliable the measure is).

A mixed-methods study was conducted with two phases. Phase one was item generation through conducting semi-structured interviews with twelve young people

experiencing paranoia, who were receiving support from a mental health service. Items were then reviewed by the researchers, considering existing measures and participant accounts to draw from the language used. Phase two was measure validation. A large online sample of young people, aged 14 to 25, were recruited from the general population to test the questionnaires and measures of similar constructs (e.g., self-esteem), and measures of related psychological symptoms or conditions: paranoia, depression, hallucinations and grandiosity.

Exploratory and confirmatory factor analyses were used to form the final measures: the Sense of Self – Youth Scale (SoS) to measure negative self-beliefs, and a complementary scale on the evidence for negative self-beliefs (SoS-E). The SoS has 20-items with four subscales: '*not good enough', 'bad', 'broken',* and *'an outcast*'. Confirmatory factor analyses demonstrated an excellent model fit. The complementary measure, SoS-E, had 18-items with seven subscales: *'thought processes', 'ability to achieve', 'negative impact on others', 'disliked/rejected by others', 'reliance on others', 'avoidance of others',* and *'change self to fit in'*. Both measures had high internal consistency (how well the questionnaire measures what you want it to measure), convergent validity (strong relationships with measures of similar constructs), and divergent validity (strong negative relationships with measures of theoretically opposite constructs, and a weak relationship with a theoretically distinct construct). Both measures were shown to have test-re-test reliability (participant scores were stable across a one-week period).

Overall, the SoS and SoS-E were shown to have good psychometric properties and may provide clinically useful measures of negative self-beliefs, and evidence for beliefs, relevant to the experience of paranoia in youth. These measures could provide information useful for targeted interventions designed to support young people in developing a positive and adaptive sense-of-self, around others and in their communities. Future research should follow up these findings to test the measures in clinical samples of young people experiencing high levels of paranoia.

Connecting Narrative

When starting the doctorate, I had a strong sense of my interests in working with adolescents and young adults who present to services with complexity, from my own experiences and difficulties in adolescence. My first assistant post was working with 14-18-year-olds who presented as 'complex' in CAMHS, and as 'at-risk-mental-state' or with a first episode of psychosis in EIP. What intrigued me was how people would present with symptom clusters that you could formulate under the terms of relational trauma, PTSD, personality disorders, depression, anxiety, obsessive compulsive traits, and/or psychosis, how much of this was based on cultural and clinician perspectives, and the extent of common underlying pathways to distress (e.g., poor sleep, negative sense-of-self, threats and forms of anxiety around others). I was struck by reports that 75% of mental health problems begin before the age of 25, and in my experience, how clinicians feel unable to help in the face of complexity. I then had a fantastic opportunity to work in the context of clinical research trials, considering patient preferences, clinical effectiveness, and feasibility of interventions in the NHS. Given this context, I was keen to explore different methodologies, with projects that lend themselves to qualitative and experimental designs.

The following narrative is a reflective account of how the research projects were developed and conducted, including a general discussion and learning points.

Systematic Review of the Literature

The SRL challenged me the most in terms of content and methods. The project was based on theories that excessive and/or unfounded ideas of threat from others (paranoia) are shaped by the way that individuals acquire social information, evaluate this in relation to themselves, and react. With my supervisor, I narrowed this down to investigate social comparison in terms of the evaluation of social information in relation to the self (a person's beliefs regarding social rank, attractiveness and belonging). These socially informed constructs are challenging to measure, and studies were typically observational.

The selection and use of quality appraisal tools was a learning curve and I found it difficult to make decisions based on criteria that appeared not to fit the methodologies they were designed to appraise. I learnt the importance of working as a research team to define steps for decision-making, and in retaining a critical stance.

Service Improvement Project

I had previously visited the Highfield Adolescent Unit to promote research studies, and had discussed sleep problems on the unit with clinicians. I had some conversations with trainees in the year above, and one spoke about a project looking at the extent of sleep problems in inpatient settings using routine outcome measures.

I reached out to local clinicians that had conducted sleep interventions in an adult inpatient setting, and wondered whether something similar could be piloted for adolescents. With further reading and consultation, it became clear that we did not have an understanding of the factors maintaining the severity and distress associated with sleep problems in this group, and what interventions were preferred. Designing this project with inpatients and clinicians was really enjoyable and afforded me insight into how research might be more collaborative, towards a co-produced model. It also gave me an appreciation that 'experts' are defined in many ways (e.g. personal/professional). Some unique challenges were recruiting adolescents and sensitively engaging them in interviews when acutely unwell. Much thought went into ethics, participant and service burden, consent, and confidentiality, and I learnt how to talk about these topics for different audiences (e.g., course panel, NHS ethics and trusts, unit clinicians, lay audiences).

Shifting my position to a 'researcher' opposed to a 'psychologist' challenged me in how much freedom I had to respond authentically and follow ideas shared within the realms of the interview schedule. Having collected a large amount of data there were many themes that appeared well-evidenced. Writing this as one paper within 5000 words was challenging.

What I learnt from this process was concise writing in a manner that allows the reader to hear participants' voices, understand theory links, and take away key messages.

Theory Driven Research Project

This was the project that I was most excited for, an area that resonates with me personally and the clinical work I am interested in. Initially, I started to design an experimental manipulation study to test whether the induction of positive self-beliefs would reduce state levels of negative self-cognitions and paranoid ideas. As we explored this, it became apparent that we did not have the tools to measure self-beliefs with precision or apparent clinical utility in this context. With my research supervisors, we decided it would be more appropriate to first improve our understanding and develop a measurement tool.

Creating a measure was a steep learning curve with multiple stages. Having designed the proposal, completed a literature search, and consulted with experts by experience in year one, I had thought it an ambitious but feasible project. Delays in sponsorship, ethics, and trust approval meant that I was unable to begin recruitment until my final year, and panic set in as I had a mixed-methods project to conduct. Delays to the SIP meant that the projects overlapped, and study days were spent travelling to the inpatient unit for SIP recruitment. This taught me lessons in managing anxiety when juggling multiple 'hats', new areas of clinical practice, teaching, and coursework simultaneously. It was important to regularly re-visit and revise my timeframes and commitments. In my career as a clinical psychologist, I will undoubtedly need these skills in organising and prioritising work.

Future Research

The research projects have been one of the most meaningful and challenging aspects of training. The anxiety of conducting projects in the context of Covid-19 and significant delays challenged me to be continually flexible in my management of workload and communication with those involved. New ways of working took me outside of my comfort

zone and have helped me in sitting with uncertainty, knowing that it is okay not to know things, and reminds me that the job is a commitment to lifelong learning.

Acknowledgements

To the young people that so openly and bravely shared their experiences with me in these projects for the improvement in how we think about, understand, and support people with mental health difficulties, thank you.

I would like to thank my external supervisors Felicity Waite, Nicola Collett, Bryony Sheaves, Jessica Bird, and Daniel Freeman. I have learnt so much about myself and my interests in working with you. Your support and guidance over these three years has been invaluable, and has continued to inspire me even when exhausted with the demands of the doctorate. Thank you for letting me stay as part of the extended O-CAP family. Thanks also to Aiden Loe for making statistics seem less daunting!

A special thank you to Ciorsdan Anderson for being a fantastic mentor, helping me to structure my time and thinking in the midst of a hectic three years. To my course tutors, Sarah Coles and Fin Williams, thank you both for entering into an anxious or 'not-knowing' place with me, and for keeping me grounded. Thank you to Hannah Stratford, Liam Russell and Becca Tompkins for your help in implementing these projects in the context of busy NHS services. Thank you also to Paul Salkovskis for helping me to plan my SIP and casting a critical eye on the write-up. Without your prompts, I may have ended up writing a book instead of a thesis.

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Appendix A

SRL: Author guidelines for submission

Psychology and Psychotherapy: Theory, Research and Practice

1. SUBMISSION

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

Once the submission materials have been prepared in accordance with the Author Guidelines, manuscripts should be submitted online at http://www.editorialmanager.com/paptrap

All papers published in the *Psychology and Psychotherapy: Theory Research and Practice* are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

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This journal will consider for review articles previously available as preprints. Authors may also post the submitted version of a manuscript to a preprint server at any time. Authors are requested to update any pre-publication versions with a link to the final published article.

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Psychology and Psychotherapy: Theory Research and Practice is an international scientific journal with a focus on the psychological aspects of mental health difficulties and well-being; and psychological problems and their psychological treatments. We welcome submissions from mental health professionals and researchers from all relevant professional backgrounds. The Journal welcomes submissions of original high quality empirical research and rigorous theoretical papers of any theoretical provenance provided they have a bearing upon vulnerability to, adjustment to, assessment of, and recovery (assisted or otherwise) from psychological disorders. Submission of systematic reviews and other research reports which support evidence-based practice are also welcomed, as are relevant high quality analogue studies and Registered Reports. The Journal thus aims to promote theoretical and research developments in the understanding of cognitive and emotional factors in psychological disorders, interpersonal attitudes, behaviour and relationships, and psychological therapies (including both process and outcome research) where mental health is concerned. Clinical or case studies will not normally be considered except where they illustrate particularly unusual

forms of psychopathology or innovative forms of therapy and meet scientific criteria through appropriate use of single case experimental designs.

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3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

- Articles should adhere to the stated word limit for the particular article type. The word limit excludes the abstract, reference list, tables and figures, but includes appendices.

Word limits for specific article types are as follows:

- Research articles: 5000 words
- Qualitative papers: 6000 words
- Review papers: 6000 words
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In exceptional cases the Editor retains discretion to publish papers beyond this length where the clear and concise expression of the scientific content requires greater length (e.g., explanation of a new theory or a substantially new method). Authors must contact the Editor prior to submission in such a case.

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Please provide an abstract of up to 250 words. Articles containing original scientific research should include the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use the headings: Purpose, Methods, Results, Conclusions.

Keywords

Please provide appropriate keywords.

Acknowledgments

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

Practitioner Points

All articles must include Practitioner Points – these are 2-4 bullet point with the heading 'Practitioner Points'. They should briefly and clearly outline the relevance of your research to professional practice. (The Practitioner Points should be submitted in a separate file.)

Main Text File

As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors.

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Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡,

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Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted.

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- **Abbreviations:** In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
- **Units of measurement:** Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website for more information about SI units.
- **Effect size:** In normal circumstances, effect size should be incorporated.
- **Numbers:** numbers under 10 are spelt out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

Wiley Author Resources

Manuscript Preparation Tips: Wiley has a range of resources for authors preparing manuscripts for submission available **here.** In particular, we encourage authors to consult Wiley's best practice tips on **Writing for Search Engine Optimization**.

Article Preparation Support: **Wiley Editing Services** offers expert help with English Language Editing, as well as translation, manuscript formatting, figure illustration, figure formatting, and graphical abstract design – so you can submit your manuscript with confidence.

Also, check out our resources for **Preparing Your Article** for general guidance and the **BPS Publish with Impact infographic** for advice on optimizing your article for search engines.

Appendix B

SRL: Search Terms

Boolean search phrases

[(paranoi* OR persecut* OR psychotic* OR psychosis* OR psychoses* OR ideas of reference OR schizophren* OR delus* OR delud* OR suspicious* OR mistrust*)

AND

(social comparison OR social position OR social standing OR social rank OR social status OR social judgement OR social defeat OR social appraisal OR social evaluation OR social hierarchy OR power differen* OR sense of belong* OR sense of inferior* or perce* inferior* OR perce* belong*)].

Thesaurus and Medical Subject Headings (MeSH)

Scopus and Web of Science do not provide a thesaurus option.

Terms for paranoia

Thesaurus and MeSH options were used in Embase, PsycINFO, Medline, and PubMed to ensure the search was inclusive: *exp paranoia/ or exp delusion/ or exp paranoid psychosis/ or exp paranoid personality disorder/or exp "paranoia (psychosis)"/or exp paranoid schizophrenia/ or exp paranoid disorders/or exp psychotic disorders/or exp paranoid schizophrenia).*

Terms for social comparison

No thesaurus or MeSH searches were included for social comparison terms. This was explored in the databases and did not yield any additional terms that were specific to the topic.

Appendix C

SRL: Data extraction headings

1. **Author (year of publication)**
2. **Study design**
3. **Sample size (*n*)**
4. **Participant characteristics: sample size of clinical and non-clinical participants, definition of groups, gender split, mean age, ethnicity, country of origin**
5. **Country in which the study was conducted**
6. **Exposure or independent variable**
7. **Outcome or dependent variable**
8. **Variables controlled for, control group**
9. **Moderators or mediators**
10. **Measure of paranoia**
11. **Measure of SC**
12. **Summary of findings (specific to paranoia and SC)**

Appendix D

SRL: Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies

(National Institute of Health, 2013)

https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools

Criteria	Yes	No	Other (N/a, NR*)
1. Was the research question or objective in this paper clearly stated?			
2. Was the study population clearly specified and defined?			
3. Was the participation rate of eligible persons at least 50%?			
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?			
5. Was a sample size justification, power description, or variance and effect estimates provided?			
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?			
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?			
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?			
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?			
10. Was the exposure(s) assessed more than once over time?			
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?			
12. Were the outcome assessors blinded to the exposure status of participants?			
13. Was loss to follow-up after baseline 20% or less?			
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?			

Note. *N/a, not applicable; NR, not reported

Guidance for Assessing the Quality of Observational Cohort and Cross-Sectional Studies

The guidance document below is organized by question number from the tool for quality assessment of observational cohort and cross-sectional studies.

Question 1. Research question

Did the authors describe their goal in conducting this research? Is it easy to understand what they were looking to find? This issue is important for any scientific paper of any type. Higher quality scientific research explicitly defines a research question.

Questions 2 and 3. Study population

Did the authors describe the group of people from which the study participants were selected or recruited, using demographics, location, and time period? If you were to conduct this study again, would you know who to recruit, from where, and from what time period? Is the cohort population free of the outcomes of interest at the time they were recruited?

An example would be men over 40 years old with type 2 diabetes who began seeking medical care at Phoenix Good Samaritan Hospital between January 1, 1990 and December 31, 1994. In this example, the population is clearly described as: (1) who (men over 40 years old with type 2 diabetes); (2) where (Phoenix Good Samaritan Hospital); and (3) when (between January 1, 1990 and December 31, 1994). Another example is women ages 34 to 59 years of age in 1980 who were in the nursing profession and had no known coronary disease, stroke, cancer, hypercholesterolemia, or diabetes, and were recruited from the 11 most populous States, with contact information obtained from State nursing boards.

In cohort studies, it is crucial that the population at baseline is free of the outcome of interest. For example, the nurses' population above would be an appropriate group in which to study incident coronary disease. This information is usually found either in descriptions of population recruitment, definitions of variables, or inclusion/exclusion criteria.

You may need to look at prior papers on methods in order to make the assessment for this question. Those papers are usually in the reference list.

If fewer than 50% of eligible persons participated in the study, then there is concern that the study population does not adequately represent the target population. This increases the risk of bias.

Question 4. Groups recruited from the same population and uniform eligibility criteria

Were the inclusion and exclusion criteria developed prior to recruitment or selection of the study population? Were the same underlying criteria used for all of the subjects involved? This issue is related to the description of the study population, above, and you may find the information for both of these questions in the same section of the paper.

Most cohort studies begin with the selection of the cohort; participants in this cohort are then measured or evaluated to determine their exposure status. However, some cohort studies may recruit or select exposed participants in a different time or place than unexposed participants, especially retrospective cohort studies–which is when data are obtained from the past (retrospectively), but the analysis examines exposures prior to outcomes. For example, one research question could be whether diabetic men with clinical depression are at higher risk for cardiovascular disease than those without clinical depression. So, diabetic men with depression might be selected from a mental health clinic, while diabetic men without depression might be selected from an internal medicine or endocrinology clinic. This study recruits groups from different clinic populations, so this example would get a "no."

However, the women nurses described in the question above were selected based on the same inclusion/exclusion criteria, so that example would get a "yes."

Question 5. Sample size justification

Did the authors present their reasons for selecting or recruiting the number of people included or analysed? Do they note or discuss the statistical power of the study? This question

is about whether or not the study had enough participants to detect an association if one truly existed.

A paragraph in the methods section of the article may explain the sample size needed to detect a hypothesized difference in outcomes. You may also find a discussion of power in the discussion section (such as the study had 85 percent power to detect a 20 percent increase in the rate of an outcome of interest, with a 2-sided alpha of 0.05). Sometimes estimates of variance and/or estimates of effect size are given, instead of sample size calculations. In any of these cases, the answer would be "yes."

However, observational cohort studies often do not report anything about power or sample sizes because the analyses are exploratory in nature. In this case, the answer would be "no." This is not a "fatal flaw." It just may indicate that attention was not paid to whether the study was sufficiently sized to answer a prespecified question–i.e., it may have been an exploratory, hypothesis-generating study.

Question 6. Exposure assessed prior to outcome measurement

This question is important because, in order to determine whether an exposure causes an outcome, the exposure must come before the outcome.

For some prospective cohort studies, the investigator enrols the cohort and then determines the exposure status of various members of the cohort (large epidemiological studies like Framingham used this approach). However, for other cohort studies, the cohort is selected based on its exposure status, as in the example above of depressed diabetic men (the exposure being depression). Other examples include a cohort identified by its exposure to fluoridated drinking water and then compared to a cohort living in an area without fluoridated water, or a cohort of military personnel exposed to combat in the Gulf War compared to a cohort of military personnel not deployed in a combat zone.

With either of these types of cohort studies, the cohort is followed forward in time (i.e., prospectively) to assess the outcomes that occurred in the exposed members compared to nonexposed members of the cohort. Therefore, you begin the study in the present by looking at groups that were exposed (or not) to some biological or behavioural factor, intervention, etc., and then you follow them forward in time to examine outcomes. If a cohort study is conducted properly, the answer to this question should be "yes," since the exposure status of members of the cohort was determined at the beginning of the study before the outcomes occurred.

For retrospective cohort studies, the same principal applies. The difference is that, rather than identifying a cohort in the present and following them forward in time, the investigators go back in time (i.e., retrospectively) and select a cohort based on their exposure status in the past and then follow them forward to assess the outcomes that occurred in the exposed and nonexposed cohort members. Because in retrospective cohort studies the exposure and outcomes may have already occurred (it depends on how long they follow the cohort), it is important to make sure that the exposure preceded the outcome.

Sometimes cross-sectional studies are conducted (or cross-sectional analyses of cohort-study data), where the exposures and outcomes are measured during the same timeframe. As a result, cross-sectional analyses provide weaker evidence than regular cohort studies regarding a potential causal relationship between exposures and outcomes. For cross-sectional analyses, the answer to Question 6 should be "no."

