The assessment of paranoia and paranoid intrusive thoughts across the continuum

of psychosis

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Declaration

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Abstract

Paranoid experiences can be understood to exist on continuum, ranging from those that cause little distress, to those that are highly distressing and impair functioning. Self-report questionnaires have enabled assessments of paranoid thought across this continuum; among both individuals with little experience of paranoia and among those whose paranoia has led to a diagnosis of psychosis. This thesis explores issues of self-report assessment of paranoid thinking. A systematic review was conducted of self-report measures of paranoia, validated for use with the general population. Nine questionnaires were identified that measured different constructs of paranoia, some specifically assessing paranoid thoughts either relating to more severe (e.g. thoughts about being persecuted) or less severe (e.g. thoughts that one is being spoken about) threats. Questionnaires that measured paranoid experiences ranging in severity, and assessed beliefs on different dimensions (e.g. distress, conviction), were considered the most comprehensive. However, no questionnaires assessed whether, in line with cognitive theory (Morrison, 2001), paranoid experiences can occur in the form of intrusive thoughts (ITs). Thus, the empirical section of this thesis reports the development of a self-report questionnaire to assess the frequency and associated distress of paranoid ITs. The questionnaire had good psychometric properties and was validated with participants who ranged across the paranoia continuum. Paranoid ITs were commonly experienced across the sample. Metacognitive beliefs about paranoid thoughts as dangerous and uncontrollable had the strongest association with more frequent, distressing paranoid ITs. Findings are discussed in relation to models of paranoia and the psychosis continuum. Clinical implications are proposed.

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Section one

A systematic review of self-report assessments of paranoia for use across the continuum of psychosis

Abstract

Objectives

To systematically appraise self-report measures of paranoia validated for use among the general population; considering how paranoia is defined (e.g. the severity of perceived threat assessed) and evidence for the questionnaires' psychometric properties. The study also aimed to review which measures were appropriate for use with clinical samples.

Design

A systematic literature search for studies reporting the validation of paranoia questionnaires was performed using PubMed, Web of Science, and PsychInfo databases. The study methodologies and psychometric properties of questionnaires were evaluated using COnsenus-based Standards for the selection of health-based Measurement Instruments appraisal tools (Mokkink et al., 2012).

Results

Twenty-five studies, describing the psychometric validation of nine paranoia/persecutory delusions measures, were identified. Two questionnaires assessed 'low-level' paranoia, whereas four assessed persecutory beliefs. The remaining questionnaires assessed paranoid thoughts encompassing both extremes. Some questionnaires also assessed the deservedness, pre-occupation, conviction, and distress associated with paranoia. Psychometric properties were sometimes additionally validated with clinical samples.

Conclusions

Questionnaires measuring a wider range of paranoid thoughts and dimensions such as pre-occupation, conviction and distress, offer the most comprehensive assessment of paranoia in both clinical and non-clinical populations. Many paranoia measures have limited, high quality evidence for their psychometric properties and therefore require further validation.

Practitioner Points

- Practitioners should select paranoia questionnaires that define paranoia appropriately and are reliable and valid.
- Questionnaires that measure a range of paranoid beliefs, and appraisals and distress, can assess a greater range of service users' experiences.

Limitations

- Freeman et al.'s (2005) paranoia hierarchy model was used to appraise how paranoia was defined within questionnaires, which influenced the interpretation of the reviewed measures.
- Non-English language papers were excluded, limiting the assessment of measures' cross-cultural validity.

Introduction

Paranoia has traditionally been conceptualised as a symptom of psychosisrelated diagnoses such as 'Schizophrenia' (American Psychiatric Association, 2013). However, increasing evidence shows that paranoid thoughts are also experienced by those without mental health difficulties (Freeman, 2006). As with other clinicallyrelevant experiences (e.g. obsessive-intrusive thoughts; Berry & Laskey, 2012; voice hearing; Beavan, Read, & Cartwright, 2011) paranoia is thought to exist on a continuum, ranging from fleeting thoughts commonly experienced across the population, to distressing 'persecutory delusions' (PDs) associated with psychosis (van Os, Linscott, Myin-Germeys, Delespaul, & Krabbendam, 2009). While paranoid thoughts at the upper end of the continuum are more likely to lead to psychosis-related diagnoses, paranoia for both clinical and non-clinical populations fluctuates in response to stressors and emotional state (Thewissen et al., 2011), suggesting that an individual's position on the continuum varies across time and situation.

What constitutes a 'paranoid' experience is not well defined. Research has often focused upon persecutory beliefs, defined as concerns about threats of current/ongoing harm to oneself, enacted by an intentional perpetrator (Freeman & Garety, 2000). However, Freeman et al. (2005) also identified paranoid thoughts relating to less severe threats of harm, such as ideas of reference and social evaluative concerns. Ideas of reference are such that "neutral events have special significance and refer to the individual personally" (Startup & Startup, 2005, p. 88) and social evaluative concerns are described as feelings of rejection or vulnerability (Freeman et al., 2005). Freeman et al. order these paranoid ideas in a hierarchy according to the severity of perceived threat, ranging from social evaluative concerns at the bottom, to extreme threats of harm at the top (Figure 1). Green et al. (2008) and Ibáñez-Casas et al. (2015) found that ideas of reference in social situations were the most commonly endorsed thoughts among the

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general population, whereas for clinical participants persecutory beliefs were most prevalent.



Figure 1. The paranoia hierarchy. Reprinted from "Psychological investigation of the structure of paranoia in the general population," by Freeman et al., 2005, *British Journal of Psychiatry*, 186, p. 427. Copyright 2001 by the Royal College of Psychiatrists. Reprinted with permission via PLSClear.

The hierarchy of perceived threat in paranoia may relate to the continuum of paranoid experience, with thoughts from the top hierarchy levels being more commonly experienced by those whose paranoia causes distress and impairs functioning. However, persecutory thoughts are also experienced among community samples (Green et al., 2008; Ibáñez-Casas et al., 2015; McKay, Langdon, & Coltheart, 2006; Van Dongen, Buck, Kool, & Marle, 2011) and one's position on the paranoia continuum is likely to be influenced by factors other than paranoid thought content alone. For example, paranoid thoughts that are more frequent, distressing, and appraised with more conviction and preoccupation are more common among clinical populations (Green et al., 2008; Ibáñez-Casas et al., 2015), and Peters, Joseph, Day, and Garety (2004) argue that the distress, conviction, and preoccupation associated with persecutory beliefs determine how 'delusion-like' they are. Alternatively, Trower and Chadwick (1995) distinguish 'poor me' paranoia, where persecution is perceived as unjust or undeserved, and 'bad me' paranoia, where persecution is perceived as a deserved consequence of an individual's actions. 'Poor me' paranoia is more common among those with psychosisrelated diagnoses (Melo & Bentall, 2013; Melo, Concoran, Shryane, & Bentall, 2009); thus an additional feature of paranoia at the upper end of the continuum may be that persecution is perceived as undeserved.

Much of our understanding of paranoia across the continuum comes from research using self-report questionnaires. However, within these questionnaires paranoia is defined and measured differently, which is likely to have influenced endorsement rates, and contributed towards the varying prevalence estimates for delusions and paranoid thoughts in the general population (Freeman, 2006). As persecutory thoughts are more common among clinical samples, and ideas of reference are more common among non-clinical samples (Green et al., 2008; Ibáñez-Casas et al., 2015), prevalence estimates are likely to be influenced by both the type of paranoid thought content from the hierarchy of severity (Freeman et al., 2005) that is being assessed, and the population to which the questionnaire is distributed to.

Aside from within large symptom inventories (e.g. Minnesota Multiphasic Personality Inventory-2 Restructured Form; Ben-Porath & Tellegen, 2011) there are no paranoia specific self-report measures that were developed primarily with clinical samples. Rather, diagnostic interview tools tend to be preferred (e.g. Composite Diagnostic Interview; Kessler, Andrews, Mroczek, Ustun, & Wittchen, 1998). However, validating questionnaires that were originally developed using general population samples with individuals with psychosis diagnoses has potential benefits. Psychotic-like experiences that occur without significant distress or impairment increase the later risk of symptoms that may warrant a clinical diagnosis (Hanssen, Bak, Bijl, Vollebergh, & van Os, 2005; Welham et al., 2009). Thus, assessing paranoia across the continuum could highlight variables that increase the likelihood of paranoia-related distress. Measures subsequently validated across the full continuum could also be used clinically to assess paranoia and monitor changes in the experience during interventions.

Aims

This review aims to critically evaluate existing self-report measures of paranoia that have been developed with general population samples, and consider the appropriateness of their subsequent validation with clinical populations. The construct of paranoia assessed within each measure is reviewed in relation to the proposed paranoia hierarchy (Freeman et al., 2005). Evidence for the psychometric properties of measures is also appraised, as this influences the meaningfulness of data produced using the questionnaires. Recommendations for research and clinical practice, in relation to previous paranoia research findings, are discussed.

Method

Search Strategy

A systematic search using PubMed, Web of Science, and PsychInfo databases was performed on January 4, 2017. Variants of terms for the construct of interest (paranoia), population for questionnaire development (general population), instrument type (questionnaire), and questionnaire properties (psychometric), were used to search the titles, abstracts, and keywords of publications. Papers containing keywords for comorbid difficulties associated with paranoia (e.g. dementia) were excluded. Appendix A lists search terms and how they were combined. Duplicate papers were removed from the search results. After abstract and title screening, papers that did not meet inclusion criteria were removed. The full text of remaining papers was screened, followed by an ancestry search of studies included after this stage. Database and ancestry searching was used to find papers pertaining to both the original development and subsequent psychometric validation of the identified questionnaires. A citation search using Google Scholar was also performed for studies documenting the initial development of each measure.

Inclusion Criteria

The following inclusion criteria were applied during screening:

- Studies must describe a *self-report* questionnaire.
- Studies must report the initial development of a questionnaire, or subsequent validation of at least one of the questionnaire's psychometric properties.
- Studies must assess psychometric properties outlined by Terwee, de Vet,
 Prinsen, and Mokkink (2011; Appendix B), or complete item-response theory analyses (Kean & Reilly, 2014), or latent class analyses (Dayton & Macready, 2006).
- All subscales of the questionnaires must assess constructs relating to paranoia, PDs, or other non-paranoid forms of delusions. Questionnaires measuring a range of delusions must have a specific PD subscale, and present psychometric data specifically relating to this subscale, rather than for the overall measure.
- In line with Freeman and Garety's (2000) definition of 'persecutory', the
 paranoia assessed must relate to fears of *present/ongoing harm* to the *self*. The
 severity of thought content assessed could reflect any part of the paranoia
 hierarchy (Freeman et al., 2005), from social evaluative concerns to persecutory
 ideation.

- Questionnaires must be validated among non-clinical samples. Studies using questionnaires with clinical samples were included only if the measure had previously been validated with a non-clinical sample, and was therefore being used across the continuum of psychosis.
- Studies must describe questionnaires developed to assess paranoia among adults (aged 18 +). However, articles describing questionnaires originally developed with adult populations, that were then applied to younger samples (aged 14 +), were included.
- Articles must be published in peer-review journals.
- Full articles must be available in English.

Exclusion Criteria

Papers were excluded if:

- Studies described observer/clinician rated assessments, or structured interview tools.
- The paranoia construct assessed did not relate to fears of ongoing harm to self. For example, if instead fears were about harm to society or specific social groups, caused by cultural phenomena (e.g. technology, climate).
- The paranoia subscale described was part of a larger questionnaire either measuring non-delusional elements of psychosis (e.g. voice hearing, negative symptoms), OR measuring various mental health difficulties (e.g. depression, personality disorder). Paranoia subscales were therefore only included if they were contained within specifically *paranoia*, or *delusion* questionnaires.
- Questionnaires solely measured cognitive biases involved in paranoia, or reactions to/appraisals of paranoid experiences.
- Questionnaires assessed paranoia solely in relation to another condition or difficulty thus not assessing paranoia distinctly, but its overlap with other

constructs. For example, dementia, Parkinson's disease, substance misuse, learning disability, paranoid personality disorder, or depression.

• Questionnaires assessed paranoia solely during childhood (< 18 years). Figure 2 illustrates the systematic search process.

Quality Appraisal

The COnsenus-based Standards for the selection of health-based Measurement Instruments (COSMIN) protocol for systematic reviews of self-report questionnaires (Terwee et al., 2011) was followed to appraise the psychometric properties of identified questionnaires.

Firstly, the quality of the *methodologies* used to assess psychometric properties was appraised (Appendix C). The COSMIN appraisal tool (Mokkink et al., 2012) assesses methodologies establishing the reliability (internal consistency, test-retest, and measurement error), validity (content/face, criterion, and construct validity – i.e. structural validity, hypothesis testing, and cross-cultural validity) and responsiveness of a measure, as well as methods involving item-response theory. For each applicable appraisal item, studies were rated 'poor', 'fair', 'good', or 'excellent' (Appendix C). The lowest item rating was taken to represent the overall methodological quality of analyses establishing that psychometric property (Terwee et al., 2012).

COSMIN definitions of psychometric properties (Appendix B) were followed. For example, while some studies claimed to evidence criterion validity by comparing clinical and non-clinical groups on their paranoia scores, COSMIN defines these analyses as assessing construct validity. If the methodology used to establish a psychometric property was cited within a different paper, where possible this was obtained and consulted for the required information (Appendix C for further details). The methodology for content validity was rated if a questionnaire was being validated for the first time, or with a new population (e.g. a new culture or clinical population).



Figure 2. A flow chart demonstrating the literature search conducted.

Secondly, the quality of the *psychometric properties* themselves was appraised, using an accompaniment to the COSMIN methodological checklist, which covered the same aspects of reliability, validity, and responsiveness (Terwee et al., 2011; Appendix B). Each psychometric property was assessed positively, negatively, or indeterminately. Standards included those such as Cronbach's alpha(s) being \geq .7, for positive internal consistency.

An overall rating for the strength of each psychometric property, for each questionnaire, was created by combining the *methodological quality appraisal score* for a psychometric property with ratings for the *quality of the psychometric property* itself (Appendix D). Evidence was rated as either positive (+) or negative (-), and could be 'strong' (+++ or ---), 'moderate' (++ or --), 'limited' (+ or -), 'conflicting' (+/-), 'unknown' (?), or 'indeterminate' (I). For example, strong positive evidence for a property was rated if there were consistent positive findings in studies of strong methodological quality. As COSMIN ratings only applied to psychometric properties that were assessed by a study, areas where there was no psychometric evidence were discussed in the narrative review.

A second, independent researcher conducted the quality appraisal procedure for studies (n = 7) relating to three paranoia questionnaires. Inter-rater reliability for thhe overall strength of evidence for psychometric properties was good (Kvalseth, 1989), with a Cohen's Kappa = .80.

Results

Twenty-six papers were identified that described psychometric properties of nine different paranoia-related questionnaires (Table 1). The Paranoia Scale (PS; Fenigstein & Vanable, 1992) and the Paranoia/Suspiciousness Questionnaire (PSQ; Rawlings & Freeman, 1996) measure commonly occurring paranoia among the general population, rather than so-called 'pathological' paranoia. The measures therefore best 12 assess the lower levels of Freeman et al.'s (2005) paranoia hierarchy. Conversely, the Persecutory Ideation Questionnaire (PIQ; McKay et al., 2006), Persecution and Deservedness Scale (PaDS; Melo et al., 2009), the Peters et al. Delusions Inventory (PDI; Peters, Joseph, & Garety, 1999), and the State Social Paranoia Scale (SSPS; Freeman et al., 2007) assess persecutory ideas, from the top levels of the paranoia hierarchy. The PaDS also assesses the perceived deservedness of persecution and the PDI assesses delusion-like qualities of persecutory ideas (conviction, pre-occupation, and distress). The final questionnaires, the Paranoia Checklist (PC; Freeman et al., 2005), State Paranoia Checklist (SPC; Schlier, Moritz, & Lincoln, 2016), and the Green et al. Paranoid Thoughts Scale (GPTS; Green et al., 2008), assess paranoia across the hierarchy, including ideas of reference and persecutory ideation.