Question 7. Sufficient timeframe to see an effect

Did the study allow enough time for a sufficient number of outcomes to occur or be observed, or enough time for an exposure to have a biological effect on an outcome? In the examples given above, if clinical depression has a biological effect on increasing risk for CVD, such an effect may take years. In the other example, if higher dietary sodium increases BP, a short timeframe may be sufficient to assess its association with BP, but a longer timeframe would be needed to examine its association with heart attacks.

The issue of timeframe is important to enable meaningful analysis of the relationships between exposures and outcomes to be conducted. This often requires at least several years, especially when looking at health outcomes, but it depends on the research question and outcomes being examined.

Cross-sectional analyses allow no time to see an effect, since the exposures and outcomes are assessed at the same time, so those would get a "no" response.

Question 8. Different levels of the exposure of interest

If the exposure can be defined as a range (examples: drug dosage, amount of physical activity, amount of sodium consumed), were multiple categories of that exposure assessed? (for example, for drugs: not on the medication, on a low dose, medium dose, high dose; for dietary sodium, higher than average U.S. consumption, lower than recommended consumption, between the two). Sometimes discrete categories of exposure are not used, but instead exposures are measured as continuous variables (for example, mg/day of dietary sodium or BP values).

In any case, studying different levels of exposure (where possible) enables investigators to assess trends or dose-response relationships between exposures and outcomes–e.g., the higher the exposure, the greater the rate of the health outcome. The presence of trends or dose-response relationships lends credibility to the hypothesis of causality between exposure and outcome.

For some exposures, however, this question may not be applicable (e.g., the exposure may be a dichotomous variable like living in a rural setting versus an urban setting, or vaccinated/not vaccinated with a one-time vaccine). If there are only two possible exposures (yes/no), then this question should be given an "NA," and it should not count negatively towards the quality rating.

Question 9. Exposure measures and assessment

Were the exposure measures defined in detail? Were the tools or methods used to measure exposure accurate and reliable–for example, have they been validated or are they objective? This issue is important as it influences confidence in the reported exposures. When exposures are measured with less accuracy or validity, it is harder to see an association between exposure and outcome even if one exists. Also as important is whether the exposures were assessed in the same manner within groups and between groups; if not, bias may result.

For example, retrospective self-report of dietary salt intake is not as valid and reliable as prospectively using a standardized dietary log plus testing participants' urine for sodium content. Another example is measurement of BP, where there may be quite a difference between usual care, where clinicians measure BP however it is done in their practice setting

(which can vary considerably), and use of trained BP assessors using standardized equipment (e.g., the same BP device which has been tested and calibrated) and a standardized protocol (e.g., patient is seated for 5 minutes with feet flat on the floor, BP is taken twice in each arm, and all four measurements are averaged). In each of these cases, the former would get a "no" and the latter a "yes."

Here is a final example that illustrates the point about why it is important to assess exposures consistently across all groups: If people with higher BP (exposed cohort) are seen by their providers more frequently than those without elevated BP (nonexposed group), it also increases the chances of detecting and documenting changes in health outcomes, including CVD-related events. Therefore, it may lead to the conclusion that higher BP leads to more CVD events. This may be true, but it could also be due to the fact that the subjects with higher BP were seen more often; thus, more CVD-related events were detected and documented simply because they had more encounters with the health care system. Thus, it could bias the results and lead to an erroneous conclusion.

Question 10. Repeated exposure assessment

Was the exposure for each person measured more than once during the course of the study period? Multiple measurements with the same result increase our confidence that the exposure status was correctly classified. Also, multiple measurements enable investigators to look at changes in exposure over time, for example, people who ate high dietary sodium throughout the follow-up period, compared to those who started out high then reduced their intake, compared to those who ate low sodium throughout. Once again, this may not be applicable in all cases. In many older studies, exposure was measured only at baseline. However, multiple exposure measurements do result in a stronger study design.

Question 11. Outcome measures

Were the outcomes defined in detail? Were the tools or methods for measuring outcomes accurate and reliable–for example, have they been validated or are they objective? This issue is important because it influences confidence in the validity of study results. Also important is whether the outcomes were assessed in the same manner within groups and between groups.

An example of an outcome measure that is objective, accurate, and reliable is death–the outcome measured with more accuracy than any other. But even with a measure as objective as death, there can be differences in the accuracy and reliability of how death was assessed by the investigators. Did they base it on an autopsy report, death certificate, death registry, or report from a family member? Another example is a study of whether dietary fat intake is related to blood cholesterol level (cholesterol level being the outcome), and the cholesterol level is measured from fasting blood samples that are all sent to the same laboratory. These examples would get a "yes." An example of a "no" would be self-report by subjects that they had a heart attack, or self-report of how much they weigh (if body weight is the outcome of interest).

Similar to the example in Question 9, results may be biased if one group (e.g., people with high BP) is seen more frequently than another group (people with normal BP) because more frequent encounters with the health care system increases the chances of outcomes being detected and documented.

Question 12. Blinding of outcome assessors

Blinding means that outcome assessors did not know whether the participant was exposed or unexposed. It is also sometimes called "masking." The objective is to look for evidence in the article that the person(s) assessing the outcome(s) for the study (for example, examining medical records to determine the outcomes that occurred in the exposed and comparison groups) is masked to the exposure status of the participant. Sometimes the person measuring the exposure is the same person conducting the outcome assessment. In this case, the outcome assessor would most likely not be blinded to exposure status because they also took measurements of exposures. If so, make a note of that in the comments section.

As you assess this criterion, think about whether it is likely that the person(s) doing the outcome assessment would know (or be able to figure out) the exposure status of the study participants. If the answer is no, then blinding is adequate. An example of adequate blinding of the outcome assessors is to create a separate committee, whose members were not involved in the care of the patient and had no information about the study participants' exposure status. The committee would then be provided with copies of participants' medical records, which had been stripped of any potential exposure information or personally identifiable information. The committee would then review the records for prespecified outcomes according to the study protocol. If blinding was not possible, which is sometimes the case, mark "NA" and explain the potential for bias.

Question 13. Follow-up rate

Higher overall follow-up rates are always better than lower follow-up rates, even though higher rates are expected in shorter studies, whereas lower overall follow-up rates are often seen in studies of longer duration. Usually, an acceptable overall follow-up rate is considered 80 percent or more of participants whose exposures were measured at baseline. However, this is just a general guideline. For example, a 6-month cohort study examining the relationship between dietary sodium intake and BP level may have over 90 percent follow-up, but a 20-year cohort study examining effects of sodium intake on stroke may have only a 65 percent follow-up rate.

Question 14. Statistical analyses

Were key potential confounding variables measured and adjusted for, such as by statistical adjustment for baseline differences? Logistic regression or other regression methods are often used to account for the influence of variables not of interest.

This is a key issue in cohort studies because statistical analyses need to control for potential confounders, in contrast to an RCT, where the randomization process controls for potential confounders. All key factors that may be associated both with the exposure of interest and the outcome–that are not of interest to the research question–should be controlled for in the analyses.

For example, in a study of the relationship between cardiorespiratory fitness and CVD events (heart attacks and strokes), the study should control for age, BP, blood cholesterol, and body weight, because all of these factors are associated both with low fitness and with CVD events. Well-done cohort studies control for multiple potential confounders.

Some general guidance for determining the overall quality rating of observational cohort and cross-sectional studies

The questions on the form are designed to help you focus on the key concepts for evaluating the internal validity of a study. They are not intended to create a list that you simply tally up to arrive at a summary judgment of quality.

Internal validity for cohort studies is the extent to which the results reported in the study can truly be attributed to the exposure being evaluated and not to flaws in the design or conduct of the study–in other words, the ability of the study to draw associative conclusions about the effects of the exposures being studied on outcomes. Any such flaws can increase the risk of bias.

Critical appraisal involves considering the risk of potential for selection bias, information bias, measurement bias, or confounding (the mixture of exposures that one cannot tease out from each other). Examples of confounding include co-interventions, differences at baseline in patient characteristics, and other issues throughout the questions above. High risk of bias translates to a rating of poor quality. Low risk of bias translates to a rating of good quality. (Thus, the greater the risk of bias, the lower the quality rating of the study.)

In addition, the more attention in the study design to issues that can help determine whether there is a causal relationship between the exposure and outcome, the higher quality the study. These include exposures occurring prior to outcomes, evaluation of a dose-response gradient, accuracy of measurement of both exposure and outcome, sufficient timeframe to see an effect, and appropriate control for confounding–all concepts reflected in the tool.

Generally, when you evaluate a study, you will not see a "fatal flaw," but you will find some risk of bias. By focusing on the concepts underlying the questions in the quality assessment tool, you should ask yourself about the potential for bias in the study you are critically appraising. For any box where you check "no" you should ask, "What is the potential risk of bias resulting from this flaw in study design or execution?" That is, does this factor cause you to doubt the results that are reported in the study or doubt the ability of the study to accurately assess an association between exposure and outcome?

The best approach is to think about the questions in the tool and how each one tells you something about the potential for bias in a study. The more you familiarize yourself with the key concepts, the more comfortable you will be with critical appraisal. Examples of studies rated good, fair, and poor are useful, but each study must be assessed on its own based on the details that are reported and consideration of the concepts for minimizing bias.

Appendix E

SRL: Downs and Black Checklist (Downs & Black, 1998)

Appendix

Checklist for measuring study quality

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
   If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described ?*
   In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*
   Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
   A list of principal confounders is provided.

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*
   Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
   In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
   This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*
   This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

yes	1
no	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
    The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity - bias

14. *Was an attempt made to blind study subjects to the intervention they have received ?*
For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*
Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls ?*
Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*
The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention/s reliable?*
Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

yes	1
no	0
unable to determine	0

Internal validity - confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*
For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*
For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*
Studies which state that subjects wererandomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*
All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

yes	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*
If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

yes	1
no	0
unable to determine	0

Power

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*
Sample sizes have been calculated to detect a difference of x% and y%.

	Size of *smallest* intervention group	
A	$<n_1$	0
B	n_1–n_2	1
C	n_3–n_4	2
D	n_5–n_6	3
E	n_7–n_8	4
F	n_9+	5

Appendix F

SIP: Interview topic guide

We'll now move onto the interview section of the meeting. We are interested to hear about your experiences of sleep difficulties in your own words, and hear your thoughts on how we can help people to sleep better on the unit, so we can learn from them. Throughout the meeting I will try to listen as much as possible and not interrupt you, so the conversation might feel a bit one sided at times. You can take your time to think about the questions I ask, and no detail is too small as everything you have to say will be important. The questions are open so that you can answer in your own way and there are no right or wrong answers as this is all about what things are like for you.

It is up to you how much you want to share with me and you don't have to answer anything you don't want to. Sometimes I might ask you to go into more detail about something, but, if you don't want to that is absolutely okay. If anything we discuss leaves you feeling upset, please let me know. We don't want it to feel difficult and we could take a break, move onto a new topic, or stop the meeting.

What you say in this meeting is confidential and will not be shared with your parent/ carer or care team, and your name will not be linked to what you say. However, if you say anything that makes me worried about yours or someone else's safety, this information will be shared with your care team on the [name of unit]. If this needed to happen, I would let you know about this first.

There are 7 main questions and we will both have a written copy of them in front of us. Sometimes I might not ask questions in the best way, so please ask if anything does not make sense. The meeting will last about 1 hour, but it may be a bit shorter or a bit longer depending on how we go. I will check the time as we go along, and I might bring us back to a topic of discussion if it feels important, or if time is running out.

There is also a tick list at the end of the meeting for you to fill in, which asks about what might be contributing to your sleep difficulties. You have the option to add things if you think something is missing. We will have a look at this after the questions.

Does everything make sense so far? Do you have any questions? If you have any questions as we go through or are unsure about anything just let me know. Ok let's begin.

Questions:

1. **I wonder if you could start by telling me about your sleep at the moment**

Prompt Questions:

- *Would it be helpful to look at the sleep questionnaire you filled in recently?*

- *When did you notice sleep becoming difficult?*
- *What was your sleep like before coming onto the unit?*
- *Thinking about your past week, could you talk me through a typical night from the evening to the next day? If this is difficult, what was your sleep like last night?*

2. **What are things like in the daytime if you've had a bad night's sleep?**

Prompt Questions:

- If your sleep is worse/ better, what are things like in the day?

- What do you think about sleep difficulties and other problems that brought you to the unit?

- I'm interested in whether you notice any changes in energy levels? How do you respond to this?

3. **You described [sleep difficulty in young person's own words]. Can you tell me a bit about how you manage this?**

Prompt Questions:

- What was that like?

- Is there anything that makes your sleep better or worse?

- Why do you think this was the case?

4. **Have you ever received any help for sleep?**

Prompt Questions:

- What was that like?

- What was helpful / less helpful?

5. **Do you have any thoughts about what might help people to sleep better on the unit?**

Prompt Questions:

- How might the staff team on the unit help people with their sleep?

- Why do you think that?

6. **Have you been given any medication to help with your sleep?**

Prompt Questions:

- If yes; what it is like taking this medication?

- When do you take this, and how long does it take for you to notice the effect you've described?

- If you're on other medication (for difficulties other than sleep), have you noticed any impact on your sleep?

Let's take a moment to read about another option for help. Would you prefer to read this yourself, or for me to read it out?

How might cognitive behavioural therapy help with sleep?

Cognitive Behavioural Therapy (CBT) involves one-on-one sessions, working with a therapist to develop personal strategies designed to help you sleep better and feel more refreshed in the daytime. This might involve trying out new sleeping habits, for example, developing a pro-sleep routine; learning ways to relax and wind-down; and doing things in the day that increase your chances of getting good sleep at night. This will involve identifying the things that affect your sleep in particular. Research has shown that this approach can help people to sleep better, but hasn't been tested on adolescent units like this one.

7. **After reading the information above, we would be interested in your thoughts on this type of therapy to help with sleep.**

Prompt Questions:

- *What do you think it would be like to have this therapy?*
- *Do you have any suggestions or advice for people offering this type of help on the unit?*
- *One thing that is important to decide is whether or not the inpatient unit is a good time for young people to get this type of help with their sleep. Balancing sleep with the other difficulties you have at the moment, is this therapy something you would be interested in?*

Thank you. We will now move onto the tick list we spoke about earlier.

Below is a list of things that people might report as getting in the way of a good night's sleep, and keep their sleep difficulties going. Please tick all the items that apply to you, and leave the rest blank. If there are other things that disrupt your sleep, feel free to add these at the end.

Unit environment	**Please tick all that apply**
My room is too light	
I'm woken up by lights or noises on the unit	
I'm too hot or cold at night	
My bed is uncomfortable	
Other young people on the unit make it hard to sleep	
Staff observations at night disrupt my sleep	
Routine	
I go to bed early and don't feel tired enough to fall sleep	
I don't get to sleep until late but I still have to get up early the next morning	
I don't feel sleepy when I go to bed at night, but struggle to wake up the next day	
I struggle to stay awake until bedtime but then wake up early the next morning	
I sleep through the morning and can't sleep the following night	
I don't have a regular bedtime and wake-up time	
I don't have things I can do to unwind before going to bed	
I use my bed for things other than sleep	
Things I do in the day	
I nap in the day and then struggle to sleep at night	
I don't do much in the day, so am not tired enough to sleep	
I do things in the evening which make me feel more awake rather than sleepy (e.g., watch TV, exercise)	
I have caffeinated drinks (e.g., tea, coffee, Cola, energy drinks) in the afternoon or evening	
I take medication, for things other than sleep, that negatively affects my sleep	
I go to bed in the daytime because I feel hopeless	
I go to bed in the daytime because I feel like I have no energy	
I go to bed in the daytime to escape how I'm feeling or experiences I'm having	
I would usually drink alcohol, smoke or take drugs at home, but I can't take them here and this affects my sleep	
Experiences when going to sleep and at night	
I don't feel relaxed when I go to bed	

I feel worried about what might happen when I go to sleep	
I worry about not being able to sleep, so I can't sleep	
I worry about other things (not sleep) and this keeps me awake	
I don't sleep much because I don't think it's important	
I feel too energised to sleep at night	
I have rituals or things I do at night that stop me from sleeping	
I have unusual experiences at night that stop me sleeping (e.g., hearing, seeing, or sensing things that other people do not)	
I experience intense thoughts or emotions when going to bed	
I have nightmares that make it hard for me to sleep	
I experience pain in bed or just before going to bed	
I feel hungry when I am lying in bed	
Are there any other things that disrupt your sleep? Please list them below: _____ _____	

Ending Questions:

- Is there anything from the tick list exercise, or from the questions earlier, that you think is important to discuss, and that we haven't talked about?

- Do you have any questions for me?

- How has it been talking today? Was there anything that was difficult or confusing? Is there anything I could have done to make it easier for you?

- Some people find it helpful for me or a member of the unit to check in with how they are feeling later on after the meeting. Is this something you would like?

General Prompts that could be used during the interview:

- You mentioned that [participant's words]
    - Can you tell me a bit more about that?
    - Can you give me an example?

- For the interviewer to check their understanding within the interview: "I might think about it like [insert paraphrase]… what do you think of that?" "How would you change that?". Or "what I've heard from you is [insert paraphrase], is that right?"

- If the interviewer thinks the participant might appreciate a break: "would you like to pause for a break here?"

Appendix G

SIP: Post-interview checklist of factors disrupting sleep

Checklist Items		Frequency of endorsement[a]
	Unit environment	
1.	My room is too light	8
2.	I'm woken up by lights or noises on the unit	12
3.	I'm too hot or cold at night	7
4.	My bed is uncomfortable	4
5.	Other young people on the unit make it hard to sleep	5
6.	Staff observations at night disrupt my sleep	11
	Routine	
7.	I go to bed early and don't feel tired enough to fall asleep	4
8.	I don't get to sleep until late, but I still have to get up early the next morning	8
9.	I don't feel sleepy when I go to bed at night, but struggle to wake the next	7
10.	I struggle to stay awake until bedtime but then wake up early the next	1
11.	I sleep through the morning and can't sleep the following night	1
12.	I don't have a regular bedtime and wake-up time	2
13.	I don't have things I can do to unwind before going to bed	3
14.	I use my bed for things other than sleep	4
	Things I do in the day	
15.	I nap in the day and then struggle to sleep at night	2
16.	I don't do much in the day, so am not tired enough to sleep	5
17.	I do things in the evening which make me feel more awake rather than sleepy	3
18.	I have caffeinated drinks (e.g., tea, coffee, Cola, energy drinks) in the	1
19.	I take medication, for things other than sleep, that negatively affects my sleep	2
20.	I go to bed in the daytime because I feel hopeless	4
21.	I go to bed in the daytime because I feel like I have no energy	4
22.	I go to bed in the daytime to escape how I'm feeling or experiences I'm	4
23.	I would usually drink alcohol, smoke, or take drugs at home, but I can't take them here and this affects my sleep	1
	Experiences when going to sleep at night	
24.	I don't feel relaxed when I go to bed	12
25.	I feel worried about what might happen when I go to sleep	6
26.	I worry about not being able to sleep, so I can't sleep	10
27.	I worry about other things (not sleep) and this keeps me awake	12
28.	I don't sleep much because I don't think it's important	1
29.	I feel too energised to sleep at night	1
30.	I have rituals or things I do at night that stop me from sleeping	2
31.	I have unusual experiences at night that stop me sleeping (e.g., hearing, seeing, or sensing things that other people do not)	2
32.	I experience intense thoughts or emotions when going to bed	9
33.	I have nightmares that make it hard for me to sleep	5
34.	I experience pain in bed or just before going to bed	0
35.	I feel hungry when I am in bed	1

Additional items from participants

My bed doesn't feel like home. Missing home makes me feel sad and restless, which stops me from sleeping	1 (P8)
Thinking about the pressure of the next day makes it difficult to get up in the morning, it feels hopeless, and this makes me feel tired and weighed down	1 (P9)

Note. [a] Number of participants who ticked 'Yes' to the corresponding item as currently interrupting their sleep on the unit.