The remaining 17 studies adapted versions of these measures or further validated their psychometric properties. Additional papers were retrieved for the PS (Barreto Carvalho et al., 2014; Combs, Penn, & Fenigstein, 2002; Smári, Stefánsson, & Thorgilsson, 1994), PSQ (Huppert, Smith, & Apfeldrof, 2002), PIQ (Jones, Fernyhough, de-Wit, & Meins, 2008; Van Dongen et al., 2011), PDI (Cella, Sisti, Rocchi, & Preti, 2011; Jones & Fernyhough, 2007; Jung et al., 2008; Lincoln, Ziegler, Lüllmann, Müller, & Rief, 2010; López-Ilundain, Pérez-Nievas, Otero, & Mata, 2006; Peters et al., 2004; Prochwicz & Gawęda, 2015; Rocchi et al., 2008; Verdoux et al., 1998), PC (Lincoln et al., 2010; Moritz, Quaquebeke, & Lincoln, 2012), and GPTS (Ibáñez-Casas et al., 2015). Lincoln et al. (2010) presented psychometric evaluations of both the PDI and the PC and findings were considered separately for each measure.

Table 1

Data extracted from included questionnaires

Study & location	Construct of paranoia/PDs	# items	Sample	Paranoia subscales	Psychometric properties
<u>PS</u>					
Fenigstein & Vanable (1992) [1] United States of America (USA)	'Normal', 'non- pathological' paranoia. Suspiciousness/assumptions of hostility reminiscent of clinical paranoia, occurring independent of psychiatric problems	20	Four different student samples, <i>n</i> ranged from 119 to 180		<i>IC.</i> All samples $\alpha \ge .81$ <i>R.</i> $r = .70$ ($n = 180$) <i>HT.</i> Negatively correlated with trust. Positively correlated with anger and belief in the control of powerful others <i>SV.</i> 1-factor structure explaining 25% of the variance ($N = 581$)
Smári et al. (1994) [2] Iceland		20	N = 30 Patients with schizophrenia diagnoses		<i>IC</i> . $\alpha = .87$ <i>HT</i> . Positively correlated with feeling of being watched and clinically assessed paranoia
Combs et al. (2002) [3] USA		20	n = 191 (non- Hispanic Whites) n = 102 (African- Americans) Students		<i>IC.</i> non-Hispanic Whites, $\alpha = .88$, African- Americans, $\alpha = .79$ <i>HT.</i> Groups differed similarly on the PS and clinical measurements of paranoia
Barreto Carvalho et al. (2014) [4] Portugal		20	N = 1218 Adolescent high school pupils aged 14 to 22	Mistrust thoughts (8-items), persecutory ideas (8-items), self-depreciation (3-items)	<i>IC</i> . $\alpha \ge .72$ for subscales <i>SV</i> . 3-factor structure explaining 46.6% of variance

(continued)

Study & location	Construct of paranoia/PDs	# items	Sample	Paranoia subscales Psychometric properties	
PSO Rawlings & Freeman (1996) [5] Australia	Paranoia/suspiciousness among the non-psychiatric population.	47	n = 264 (Sample 1) n = 297 (Sample 2) Students	Sample 1)InterpersonalIC. $\alpha = .87$ (total scale, $n = 297$), α ranged betweeSample 2)suspiciousness/hostility (12- items), negative mood/withdrawal (7-items), anger/impulsiveness (9-items), mistrust/wariness (6-items), perceived hardship/resentment (7-items) Six-items had no subscaleIC. $\alpha = .87$ (total scale, $n = 297$), α ranged betwee 64 to .89 for subscales ($N = 561$) $R. r = .82 (n = 74)$	
Huppert et al. (2002) [6] USA			n = 33 (patients with schizophrenia- related diagnoses) n = 46 (patients with anxiety/depression)		<i>IC.</i> Total scale $\alpha \ge .85$ for both samples <i>R.</i> $r = .67$ ($n = 23$) <i>HT.</i> Positively correlated with self-reported anxiety/depression for both samples
PIO McKay et al. (2006) [7] Australia	'Persecutory' ideation	10	n = 98 (students) n = 25 (patients with experience of PDs)		<i>IC.</i> α = .87 (students) and .90 (patients) <i>HT.</i> Positively correlated with PSQ scores. Correlation with observer-rated PDs among clinical participants
Jones et al. (2008) [8] United Kingdom (UK)		Reduce from 10 to 7- items	n = 183 (PIQ e- questionnaire) n = 188 (paper- version of PIQ) Students		<i>IC.</i> $\alpha \ge$ 84 for PIQ-7 and PIQ-10 (paper and online versions) <i>SV.</i> 1-factor structure, excluding three items from original measure, demonstrated with both samples
Van Dongen et al. (2011) [9] Holland		10	n = 269 (community sample) n = 88 (individuals with schizophrenia- related diagnoses)		<i>IC.</i> α = .78 (community sample) and .89 (clinical sample) <i>R.</i> ICC = .82 (<i>n</i> = 38, community participants) <i>HT.</i> Positively correlated with positive psychotic symptoms, but not substantially more correlated with PDs specifically (minimal divergence) Higher scores among clinical participants (continued)

Study & location	Construct of paranoia/PDs	# items	Sample	Paranoia subscales	Psychometric properties
PaDS					
Melo et al. (2009) [10] UK/Portugal	Persecutory beliefs and the perceived 'deservedness' of persecution.	10	n = 318 (British students) n = 290 (Portuguese students) n = 45 (patients with PDs)	Persecution beliefs and deservedness beliefs relating to the same 10-items	Analyses using combined British/Portuguese sample: $IC. \ \alpha = .84$ (Persecution). For deservedness calculated an ICC = .38. SV. 1-factor structure explaining 42% of the variance (Persecution subscale). 1-factor structure (deservedness subscale) HT. PS scores and depression correlated strongly with Persecution and moderately with Deservedness CCV. 'Substantially identical' factor structures for British and Portuguese samples independently Higher persecution scores for patients compared with students (HT)
PDI Peters et al. (1999) [11] UK	PDs in the general population. Attenuated versions of delusions	40	N = 272. (students and researcher acquaintances)	5-item subscale designed to assess PDs. However, factor analysis found three paranoia- related subscales: persecution (5-items), suspiciousness (3- items), and paranoid ideation (4-items) Items assessed on dimensions of conviction, pre-occupation and distress	<i>SV</i> . 11-factor structure explaining 59% of the variance
Verdoux et al. (1998) [12] France		21	<i>N</i> = 444 (GP surgery attendees)	One PD-related subscale: "suspiciousness and persecutory ideas" (4-items)	<i>SV</i> . 7-factor structure explaining 55.3% of the variance

(continued)

Study & location	Construct of paranoia/PDs	# items	Sample	Paranoia subscales	Psychometric properties
<u>PDI</u>					
Peters et al. (2004) [13] UK		21	N = 444 (university staff, students and research acquaintances)	Two items selected from each of the three PD-related, factor analytically identified subscales by Peter's et al. (1999)	<i>SV.</i> Select the two highest loading items from each factor identified by Peters et al. (1999) to create a shortened questionnaire
Jung et al. (2008) [14] Korea		40	N = 310 (community sample)	Initially identify "persecutory ideas" and "jealousy and suspiciousness" subscales - do not state number of items The authors later conclude that a unidimensional scale is more appropriate	<i>SV.</i> 10-factor structure explaining 57% of the variance. However, they argue that the dominant factor suggests a unidimensional structure (unrotated explains 26% of variance)
Jones & Fernyhough (2007) [16] UK		21	N = 493 (students)	Dispute the existence of previously established paranoia-related subscales	<i>IC.</i> Verdoux et al.'s (1998) suspiciousness and persecutory ideas subscale ($\alpha = .50$) López-Ilundain et al.'s (2006) paranoid subscale ($\alpha = .26$) <i>SV.</i> Lack of "valid multifactorial structure"
López-Illudain et al. (2006) [15] Spain		21	N = 356 (community sample)	Factor analysis identified a "paranoid" subscale (2-items)	<i>SV</i> . 7-factor structure explaining 53.7% of the variance
Rocchi et al. (2008) [17] Italy		21	n = 89 (outpatients with psychosis- related diagnoses n = 210 (community sample)	Refer to a "paranoia dimension" of the PDI (4- items)	For combined clinical/non-clinical sample: largest class found in latent class analysis ($n = 140$; 41.1%) related to a high probability of endorsing PDI items from the paranoia dimension
					(continued)