Item on checklist		Participant Endorsement of Items (Ticked 'Yes')											
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12
Unit environment	1	*		*	*	*	*	*	*			*	
	2	*	*	*	*	*	*	*	*	*	*	*	*
	3			*		*	*	*	*		*	*	
	4	*	*		*				*				
	5					*			*	*	*	*	
	6		*	*	*	*	*	*	*	*	*	*	*
Routine	7			*				*	*	*			
	8	*		*	*	*		*	*	*	*		
	9			*	*	*		*	*		*		*
	10								*				
	11												*
	12				*	*							
	13			*		*	*						
	14					*			*	*			*
Things I do in the day	15			*									*
	16		*	*	*						*	*	
	17		*			*				*			
	18							*					
	19						*			*			
	20								*	*	*		*
	21		*						*	*	*		
	22								*	*	*		*
	23						*						
Experiences at night	24	*	*	*	*	*	*	*	*	*	*	*	*
	25	*					*	*	*	*			*
	26	*	*	*	*	*	*	*	*		*		*
	27	*	*	*	*	*	*	*	*	*	*	*	*
	28							*					
	29		*										
	30			*						*			
	31								*				*
	32		*	*	*	*	*		*	*	*		*
	33	*					*	*	*				*
	34												
	35		*										

Appendix H - H.a

SIP: Quotes on the impact of poor sleep

Theme	Subtheme	Participant Number	Participant Quotes
Experience of sleep problems	Reciprocal relationships of sleep, mood, and engagement	P2	'If I had a bad night's sleep it does affect my mood quite a lot, cause I have Bipolar so, if I don't sleep my mood goes up, that makes me more unpredictable and hyper during the day... more active and talkative, but not in a good way, it's all too much... I'll be pacing the corridors. [...] Then when my mood is high, I definitely struggle to sleep'.
		P4	'There's been quite a few times where I've had to take a nap in the day because I'm so exhausted. I don't want to speak to people because I can't be bothered. I don't want to do anything... I find it's worse in the mornings, in the evenings I start to wake up'.
		P6	'[After a bad night's sleep] I have schoolwork or a group... but I can't... I find myself having conversations where I forget what the other persons just said'.
		P8	'...with poor sleep one of the biggest things I struggle with is rationalising and thinking logically... if I had a meal, thinking maybe it was much bigger than it was. Then poor sleep again. Having good sleep means I realise... that's just a normal portion'. 'After a bad night I'm tired and not doing much through the day, but then more awake at night again. Then probably mood changes from being a lot more tired... to not being happy, more sad'. 'When people have more sleep, they're more energetic, they wanna interact with more people... when others interact with you... it makes you get involved and you feel a bit happier around people doing things. I think that helps me sleep better'.
		P9	'Poor sleep means I'm low, don't want to socialise, I can't engage in the treatment because I can't focus...'
		P12	'When I don't sleep, I'm really tired... lack of energy... lack of concentration....up in school I get agitated very easily, fidgety...just needing a break, to stop'.

Appendix H - H.b

SIP: Quotes on threat-based appraisals at night

Theme	Subtheme	Psychiatric diagnosis	Participant Quotes
Factors disrupting sleep	Anxiety related hyper-arousal	OCD	'...it's feeling guilty and images...feeling regretful for the things I've done in the day that make mum unsafe...I feel responsible...I wake up anxious feeling like I've forgotten to do something.' (P9)
		AN	'...people are moving round, I get the thought, I should be moving round instead of sleep...I worry about food and exercise at night, feeling that I'm lazy because I'm already in bed...others are moving so why aren't I... I'm anxious and feeling compelled that I need to do it.' (P11) 'When I went to bed, it was always constantly thinking about things. Like my brain could not switch off thinking about, today, how this day went and then thinking about, oh no what's the day going to be like tomorrow? ... Worrying about the food that I ate that day and worrying about... how that would affect me ... stuff to do with weight.' (P8) 'Sleep was a bit disrupted... stuff with my eating disorder, so I was quite like physically unwell. It made me feel a bit anxious, because there was sort of stuff with my heart, and so it was... a bit worrying to notice it at night.' (P5)
		SA	'I couldn't ring my mum anymore, I got really stressed and thought my mum didn't like me and that she wanted to take away that one part of the day we had together... I got really distressed and he [staff member] retracted that, but the damage had been done. And I haven't called my mum since but that was when... that night I fell asleep at 4.30... and then it just got later and later.' (P1)
		EUPD, AD	'I get a lot of paranoid thoughts, and that kind of comes in at night a lot... people are watching me, somebody is coming to hurt me, things like that... it's really quiet at night as well, so it's the perfect opportunity for something bad to happen. It makes me feel more vulnerable. ... I will get horrible images in my head of things happening.' (P12)

Appendix I

SIP: Recommendations for service development

Area	Recommendations
Addressing environmental factors which disrupt sleep	*Sleep environment* • To consider preferences for a supportive sleep environment and help with implementation (e.g., arranging items to be brought from home to increase familiarity, setting a reminder for clinicians regarding open window arrangements or time-specific checks). *Sensory overload* • Consider ways to reduce levels of noise and light exposure at night. Individual strategies may be useful, e.g., use of noise cancelling ear buds, white noise machines. *Night-time observations* • Clinicians to explain the rationale and process of night-time observations to support patient understanding, agency in decisions, and allow for tailored approaches. To ask and document individual patient preferences (e.g., checks through window in door). *Routine weigh-ins* • To consider whether 6am weigh-ins for patients with eating disorders can be moved to an alternative time in day, with consideration of nursing capacity and shift hours. This aims to avoid anxiety-provoking tasks early morning or evening, to support a healthier total sleep duration and take into account the delayed sleep-wake cycle in adolescence.
Parasomnias that cause night-time waking's and hyperarousal	• Routine assessment of parasomnias (nightmares, dissociative experiences, and sleepwalking) and continue helpful adaptations to care plans which support patients in feeling safer at night (e.g., night shift staff updated on specific strategies such as sensory box with soothing items). • Consider specific evidence-based provision of psychological intervention for nightmares.

Fatigue and non-restorative daytime rest:	• To identify patients who use bed as a place to rest due to fatigue in the day (also applies to those using bed as an escape from sensory overload or internal distress). Identify places on the unit, other than bed, that they can use as a quiet relaxation space to rest or 'escape' during the day and at night. For those physically compromised or would fear embarrassment at getting up/ out of their room – identify an area of the room such as a chair and a relaxing activity at night that they can go to if unable to sleep. • To discourage daytime napping or restrict to 30 minutes, and provide education on the link between daytime sleep, low activity sleeps, and sleep dysregulation. • Consider integration of psychological support: psychoeducation and experiments to learn that activity and light foster daytime energy.
Managing intense emotions at night	*Hyperarousal* • Build on use of intensive nurse support (INS) in evenings to support evening wind down. To avoid topics leading to anxiety processes and hyperarousal (e.g., new topics and skills, incident debriefs - if patient wishes, small debrief where clinician offers non-directive support and then re-direct focus to wind down). To manage capacity, early identification and intervention may be offered for those admitted in line with patient preferences. E.g., implement for 1-week and review. • Consider whether an intervention such as CBTi may be feasible, with cognitive work to address threat cognitions and worry processes identified as disrupting sleep (Sheaves, Freeman, et al., 2018). This has implications for training of staff or an increase in resource to enable clinicians trained in CBTi to offer this type of intervention. *Hopelessness* • Fostering hope. Psychoeducation on the link between better sleep and improved mood to promote engagement. • Sharing the evidence-base and positive outcomes for benefits of working on sleep, in particular using a CBTi approach, with young people early on to foster hope and expectations of positive outcomes. Gains are typically early in CBTi (around stimulus control and sleep restriction methods) which may give young people a positive experience of help/ treatment to support further engagement in treatments on the unit. *Interrupting depressive rumination*

	• Important to consider supporting the association of bed with the body's sleep response. If bed is currently cueing wakefulness due to intense emotions, identify a room where patients can go if unable to sleep, or encourage quiet wind-down tasks in a separate area of their room, and return to bed when tired.
Supportive and consistent relationships to settle in the evening:	• Someone taking an empathic interest in helping patients settle in the evening. This appeared in reports as a strength on the unit – to encourage this as routine to ask patients if they need anything in the evening to overcome barriers of patients feeling unable to seek help themselves. To consider incorporation into early night-time observations.
Implementation of psychological interventions	• Consider introducing an evidence-based intervention of an adapted first-line sleep treatment, CBTi, within care plan, which may often be an addition (e.g., to CBTe or DBT offered). • Preference for 1:1, short and regular, e.g., 30 minutes twice weekly. Focusing on developing individually tailored help for sleep. • Cognitive work addressing dysfunctional beliefs about sleep and this being catastrophic. Setting realistic expectations for sleep with comorbid conditions and schedule of needed medications.
Physical activity in the daytime	• Encourage physical activity consistent with care plan. • A caveat to this is participants with eating disorders who are physically compromised, and how to support physical activity whilst managing the compulsion to over-exercise. Consideration of needs related to eating disorder treatment if relevant.
Medication	• Recognition of the benefits and challenges, hence the need to learn from patients about effects on sleep and working closely with prescriber to optimise benefits on sleep.
Future research	*Future research may be beneficial in the following areas:* • A pilot of psychological intervention for sleep on the unit. • Further methods of monitoring sleep problems during inpatient stay and after discharge (e.g., sleep diaries, actigraphy). • Systemic investigation of effects of medication on sleep. • Further investigation on the relationship between eating disorders and sleep disruption on the unit. E.g., unhelpful sleep habits.

Appendix J – J.a

SIP sponsorship - Data protection impact assessment

Data Protection Impact Assessment: if you are processing personal information you must consider completing a DPIA (Covid Short Form)

Screening Checklist (Highlight in red which apply)	
Use new technologies, or Innovative technological or organisational solutions.	Process personal data which could result in a risk of physical harm in the event of a security breach.
Combine, compare or match data from multiple sources or process special category data or criminal offence data on a large scale'	Processing of sensitive data or data of a highly personal nature, or process data concerning vulnerable data subjects.
Use automated decision making or special category data to help make decisions someone's access to a service, opportunity or benefit	Process personal data without providing a privacy notice directly to the individual

Sleep problems in adolescent inpatient settings

Step 1: What Is this DPIA for?

Purpose: Research project to be undertaken to enhance understanding of sleep problems in adolescent inpatient settings. The Chief Investigator is engaged in the Doctorate in Clinical Psychology at the Oxford Institute of Clinical Psychology Training & Research (OXICPTR), University of Oxford.

Study short title: Understanding Sleep Problems in Adolescent Inpatient Settings V1.0

Research Design: Qualitative cross-sectional design (semi-structured interviews at one point in time).

Participants: Fifteen patients (aged 11 to 18) screening positive for insomnia will be recruited from inpatient Child and Adolescent Mental Health Services (Tier 4) in Oxford Health NHS Foundation Trust (OHFT).

Primary Recruitment Site: Highfield Adolescent Inpatient Unit based at Warneford Hospital, Oxford.

Research data collection and recording: An encrypted and password protected Dictaphone provided by the CI's supervisor (BS) and OHFT computer (based at the Warneford Hospital, Oxford) will be used for the purposes of data collection and storage below which the CI has access to within their role of employment by OHFT as a Trainee Clinical Psychologist.

Data collection at assessment point:

At the initial meeting with the researcher, the young person will be asked to complete the Sleep Condition Indicator (Espie et al., 2014) to provide descriptive data on severity of sleep difficulties indicative of insomnia, and to complete a consent (aged 16 or over) or assent (aged 15 or under) form. If aged 15 or under, a parent or caregiver will first need to provide written consent before young person assent is sought. These forms will be completed using physical materials and stored at the recruitment site. Three of the named research collaborators are clinical staff members at the Highfield Unit and have confirmed that storage at the site in a locked filing cabinet will be feasible.

As soon as is practicable, physical copies will be scanned and saved on an OHFT server (CI's Oxford Health OneDrive account) and physical copies will then be shredded.

Data collection after informed written consent:

A standardised electronic form will be used by the CI to collect participant demographic data from electronic medical records in the least burdensome manner. All participants will need to consent to this at the written consent/ assent form stage before medical records can be accessed by the research team. Information collected will include age, gender, ethnicity, admission date, duration of inpatient stay at point of study interview, official and working mental health diagnoses, current medication, and any previous sleep intervention(s) received. The forms will be nameless and saved on an OHFT server (CI's Oxford Health OneDrive account). This information will be stored separately to any other research or personal data and will not be able to be linked to any other data sets, no participant code or ID will be used.

An interview schedule/ topic guide has been created for the semi-structured interviews, which will be administered by the CI to explore adolescent inpatient experiences of sleep difficulties and their preferences for treatment interventions. The information sheets, consent forms and interview schedule have been created in consultation with researchers and clinicians who have expertise in sleep during adolescence, and with three clinical staff members and three young people at the primary recruitment site (Highfield Unit). Interviews will be audio-recorded using an encrypted and password protected Dictaphone provided by the CI's supervisor (BS). Recordings will be uploaded and stored on the Chief Investigator's OHFT OneDrive account. The recording will be immediately deleted on the Dictaphone/ recording device once uploaded and the copy on the OHFT server will be deleted once data analysis is complete and as soon as it is practicable to do so. Recordings will be transcribed by the Chief Investigator (CI; Miriam Kirkham) using Microsoft Word on an Oxford Health Computer (at Warneford Hospital, Oxford) and stored on the CI's OHFT OneDrive account.

Interviews: The request and use of information has been designed to have as minimal impact on participant's information rights as possible. The interview schedule has been designed to minimise the chance any identifiers are mentioned, and this will be explained to participants before the interview and audio-recording is started. Identifiers that are inadvertently mentioned will be removed at transcription stage as soon as they are identified. It will not be possible to remove these from the audio-recording. Participants will be made aware in the informed consent process that direct quotations from the interview may be used as part of written reports and for teaching purposes, and that these will be anonymised.

A checklist of common maintenance factors for adolescent insomnia has been developed for participants to complete at the end of interviews in collaboration with researchers and clinicians with experience in this area. This tool will be regularly reviewed and adapted as interviews progress and participants are invited to add their own items. This tool will facilitate the development and implementation of specific sleep-focused formulations and interventions. An example tool developed for an adult inpatient setting is shown in a study by Sheaves and colleagues (2018b, referenced in study protocol). This data is anonymous and will be stored on the CI's OHFT OneDrive account. As it is anonymous there will be no ID or link to any other data sets.

Personal data collection and recording:

Participant names and contact details will be collected to send a summary of the study results if requested by the participant (asked as part of the consent form). This information will be recorded electronically on Microsoft Excel and stored on the CI's OHFT OneDrive account on a secure server provided by OHFT. This information will be stored separately from any research or clinical data and will not be able to be linked to any other data sets (no code or ID will be used). Personal data will be stored for one year, after which it will be destroyed by the CI (custodian of the data).

For access to data see step 2

Step 2: Describe the processing

Nature

- How you collect, use, store and delete data:

- Where is the data from, is it to be shared, with who, what is the data flow:

For collection of data see description in Step 1 above.

Access to data:

The CI is the custodian of the data (data manager), and other named members of the research team will have access to the data. Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Data Processing:

Interviews will be fully transcribed by the CI who has previous experience as a transcriber. Transcription will be verbatim and pauses and repetitions will be recorded since these can have important implications for meaning. Transcriptions will be anonymised (any identifiable information accidentally disclosed during interview will be removed as soon as identified by the CI). NVivo software will be used to support the analysis of research data/ transcriptions by thematic analysis. All data will be stored on the CI's OHFT OneDrive account on an encrypted OHFT server. To ensure credibility of the transcripts, analysis, and interpretation, a second member of the research team (BS) will listen to early recordings in order to check written transcripts for accuracy, and to discuss emerging themes. Supervision with members of the research team will be used to consider the interview process and coding, generation, and refinement of themes.

Anonymised transcripts (research data) will be moved outside of the Trust firewall for the purpose of analysis only using NVivo on a University of Oxford computer based at Warneford Hospital, Oxford. No other research data and no personal data will be transferred outside of Oxford Health for any purposes. A secure link will be sent from the CI's OHFT OneDrive account to the CI's University email address in order to access anonymised transcripts for analysis and the CI will use external (University of Oxford) log in details to access this.

Data from the demographics form (collected from participants medical records and consented to by participants) and Sleep Condition Indicator (SCI; measure at point of assessment) will be important to describe the sample and will be stored electronically on the CI's OHFT OneDrive account on an encrypted OHFT server. This data will be separate from all other data, nameless, and will not be linked to any other research data.

Personal data (name and contact details) will be collected from participants as part of the consent process (item on consent forms relating to this). This is voluntary for the purposes of sending participants a summary of the study results. This data will be stored electronically on the CI's OHFT

OneDrive account on an encrypted OHFT server. Personal data will be stored separately and will not be linked to any other data.

Data Recording and Management:

The study will comply with the Data Protection Act, which requires all data to be stored in line with data protection regulations, and data to be anonymised as soon as it is practical to do so. The report of the study will not identify any individuals. Data management will adhere to OHFT Information Governance policies.

- Data from interviews will be audio-recorded using an encrypted and password protected Dictaphone provided by CI's supervisor (BS) and transferred for storage onto an encrypted server provided by OHFT (CI's Oxford Health OneDrive account). The recording on the Dictaphone/ audio device will be immediately deleted once transferred, and the recording on the OHFT server will be deleted once data analysis is complete and as soon as it is practicable to do so.
- Physical data, inclusive of the SCI at assessment point and the original consent form, and paper copies of information sheets and the interview schedule will be stored in a locked filing cabinet at the participating service. Three of the named research collaborators are in clinical roles at the participating site (Highfield Unit) and have confirmed that this is feasible.
- Electronic data, inclusive of demographic information collected by the CI from care records, will be nameless and entered onto a secure password protected database, saved on the OHFT server (CI's Oxford Health OneDrive account).
- Information on the researcher's observations and reflections will be saved on the OHFT server and not refer to any individuals (CI's OHFT OneDrive account).