Study & location	Construct of	# items	Sample	Paranoia subscales	Psychometric properties
	paranoia/PDs				
<u>PDI</u>					
Lincoln et al. (2010) [18] Germany		40	N = 80 (patients with psychosis- related diagnoses)	Peters et al. (1999) original 5- item PD scale	<i>HT</i> . Positively correlated with observer-rated PDs (<i>r</i> < .5)
Cella et al. (2011) [19] UK & Italy		21	n = 400 (British) n = 400 (Italian) Community samples		For combined British/Italian sample: latent class analysis identified a class ($n = 330$; 41.3%) associated with endorsement of two items with paranoid themes
Prochwicz & Gawęda (2015) [20] Poland		40	N = 421 (community sample)	Initially identified subscales for 'suspiciousness', 'ideation of persecution and body distortion', and 'ideation of persecution' - number of items not reported The authors later argue for a unidimensional scale	<i>SV</i> . 14-factor structure explaining 58.68% of variance. However, scree plot suggests a unifactorial structure
<u>SSPS</u>					
Freeman et al. (2007) [21] UK	Assesses the expectation of harm from an intentional perpetrator in a recent situation	10	n = 100 (community sample) n = 64 (students) n = 21 (those at high risk of developing psychosis)		<i>IC.</i> $a \ge .84$ for all samples <i>R</i> . ICC = .74 ($n = 42$) <i>HT</i> . Positively correlated with other paranoia assessments
<u>PC</u>					
Freeman et al. (2005) [22] UK	Assesses paranoid thoughts of a "more clinical nature" than the PS	18	N = 1202 (students)	Items rated on dimensions of frequency, conviction and distress	<i>IC.</i> $\alpha \ge .90$ for all rating scales <i>HT:</i> positively correlated with PS scores (continued)
18					

Study & location	Construct of paranoia/PDs	# items	Sample	Paranoia subscales	Psychometric properties
PC Lincoln et al. (2010) [18] Germany		18	N = 80 (patients with psychosis- related diagnoses)	Items rated on dimensions of frequency, conviction and distress	<i>HT</i> . Positively correlated with observer-rated PDs ($r < .5$)
Moritz et al. (2012) [23] Germany		18	N = 1899 (community sample)	'Unspecified suspiciousness' (11-items) and 'psychotic paranoia' (5-items) 2 items had no subscale.	SV. 2-factor structure explaining 64% of the variance
SPC Schlier et al. (2016) [24] Germany	State-adapted version of the PC assessing paranoia "in the moment", rather than as a trait	13, 5, and 3- item versions	n = 1893 (community sample 1) n = 1966 (community sample 2)		Sample 1: SV. 1-factor structure for all versions RSP. Change effect size for 13-item, $d = .17$, 5- item, $d = .19$, and 3-item SPCs, $d = .27$ HT: Positively correlated with paranoia and social anxiety. Expected relationships with positive and negative emotions Sample 2: IC: $\alpha \ge .74$ for all versions
<u>GPTS</u> Green et al. (2008) [25] UK	Assesses a hierarchy of paranoid thoughts; from social reference thoughts to persecutory ideas.	32	n = 353 (university staff or students) n = 50 (individuals with PDs)	Persecution (16-items) and social reference (16-items) Items rated on dimensions of preoccupation, conviction, and distress	<i>FA</i> . On pool of 95 items. 2-factor structure explaining 49.7% of the variance (non-clinical sample). 16-tems per factor selected <i>IC</i> . $\alpha \ge .90$ for both samples on both subscales <i>R</i> . ICC $\ge .80$ for all subscales ($n = 164$, non-clinical) <i>HT</i> . Positively correlated with other measures of paranoia, anxiety and depression. Higher scores in clinical group <i>RSP</i> . GPTS change scores correlated with change scores on interview-based paranoia measure ($n = 30$, clinical sample) (continued)

Study & location	Construct of paranoia/PDs	# items	Sample	Paranoia subscales	Psychometric properties
<u>GPTS</u>					
Ibáñez-Casas et al. (2015) [26] Spain		32	n = 151 (community sample) n = 40 (patients with delusions)	Persecution (16-items) and social reference (16-items)	<i>IC</i> : $\alpha \ge .90$ for both samples on all subscales <i>SV</i> : 2-factor structure explaining 61.7% of the variance (non-clinical sample) <i>HT</i> . Positively correlated with PDI. Smaller correlation with anxiety and depression measures. Higher scores for clinical group: cut off of 92 gives 97.35% specificity and 65% sensitivity.

Note. IC = Internal Consistency, R = Reliability, CV = Content Validity, SV = Structural Validity, HT = Hypothesis Testing, CCV = Cross-Cultural Validity, RSP = Responsiveness. ICC = intraclass correlation coefficient. For FA explained variance is included in the table where reported.

Quality Analysis

Methodological quality ratings for each paper are shown in Table 2 (Appendix C for full ratings), along with ratings illustrating the overall strength of evidence for each measure's psychometric properties.

Many studies did not describe how missing data were handled. As this can be a source of bias (Mokkink et al., 2012), such study methodologies were not rated better than 'fair'. Furthermore, the limited piloting of questionnaires meant that content validity and cross-cultural validity methodologies were rated 'poor', and no good psychometric evidence for these properties was reviewed. Methodologies for assessing structural validity and testing construct validity hypotheses were relative strengths for many studies, and accordingly these properties received stronger ratings. No studies assessed measurement error, criterion validity, or used item-response theory. Only two studies assessed the responsiveness of a questionnaire to measure change over time.

Measures Assessing the Lower Paranoia Hierarchy

The PS (Fenigstein & Vanable, 1992) and the PSQ (Rawlings & Freeman, 1996) were designed to assess 'normal', 'non-pathological' paranoia, and their included items best reflected social evaluative concerns and ideas of reference within the lower levels of Freeman et al.'s (2005) hierarchy. Items from both measures also go beyond the hierarchy, assessing constructs related to paranoia, such as self-depreciation (PS; Barreto Carvalho et al. 2014) and anger/impulsiveness (PSQ; Rawlings & Freeman, 1996). Persecutory ideas from the top of the paranoia hierarchy are not assessed; described as "obviously psychotic" (Fenigstein & Vanable, 1992, p. 131) and less relevant to the 'normal' population.

Table 2

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	Internal consistency	Reliability	Content validity	Structural validity	Hypothesis testing	Cross-cultural validity	Responsiveness
Paranoia Scale	J			J.	6	J.	
Evidence for psychometric property	++	-	+		++	?	
Methodological quality of studies							
Fenigstein & Vanable (1992)	Fair	Fair	Good	Fair	Poor		
Smári et al. (1994)	Poor		Poor		Fair	Poor*	
Combs et al. (2002)	Poor		Poor		Fair	Poor	
Barreto Carvalho et al. (2014)	Fair		Poor	Fair		Poor*	
PSQ							
Evidence for psychometric property	-	+	Ι	Ι	?		
Methodological quality of studies							
Rawlings & Freeman (1996)	Fair	Fair	Fair	Fair			
Huppert et al. (2002)	Poor	Poor	Poor		Poor		
PIQ							
Evidence for psychometric property	+	+	?	Ι	+	?	
Methodological quality of studies							
McKay et al. (2006)	Poor		Poor		Fair		
Jones et al. (2008)	Fair			Fair			
Van Dongen et al. (2011)	Poor	Fair	Poor		Poor	Poor	

(continued)

	Internal consistency	Reliability	Content validity	Structural validity	Hypothesis testing	Cross-cultural validity	Responsiveness
PaDS							
Evidence for psychometric property	P: ++		?		P: +	?	
	D: ?				D: -		
Methodological quality of studies							
Melo et al. (2009)	P: Good		Poor	Good	Fair	Poor	
	D: Poor						
PDI							
Evidence for psychometric property	-		?	+/-	-	?	
Methodological quality of studies							
Peters et al. (1999)			Poor	Good			
Verdoux et al. (1998)			Poor	Fair		Poor	
Peters et al. (2004)			Poor				
Jung et al. (2008)			Poor	Fair		Poor	
López-Illundain et al. (2006)			Poor	Fair		Poor	
Jones & Fernyhough (2007)	Fair			Fair			
Rocchi et al. (2008)			CNR			Poor*	
Lincoln et al. (2010)			CNR		Fair	Poor*	
Cella et al. (2011)			CNR			Poor*	
Prochwicz & Gawęda (2015)			Poor	Fair		Poor	

(continued)

	Internal consistency	Reliability	Content validity	Structural validity	Hypothesis testing	Cross-cultural validity	Responsiveness
SSPS							
Evidence for psychometric property	?	+	?		+		
Methodological quality of studies							
Freeman et al. (2007)	Poor	Fair	Poor		Fair		
PC							
Evidence for psychometric property	?		?	+	+/-	Ι	
Methodological quality of studies							
Freeman et al. (2005)	Poor		Poor		Fair		
Lincoln et al. (2010)			CNR		Fair	Poor*	
Moritz et al. (2012)			CNR	Fair		Fair*	
SPC							
Evidence for psychometric property	+		CNR	Ι	+	Ι	?
Methodological quality of studies							
Schlier et al. (2016)	Fair		CNR	Fair	Fair	Fair*	Poor
GPTS							
Evidence for psychometric property	?	++	++	?	++	?	?
Methodological quality of studies							
Green et al. (2008)	Poor	Good	Poor	Poor	Fair		Poor
Ibáñez-Casas et al. (2015)	Poor		Excellent	Poor	Fair	Poor	

Note. +++ or --- (strong positive or negative evidence), ++ or - (moderate positive or negative evidence), '+ or - (limited positive or negative evidence), +/- (conflicting findings), ? (only studies of poor methodological quality), or I (quality not possible to determine). P = persecution subscale. D = deservedness subscale. If information was in a non-English language paper, either no items in an appraisal section could be rated (CNR) or ratings were based on a subset of items (*). Cross-cultural validity rated for studies using measures in a different language or culture.

Rawlings and Freeman (1996) identified a 5-factor structure for the PSQ without stating the explained variance. The factor structure of the PS was also unclear, with Fenigstein and Vanable (1992) retaining a 1-factor structure, whereas with Portuguese adolescents, Barreto Carvalho et al. (2014) retained a 3-factor structure. This could reflect problems with the initial factor analysis, or the measure's limited validity across age or cultures. Evidence for the cross-cultural validity of the PS was poor, as studies did not conduct factor analyses and used samples dissimilar to the original development sample (Combs et al., 2002; Smári et al., 1994). The PS had evidence of good internal consistency and some mixed findings regarding construct validity (Barreto Carvalho et al., 2014; Combs et al., 2002; Fenigstein & Vanable, 1992; Smári et al., 1994). However, its test-retest reliability correlations were not adequate (Fenigstein & Vanable, 1992). Test-retest reliability was evidenced for the PSQ. However, no other psychometric properties were rated positively, often due to methodological limitations (Rawlings & Freeman, 1996).

The PS (Smári et al., 1994) and PSQ (Huppert et al., 2002) were validated with clinical participants. However, there was little consideration of how appropriate these specifically 'non-clinical' assessments were for clinical population, and they arguably could not measure the range of potential paranoid thoughts experienced by those diagnosed with schizophrenia.

Measures Assessing the Upper Paranoia Hierarchy

The PIQ (McKay et al., 2006), PaDS (Melo et al., 2009), PDI (Peters et al., 1999), and SSPS (Freeman et al., 2007) were designed with scales to measure persecutory beliefs, reflecting the upper levels of the paranoia hierarchy (Freeman et al., 2005). The PIQ, PaDS, and SSPS used Freeman and Garety's (2000) definition of 'persecutory' when designing items, and the PDI used a definition developed by experts. However, PaDS items sometimes 'imply' persecutory ideas (Melo et al., 2009); it being questionable whether items such as "There are people that think of me as a bad person" specifically assess a perception of being at risk of harm. The PDI rates delusions on dimensions of conviction, pre-occupation and distress, whereas the PaDS also measures how deserved persecution is perceived to be (Trower & Chadwick, 1995). While the 'persecution' scale of the PaDS had some acceptable psychometric properties, the properties of the 'deservedness' subscale are less evidenced, due to high amounts of missing data (Melo et al., 2009).

The PDI has items to assess PDs, alongside questions assessing other types of delusions (e.g. grandiose; Peters et al., 1999). Statements were worded to represent 'attenuated' versions of delusions, appropriate for general population samples. Although the 40-item PDI was designed with four PD items, Peters et al. (1999) identified three components through factor analysis which relate to 'paranoia', covering a broader construct than just persecution (e.g. suspiciousness). However, Peters et al. argued that they had not aimed to "measure a limited number of well-defined subscales… but rather to sample as wide a variety of delusions as possible" (p. 562).

Six further studies reported PDI subscales relating to paranoia (Jung et al., 2008; López-Ilundain et al., 2006; Peters et al., 1999; Peters et al., 2004; Prochowitz & Gawęda, 2015; Verdoux et al., 1998), with a lack of consistency in the subscales identified. Furthermore, Jones and Fernyhough (2007) demonstrated the inadequate internal consistency of previously identified paranoia subscales of the PDI, and reported a better fitting unidimensional factor structure, measuring general delusion-proneness. Similarly, while Jung et al. (2008) and Prochowitz and Gawęda (2015) initially extracted factors relating to persecution, they argued that the first factor is highly dominant and suggested that a unidimensional factor structure is preferable. Finally, although latent class analyses using the PDI identified a 'paranoid' class of participants, the 'paranoid' items endorsed by participants were not consistent across samples (Cella et al., 2011; Rocchi et al., 2008).

Both the SSPS (Freeman et al., 2007) and 10-item PIQ (McKay et al., 2006; Van Dongen et al., 2011) had evidence of construct validity and test-retest reliability. However, they were designed as unidimensional scales, without any assessment of structural validity (Freeman et al., 2007; McKay et al., 2006). Jones et al. (2008) did show that a 7-item PIQ had good internal consistency and better fitted a unidimensional structure than the 10-item measure.

The SSPS assesses *state* persecutory ideation (as opposed to persecutory ideas over weeks/months) and was designed for studies where paranoia is assessed in a virtual reality (VR) environment (Freeman et al., 2007). However, there has been no assessment of its responsiveness to momentary changes in paranoia.

Content validity and cross-cultural validity ratings were poor for all measures assessing the upper paranoia hierarchy, due to methodological limitations. For the PDI, factor structures were variable and cross-cultural validity could not always be assessed because papers were not available in English (German version; Lincoln, Keller, & Rief, 2009; Italian version; Preti, Marongiu, Petretto, Miotto, & Masala, 2002).

Most psychometric properties for the persecutory measures were established with non-clinical populations. However, the PIQ was also validated with clinical participants (McKay et al., 2006). Construct validity hypotheses for PIQ, PaDS, and PDI were also supported, showing significant differences in scores between clinical and non-clinical samples (McKay et al., 2006; Melo et al., 2009), and correlations with observer-rated PDs (Lincoln et al., 2010; McKay et al., 2006).

Measures Assessing Paranoia Spanning the Full Hierarchy

Rather than focusing upon the lower or upper paranoia hierarchy, the PC (Freeman et al., 2005) and GPTS (Green et al., 2008) assess a range of paranoid

thoughts at all levels. Freeman et al. (2005) did not establish an *a priori* construct for their measure, but based upon their findings argued that the PC assesses a hierarchy of paranoid thought (Figure 1), from social evaluative concerns up to persecutory beliefs. Green et al. (2008) later used this hierarchy to structure the GPTS item generation.