The interview schedule has been designed to minimise the chance any identifiers are mentioned, and this will be explained to participants before the interview and audio-recording is started. Identifiers that are inadvertently mentioned will be removed at transcription stage as soon as they are identified. It will not be possible to remove these from the audio-recording.

All data entry will be double checked for accuracy by the lead researcher (MK). Patient identifiable information will be removed, and research data destroyed within 3 years of collection, in line with NHS and host institution policy. Retention commences upon the final participant's last contact with the researcher. Patients will be offered a copy of the signed consent form and originals stored in a secure filing cabinet at the participating unit.

Personal data such as participant names and contact details will not be stored with any research or clinical data. Any paper copies of interview materials will be stored for up to three years in a locked cabinet in a locked office at the participating service.

Participants' names and contact details will be collected to send a summary of the study results if requested and stored separately from any clinical data. This information will be recorded electronically on Microsoft Excel and stored on the CI's OHFT OneDrive account on a secure server provided by OHFT. This personal data will be stored for one year, after which it will be destroyed by the CI (custodian of the data).

For information on data retention and deletion see section titled 'Scope' below.

Scope

- **What data is it, is it special category:** Yes. Data collected will be specific to adolescent (aged 11 to 18 in line with age range of primary recruitment site) inpatient experiences of sleep difficulties and preferences for intervention in this area. The SCI measure at point of assessment will be stored with no personally identifiable information. Interview transcripts will be anonymised and any identifiable information accidentally disclosed during the interview will be

removed at transcription stage. Participant demographic information will be nameless for the purposes of sample description in the study report only.

- **Volume collected and used, number of people, frequency:** Fifteen young people will be recruited. It is likely that most of the young people at point of invitation and meeting the researcher will be suitable and meet study inclusion criteria due to close liaison between with CI and the clinical team at the recruitment site. Recruitment will begin at the Highfield Adolescent Inpatient Unit and recruitment at other Tier 4 CAMHS sites within the trust will be considered according to recruitment rates. Three clinical members of staff at the Highfield Unit are directly involved in the research study as collaborators and will be involved in the recruitment process.

- **Storage period, area covered:** In line with national guidance data will be collected until the recruitment target of fifteen is met or the study end date is reached (24th June 2022). Retention commences upon the final participant's last contact with the researcher. Research and personal data will be stored separately on the CI's OHFT OneDrive account on a secure server provided by OHFT. Research data will be destroyed 3 years after publication or public release of the research, and personal data will be kept for 1 year (starting from point of retention as defined above) before being destroyed. The CI will be responsible for destroying research and personal data as custodian of the data. This is in line with the standard retention period for research data and is held and processed in accordance with the Data Protection Act 2018.

Context

- **Relationship with individuals, control by them, is there a reasonable expectation:**

We anticipate few ethical concerns for young people entering this study as the only requirements are to complete a brief measure of sleep disturbance at the point of screening/ assessment, which is a routine measure used on the Highfield Unit typically taking 5 minutes, and to complete a one-off interview regarding their experiences of sleep disturbance and opinions on intervention(s). The main ethical concerns are potential burden on participants and potential interviews to elicit distress. It is our experience that the majority of patients value the additional opportunity to share their experiences. Indeed, the process of qualitative interview is in itself an ethical engagement, as the focus is on the person's experiences, is participant led, and is empowering. A topic guide will be used to structure the interview and, in keeping with good qualitative and clinical practice, this will be tailored to individual experience and is flexible. At the Highfield Unit, three young people have been consulted to ensure the project is sound from the perspective of a young person with current experience of mental health difficulties and receiving care as an inpatient, and changes to the information sheets, consent forms, and topic guide were made accordingly.

Steps will be taken to minimize a potential power imbalance between the interviewer (CI) and participants. Interviews will be scheduled at a time and location of the participant's choice (where possible in a ward setting or online). The interviewer will remind participants they can choose not to answer questions and that information will only be shared with the care team if significant risk is identified. In addition, the interview will emphasise that the intention of this research is to learn from their experiences and ensure their opinions are central to future consideration of sleep interventions.

Clear information is provided to participants on the use of their data and the retention periods in the three information sheets (young people aged 15 and under, parents of those aged 15 or under, and young people aged 16 or above).

- **Children or vulnerable groups, prior concerns, security issues, is it novel:**

Data will be collected with young people aged 11 to 18 who are receiving inpatient care within OHFT at point of recruitment.

Information on scientific justification of novelty of research described in Step 4.

- **State of technology, public concern, code of conduct or certification scheme:** N/a

Purposes

- Aim and effect on individuals:

Aims:

The study has three main aims. First, to understand the lived experience of sleep disturbance in adolescents admitted at acute crisis to psychiatric wards (understanding the types of sleep problems, and both impact and interaction with other difficulties). Second, to understand adolescent perspectives on what maintains sleep disturbance in this context (acute mental illness and receiving care from an inpatient service). Third, to understand adolescent perspectives on sleep interventions, with reference to evidence-based interventions (CBT-I, medication, environmental changes) and potential modifications needed to optimise efficacy for an inpatient setting.

Rationale and benefits:

Sleep disturbance on adolescent inpatient units has been identified as a clinical problem that requires research and the development and modification of evidence-based interventions (Preyde, Tran, Parekh, & Heintzman, 2018). Examining treatment needs and preferences to then inform treatment development and inpatient environments is the next step.

Evidence from community adolescent and adult inpatient samples shows that insomnia is readily treatable using CBT-I, and that inpatient units may be able to implement short-term interventions that promote sleep (Blake et al., 2017; Sheaves et al., 2018a). Adaptations that take into account the service setting (unit environment and medications that affect sleep) and developmental stage of service users will be crucial.

Research investigating adolescent perspectives of sleep disruption and maintenance factors on inpatient units could lead to improvements in inpatient care and indicate treatment preferences and how interventions might be adapted. An in-depth understanding of young people's perspectives should inform treatment development (refining psychological theory, insight into change processes), engagement and clinical benefit (Medical Research Council, 2006). Gaining a service-user perspective to understand young people's experiences of sleep difficulties on an inpatient unit and their view on what might help and be acceptable as an intervention will inform the development of effective treatment approaches.

It is necessary to collect and process personal data as part of this research project. Information is anonymised for the purposes of analysis and is not retained in an identifiable form.

Please refer to scientific justification and assessment of scientific quality in Step 4 for more information.

Step 3: Consultation process

What stakeholders, sought views, why not:

- The CI's educational institution (OXICPTR) has formally assessed the scientific quality and clinical rationale for the project during a Proposal Approval Session (PAS) and given formal approval for the project.
- The study design, information sheets, consent forms, and interview schedule have been created and developed in consultation with researchers and clinicians who have expertise in sleep during

adolescence, and reviewed by three clinical staff members and three young people receiving care at the primary recruitment site (Highfield Unit), with changes made accordingly.

Step 4: Assess necessity and proportionality

The legal basis for the processing of personal data within this research project is 'a task in the public interest'. Informed consent procedures are also necessary to satisfy ethical considerations.

Scientific justification of the research project:

Sleep disturbance on adolescent inpatient units has been identified as a clinical problem that requires research and the development and modification of evidence-based interventions (Preyde, Tran, Parekh, & Heintzman, 2018). This has been recognised at the Highfield Adolescent Unit: reported by unit staff and shown in a recent study on the prevalence and correlates of insomnia (Johnsen et al., in prep). Examining treatment needs and preferences to then inform treatment development and inpatient environments is the next step.

Evidence from community adolescent and adult inpatient samples shows that insomnia is readily treatable using CBT-I, and that inpatient units may be able to implement short-term interventions that promote sleep (Blake et al., 2017; Sheaves et al., 2018a). Adaptations that take into account the service setting (unit environment and medications that affect sleep) and developmental stage of service users will be crucial.

Research investigating adolescent perspectives of sleep disruption and maintenance factors on inpatient units could lead to improvements in inpatient care and indicate treatment preferences and how interventions might be adapted. An in-depth understanding of young people's perspectives will inform treatment development (refining psychological theory, insight into change processes), engagement and clinical benefit (Medical Research Council, 2006). Gaining a service-user perspective to understand young people's experiences of sleep difficulties on inpatient units and their view on what might help and be acceptable as an intervention will inform the development of effective treatment approaches.

Assessment of scientific quality:

The CI's educational institution formally assessed the scientific quality and clinical rationale for the project during a Proposal Approval Session (PAS). This involved presentation of the project to the PAS panel, consisting of the institute director and senior members of the institute research team who subsequently approved this project. The approval of this projects means that it met the required level of scientific value (evidence of project approval by the institution is uploaded as an appendix to this form). In addition, the CI and their research team have reviewed the scientific quality of the research throughout the formation stages.

Ethical stance:

The process of qualitative interview is in itself an ethical engagement, as the focus is on the person's experiences, is participant led, and is empowering. A topic guide will be used to structure the interview and, in keeping with good qualitative and clinical practice, this will be tailored to individual experience and is flexible.

Step 5: Risk Assessment and Mitigation

Describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary.	Likelihood of harm 1 to 5	Severity of harm 1 to 5	Overall risk 1 x 2

Risk of data loss or unlawful processing is minimal in this research study and the research team have processes in place to ensure participants anonymity is maintained. All electronic data is stored on a OHFT Trust server and physical data stored in a locked filing cabinet on OHFT Trust premises / within a trust health service. A corporate risk assessment has been undertaken by the CI and the internal course supervisor to confirm that any material risks are minimal and highly unlikely to occur.	Low	Low	

6: Measures to reduce or eliminate risks identified as medium or high risk above			
Options to reduce or eliminate risk.	Effect on risk	Residual risk	Measure approved

Step 7: Sign off and record outcomes

Item	**Name/date**	**Notes**
Measures approved by:		Integrate actions back into project plan, with date and responsibility for completion
Residual risks approved by:		If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:	 5 May 2021	DPO should advise on compliance, step 6 measures and whether processing can proceed
Summary of DPO advice:		
DPO advice accepted or overruled by:		If overruled, you must explain your reasons
Comments:		

Appendix J - J.b

SIP sponsorship with Oxford Health NHS Foundation Trust

Natalia Jastrzębska
Research Manager
Research and Development Department
Warneford Hospital
Oxford
OX3 7JX
Email: research@oxfordhealth.nhs.uk
10/05/2021

Confirmation of Sponsorship

Re: Understanding Sleep Problems in Adolescent Inpatient Settings
Research and Development Reference: 15312

Dear Miriam Kirkham,

On behalf of Oxford Health NHS Foundation Trust, I am pleased to confirm Oxford Health NHS Foundation Trust will act as a sponsor for the above research as outlined in the application received. Protocol Version 1 dated 19/04/2021 is recognised as the most current to date.

Conditions of Approval
The following conditions apply to this approval:
a) The study sponsorship is confirmed subject to formal approval from HRA and any other relevant approving body.
b) Should you plan to leave your position in OHFT, you will notify R&D immediately of your plans, to enable discussions around the future of study conduct.
c) The Trust expects the named Principal Investigator to allocate regular support time to the study; this must be agreed with the research team prior to the study commencing. This may be reviewed by R&D at any time.
d) All relevant documents will be maintained and will be sent to research@oxfordhealth.nhs.uk, to facilitate compliance checks, formal audits and regulatory inspections.
e) You will notify R&D via the email above of any amendments.
f) You will promptly inform R&D via the email above of the end of the study.

I wish you every success with the study. Yours sincerely,

Natalia Jastrzębska Research Manager
Sponsorship letter v2, January 2020

Appendix J - J.c

SIP NHS ethics approval letter

South Central - Oxford B Research Ethics Committee
Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
Telephone: 0207 104 8028

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

06 July 2021

Miss Miriam Kirkham
Oxford Institute of Clinical Psychology Training & Research Isis Education Centre,
Warneford Hospital
Oxford, OX3 7JX

Dear Miss Kirkham

Study title: Sleep Problems in Adolescents Admitted at Acute Crisis to Psychiatric Wards: Understanding Experiences and Treatment Preferences

REC reference: 21/SC/0186

Protocol number: 1

IRAS project ID: 290533

South Central - Oxford B Research Ethics Committee

Thank you for your letter of 28 June 2021, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies

2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registratio n-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-respo nsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-sum maries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your

study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*

Interview schedules or topic guides for participants [Tracked V1.1 changes_Topic Guide] IRAS Application Form [IRAS_Form_19052021]

Letter from sponsor [Sponsorship Letter] V1.0 Non-validated questionnaire [Demographics Form] V1.0 Other [Participant Withdrawal Form] V1.0 Other [CI Response_Ethical Review_Further Information Required] V1.0

Participant consent form [Tracked changes_Assent Form 15 and V1.1 under]
Participant consent form [Tracked changes_Consent Form 16+] V1.1

Participant consent form [Tracked changes_Consent Form Parents] V1.1

Participant information sheet (PIS) [Tracked Changes_PIS aged 15 V1.1 and under]
Participant information sheet (PIS) [Tracked changes_PIS aged 16 V1.1 and above]

Participant information sheet (PIS) [Tracked Changes_PIS Parents/ V1.1 Carers]
Research protocol or project proposal [Research Protocol] V1.0

Summary CV for Chief Investigator (CI) [CI CV] V1.0 Summary CV for student [CI CV] V1.0
Summary CV for supervisor (student research) [Supervisor CV] V1.0 Summary CV for supervisor (student research) [Supervisor CV] V1.0 Validated questionnaire [Sleep Condition Indicator]

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 290533 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project. Yours sincerely

pp.



Mr Chris Foy Chair

Email: oxfordb.rec@hra.nhs.uk
Enclosures: "After ethical review – guidance for researchers" *[SL-AR2] Copy to:* Brandy Coote, Oxford Health NHS Foundation Trust

approvals@hra.nhs.uk

Appendix J - J.d

SIP: Research and development confirmation of capacity and capability letter

Professor Andrea Cipriani Associate Director of Research & Development
Warneford Hospital
Warneford Lane
Oxford
OX3 7JX
Email: research@oxfordhealth.nhs.uk
09/08/2021

Confirmation of Capacity and Capability

Re: Understanding Sleep Problems in Adolescent Inpatient Settings

Research and Development Reference: 15312
IRAS Reference: 290533
Research Ethics Committee Reference: 21/SC/0186

NIHR Portfolio Ref: NA
Sponsor: Oxford Health NHS Foundation Trust

Dear Miriam,

On behalf of Oxford Health NHS Foundation Trust, I am pleased to confirm Trust Capacity and Capability for the above research as outlined in the application received. The study is not supported by a Research Delivery Team.

The study team members are as follows: Miriam Kirkham; Bryony Sheaves; Jessica Bird; Tony James; Hannah Stratford and Paul Salkovskis.

Approved Documents

Protocol Version 1 dated 19/04/2021 is recognised as the most current to date.

The documents approved for use at this Trust are as listed in the following approval documents:
Health Research Authority Letter dated: 06/07/2021
Research Ethics Full Approval Letter dated: 06/07/2021

Any subsequent, relevant amendments are additionally included to date.

Metrics and Recruitment

First participant target date: 06/09/2021 Recruitment target figure: 12-15 Recruitment target date: 24/06/2022 Anticipated study end date: 24/06/2022

To comply with national research performance requirements the Trust will monitor and publish recruitment for your study:
1.Performance of the recruitment of the first participant.

2.Recruiting planned participants to time and target.

Reporting recruitment via Siteline

As confirmed during the study set-up study accruals will be recorded via Siteline. It was agreed that Miriam Kirkham will update the records at least one a month and no later than 7th of each month (e.g. by 7th August upload accruals for July etc.)

Should you feel at any time that you will be unable to realistically achieve your contracted recruitment target, please get in touch with the Research Team on research@oxfordhealth.nhs.uk as soon as possible.

Conditions of Approval

The following conditions apply to this approval:
a) The study is conducted in compliance with all the relevant legislation and the relevant OHFT policies.
b) All staff working on the study have the appropriate training and experience and have responsibilities formally delegated to them.
c) Should you plan to leave your position in OHFT, you will notify R&D immediately of your plans, to enable discussions around the future of study conduct.
d) The Trust expects the named Principal Investigator to allocate regular support time to the study; this must be agreed with the research team prior to the study commencing. This may be reviewed by R&D at any time.
e) All relevant documents will be maintained and will be sent to research@oxfordhealth.nhs.uk, to facilitate compliance checks, formal audits and regulatory inspections.

1. f) You will notify R&D via the email above of any protocol amendments.
2. g) You will promptly inform R&D via the email above of the end of the study.
3. h) You will respond in timely manner to R&D periodic checks email.

I wish you every success with the study. Yours sincerely,



Professor Andrea Cipriani
Associate Director of Research & Development

Appendix K

TDRP: Author Submission Guidelines

Behaviour and Cognitive Psychotherapy

https://www.cambridge.org/core/journals/behavioural-and-cognitive-psychotherapy/information/instructions-contributors

Preparing Your Manuscript

Articles must be under 5,000 words at the point of submission, excluding references, tables and figures. Manuscripts describing more than one study may exceed no more than 6000 words but please make this clear in your cover letter.

Brief Clinical Reports should be no more than 1800 words (see more information below).

Please note that we currently do not usually accept studies carried out on student samples unless there is a clear indication of generalisability to clinical populations.

The journal strongly encourages blind review. Authors who want a blind review should indicate this at the point of submission of their article, omitting details of authorship and other identifying information from the main manuscript. Authors who do not omit this information will be assumed as submitting a non-blinded manuscript.

All submissions should be submitted via this portal: http://mc.manuscriptcentral.com/babcp

Research Transparency
Behavioural and Cognitive Psychotherapy believes in the importance of transparent and reproducible research. We therefore strongly encourage authors to make their evidence, data and other materials that underpin their findings openly available to readers which is outlined in our Research Transparency Policy. Authors will be asked on submission to include in their cover letter to the Editor whether they have made their data publicly available and confirm the inclusion of the Data Availability Statement. If the authors are not making their data publicly available, we ask them to state the reason why in their cover letter.

Article Types

Main
Reports of original research employing experimental or correlational methods and using within or between subject designs. Review or discussion articles that are based on empirical data and that have important new theoretical, conceptual or applied implications.

Empirically Grounded Clinical Interventions
This section is intended for reviews of the present status of treatment approaches for specific psychological problems. It is intended that such articles will draw upon a combination of treatment trials, experimental evidence and other research, and be firmly founded in phenomenology. It should take account of, but also go beyond, treatment outcome data.