The PC assesses paranoia on dimensions of conviction and distress (Freeman et al., 2005), and the GPTS on dimensions of preoccupation, conviction, and distress (Green et al., 2008). Factor analyses showed that both measures have a 2-factor structure ('persecution' & 'social reference'; Green et al., 2008; Ibáñez-Casas et al., 2015; 'normal suspicions' & 'pathological delusions'; Moritz et al., 2012). For the GPTS (Green et al., 2008), factors mapped on to the lower and higher ends of the paranoia hierarchy. However, methodologies were rated poorly for structural validity, internal consistency, and cross-cultural validity, due to sample size limitations (Green et al., 2008; Ibáñez-Casas et al., 2015). For the PC, some items from the 'pathological' factor did not reflect extreme persecutory beliefs from the paranoia hierarchy, and were instead described as 'clinically relevant' because they are bizarre and reflect 'first-rank' symptoms (Moritz et al., 2012; e.g. I detected coded messages about me in the press/TV/Radio).

The GPTS was designed for use across the continuum of psychosis, with clinical and non-clinical participants involved in the measure's validation, providing some moderate evidence for its psychometric properties (.g. reliability, hypothesis testing; Green et al., 2008; Ibáñez-Casas et al., 2015). The PC was subsequently applied with a clinical sample, where Lincoln et al. (2010) found a correlation between scores and observer-rated PDs. Lincoln et al. (2010) and Moritz et al. (2012) reported that the German version of the PC has good psychometric properties. However, the cited papers were not available in English (Lincoln et al., 2009). Furthermore, although Freeman et al. (2005) reported good internal consistency for the English PC, the unidimensionality of the scale is not evidenced.

The PC has also been developed in to a state measure of paranoia (SPC; Schlier et al., 2016); the 18 items were rephrased to ask how much they apply 'at the moment'. Schlier et al. (2016) generated 13-item, 5-item, and 3-item SPC scales, and demonstrated that the shorter scales (5-item and 3-item) were more responsive to momentary changes in paranoia. However, the data used were obtained from other studies with methodological limitations. Further comparison with other measures would also clarify that the SPC versions are appropriately responsive. All SPCs were undimensional scales (although no explained variance was reported) with good internal consistency. The 13 and 5-item measures were argued to encompass all levels of the paranoia hierarchy, with the 3-item version having reduced content validity, but still capturing key elements of persecutory thinking (Schier et al., 2016).

Discussion

This review aimed to critically evaluate existing self-report measures of paranoia, based upon the constructs of paranoia that they assess and their psychometric properties. While the review identified measures developed in non-clinical populations, their applicability to clinical samples was also reviewed.

Nine questionnaires were identified, assessing paranoid beliefs relating to either the lower or upper levels of the paranoia hierarchy, or encompassing the full hierarchy (Freeman et al., 2005). A comprehensive conceptualisation of paranoia should include thoughts relating to varying degrees of threat *and* consider associated appraisals and distress. The PC (Freeman et al., 2005) and GPTS (Green et al., 2008) were the two measures fulfilling these criteria, capturing social reference paranoid thoughts commonly experienced across the population, as well as persecutory beliefs common among clinical samples, and endorsed by some of the general population. Between these measures, the GPTS has the most evidence for good psychometric properties among clinical and non-clinical populations (Green et al., 2008; Ibáñez-Casas et al., 2015), and therefore offers the most valid and informative assessment of paranoia across the continuum of psychosis. However, some psychometric findings (e.g. internal consistency, structural validity) require replication with a larger sample.

The PS (Fenigstein & Vanable, 1992) and PSQ (Rawlings & Freeman, 1996) were designed to measure 'subclinical' paranoia (reminiscent of social evaluative concerns described by Freeman et al., 2005), as opposed to persecutory beliefs from the upper hierarchy. However, more recent research challenges the assumption that persecutory beliefs are always associated with psychosis, showing that they are also endorsed by some non-clinical participants (Green et al., 2008; McKay et al., 2006). By excluding supposedly 'extreme' paranoid thoughts, the PS and PSQ are unable to capture the range of paranoid experiences among a non-clinical sample, and are even less applicable for those with psychosis, who have more persecutory beliefs.

The PDI (Peters et al., 1999), PaDS (Melo et al., 2009), PIQ (McKay et al., 2006), and SSPS (Freeman et al., 2007) measure persecutory ideas evident in the upper paranoia hierarchy (Freeman et al., 2005). Researchers may assess persecutory beliefs in isolation, due to their clinical relevance. However, ideas of reference, which are not assessed by these questionnaires, may also be clinically-relevant if they cause distress and impairment. Some of the persecutory questionnaires do assess appraisals of beliefs, such as perceived deservedness (PaDS; Melo et al., 2009) and conviction, pre-occupation, and distress (PDI; Peters et al., 1999). The psychometric properties of the PaDS deservedness scale (Melo et al., 2009), however, require further validation. Furthermore, the evidence reviewed suggested that the PDI should be used to assess general delusion proneness, rather than PDs specifically. Although only papers reporting paranoia-related subscales were included in this review, the use of the PDI to

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assess general delusion-proneness is also supported by other factor-analytic studies (Fonseca-Pedrero, Paino, Santarén-Rosell, Lemos-Giráldez, & Muñiz, 2012; Kim et al., 2013).

The PIQ (McKay et al., 2006) does not assess appraisals of persecutory ideas, but has more evidence for acceptable psychometric properties with clinical and nonclinical populations. However, further factor analyses are required to establish whether a 10-item or 7-item measure is preferable. Given the increasing popularity of VR studies the SSPS (Freeman et al., 2007) is also a useful tool, but requires further evaluation of its responsiveness.

When measuring persecutory beliefs from the top of the hierarchy (Freeman et al., 2005), prevalence rates are likely to be lower in the general population (e.g. PIQ; McKay et al., 2006), whereas scores obtained using the PS (Feningstein & Vanable, 1992) and PSQ (Rawlings & Freeman, 1996) may be higher. However, total scores from the latter measures do not indicate the prevalence of paranoia specifically, as they include the assessment of associated experiences (e.g. anger/impulsivity). Measures such as the GPTS (Green et al., 2008) and PC (Freeman et al., 2005) therefore offer the best estimates of paranoia prevalence, capturing the full range of potential paranoid thoughts.

The limitations of the reviewed questionnaires have implications for studies that have used these measures. For example, by excluding the measurement of persecutory beliefs, studies using the PS and PSQ in clinical samples (e.g. Smári et al., 1994; Craig, Hatton, Craig, & Bentall, 2004) are unlikely to have measured a construct of paranoia appropriate for this population. Similarly, studies identifying PDI subscales that measure specific types of delusions, such as PDs (e.g. Jung et al., 2008), are using the measure in a way not intended by its original authors (Peters et al., 1999). Studies using the PDI to report the prevalence of PDs (e.g. Verdoux et al., 1998) may therefore not have assessed these experiences appropriately.

Finally, studies using the SSPS in VR settings (e.g. Freeman et al., 2015) have only assessed persecutory thoughts, therefore not capturing potentially more commonlyoccurring thoughts from the lower paranoia hierarchy (Freeman et al., 2005). The SPC (Schlier et al., 2016) is a state measure assessing a broader range of paranoid experiences, but requires further psychometric validation (e.g. reliability, structural validity).

Clinical Implications

When using paranoia questionnaires in practice, clinicians should consider that measures assessing the full paranoia hierarchy (GPTS; Green et al., 2008; PC; Freeman et al., 2005) will assess a greater range of service users' experiences. Thoughts from the upper section of the hierarchy may be experienced frequently, and thoughts from the lower hierarchy still have potential to cause distress. Relatedly, measures assessing distress (GPTS; Green et al., 2008; PC; Freeman et al., 2005) can highlight more troubling paranoid experiences and evaluate distress reduction during therapy, which may be a better outcome than reductions in paranoid thought frequency. The GPTS (Green et al., 2008) and PC (Freeman et al., 2005) also assess appraisals of paranoid thoughts and could be used to assess the outcomes of interventions which aim to target these (e.g. metacognitive therapy; Moritz & Woodward, 2007).

Of the measures assessing a range of paranoid thoughts, along with appraisals and distress, the GPTS (Green et al., 2008) has the most robust psychometric evidence obtained using clinical participants and is therefore the most recommended. The GPTS could be a particularly useful in Early Intervention services, as its scope makes it appropriate to assess paranoia among those with psychosis, and those at risk of developing it, who may have fewer persecutory thoughts and less distress. Clinicians may wish to use other measures for specific purposes. If persecutory ideas specifically are an individual's primary difficulty, the PIQ (McKay et al., 2006) could be used, and is the persecutory measure most validated with clinical samples. Clinicians might also wish to assess the perceived deservedness of persecution, and could therefore use the PaDS (Melo et al., 2009). However, they should be aware of the limitations of using these measures, highlighted in this review.

Limitations

The questionnaires favoured in this review were based upon (GPTS; Green et al., 2008), or resulted in (PC; Freeman et al. 2005), the development of Freeman et al.'s (2005) paranoia hierarchy. The hierarchy is one conceptualisation of paranoia, and adopting an alternative model may have influenced the review's conclusions. However, Freeman et al.'s hierarchy is currently the most comprehensive model of paranoia, with other research often failing to distinguish paranoid and persecutory beliefs (McKay et al., 2006).

The COSMIN protocol for systematic reviews of questionnaire properties (Terwee et al., 2011) suggests doing an initial database search to identify relevant measures, and a subsequent one including the names of instruments found in the initial search, along with terms for measurement properties and the target population. However, in the current review a single database search was completed; including search terms to identify both relevant questionnaires and papers which explored measurement properties. Thus, newly developed paranoia questionnaires which did not report psychometric properties in their abstract could have been missed. To compensate for this, the search term 'develop*' was instead used to identify any such papers.

Most studies included in the review were appraised poorly on particular COSMIN items (e.g. not reporting missing data, not piloting items), meaning that properties were rated 'fair' or 'poor', even if other criteria were met at a 'good' or

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'excellent' level. Those reviewing other self-report measures have described COSMIN criteria as overly strict (Burton, Abbott, Modini, & Touyz, 2016). However, evaluating psychometric properties in accordance with gold standard recommendations facilitated a higher quality systematic review. Furthermore, the methodological weaknesses identified illustrate areas of improvement for future research.

Non-English papers were not accessed, limiting the ability to thoroughly evaluate the cross-cultural validity of some questionnaires (e.g. the Korean PaDS; Ko & Kim, 2016; and the Iranian GPTS; Abdolmohammadi, Mohammadzadeh, Ahmadi, & Ghadiri Sourman, 2016). As papers were only included in the review if their abstract mentioned psychometric properties, some psychometric data may also have been missed. However, the search strategy employed is recommended for systematic reviews (Terwee et al., 2011), due to challenges identifying wider studies systematically, and to exclude studies without specific hypotheses about reliability or validity.

Future Research

Future research could assess beliefs lower down the paranoia hierarchy in clinical populations, examining their associated distress and comparing this with persecutory beliefs, higher in the hierarchy. Furthermore, building upon findings using observer-rated tools that non-distressing paranoid beliefs are predictive of later paranoia-related distress and psychosis (e.g. Hanssen et al., 2005; Welham et al., 2009), self-report questionnaire could be used longitudinally to examine the role of frequency, content, and appraisals made about paranoid thoughts in this process. For example, persecutory thoughts that are appraised as preoccupying and convincing may be associated with an increased risk of later psychosis.

Future studies using paranoia questionnaires should validate the psychometric properties rated poorly in this review using rigorous methodologies recommended by COSMIN (Mokkink et al., 2012), to ensure that the reviewed studies' methodological

limitations are not repeated. Those developing new questionnaires should also pilot items with experts with professional and lived experience of paranoia, to ensure that the content reflects realistic paranoid experiences.

Finally, there are gaps in the scope of existing paranoia measures. For example, although paranoid imagery is prevalent among those with PDs (Schulze, Freeman, Green, & Kuipers, 2013), all of the included questionnaires focussed upon beliefs and thoughts. Furthermore, although cognitive models conceptualise psychotic experiences as intrusions into awareness (Morrison, 2001), no measures have assessed whether paranoid experiences are intrusive (i.e. appear in our minds repeatedly, against our will, and are difficult to dismiss; Rachman, 1981). Developing a valid means of assessing paranoid intrusive experiences may further our understanding of these experiences.

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Appendix A

Search strategy

Table A1

Search terms used in systematic search

Paranoia terms		<u>Target</u>		Questionnaire		Psychometric	Excluded terms
		population		terms		terms	
Paranoi*		"general		Questionnaire		Psychometric	dementia,
Persecut*		population"		Scale*		Reliab*	alzheimer's,
Delusion*		Non-clinical		Index		Valid*	parkinson's,
Suspicious*	&	Nonclinical	&	Inventory	&	Structure	learning
"Unusual		Sub-clinical		Checklist		Develop*	disabili*,
belief*"		Subclinical		Survey		"internal	intellectual
"Unusual		Public		Assessment		consistency"	disabilit*
experience*"		Student				"factor	
1		Community				analysis"	
		Non-				"latent factor*"	
		psychiatric				"latent	
		"Normal				structure*"	
		population"				"principal	
						components	
						analysis"	

Example of input to database search engine:

(paranoi* OR persecut* OR delusion* OR suspicious* OR "unusual belief*" OR "unusual experience*") AND ("general population" OR non-clinical OR nonclinical OR sub-clinical OR subclinical OR public OR student OR community OR non-psychiatric OR "normal population") AND (questionnaire* OR scale* OR index OR inventory OR checklist OR survey OR assessment) AND (psychometric OR reliab* OR valid* OR structure OR develop* OR "internal consistency" OR "factor analysis" OR "latent factor" OR "principal components analysis") NOT parkinson's NOT alzheimer's NOT dementia NOT delirium NOT "intellectual disabilit*" NOT "learning disabilit*"

Appendix B

Table B1

COGMIN	1 1	• 1	•, •	C	· ·	, •
$(()) \times (V) / V$	recommended	annraisal	criteria	tor i	auestionnaire	nronerties
CODMIN	recommentaca	appraisai	criteria,	,0, ,	questionnente	properties

Domain	Definition	Appraisal criteria
Reliability		
Internal	Interrelatedness among scale items	P: Cronbach's alpha(s) $\geq .7$
		I: No Cronbach's alphas, or dimensions undetermined
		N: Cronbach's alpha(s) $< .7$
Test-retest	The proportion of the variance in measurements	P: Intra-class correlation/weighted Kappa $\geq .7$, or, Pearson's r $\geq .8$
	which is due to 'true' differences between patients	I: Neither of the above analyses reported
		N: Intra-class correlation/weighted Kappa $< .7$, or Pearson's r $< .8$
Validity	Whether scores on an instrument adequately reflect	
Criterion	a 'gold standard'. The only real gold standard	P: Criterion variable is a 'gold standard' assessment of the construct. Correlation \geq
	comparator instrument is another version of the	.7
	same measure. Other comparators are often wrongly	I: No information. No arguments that criterion variable is 'gold standard'
	considered as gold standard	N: Correlation with gold standard < ./
Content	How well an instrument reflects the construct to be	P: Items relevant to construct and target population, and questionnaire is
	measured	comprehensive
		I:Not enough information
		N: Some items irrelevant to construct, or for target population, or questionnaire is
		not comprehensive
Construct Validity		
Hypothesis testing	How consistent instrument scores are with	P: Correlations with associated measures \geq .5, or at least 75% results are in
	hypotheses. For example, about relationships with other instruments (convergent/divergent validity) or	accordance with hypotheses and correlations with related constructs are higher than with unrelated constructs
	differences between relevant groups (known-groups	I: No information or correlations solely with unrelated constructs presented
	validity).	N: Correlations with associated measures < .5, or less than 75% of hypotheses
	57 	accepted (continued)
		(continued)