Brief Clinical Reports
Material suitable for this section includes unusual case reports and accounts of potentially important techniques, phenomena or observations; for example, descriptions of previously unreported techniques, outlines of available treatment manuals, descriptions of innovative variations of existing procedures, details of self-help or training packages, and accounts of the application of existing techniques in novel settings. The BCR section is intended to extend the scope of the clinical section. **Submissions to this section should be no longer than 1800 words and should include no more than six references, one table or figure, and an extended report that contains fuller details. There are no restrictions on the size or format of the extended report as it will be published online only.** It may, for instance, be a treatment manual, a fully detailed case report, or a therapy transcript. If a submission is accepted for publication as a Brief Clinical Report, the author(s) must be prepared to send the fuller document to those requesting it, free of charge. The extended document will also be mounted on the journal's website as a PDF format (the document will not be copyedited).

Study Protocols
Protocols of proposed and ongoing trials in behavioural and cognitive therapies will be considered. Your study must be registered and have ethical approval, and proof of this will be required. The abstract should be structured under the following four headings; Background, Aims, Method, Discussion.

Please use the Standard Protocol Items: Recommendations for Interventional Trail (SPIRIT) checklist for protocols of randomised controlled trials (see the reporting standards section below). Manuscripts should be under 2000 words at the point of first submission, and include no more than 15 references, and no more than three tables/figures in total. A PDF with additional, unlimited text, figures and tables may be included designated for online only publication.

The journal also occasionally publishes Editorials, however these are published by invitation only and should not be submitted unsolicited.

Style Guide

The following should be included in all manuscripts:

Title page
This should be a separate file to the main text to ensure blind review.

The title should phrase concisely the major issues. Author(s) to be given with departmental affiliations and addresses, grouped appropriately. A running head of no more than 40 characters should be indicated.

The following statements should be included on the title page:

Acknowledgements
You may acknowledge individuals or organizations that provided advice, support (non-financial).

Conflict of Interest
Authors should include a Conflicts of Interest declaration in their title page. Conflicts of Interest are situations that could be perceived to exert an undue influence on an author's

presentation of their work. They may include, but are not limited to, financial, professional, contractual or personal relationships or situations. Conflicts of Interest do not necessarily mean that an author's work has been compromised. Authors should declare any real or perceived Conflicts of Interest in order to be transparent about the context of their work. If the manuscript has multiple authors, the author submitting the title page must include Conflicts of Interest declarations relevant to all contributing authors.

Example wording for your Conflicts of Interest declaration is as follows: "Conflicts of Interest: Author A is employed at company B. Author C owns shares in company D, is on the Board of company E and is a member of organisation F. Author G has received grants from company H." If no Conflicts of Interest exist, your declaration should state "Conflicts of Interest: None".

Data Availability Statement
This is a brief statement about whether the authors of an article have made the evidence supporting their findings available, and if so, where readers may access it. More information on Data Availability Statements and example statements can be found here. Please note that if you are not making your data publicly available, we ask you to state the reason why in your cover letter to the Editor.

Financial support
Please provide details of the sources of financial support for all authors, including grant numbers. For example, "This work was supported by the Medical research Council (grant number XXXXXXX)". Multiple grant numbers should be separated by a comma and space, and where research was funded by more than one agency the different agencies should be separated by a semi-colon, with "and" before the final funder. Grants held by different authors should be identified as belonging to individual authors by the authors' initials. For example, "This work was supported by the Wellcome Trust (A.B., grant numbers XXXX, YYYY), (C.D., grant number ZZZZ); the Natural Environment Research Council (E.F., grant number FFFF); and the National Institutes of Health (A.B., grant number GGGG), (E.F., grant number HHHH)". Where no specific funding has been provided for research, please provide the following statement: "This research received no specific grant from any funding agency, commercial or not-for-profit sectors."

Main Text (anonymised with no author information)
This should be uploaded as a .doc file with the following running order. The following format is based on APA style which should be followed throughout: http://www.apastyle.org/

Abstract
Should consist of no more than 250 words and structured under the following five headings: Background, Aims, Method, Results, and Conclusions. Include up to six key words that describes the article.

Main Text
This should contain the sections **Introduction** (including overview and theoretical background), **Method** (participants, design, data analyses and Ethical Statement- see below), **Results** (described in detail with summary figures and tables), **Discussion** (including conclusions and limitations).

Ethical statements
All papers should include a statement indicating that authors have abided by the Ethical

Principles of Psychologists and Code of Conduct as set out by the BABCP and BPS. If preferred, authors based outside of the UK may state research has conformed to the Declaration of Helsinki. Authors should also confirm if ethical approval was needed, by which organisation, and provide the relevant reference number. If no ethical approval was obtained, the authors should state what governance arrangements were in place (e.g. audit committee approval). We also expect authors to respect human participants' right to privacy, and to gain any necessary informed consent to publish before submitting to us and include a statement in their manuscript that consent has been obtained. Where case reports are detailed in a submission, the author must state that the person described has seen the submission in full and agreed to it going forward for publication.

References

Please use APA style for the in-text citations and references. In the reference list there is an additional requirement that author names be listed in **bold face**. For example:

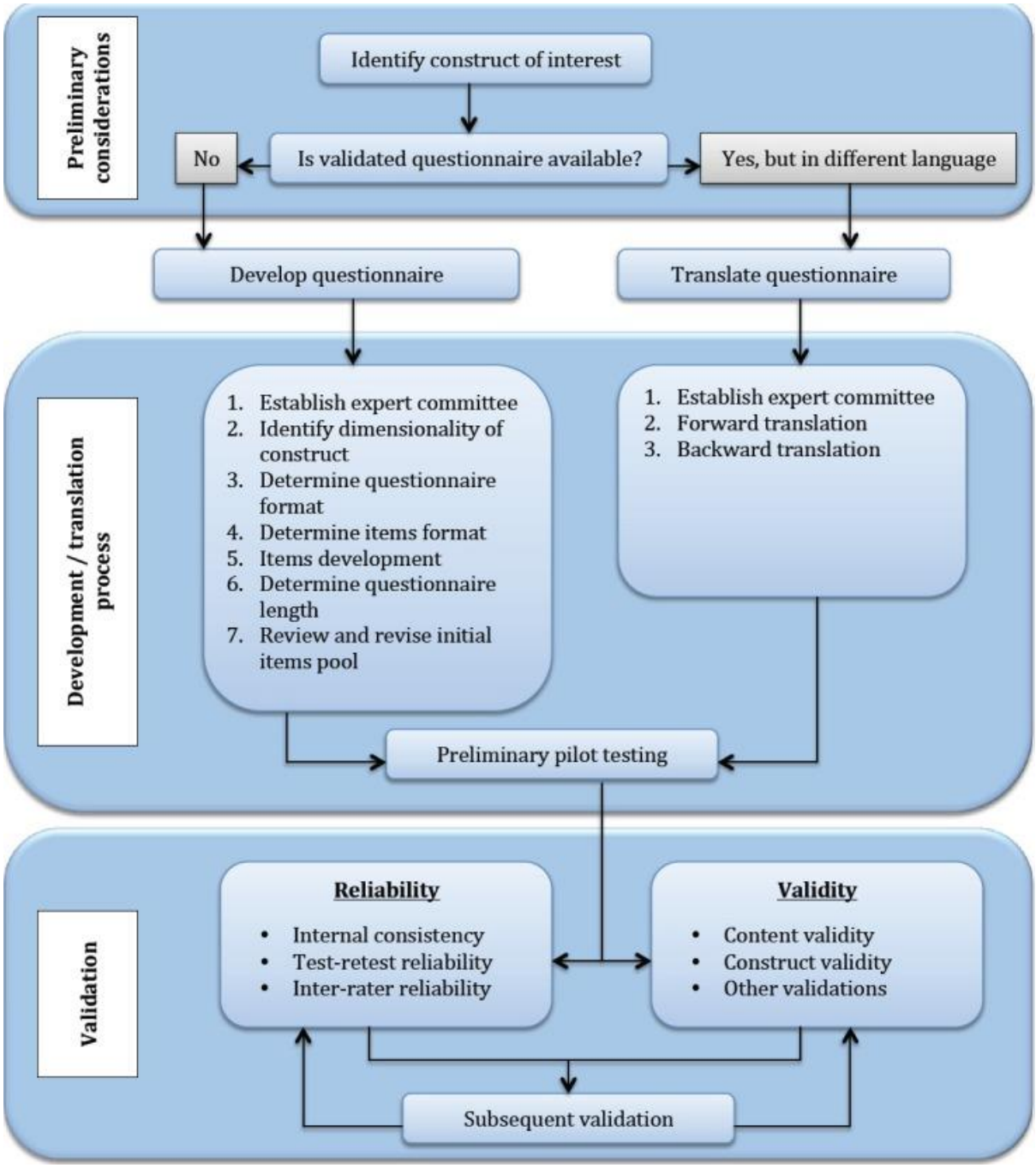
Grady, J. S., Her, M., Moreno, G., Perez, C., & Yelinek, J. (2019). Emotions in storybooks: A comparison of storybooks that represent ethnic and racial groups in the United States. *Psychology of Popular Media Culture, 8*(3), 207–217. https://doi.org/10.1037/ppm000...

Authors are encouraged to make use of referencing software packages (e.g. Endnote, Mendeley, Reference Manager etc.) to assist with formatting - extensions for APA formatting are easily accessible. Authors are also reminded to use bold face for author names in the reference list.

Appendix L

TDRP: Questionnaire Development (Tsang, Royse, & Terkawi, 2017)

Questionnaire development includes establishing an expert committee, identifying construct dimensions, selecting questionnaire and item format, developing items, determining questionnaire length, revising the item pool, and preliminary validation (Tsang, Royse, & Terkawi, 2017).



Appendix M

TDRP: Patient and public involvement advertisement

Self-Confidence in Young People who Feel Mistrustful of Others

What's the Project?

Feeling mistrustful and suspicious of other people is common, but when we feel this way repeatedly it can have a big impact on our lives, making it harder to trust friends and feel safe in social situations. We might get thoughts that others are deliberately trying to upset or hurt us. When we feel this way, our confidence can take a knock. We might have thoughts such as 'I'm an outsider' or 'there's something wrong with me' or 'I'm weak'. Thinking of ourselves as vulnerable and different, rather than confident and successful, will affect how we feel and our relationships.

For this project, we plan to create a questionnaire that measures how young people (who are feeling mistrustful of others) think and feel about themselves. By understanding and measuring these experiences, we hope that future support to improve young people's confidence will be better and more specific to individuals.

We plan to have interviews with 12 young people (aged 14-25) who are seeking help from mental health services and are feeling mistrustful or suspicious of others. In these interviews, we will ask questions to find out how they think and feel about themselves, in order to develop the new measure. We will then test the new measure by asking a large number of young people to try it out in an online survey.

What's the opportunity?

We are looking for young people to help shape this project, drawing from their own experiences to ensure the work is appropriate, meaningful and accessible for those taking part. You can be involved in one aspect or the whole project. We need your help on three parts:

1. Helping to set up the project. This will involve some reading about the project (such as information sheets and advertisements, for up to 1 hour) and meeting with the researcher (online, for up to 1 hour). This meeting will be to discuss your feedback, and to think about what questions we want to ask young people at interview.

2. Refining the questionnaire. We will ask people to look at a list of items that could be part of the questionnaire, and will be asking for some written feedback on this. We think this will take about 1 hour.

3. The findings. This will involve giving written feedback by email or meeting the researcher, to think about the findings of the study. We would like your help in making sure we have understood the ideas and how we talk about them with others. We think this will take about 1 hour.

What's required of me?

- You need to be aged 14 to 25

- Having a device with a (relatively) stable internet connection for meetings, or having access to a phone

- Having some experience (past or present) of feeling mistrustful of others

I'm interested! Who do I contact?

Please contact Miriam (the researcher) and provide your contact details if you would like to be involved, by email: Miriam.kirkham@hmc.ox.ac.uk or phone/ text: 07547 709 650

What's the deadline to apply?

We would like you to be involved as soon as possible! If you are interested, please get in touch in the next few days. We will be open to people joining up until Friday 27th November 2020, and hope to have 5 young people involved!

Appendix N

TDRP: Interview schedule

Introduction

We'll now move onto the interview section of the meeting. We are interested to hear about how you see yourself and the types of thoughts you have about yourself, in your own words. We hope to learn from this and develop a questionnaire that helps young people express their thoughts and receive the right kind of help for them.

Throughout the meeting I will try to listen as much as possible and not interrupt you, so the conversation might feel a bit one sided at times. You can take your time to think about the questions I ask, no detail is too small as everything you have to say will be important. The questions are open so that you can answer in your own way and there are no right or wrong answers, this is all about what things are like for you.

It is up to you how much you want to share with me, and you don't have to answer anything you don't want to. Sometimes I might ask you to go into more detail about something, but, if you don't want to that is absolutely okay. If anything we discuss leaves you feeling upset please let me know. We don't want it to feel difficult and we could take a break, move onto a new topic, or stop the meeting.

What you say in this meeting is confidential and will not be shared with your parent/ carer or care team, and your name will not be linked to what you say. However, if you say anything that makes me worried about yours or someone else's safety, this information will be shared with your care team. If this needed to happen, I would let you know about this first.

There are 6 main questions, and we will both have a written copy of them in front of us. Sometimes I might not ask questions in the best way, so please ask if anything does not make sense. The meeting will last up to 1 hour, but it may be a bit shorter depending on how we go. I will check the time as we go along, and I might bring us back to a topic of discussion if it feels important or if time is running out.

Does everything make sense so far? Do you have any questions? If you have any questions as we go through or are unsure about anything just let me know. Ok let's begin.

Questions:

3. **I wonder if you could start by telling me a little bit about yourself and your interests?**

Prompt Questions:

- *What do you like to do in school? Outside of school?*
- *What do you like to do when you are by yourself or with family/ friends?*

4. **Can you tell me how you might describe yourself?**

Prompt Questions:

- *Where do you think that idea about yourself might have come from?*
- *Would it be helpful to think about how a friend or family member might describe you?*
- *If you were being your harshest critic, how would you describe yourself?*
- *If you were being your greatest supporter, how would you describe yourself?*

5. **Can you tell me about a recent time when you have felt proud of yourself, or when something has gone well?**

Prompt Questions:

- *This might be at home/ school/ hobbies/ with friends?*
- *What was that like? Did you have specific thoughts or feelings about yourself at that time?*

6. **Can you tell me about a recent time when you have felt bad about yourself, or when something has gone badly?**

Prompt Questions:

- *This might be at home/ school/ hobbies/ with friends?*
- *What was that like? Did you have specific thoughts or feelings about yourself at that time?*

7. **Sometimes when we feel bad about ourselves, we might compare ourselves to other people. Do you find that you compare yourself to other people at times?**

Prompt Questions:

- *When might that happen?*
- *What do you notice about yourself when this happens?*
- *Did you have specific thoughts or feelings about yourself at that time?*

8. **Can you tell me about a recent time when you have felt worried, unsafe, or vulnerable around other people?**

Prompt Questions:

- *It might be around family, friends, or strangers? At home / school/ when outside?*
- *What were you thinking and feeling at the time? Did you have any specific thoughts about yourself?*

Thank you

Ending Questions:

- Is there anything that you think is important to discuss that we haven't talked about?

- Do you have any questions for me?

- How has it been talking today? Was there anything that felt difficult or confusing? Is there anything I could have done to make it easier for you?

- Some people find it helpful for me to check in with how they are feeling later on after the meeting, or to ask a member of their care team or family to check on them later in the week. Is this something you would like?

General prompts that can be used during the interview:

- You mentioned that [participant's words]
    - Can you tell me a bit more about that?
    - Can you give me an example?

- For the interviewer to check their understanding within the interview: "I might think about it like [insert paraphrase]… what do you think of that?" "How would you change that?". Or, "what I've heard from you is [insert paraphrase], is that right?"

- If the interviewer thinks the participant might appreciate a break: "would you like to pause for a break here?"

Appendix O

TDRP: Phase one screening measure and severity thresholds

The Bird Checklist of Adolescent Paranoia (B-CAP, Bird et al., 2020)

This form is about worries you may have about other people. Please circle how often you have had each thought over ***the last 2 weeks***

	Never	Once	Couple of times	Few times a week	Every day	All the time
People at school are trying to make me feel unwanted	0	1	2	3	4	5
I'm sure people are gossiping about me on social media	0	1	2	3	4	5
I am being pushed out of conversations on purpose	0	1	2	3	4	5
My friends or partner are ignoring my messages to upset me	0	1	2	3	4	5
People are trying to embarrass me in class on purpose	0	1	2	3	4	5
People are making sly comments to upset me	0	1	2	3	4	5
I think people are lying to me on purpose	0	1	2	3	4	5
People say things under their breath to wind me up	0	1	2	3	4	5
Nasty tricks are being played on me	0	1	2	3	4	5
People are trying to confuse me on purpose	0	1	2	3	4	5
Groups of people are planning against me	0	1	2	3	4	5
People are collecting my information or photos to use against me	0	1	2	3	4	5
I'm sure people are seeking revenge on me	0	1	2	3	4	5
I feel like I am being followed or stalked	0	1	2	3	4	5
I am scared of what strangers will do to me	0	1	2	3	4	5
People will try to kidnap me	0	1	2	3	4	5

I could be attacked at any time	0	1	2	3	4	5
I feel unsafe around people everywhere I go	0	1	2	3	4	5

Severity ranges for B-CAP total scores (Bird et al., 2020)

Category	Score	Description
Average	0-22	Normal level of suspicious thinking at less than 0.70 SDs above average for adolescents
Mildly elevated	23-39	Mildly elevated suspicious thinking at 0.75-1.40 SDs above average for adolescents
Moderate	40-53	Moderate paranoia at 1.45-1.95 SDs above average for adolescents
High	54-70	High level of paranoia at 2.00-2.60 SDs above average for adolescents
Severe	71-90	Severe level of paranoia at greater than 2.65 SDs above average for adolescents

Appendix P

TDRP: Thematic analysis steps (Braun & Clark, 2006; Terry et al., 2017)

Transcripts were read and re-read by MK to become familiar and immersed in the data. Regular supervision with the research team was used to develop themes (generation, refinement, and classification). A preliminary coding framework which incorporated multiple perspectives on the data was agreed, corresponding to overarching topics of the interview.

Phase	Process
1. Familiarizing yourself with your data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Appendix Q

TDRP: Questionnaire Item Pools

SoS 72-Item Pool

1. Thoughts About Myself:

Please read each word below and rate how much you *believe this is true*.
Try to rate based on how you think about yourself *most of the time*.

Statements: ***I believe that I am...***	**How much I believe this is true**				
	Not at all	**Slightly**	**Some-what**	**Very much**	**Totally**
1. Less than others	0	1	2	3	4
2. Unlikable	0	1	2	3	4
3. Powerless	0	1	2	3	4
4. Unlovable	0	1	2	3	4
5. A villain	0	1	2	3	4
6. Bad	0	1	2	3	4
7. Deserving of bad things	0	1	2	3	4
8. Not understandable	0	1	2	3	4
9. Gossiped about	0	1	2	3	4
10. Dangerous	0	1	2	3	4
11. Nasty	0	1	2	3	4
12. Laughable	0	1	2	3	4
13. Overlooked	0	1	2	3	4
14. Wrong	0	1	2	3	4
15. Empty	0	1	2	3	4
16. A low life	0	1	2	3	4
17. Flawed	0	1	2	3	4
18. Ruined	0	1	2	3	4
19. Defeated	0	1	2	3	4
20. Dull	0	1	2	3	4
21. Exposed	0	1	2	3	4
22. Scum	0	1	2	3	4
23. Doomed	0	1	2	3	4
24. Mad	0	1	2	3	4
25. Forgotten	0	1	2	3	4
26. Annoying	0	1	2	3	4
27. A failure	0	1	2	3	4
28. Too sensitive	0	1	2	3	4
29. Pathetic	0	1	2	3	4

30. Disgusting	0	1	2	3	4
31. Out of luck	0	1	2	3	4
32. Too different to others	0	1	2	3	4
33. Not good enough	0	1	2	3	4
34. Stupid	0	1	2	3	4
35. Too reliant on others	0	1	2	3	4
36. Ignored	0	1	2	3	4
37. Ugly	0	1	2	3	4
38. Inadequate	0	1	2	3	4
39. Out of control	0	1	2	3	4
40. Dirty	0	1	2	3	4
41. Unskilled	0	1	2	3	4
42. Undesirable	0	1	2	3	4
43. Useless	0	1	2	3	4
44. Toxic	0	1	2	3	4
45. At the bottom	0	1	2	3	4
46. Singled out	0	1	2	3	4
47. Slow	0	1	2	3	4
48. Wounded	0	1	2	3	4
49. Cursed	0	1	2	3	4
50. Tainted	0	1	2	3	4
51. Nothing	0	1	2	3	4
52. Defective	0	1	2	3	4
53. Worthless	0	1	2	3	4
54. Damaged	0	1	2	3	4
55. Feeble	0	1	2	3	4
56. Not capable	0	1	2	3	4
57. Boring	0	1	2	3	4
58. Weak	0	1	2	3	4
59. Trouble	0	1	2	3	4
60. Neglected	0	1	2	3	4
61. Odd one out	0	1	2	3	4
62. Hated	0	1	2	3	4
63. Hurt	0	1	2	3	4
64. A burden to others	0	1	2	3	4
65. Selfish	0	1	2	3	4
66. Very unlucky	0	1	2	3	4
67. Inferior	0	1	2	3	4
68. Unwanted	0	1	2	3	4
69. An outcast	0	1	2	3	4
70. Contaminated	0	1	2	3	4

71. Broken	0	1	2	3	4
72. Too much	0	1	2	3	4

SoS-E 41-Item Pool

1. The things that affect how I see myself

Please read the statements and rate *how often this happens for you*

Statements:	**How often**				
	Never	**Rarely**	**Some-times**	**Often**	**Always**
1. I have bad thoughts	0	1	2	3	4
2. I say or do bad things	0	1	2	3	4
3. I make other people feel bad	0	1	2	3	4
4. I get things wrong	0	1	2	3	4
5. I can't control my response to difficult thoughts or feelings	0	1	2	3	4
6. I am not much use to other people	0	1	2	3	4
7. I can't keep up with my changing thoughts and feelings	0	1	2	3	4
8. I don't know what to say or do around other people	0	1	2	3	4
9. I give up on things too easily	0	1	2	3	4
10. I fail at things I set out to do	0	1	2	3	4
11. I let other people down	0	1	2	3	4
12. I have to change what I think around other people	0	1	2	3	4
13. I get confused	0	1	2	3	4
14. I look like rubbish	0	1	2	3	4
15. I have to change who I am around other people	0	1	2	3	4
16. I make other people angry	0	1	2	3	4
17. I get called names by other people	0	1	2	3	4

18.	I find that other people leave me	0	1	2	3	4
19.	I say too little to other people	0	1	2	3	4
20.	I can't think clearly	0	1	2	3	4
21.	I don't feel much	0	1	2	3	4
22.	I can't make decisions	0	1	2	3	4
23.	I let small things affect me	0	1	2	3	4
24.	I rely on other people for approval	0	1	2	3	4
25.	I change my mind all the time	0	1	2	3	4
26.	I rely on other people to solve my problems	0	1	2	3	4
27.	I get visibly anxious in front of people	0	1	2	3	4
28.	I hear that other people dislike parts of me (e.g., my appearance, sexuality, religion, race)	0	1	2	3	4
29.	I try to keep to myself	0	1	2	3	4
30.	I can't trust my senses	0	1	2	3	4
31.	I say too much to other people	0	1	2	3	4
32.	Other people often have to look after me	0	1	2	3	4
33.	I misread other people	0	1	2	3	4
34.	I think too much	0	1	2	3	4
35.	I go with my first thought	0	1	2	3	4
36.	I have to think about myself a lot	0	1	2	3	4
37.	I annoy other people with how I act	0	1	2	3	4
38.	I find that I'm too slow at things	0	1	2	3	4
39.	I doubt myself	0	1	2	3	4
40.	I don't feel able to motivate myself	0	1	2	3	4
41.	I get told off	0	1	2	3	4

Appendix R - R.a

TDRP: Phase two measure validation - advertisements

Social media image:



Twitter and Instagram:

Can you help us with #mentalhealthresearch? We are researchers at #OxfordUniversity looking for young people (aged 14 to 25) to take part in an online study about self-confidence and experiences of feeling mistrustful of others. You need to live in the UK to participate. Learn more here: *[Link to electronic information sheet]*

Facebook message or online chat group text on message boards:

Dear XXX group/Facebook page,

Can you help us with #mentalhealthresearch? We are researchers at #OxfordUniversity looking for young people aged 14 to 25 and living in the UK to complete an online study about self-confidence and experiences of feeling mistrustful of others.

How we think and feel about ourselves shapes our interactions with the world. Together with young people who experience difficulties with trust and feeling safe around others, we have created a new questionnaire to measure how we think about ourselves.

In this study, we want to find out if this questionnaire is helpful in understanding how we think about ourselves and others. We hope this will be help us understand how best to help young people in the future.

If this is something that interests you, please follow the link to find out more: *[Link to electronic information sheet]*. Please feel free to contact me if you have questions. My email address is given on the Information Sheet.

With best wishes, Miriam

Appendix R - R.b

TDRP: Phase two measure validation – questionnaires

IRAS ID: 291160
Participant Identification Number: [Autofilled on Qualtrics Platform]
Date Completed: [Autofilled on Qualtrics Platform]

QUESTIONNAIRE MEASURES

1. Demographics Form

Information about you:

What is your age? _____

What is your gender? _____

What is your ethnicity?

- White – British
- White – Irish
- White – any other white background
- Black/Black British – Caribbean
- Black/Black British – African
- Black/Black British – any other black background
- Mixed – White and Black Caribbean
- Mixed – White and Black African
- Mixed – White and Asian
- Any other mixed background
- Asian/British Asian – Indian
- Asian/British Asian – Pakistani
- Asian/British Asian – Bangladeshi
- Asian/British Asian – any other Asian background
- Chinese
- Other (please state):_____

Have you ever experienced mental health difficulties?

- Yes
- No

Do you have any diagnosed mental health difficulties?

- Yes
- No

If yes, please select what diagnoses:

- Prefer not to say
- Anxiety
- Depression
- Psychosis
- Bipolar disorder
- Post-traumatic stress disorder
- Personality Disorder
- Obsessive Compulsive Disorder
- Anorexia
- Bulimia
- Substance use disorder / addiction
- Specific phobia
- Other: _____

Are you currently accessing support from a mental health service?

- Yes
- No

2. SoS 72-item pool (Appendix Q)

3. SoS-E 41-item pool (Appendix Q)

4. The Bird Checklist of Adolescent Paranoia (B-CAP)

This form is about worries you may have about other people. Please rate how often you have had each thought over the ***last two weeks.***

Statements	Never	Once	Couple of times	Few times a week	Every day	All the time
People at school are trying to make me feel unwanted	0	1	2	3	4	5
I'm sure people are gossiping about me on social media	0	1	2	3	4	5
I am being pushed out of conversations on purpose	0	1	2	3	4	5
My friends or partner are ignoring my messages to upset me	0	1	2	3	4	5
People are trying to embarrass me in class on purpose	0	1	2	3	4	5
People are making sly comments to upset me	0	1	2	3	4	5
I think people are lying to me on purpose	0	1	2	3	4	5
People say things under their breath to wind me up	0	1	2	3	4	5
Nasty tricks are being played on me	0	1	2	3	4	5
People are trying to confuse me on purpose	0	1	2	3	4	5
Groups of people are planning against me	0	1	2	3	4	5
People are collecting my information or photos to use against me	0	1	2	3	4	5
I'm sure people are seeking revenge on me	0	1	2	3	4	5
I feel like I am being followed or stalked	0	1	2	3	4	5
I am scared of what strangers will do to me	0	1	2	3	4	5
People will try to kidnap me	0	1	2	3	4	5
I could be attacked at any time	0	1	2	3	4	5
I feel unsafe around people everywhere I go	0	1	2	3	4	5

5. Brief Core Schema Scale (BCSS)

Questions on how you think about yourself and others

This questionnaire lists beliefs that people can hold about themselves and other people. Please indicate whether you hold each belief (NO or YES). If you hold the belief then please indicate how strongly you hold it by circling a number (1–4). Try to judge the beliefs on how you have generally, over time, viewed yourself and others. Do not spend too long on each belief. There are no right or wrong answers and the first response to each belief is often the most accurate.

Statement:		**How strongly you agree or disagree**			
Myself	**No/ Do not believe it**	**Believe it slightly**	**Believe it moderately**	**Believe it very much**	**Believe it totally**
I am unloved	0	1	2	3	4
I am worthless	0	1	2	3	4
I am weak	0	1	2	3	4
I am vulnerable	0	1	2	3	4
I am bad	0	1	2	3	4
I am a failure	0	1	2	3	4
I am respected	0	1	2	3	4
I am valuable	0	1	2	3	4
I am talented	0	1	2	3	4
I am successful	0	1	2	3	4
I am good	0	1	2	3	4
I am interesting	0	1	2	3	4
Other people					
Other people are hostile	0	1	2	3	4
Other people are harsh	0	1	2	3	4
Other people are unforgiving	0	1	2	3	4
Other people are bad	0	1	2	3	4
Other people are devious	0	1	2	3	4
Other people are nasty	0	1	2	3	4
Other people are fair	0	1	2	3	4
Other people are good	0	1	2	3	4
Other people are trustworthy	0	1	2	3	4
Other people are accepting	0	1	2	3	4
Other people are supportive	0	1	2	3	4
Other people are truthful	0	1	2	3	4

6. The Rosenberg Self-Esteem Scale (RSES)

Below is a list of statements dealing with your general feelings about yourself. Please indicate how strongly you agree or disagree with each statement.

Statement	How strongly you agree or disagree			
On the whole, I am satisfied with myself	Strongly Agree	Agree	Disagree	Strongly Disagree
At times I think I am no good at all	Strongly Agree	Agree	Disagree	Strongly Disagree
I feel that I have a number of good qualities	Strongly Agree	Agree	Disagree	Strongly Disagree
I am able to do things as well as most other people	Strongly Agree	Agree	Disagree	Strongly Disagree
I feel I do not have much to be proud of	Strongly Agree	Agree	Disagree	Strongly Disagree
I certainly feel useless at times	Strongly Agree	Agree	Disagree	Strongly Disagree
I feel that I'm a person of worth, at least on an equal plane with others	Strongly Agree	Agree	Disagree	Strongly Disagree
I wish I could have more respect for myself	Strongly Agree	Agree	Disagree	Strongly Disagree
All in all, I am inclined to feel that I am a failure	Strongly Agree	Agree	Disagree	Strongly Disagree
I take a positive attitude toward myself	Strongly Agree	Agree	Disagree	Strongly Disagree

7. Social Comparison Scale (SCS)

Please circle a number at a point which best describes the way in which you see yourself in **comparison to others**. For example: Short 1 2 3 4 5 6 7 8 9 10 Tall

If you put a mark at 3 this means you see yourself as shorter than others; if you put a mark at 5 (middle) about average; and a mark at 7 somewhat taller.

In relationship to others I feel:											
Inferior	1	2	3	4	5	6	7	8	9	10	Superior
Incompetent	1	2	3	4	5	6	7	8	9	10	More Competent
Unlikeable	1	2	3	4	5	6	7	8	9	10	More likeable
Left out	1	2	3	4	5	6	7	8	9	10	Accepted
Different	1	2	3	4	5	6	7	8	9	10	Same
Untalented	1	2	3	4	5	6	7	8	9	10	More talented
Weaker	1	2	3	4	5	6	7	8	9	10	Stronger
Unconfident	1	2	3	4	5	6	7	8	9	10	More confident
Undesirable	1	2	3	4	5	6	7	8	9	10	More desirable
Unattractive	1	2	3	4	5	6	7	8	9	10	More attractive
An outsider	1	2	3	4	5	6	7	8	9	10	An insider

8. The Patient Health Questionnaire-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?

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

9. Specific Psychotic Experiences Questionnaire - Hallucinations (SPEQ-H)

These questions relate to a wide variety of experiences and perceptions. Some of these may be relevant to you and some will not be, but please try to respond to every statement. There are no right or wrong answers. Please rate ***how frequently*** you have the following experiences.

Statements	Not at all	Rarely	Once a month	Once a week	Several times a week	Daily
Hear sounds or music that people near you don't hear?	0	1	2	3	4	5
See things that other people cannot?	0	1	2	3	4	5
Feel that someone is touching you, but when you look nobody is there?	0	1	2	3	4	5
Hear noises or sounds when there is nothing about to explain them?	0	1	2	3	4	5
Detect smells which don't seem to come from your surroundings?	0	1	2	3	4	5
See shapes, lights, or colors even though there is nothing really there?	0	1	2	3	4	5
Notice smells or odors that people next to you seem unaware of?	0	1	2	3	4	5
Experience unusual burning sensations or other strange feelings in or on your body that can't be explained?	0	1	2	3	4	5
Hear voices commenting on what you're thinking or doing?	0	1	2	3	4	5

10. Specific Psychotic Experiences Questionnaire - Grandiosity (SPEQ-G)

Please rate the following statements according to how much they apply to you, based on your thoughts and feelings over ***the last month***.

Statements	Not at all	Somewhat	A great deal	Completely
I am, or am destined to be, someone very important	0	1	2	3
Everyone is going to know about me because of my greatness	0	1	2	3
I am a very special or unusual person	0	1	2	3
I am much more unique than anyone else	0	1	2	3
I have special abilities that others do not	0	1	2	3
Everything I do is great	0	1	2	3
I have many great ideas	0	1	2	3
I have a special mission	0	1	2	3

Appendix R - R.c

Phase two debrief page

Presented at the beginning of online survey:

Chief Investigator: Miriam Kirkham
Email: Miriam.kirkham@hmc.ox.ac.uk

Before you Start

Seeking a safe space to talk? The Samaritans are free to call, day or night, on 116 123

Advice and Support

The NHS can help if you think you are experiencing mental health difficulties and are seeking support. There are also many charities who can provide advice, emotional and practical support. If you are concerned about your mental health, we encourage you to speak to a close family member or friend, and your GP who can then refer you for further help.

Sources of advice and support

- Your General Practitioner
- NHS 111
- Helplines:
    - The Samaritans 116 123
    - SANE 0300 304 7000 or http://www.sane.org.uk/

Presented at the end of the online survey:

Chief Investigator: Miriam Kirkham
Email: Miriam.kirkham@hmc.ox.ac.uk

Debrief Page

Seeking a safe space to talk? The Samaritans are free to call, day or night, on 116 123

Thank you for taking part in this study, we really appreciate your help!

We will ask some participants to complete one questionnaire again one week from today, this will take 5 minutes. This is optional and you may or may not be invited to do this. Please tick the box if you are happy to do this. ☐

- If yes please provide your email or mobile number: _____

Please tick this box if you would like to receive a summary of the research findings at the end of the study. This may be a while after you have taken part. ☐

- If yes please provide your email or mobile number: _____

Further Questions?

If you have any questions about the study please feel free to contact a member of the research team:

Miriam Kirkham (Trainee Clinical Psychologist)
Email: Miriam.Kirkham@hmc.ox.ac.uk, Telephone number: 07547 709650

Dr Felicity Waite (Clinical Psychologist and Supervisor)
Email: Felicity.Waite@sjc.ox.ac.uk, Telephone number: 01865 618192

Dr Ciorsdan Anderson (Clinical Psychologist and Supervisor)
Email: Ciorsdan.Anderson@hmc.ox.ac.uk, Telephone number: 01865 226 431

Advice and Support
The NHS can help if you think you are experiencing mental health difficulties and are seeking support. There are also many charities who can provide advice, emotional and practical support. If you are concerned about your mental health, we encourage you to speak to a close family member or friend, and your GP who can then refer you for further help.

Sources of advice and support

- Your General Practitioner
- NHS 111

- Helplines:
    - The Samaritans 116 123
    - SANE 0300 304 7000 or http://www.sane.org.uk/

Do you know someone who might want to take part?

If you know anyone who may like to participate in this study, you are welcome to provide them with the study link:

Aged 16 to 25: *[Link]*
Aged 14 to 15? A parent or carer will first need to give consent using this link: *[Link]*

Appendix S

TDRP: Sample size determination

Phase 1: Qualitative interviews

A sample of 12 young people will be recruited to allow for an in-depth analysis of the data and yield important insights into the self-concept of young people experiencing paranoia from a range of perspectives (e.g. range of age, gender, and mental health presentations). This is similar to recent studies that have used comparable methodology to create a measure of cognitions in populations experiencing paranoia (Černis et al., 2020). We anticipate that data saturation may not be 'achievable' with reference to critical discussions on the concept of a saturation point (Braun, & Clarke, 2021). It is proposed that a sample of 12 provides sufficient sample size to address the aims of this study in a meaningful way.

Phase 2: Measure validation

Literature examining the sample sizes used to validate newly developed measures indicates that 90% of studies have a sample size greater than or equal to 100 (Anthoine et al., 2014), however recommendations are variable. It is recommended for factor analyses that the subject-to-item ratio is used to determine sample size with a minimum ratio of 5:1 (Bryant & Yarnold, 1995; Suhr, 2006). Therefore, minimum sample size required for EFA and CFA was 720 for the SoS, and 410 for the SoS-E.

Test-re-test

A minimum sample of 55 young people will be recruited from the participant pool in Phase 2 to determine test-re-test reliability of new measures, by repetition of data collection at a second time point (1-week later). Minimum sample size is based on a calculation paper of Intraclass Correlation Coefficients (ICCs) by Walter, Eliasziw, and Donner (1998) and using the following parameters: Minimum acceptable reliability (ICC) ($\rho 0$): 0.6, expected reliability (ICC) ($\rho 1$): 0.8, significance level (α): 0.05 (two-tailed), power ($1 - \beta$): 80%, number of repetitions per subject (k): 2, expected dropout rate: 10%.

Appendix T

TDRP: Recommended thresholds for good model fit (Hu and Bentler, 1999)

Fit index	Recommended thresholds
Chi square ratio	< 3 = good
Comparative fit index (CFI)	> 0.9 = acceptable > 0.95 = good
Tucker-Lewis index	> 0.9 = acceptable > 0.95 = good
Root mean square error of approximation (RMSEA)	< 0.10 = acceptable < 0.06 = good
Standardised root mean square residual (SRMR)	< 0.06 = good

Appendix U

TDRP: Demographics of online validation sample

Demographics	Total sample completed SoS (*n*=1200)	Total sample completed SoS-E (*n*=1104)	Total sample completed all measures (*n*=937)
Age (years)			
14	38 (3.2%)	34 (3.1%)	25 (2.7%)
15	99 (8.3%)	92 (8.3%)	76 (8.1%)
16	306 (25.5%)	276 (25.0%)	230 (24.5%)
17	392 (32.7%)	361 (32.7%)	303 (32.3%)
18	60 (5%)	56 (5.1%)	48 (5.1%)
19	66 (5.5%)	61 (5.5%)	53 (5.7%)
20	51 (4.3%)	45 (4.1%)	39 (4.2%)
21	35 (2.9%)	32 (2.9%)	28 (3.0%)
22	33 (2.8%)	32 (2.9%)	27 (2.9%)
23	47 (3.9%)	44 (4.0%)	44 (4.7%)
24	34 (2.8%)	33 (3.0%)	27 (2.9%)
25	39 (3.3%)	38 (3.4%)	37 (3.9%)
Gender			
Female	855 (71.3%)	785 (71.1%)	646 (70.4%)
Male	188 (15.7%)	174 (15.8%)	141 (15.4%)
Non-binary	94 (7.8%)	86 (7.8%)	78 (8.5%)
Genderfluid	18 (1.5%)	15 (1.4%)	13 (1.4%)
Agender	8 (0.7%)	8 (0.7%)	8 (0.9%)
Trans (masculine/ feminine)	21 (1.8%)	20 (1.8%)	17 (1.9%)
Prefer not to say	16 (1.3%)	16 (1.4%)	14 (1.5%)
Ethnicity			
White British	786 (65.5%)	728 (65.9%)	624 (52%)
White Irish	15 (1.3%)	15 (1.4%)	12 (1.0%)
White-Any other background	124 (10.3%)	109 (9.9%)	93 (7.8%)
Black British-Caribbean	10 (0.8%)	8 (0.7%)	8 (0.7%)
Black British-African	22 (1.8%)	22 (2.0%)	18 (1.5%)
Black British-Any other background	3 (0.3%)	2 (0.2%)	1 (0.1%)
Mixed White and Black Caribbean	7 (0.6%)	7 (0.6%)	5 (0.4%)
Mixed White and Black African	11 (0.9%)	10 (0.9%)	9 (0.8%)
Mixed White and Asian	33 (2.8%)	30 (2.7%)	27 (2.3%)
Any other mixed background	20 (1.7%)	18 (1.6%)	15 (1.3%)
Asian British-Indian	43 (3.6%)	40 (3.6%)	34 (2.8%)
Asian British-Pakistani	31 (2.6%)	27 (2.4%)	24 (2.0%)
Asian British-Bangladeshi	13 (1.1%)	11 (1.0%)	9 (0.8%)
Asian British-Other Asian background	37 (3.1%)	34 (3.1%)	25 (2.1%)
Chinese	27 (2.3%)	26 (2.4%)	20 (1.7%)
Other	18 (1.5%)	17 (1.5%)	13 (1.1%)

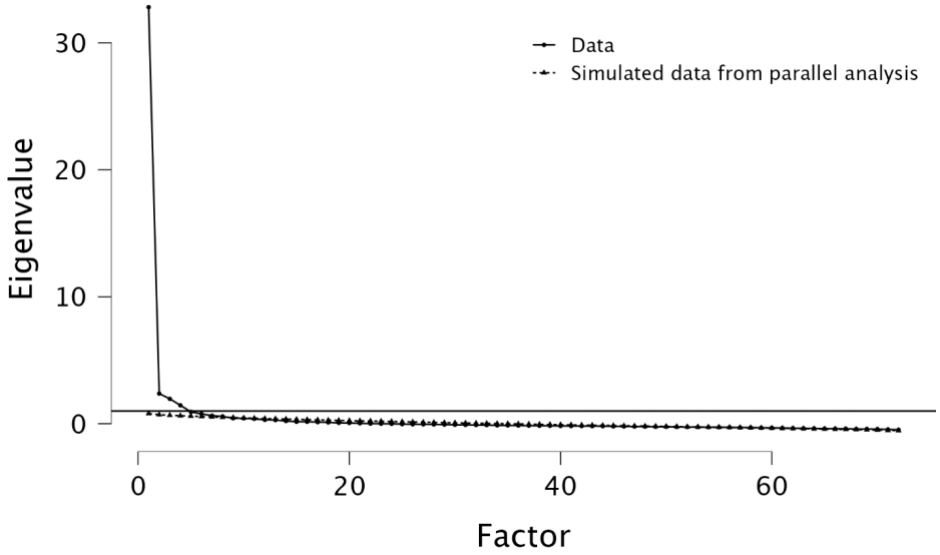
Appendix V - V.a

TDRP: Decisions in EFA for the SoS

It was important when revising the questionnaire to refer constantly to the original research questions that were being addressed and retain items that were thought to reflect the underlying theoretical domains of the questionnaire. An initial 8-factor structure was suggested in EFA using principal axis factoring with oblique rotation. Examination of the scree plot indicated a possible 4 or 5 factor structure. On examination of the 8-factor solution, 3 factors had one or two items only with low loadings, and EFA was conducted with these factors removed, using a manual input of 5 factors. In this model, 1 factor had three items, all of which had higher loadings on different factors, therefore was removed and a 4-factor model run. This appeared a good fit for the data, all factors had 7 or more items with loadings above 0.4.

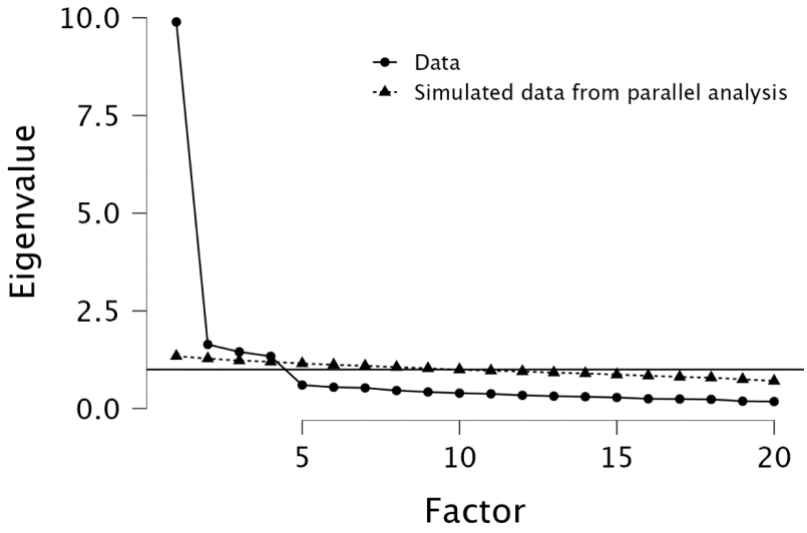
Nine items were removed as they did not load on a factor and were not deemed necessary to retain from visual inspection (8, 9, 15, 16, 22, 39, 55, 62, 72). Once removed, an additional item did not load above 0.4 on any factor and was removed (40). Items typically had cross-loadings across factors, which is unsurprising given the theoretical underpinning that negative self-beliefs are highly related. Items were retained if they had a distinct loading on one factor compared to loadings on all others. Items which did not demonstrate a difference of 0.20 between their primary and alternative factor loadings (Howard, 2015) were considered for removal. Applying this rule and considering theoretical consistency with the factor, items were removed (2, 3, 4, 7, 12, 14, 18, 19, 21, 23, 24, 25, 26, 28, 30, 31, 34, 35, 45, 47, 49, 50, 51, 52, 58, 59, 60, 65, 66, 68, 70). Items which appeared redundant were also removed (11, 20, 33, 41, 56, 67). To create a brief questionnaire, items with weaker factor loadings on their primary factor were removed (13, 17, 46, 57, 64). This led to a 20-item measure.

Scree plot (72-item pool for SoS)



Scree Plot (20-item, 4-factor solution SoS):

Scree plot



Factor Characteristics of the 20-item, 4-factor solution SoS:

Factor Characteristics

	Unrotated solution			Rotated solution		
	SumSq. Loadings	Proportion var.	Cumulative	SumSq. Loadings	Proportion var.	Cumulative
Factor1	9.559	0.478	0.478	5.431	0.272	0.272
Factor2	1.283	0.064	0.542	2.902	0.145	0.417
Factor3	1.108	0.055	0.597	2.379	0.119	0.536
Factor4	1.003	0.050	0.648	2.240	0.112	0.648

SoS CFA Model Output (RStudio):

```
Estimator                                      ML
  Optimization method                      NLMINB
  Number of model parameters                   46

  Number of observations                      600

Model Test User Model:
                                      Standard      Robust
  Test Statistic                       442.301     377.859
  Degrees of freedom                       164         164
  P-value (Chi-square)                   0.000       0.000
  Scaling correction factor                          1.171
      Yuan-Bentler correction (Mplus variant)

Model Test Baseline Model:

  Test statistic                      7915.374    6531.881
  Degrees of freedom                       190         190
  P-value                                0.000       0.000
  Scaling correction factor                          1.212

User Model versus Baseline Model:

  Comparative Fit Index (CFI)            0.964       0.966
  Tucker-Lewis Index (TLI)               0.958       0.961

  Robust Comparative Fit Index (CFI)                 0.967
  Robust Tucker-Lewis Index (TLI)                    0.962

Loglikelihood and Information Criteria:

  Loglikelihood user model (H0)         -16655.760  -16655.760
  Scaling correction factor                          1.045
    for the MLR correction
  Loglikelihood unrestricted model (H1) -16434.610  -16434.610
  Scaling correction factor                          1.143
    for the MLR correction

  Akaike (AIC)                        33403.521   33403.521
  Bayesian (BIC)                      33605.779   33605.779
  Sample-size adjusted Bayesian (BIC) 33459.742   33459.742

Root Mean Square Error of Approximation:

  RMSEA                                  0.053       0.047
  90 Percent confidence interval - lower 0.047       0.041
  90 Percent confidence interval - upper 0.059       0.052
  P-value RMSEA <= 0.05                  0.185       0.831
```

Robust RMSEA	0.050
90 Percent confidence interval - lower	0.044
90 Percent confidence interval - upper	0.057

Standardized Root Mean Square Residual:

SRMR	0.040	0.040

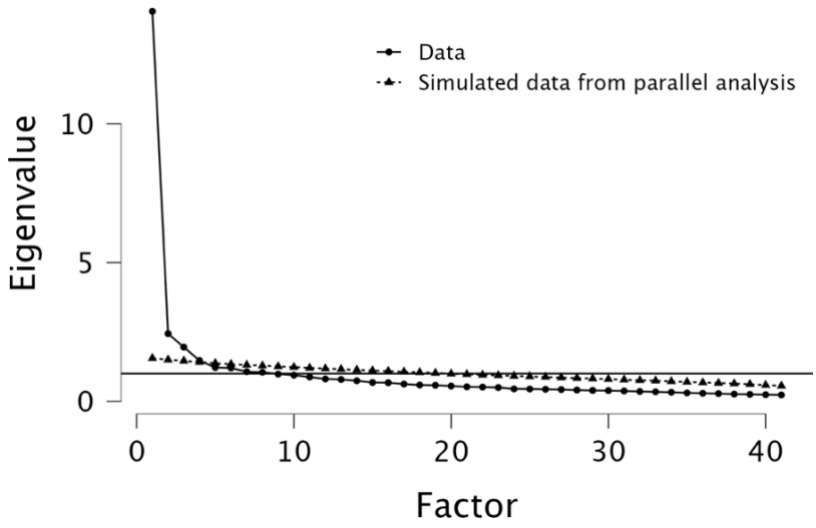
Appendix V - V.b

TDRP: Decisions in EFA for the SoS-E

The Kaiser-Meyer-Olkin measure of sampling adequacy was .937, Bartlett's test of sphericity was significant ($\chi^2(820.00)=9769.435$, $p<.001$), and communalities for all items were ≥.30. With these conditions satisfied, adequate common variance was assumed, and factor analysis considered appropriate.

An initial 9-factor structure was suggested in EFA using principal axis factoring with oblique rotation. The scree plot was ambiguous and indicated a possible 6 to 9 factor structure. One item had a negative loading on factor 7, with no positive factor loadings, and was removed (31). Ten items were removed as they did not load onto any factors >.4 and were not deemed necessary from visual inspection (6, 11, 22, 25, 27, 33, 35, 36, 37, 41). After removal, additional items did not load onto any factor >.4 and were removed (14, 21, 24, 30). Items were retained based on distinct loading on one factor compared to loadings on others. Items which did not demonstrate a difference of .20 between their primary and alternative factor loadings (Howard, 2016) were considered for removal. Applying this rule and considering theoretical consistency with the factor led to the removal of further items (4, 5, 8, 13, 16, 23, 38, 40). This resulted in 18-item measure. Parallel analysis suggested a 7-factor solution at this point in the analysis and explained 56.8% of the variance.

Supporting figure: scree plot (41-item SoS-E)



Supporting table: factor characteristics in EFA (18-item SoS-E, 7-factor solution)

Factor Characteristics

	Unrotated solution			Rotated solution		
	SumSq. Loadings	**Proportion var.**	**Cumulative**	**SumSq. Loadings**	**Proportion var.**	**Cumulative**
Factor 1	5.354	0.297	0.297	2.178	0.121	0.121
Factor 2	1.205	0.067	0.364	1.557	0.086	0.207
Factor 3	1.053	0.058	0.423	1.558	0.087	0.294
Factor 4	0.806	0.045	0.468	1.439	0.080	0.374
Factor 5	0.661	0.037	0.504	1.275	0.071	0.445
Factor 6	0.598	0.033	0.538	1.060	0.059	0.504
Factor 7	0.541	0.030	0.568	1.150	0.064	0.568

SoS-E CFA Model Output (RStudio):

Estimator	ML
Optimization method	NLMINB
Number of model parameters	57
Number of observations	552

Model Test User Model:

	Standard	Robust
Test Statistic	269.305	249.886
Degrees of freedom	114	114
P-value (Chi-square)	0.000	0.000
Scaling correction factor		1.078
Yuan-Bentler correction (Mplus variant)		

Model Test Baseline Model:

Test statistic	3806.673	3434.059
Degrees of freedom	153	153
P-value	0.000	0.000
Scaling correction factor		1.109

User Model versus Baseline Model:

Comparative Fit Index (CFI)	0.957	0.959
Tucker-Lewis Index (TLI)	0.943	0.944
Robust Comparative Fit Index (CFI)		0.960
Robust Tucker-Lewis Index (TLI)		0.946

Loglikelihood and Information Criteria:

Loglikelihood user model (H0)	-13521.498	-13521.498
Scaling correction factor for the MLR correction		1.071
Loglikelihood unrestricted model (H1)	-13386.846	-13386.846
Scaling correction factor for the MLR correction		1.076
Akaike (AIC)	27156.997	27156.997
Bayesian (BIC)	27402.869	27402.869
Sample-size adjusted Bayesian (BIC)	27221.926	27221.926

Root Mean Square Error of Approximation:

RMSEA	0.050	0.046
90 Percent confidence interval - lower	0.042	0.039
90 Percent confidence interval - upper	0.057	0.054
P-value RMSEA <= 0.05	0.515	0.773
Robust RMSEA		0.048
90 Percent confidence interval - lower		0.040
90 Percent confidence interval - upper		0.056

Standardized Root Mean Square Residual:

SRMR	0.038	0.038

Appendix W

Correlations (Spearman's Rho) of SoS and SoS-E total scores and subscales

Variable	SoS total	1	2	3	4	SoS-E total	1	2	3	4	5	6
SoS total (Negative sense-of-self)	-											
1. Not good enough	0.905	-										
2. Bad	0.719	0.552	-									
3. Broken	0.806	0.613	0.512	-								
4. An outcast	0.749	0.555	0.444	0.534	-							
SoS-E total (Evidence for negative self)	0.817	0.745	0.588	0.617	0.674	-						
1. Thought processes	0.730	0.673	0.502	0.627	0.533	0.820	-					
2. Ability to achieve	0.500	0.515	0.356	0.332	0.357	0.660	0.491	-				
3. Negative impact on others	0.480	0.394	0.600	0.339	0.304	0.557	0.398	0.324	-			
4. Disliked/ rejected by others	0.618	0.513	0.425	0.508	0.587	0.707	0.463	0.310	0.368	-		
5. Avoidance of others	0.348	0.337	0.162	0.220	0.403	0.582	0.330	0.232	0.105*	0.260	-	
6. Reliance on others	0.412	0.404	0.300	0.302	0.310	0.576	0.427	0.417	0.243	0.237	0.150	-
7. Change self to fit in	0.567	0.494	0.417	0.399	0.551	0.704	0.473	0.398	0.360	0.464	0.332	0.303

Note. All correlations significant at the threshold $p < .001$, with the exception of SoS-E Avoidance of others and SoS-E Negative impact on others (*$p = .001$)

Appendix X - X.a

TDRP - University of Oxford Sponsorship

RESEARCH SERVICES
Clinical Trials and Research Governance
Joint Research Office
Boundary Brook House
Churchill Drive
Headington, Oxford
OXON
OX3 7GB

To whom it may concern Date: 05/07/2021

Dear Sir/Madam,

Title: Self-Concept in Young People with Paranoia: Development of an Assessment Tool. PID: 15606 Protocol Date 19TH April 2021/Version:1.0

The above study has been designed by Ms Miriam Kirkham and colleagues at the University of Oxford and funded by the Oxford Institute of Clinical Psychology Training. I confirm that the University will accept the role of Research Sponsor of this Study and will comply with the requirements of the UK Policy Framework for Health and Social Care Research October 2017.

Insurance-provided indemnity arrangements are in place for the project: Newline Underwriting Management Ltd., at Lloyd's of London.

Sponsorship is confirmed subject to the condition that the following are sent to Clinical Trials and Research Governance for review prior to submission to the Research Ethics Committee. Failure to do so may compromise insurance cover for the project.

- Any minor or substantial amendments
- Any extension to the study end date
- Addition of any new research site or patient identification centre

In addition, annual progress reports, the end of study notification and final report must be copied to Clinical Trials and Research Governance.
Lastly, where they exist, University Core SOPs must be followed by default for all clinical research sponsored by the University. Further information can be found here: https://researchsupport.admin.ox.ac.uk/ctrg/resources

Any communications relating to Research Sponsorship should be directed to the undersigned.

Yours faithfully
Nigel Wellman



Senior Clinical Research Support Manager

Tel: +44 (0)1865 616480 Email: https://researchsupport.admin.ox.ac.uk/contacts/ctrg

Appendix X - X.b

TDRP: NHS ethics approval letter



South West - Frenchay Research Ethics Committee
Ground Floor
Temple Quay House
2 The Square
Bristol
Email: frenchay.rec@hra.nhs.uk
BS1 6PN

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

07 September 2021

Miss Miriam Kirkham
Trainee Clinical Psychologist
Oxford Health NHS Foundation Trust
Oxford Institute of Clinical Psychology Training & Research
Isis Education Centre, Warneford Hospital
Oxford
OX3 7JX

Dear Miss Kirkham

Study title:	**Self-Concept in Young People with Paranoia: Development of an Assessment Tool**
REC reference:	**21/SW/0100**
Protocol number:	**000000**
IRAS project ID:	**291160**

Thank you for your correspondence, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and lead reviewer.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registratio n-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-respo nsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.
Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-sum maries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Phase 2_Social Media Recruitment Materials_Text and Images]	V1.1	23 August 2021
Copies of materials calling attention of potential participants to the research [Track changes_Phase 2_Social Media Adverts]	V1.1	23 August 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Schedule of Insurance]	V1.0	05 July 2021
Interview schedules or topic guides for participants [Phase 1_Topic Guide]	V1.0	24 July 2021
IRAS Application Form [IRAS_Form_12072021]		12 July 2021
Letter from sponsor [Signed Sponsor Letter]	V1.0	05 July 2021
Non-validated questionnaire [Phase 1_Demographics Form]	V1.0	19 April 2021
Other [Phase 1_Withdrawal Form]	V1.0	19 April 2021
Other [Phase 2 and 3_Online Debrief Text]	V1.1	23 August 2021
Other [Phase 2 and 3_Start Debrief Page]	V1.0	23 August 2021
Other [Ethical Review Response from CI]	V1.0	24 August 2021
Participant consent form [Phase 1_Parent/ Carer Consent Form]	V1.0	19 April 2021

Participant consent form [Phase 1_Parent/Carer_Remote Consent Form]	V1.0	14 June 2021
Participant consent form [Phase 2_16 to 25_Remote Consent Form]	V1.0	14 June 2021
Participant consent form [Phase 1_15 and under_Assent Form]	V1.1	23 August 2021
Participant consent form [Phase 1_15 and under_Remote Assent Form]	V1.1	23 August 2021
Participant consent form [Phase 1_16 to 25_Remote Consent Form]	V1.1	23 August 2021
Participant consent form [Phase 2_Parent/Carer_Consent Form]	V1.1	23 August 2021
Participant consent form [Phase 2_15 and Under_Assent Form]	V1.1	23 August 2021
Participant consent form [Phase 2_16 to 25_Consent Form]	V1.1	23 August 2021
Participant information sheet (PIS) [Phase 2_Parent/ Carer_PIS]	V1.0	19 April 2021
Participant information sheet (PIS) [Phase 2_15 and Under_PIS]	V1.0	24 July 2021
Participant information sheet (PIS) [Phase 2_16 to 25_PIS]	V1.0	24 July 2021
Participant information sheet (PIS) [Phase 1_PIS Parent/ Carer]	V1.1	23 August 2021
Participant information sheet (PIS) [Track changes_Phase 1_PIS Parent/ Carer]	V1.1	23 August 2021
Participant information sheet (PIS) [Phase 1_PIS 15 and under]	V1.1	23 August 2021
Participant information sheet (PIS) [Track changes_Phase 1_PIS 15 and under]	V1.1	23 August 2021
Participant information sheet (PIS) [Phase 1_PIS 16 to 25]	V1.1	23 August 2021
Participant information sheet (PIS) [Track changes_Phase 1_PIS 16 to 25]	V1.1	23 August 2021
Research protocol or project proposal [Study Protocol]	V1.1	23 August 2021
Summary CV for Chief Investigator (CI) [CI Research CV]	V1.0	19 April 2021
Summary CV for supervisor (student research) [Supervisor CV_FW]	V1.0	19 April 2021
Summary CV for supervisor (student research) [Supervisor CV_CA]	V1.0	19 April 2021
Summary CV for supervisor (student research) [Supervisor CV]	V1.0	20 July 2021
Validated questionnaire [Phase 1_Questionnaire Measure]	V1.0	19 April 2021
Validated questionnaire [Phase 2_Validated Questionnaire Measures]	V1.1	23 August 2021
Validated questionnaire [Track changes_Phase 2_Questionnaire Measures]	V1.1	23 August 2021

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 291160 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. V. Swift

Mr Stephen Draper Chair

Email: frenchay.rec@hra.nhs.uk

Copy to: Carol Cornelius

Lead Nation England: approvals@hra.nhs.uk

Appendix X - X.c

TDRP: Oxford Health NHS Foundation Trust research and development

confirmation of capacity and capability

Professor Andrea Cipriani
Associate Director of Research & Development
Warneford Hospital
Warneford Lane
Oxford
OX3 7JX
Email: research@oxfordhealth.nhs.uk
18/11/2021

Confirmation of Capacity and Capability

Re: Self-Concept in Young People with Paranoia: Development of an Assessment Tool
Research and Development Reference: 15606
IRAS Reference: 291160
Research Ethics Committee Reference: 21/SW/0100
NIHR Portfolio Ref: N/A
Sponsor: University of Oxford

Dear Miriam,

On behalf of Oxford Health NHS Foundation Trust, I am pleased to confirm Trust Capacity and Capability for the above research as outlined in the application received.

The study is not supported by a Research Delivery Team.

The study team members are as follows: Miriam Kirkham, Ciorsdan Anderson and Felicity Waite.

Approved Documents

Protocol Version 1.1 dated 23/08/2021 is recognised as the most current to date.

The documents approved for use at this Trust are as listed in the following approval documents:
Health Research Authority Letter dated: 07/09/2021
Research Ethics Full Approval Letter dated: 07/09/2021

Any subsequent, relevant amendments are additionally included to date.

Metrics and Recruitment

First participant target date: 04/12/2021
Recruitment target figure: 24
Recruitment target date: 01/07/2022
Anticipated study end date: 30/09/2022

To comply with national research performance requirements the Trust will monitor and publish recruitment for your study:
1.Performance of the recruitment of the first participant.
2.Recruiting planned participants to time and target.

Reporting recruitment via Siteline

As confirmed during the study set-up study accruals will be recorded via Siteline. It was agreed that Miriam Kirkham will update the records at least one a month and no later than 7th of each month (e.g. by 7th August upload accruals for July etc.)

Should you feel at any time that you will be unable to realistically achieve your contracted recruitment target, please get in touch with the Research Team on research@oxfordhealth.nhs.uk as soon as possible.

Conditions of Approval

The following conditions apply to this approval:
a) The study is conducted in compliance with all the relevant legislation and the relevant OHFT policies.
b) All staff working on the study have the appropriate training and experience and have responsibilities formally delegated to them.
c) Should you plan to leave your position in OHFT, you will notify R&D immediately of your plans, to enable discussions around the future of study conduct.
d) The Trust expects the named Principal Investigator to allocate regular support time to the study; this must be agreed with the research team prior to the study commencing. This may be reviewed by R&D at any time.
e) All relevant documents will be maintained and will be sent to research@oxfordhealth.nhs.uk, to facilitate compliance checks, formal audits and regulatory inspections.
f) You will notify R&D via the email above of any protocol amendments.
g) You will promptly inform R&D via the email above of the end of the study.
h) You will respond in timely manner to R&D periodic checks email.

I wish you every success with the study.

Yours sincerely,



Professor Andrea Cipriani
Associate Director of Research & Development
Non-CTIMP C&C letter v4, July 2021

Appendix X - X.d

TDRP: Berkshire Healthcare NHS Foundation Trust research and development

confirmation of capacity and capability

Research & Development
Psychology Department
University of Reading
Whiteknights Road Earley RG6 6AL
t: **0118 378 5650** f: **0118 378 5705**
e: **research@berkshire.nhs.uk**

16th September 2021

Dear Miriam Kirkham

RE: CONFIRMATION OF CAPACITY AND CAPABILITY

Study Title: Self-Concept in Young People with Paranoia

BHFT REF: 2021-30 IRAS Project ID: 291160 Non- Portfolio study

I am pleased to confirm that Berkshire Healthcare NHS Foundation Trust (BHFT) has the capacity and capability to undertake the above named research study. This confirmation is dependent on formal approval from the HRA, which includes a favourable ethical opinion (where required) from a National Research Ethics Service Committee if applicable. The HRA approved documents should be provided to us, and where appropriate, all localised patient facing documents.

Berkshire Healthcare NHS Foundation Trust agrees to start this study on 17/09/2021 as previously discussed with you. This confirmation of capacity and capability is dependent on you and the sponsor commencing the study within 3 months from the date of this letter. If the study does not commence by 17/12/2021 then please notify the R&D office as the Trust position may have changed and this confirmation of capacity and capability may need to be reassessed. This study ends on 01/09/2022.

Recruitment

You are required to inform us the number of participants recruited on a monthly basis until the end of the study. The Trust's involvement in your study will end on 01/09/2022. Please provide us with the end of study report when you finish your study activities and do contact the R&D department should you have any concerns research@berkshire.nhs.uk

Access to NHS for Research Purposes

Completion of a Research Passport Application may be required for researchers who do not hold a substantive or honorary contract with an NHS organisation. Research activity should not take place at this site until either a Letter of Access or Honorary Research Contract has been issued for individuals where this applies. Please contact the R&D office to check if this is required.

Governance & Compliance

It is the Trust's expectation that the study will comply with all applicable and relevant laws, such as the General Data Protection Regulation (GDPR) May 2018, the Human Tissue Act (2004), the Mental Capacity Act (2005) and adheres to the UK Policy Framework for Health and Social Care Research (2018), the principles of (ICH) Good Clinical Practice (GCP) and the NHS Confidentiality Code of Practice (Nov 2003) and if applicable the Clinical Trial regulations.

Berkshire Healthcare Foundation Trust R&D Website

In order to comply with the UK Policy Framework for Health and Social Care Research (2018) and your ethical approval we will list your study on our Trust's website.

Please note that the Trust, as host organisation, is required to monitor research to ensure compliance with the UK Policy Framework and other legal and/or regulatory requirements and you may be asked to provide access to authorised individuals from the R&D office for monitoring or audit purposes.

In working with the Trust there is an expectation that the following are provided to the R&D office in a timely manner;

- date of first participant recruited
- ongoing recruitment figures
- copy of reports to the HRA/REC
- any substantial or non-substantial changes relevant to the BHFT
- final report on completion of the study
- any publications arising from the study
- immediate notification of changes in involvement of key site personnel

If you wish to discuss this further, please do not hesitate to

contact the R&D Office. Kind regards



Stephen Zingwe

Appendix X - X.e

TDRP: Amendment documentation

Amendment tool completed 28/02/2022

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Self-Concept in Young People with Paranoia			
IRAS project ID* (or REC reference if no IRAS project ID is available):	291160			
Sponsor amendment reference number*:	Amendment 1			
Sponsor amendment date* (enter as DD/MM/YY):	28 February 2022			
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	(1) As requested by REC, the questionnaires created in Study Phase 1 (qualitative interviews) are now submitted for approval, for use in Study Phase 2 (online validation of questionnaires). (2) Two additional items/ questions have been added to the demographics form. (3) Addition of screening tool for depression (PHQ-9). (4) Recruitment number for Study Phase 2 online validation altered to a minimum of 1000, and Phase 3 test re-test reliability to a sample of 100, due to the increased questionnaire length and sample size required for statistical analysis. (5) Change 4 sample sizes have been amended on the study Protocol.			
Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	**Yes**		No	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	**Yes**		No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		**No**	
Which nations had participating non-NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating non-NHS/HSC organisations after this amendment?	**Yes**	No	No	No

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1

Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	(1) Two new questionnaires created in Phase 1, this was a planned aspect of the research study and accounted for in study set-up. This is questionnaire 2 and 3 in the document: Phase 2_Questionnaire Measures_V2.0_28.02.2022_291160

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No

Remove all changes below

Change 2

Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	(2) Addition of two items to demographics form, this is not anticipated to have an impact on resources. This is located under '1. Information about you' in the document: Phase 2_Questionnaire Measures_V2.0_28.02.2022_291160

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No

Remove all changes below

Change 3

Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	(3) Addition of 9-item questionnaire (Patient Health Questionnaire-9) is not anticipated to have an impact on resources. This is questionnaire 8 in the document: Phase 2_Questionnaire Measures_V2.0_28.02.2022_291160

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No

Remove all changes below

Change 4

Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Other significant change to study design that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information In particular, please describe why this	(4) Alteration in minimum sample size of Phase 2 online recruitment to 1000, and Phase 3 to 100, to account for length of additional questionnaires and sample size needed for validation

change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	and test re-test reliability. Online recruitment will be advertised as planned in original submission, with no additional burden on participating sites. The protocol has been amended to reflect this and a tracked changes document submitted: Protocol_V2.0_28.02.2022_291160_Tracked Changes

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No

Remove all changes below

Change 5	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Protocol - Substantial changes (e.g. affecting safety or the scientific value of the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	(5) As reflected in study design change above, minimum sample is altered in Phase 2 to online recruitment of 1000, and Phase 3 to 100, to account for length of additional questionanires and sample size needed for validation and test re-test reliability. The protocol has been amended to reflect this change and a clean and tracked changes version submitted. This change is not expected to have an impact on the safety of the study. It is expected to improve the power of the study to draw conclusions about the new questionnaires psychometric properties, validity and reliability.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No

Add another change

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Carol Cornelius
Email address:*	carol.cornelius@admin.ox.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies																
UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	t Authority ledicines	t Authority evices		Assurance	vernance	A)			HCRW Approval	A)		:C)	oordinating function		Guardians		oordinating function

	REC	Competer MHRA - N	Competer MHRA - D	ARSAC	Radiation	UKSW Gc	REC (MC	CAG	HMPPS	HRA and	REC (AW	PBPP	SPS (RAE	National c	HSC REC	HSC Data	Prisons	National c	Category:
Change 1:	Y					Y				Y									C
Change 2:	Y					Y				Y									C
Change 3:	Y					Y				Y									C
Change 4:	Y					Y				Y									C
Change 5:	Y					Y				(Y)									A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y									
Notification only:	N					N				N									
Overall amendment type:	Substantial																		
Overall Category:	A																		

Amendment - NHS ethics approval

South West - Frenchay Research Ethics Committee
Ground Floor
Temple Quay House
2 The Square
Bristol
Email: frenchay.rec@hra.nhs.uk
BS1 6PN

Tel: 0207 104 8379

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

24 March 2022

Miss Miriam Kirkham
Oxford Institute of Clinical Psychology Training & Research
Isis Education Centre, Warneford Hospital
Oxford
OX3 7JX

Dear Miss Kirkham

Study title:	**Self-Concept in Young People with Paranoia: Development of an Assessment Tool**
REC reference:	**21/SW/0100**
Amendment number:	**Amendment 1**
Amendment date:	**28 February 2022**
IRAS project ID:	**291160**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [291160_Amendment 1_]		08 March 2022
Non-validated questionnaire [Phase 2_Questionnaire Measures_V2.0_28.02.2022_291160_Tracked Changes]	V2.0	28 February 2022
Non-validated questionnaire [Phase 2_Questionnaire Measures_V2.0_28.02.2022_291160]	V2.0	28 February 2022
Research protocol or project proposal [Protocol_V2.0_28.02.2022_291160_Tracked Changes]	V2.0	28 February 2022
Research protocol or project proposal [Protocol_V2.0_28.02.2022_291160]	V2.0	28 February 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-andimproving-research/learning/

IRAS Project ID - 291160:	**Please quote this number on all correspondence**

Yours sincerely



Mr Stephen Draper Chair

E-mail: frenchay.rec@hra.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Amendment – Correspondence with Approvals Administrator

From: frenchay.rec@hra.nhs.uk <noreply@harp.org.uk>
Date: Thursday, 24 March 2022 at 11:13
To: Miriam Kirkham <miriam.kirkham@hmc.ox.ac.uk>, CTRG Sponsorship Correspondence <ctrg@admin.ox.ac.uk>
Subject: IRAS PROJECT ID 291160, REC Reference 21/SW/0100 Confirmation of favourable opinion for substantial amendment

Dear Miss Kirkham

IRAS project ID:	291160
REC reference:	21/SW/0100
Short Study title:	Self-Concept in Young People with Paranoia - Version 1.0
Date complete amendment submission received:	08 March 2022
Amendment No./ Sponsor Ref:	Amendment 1
Amendment Date:	28 February 2022
Amendment Type:	**Substantial**
Outcome of HRA Assessment	**This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.**

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

HRA and HCRW Approval Status

As detailed above, **this email also constitutes HRA and HCRW Approval for the amendment**. No separate confirmation of HRA and HCRW Approval will be issued.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

If you require further information, please contact me.

Kind regards

Theodora Chortara
Approvals Administrator

Ground Floor | Temple Quay House | Health Research Authority | BS1 6PN
T. 0207 104 8379
E. frenchay.rec@hra.nhs.uk
W. www.hra.nhs.uk

South West - Frenchay Research Ethics Committee

Attendance at Sub-Committee of the REC in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Stephen Draper	Retired Head teacher	Yes	Chair
Ms Jaana Tuominen	Assistant Gynaecology Oncology MDT Coordinator	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Theodora Chortara	Approvals Administrator

References for Appendices

Please note: Only references from the appendices that are not previously reported in the section of main references are presented

Anthoine, E., Moret, L., Regnault, A., Sébille, V., & Hardouin, J. B. (2014). Sample size used to validate a scale: a review of publications on newly developed patient reported outcomes measures. *Health and quality of life outcomes*, *12*(1), 1-10.

Braun, V., & Clarke, V. (2021). To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. *Qualitative research in sport, exercise and health*, *13*(2), 201-216.

Černis, E., Bird, J. C., Molodynski, A., Ehlers, A., & Freeman, D. (2020). Cognitive appraisals of dissociation in psychosis: a new brief measure. *Behavioural and Cognitive Psychotherapy*, 1-13.

Walter, S.D., Eliasziw, M., & Donner, A. (1998). Sample size and optimal designs for reliability studies. *Statistics in medicine, 17*, 101-110.