Domain	Definition	Appraisal criteria
Cross-cultural validity	Whether items on a translated or culturally adapted	P. No difference in factor structure or important differential item functioning (DIF)
	instrument adequately reflect of the performance of	between versions
	items on the original instrument.	I: Factor analysis not applied and DIF not assessed
		N: Differences in factor structure or DIF between languages
	Whether scores on an instrument adequately reflect	
Structural validity	the dimensionality of the construct to be measured.	P: Factors explain at least 50% of the variance
-	-	I: Explained variance not mentioned, or factor analysis not completed.
		N: Factors explain < 50% variance
	The ability of an instrument to detect change over	
	time in the construct to be measured.	
Responsiveness		P: Correlation with changes on instruments measuring the same construct ≥ 0.5 OR
		at least 75% of results in accordance with hypotheses OR area under the curve ≥ 0.7
		and correlations with changes in related constructs are higher than unrelated
		constructs
		I: Appropriate analyses not conducted, or solely correlations determined with
		unrelated constructs.
		N: Responsiveness analyses conducted but criteria not met
Note. Information in t	able obtained from Terwee et al. (2011) and M	Mokkink et al. (2012). $P = Positive evidence$, $I = indeterminate evidence$, $N =$

negative evidence

Appendix C

Methodological appraisal scoring

Table C1

Summary of COSMIN criteria adapted from

Interna	al Consistency	Excellent	Good	Fair	Poor
Design	requirements				
1.	Was the percentage of missing items given?	10,22	1,2,3,4,5,6,7,8,9,16, 21,24,25,26		
2.	Was there a description of how missing items were handled?	22,25	10	1,2,3,4,5,6,7,8,9,16, 24,26,21	
3.	Was the sample size included in the internal consistency analysis adequate?	1,3,4,5,8,9(non- clinical),10,16,21,22, 25,24,26 (non-clinical)	7(non- clinical),9(clinical),25	2,6,26(clinical)	7(clinical)
4.	Was the unidimensionality of the scale checked? Using factor analysis or Item Response Theory?	1,4,5,8,10, 24,25,26	16		2,3,6,7,9,21,22
5.	Was the sample size included in the unidimensionality analysis adequate?	1,4,5,8,10,16, 24			25, 26
6.	Was internal consistency calculated for each (unidimensional) (sub)scale separately?	1,4,5,8,10,16,24,25 26			2,3,6,7,9,21,22
7.	Were there any important flaws in the design of methods of the study?	1,2,3,4,5,7,8,9,10,16, 21,22,24,25,26		6	
Statistic	cal methods	1 2 2 4 5 6 7 8 0 10			
8.	Was Cronbach's alpha calculated?	1,2,3,4,5,6,7,8,9,10 (persecution),16,21,22, 24,25,26			10(deservedness)
		27,23,20			(continued)

Reliabi	lity (test-retest)	Excellent	Good	Fair	Poor
1.	Was the percentage of missing items given?		1,5,6,9,21,25		
2.	Was there a description of how missing items were handled?	25		1,5,6,9,21	
3.	Was the sample size used in the analysis adequate?	1,25	5	9,21	6
4.	Were at least 2 measurements available?	1,5,6,9,21,25			
5.	Were the administrations independent?		1,5,6,9,21,25		
6.	Was the time interval stated?	1,5,6,9,25		21	
7.	Were patients stable in the interim period on the construct to be measured?		1,5,6,9,21,25		
8.	Was the time interval appropriate?	25		1,5,6,9	
9.	Were the test conditions similar for both measurements? E.g. type of administration, environment, instructions		1,6,9,21,25	5	
10.	Were there any important flaws in the design or methods of the study?	1,5,9,21,25		6	
<u>Statistic</u>	<u>cal methods</u>				
11.	Was an intraclass correlation coefficient calculated?	9,21,25		1,5,6	
Conten	t Validity ^a	Excellent	Good	Fair	Poor
1.	Was there an assessment of whether all items refer to relevant aspects of the construct to be measured?	7,11,13,25	1,5,10,21,24		22
2.	Was there an assessment of whether all items are relevant for the study population? (age, gender, country, setting) i.e. by piloting items	1,5,26			2,3,4,6,7,9,10,11, 12,13,14,15,20,22, 21,24,25
3.	Was there an assessment of whether all items are relevant for the purpose of the measurement instrument? (discriminative, and/or predictive)	7,11,13,21	1,5,10,22,25		24
	evaluative, and/or predictive)				(continued)

Conten	t Validity ^a	Excellent	Good	Fair	Poor
4.	Was there an assessment of whether all items together comprehensively reflect the construct to be measured?	1,24,25		5,7,10,11,13,22	
5.	Were there any important flaws in the design of the study?	1,2,3,4,5,7,9,10,11,12, 13,14,15,22,21,24,25, 26	21	6,20	
Structu	ıral Validity	Excellent	Good	Fair	Poor
1.	Was the percentage of missing items given?	10	1,4,5,8,11/13,12,14,15, 16,20,23,24,25,26		
2.	Was there a description of how missing items were handled?	11/13, 25	10	1,4,5,8,12,14,15,16, 20, 23,24,26	
3.	Was the sample size used in the analysis adequate?	1,4,5,8,10,12,14,15,16, 20,23, 24	11/13		25,26
4.	Were there any important flaws in the design of the study	1,4,5,8,10,11/13,12,14,15 16, 23,24,25,26		20	
<u>Statistic</u> 5.	cal methods Was exploratory or confirmatory factor analyses performed?	1,4,5,8,10,11/13,12,14,15 16,20, 23,24,25,26			
Hypoth	nesis testing (convergent & divergent validity)	Excellent	Good	Fair	Poor
1.	Was the percentage of missing items given?	10,22	1,2,3,6,7,9,18,21,24,25, 26		
2.	Was there a description of how missing items were handled?	22,25	10	1,2,3,6,7,9,21,24,26, 18	
3.	Was the sample size used in the analysis adequate?	1,3,9,10,21, 22,25(non- clinical),26(non-clinical)	6,7(non-clinical),25 (clinical),18	2,24,26(clinical)	7(clinical)
4.	Were hypotheses regarding correlations or mean formulated <i>a priori</i> (i.e. before data collection)?		2	1,3,6,7,9,10,21,22,24, 25,26	
5.	Was the expected direction of correlation or mean differences formulated <i>a priori</i>	1,2,24,25	3,6,7,9,10, 21,22,26,18	,	(continued)

Hypoth	nesis testing (convergent & divergent validity)	Excellent	Good	Fair	Poor
6.	Was the expected absolute or relative magnitude of correlations or mean differences included in the hypotheses?		1,2,3,6,7,9,10, 21,22, 25,26,18		
7.	Convergent validity: adequate description of the comparator instrument?	2,3,9,10,21,24,25,26,18		1,7,22	6
8.	Convergent validity: were measurement properties of the comparator instrument adequately described?	18	3,10, 25,26	2,6,7,21,22,24	1,9
9.	Were there any important flaws in the design of the study?	1,2,3,7,9,10,22,24,25, 26		6	
Statistic	cal methods				
10.	Were design and statistical methods adequate for the hypotheses to be tested?		1,2,3,6,7,9,10,21, 22,24,25,26,18		
Cross-c	cultural validity ^a	Excellent	Good	Fair	Poor
1.	Was the percentage of missing items given?	10	2,3,4,9,12,14,15,17,18, 19,20,23,24,26		
2.	Was there a description of how missing items were handled?		10	2,3,4,9,12,14,15,17, 18,19,20, 23,24,26	
3.	Was the sample size used in the analysis adequate?	3,4,9,10,12,14,15,17, 18,19,20,23,24			2,26
4.	Were both the original language in which the HR-PRO instrument was developed and the language in which the instrument was translated described?	2,4,9,10,12,14,15,16, 17,18,19,20,23,26			
5.	Was the expertise of people involved in translation adequately described? E.g. expertise in the disease, expertise in the construct, expertise in the language		10,20,26	9,12,14,15	
6.	Did the translators work independently from each other?	10,26	9,12,14,20	15	
7.	Were items translated backward and forward?	26	14	9,12,14,15,20	
8.	Was there adequate description of how differences between original and translated versions were resolved?		9,10,12,14,15,20,26		(continued)

Cross-c	ultural validity ^a	Excellent	Good	Fair	Poor
9.	Was the translation reviewed by a committee? ^a		9,10,12,14,15,20,26		
10.	Was the instrument pre-tested to check interpretation, cultural relevance of the translation, and ease of comprehension? ^a	26		26	9,10,12,14,15,20
11.	Was the sample used in the pre-test adequately described?				
12.	Were all samples similar for all characteristics except for language and/or cultural background?			9,12,14,15,20,26	2,3,4,10,17
13.	Were there any important flaws in the design of the study	2,3,4,9,10,12,14,15,17, 18,19,23,24,26		20	
Statistic	al methods				
14.	Was confirmatory factor analyses performed?	4,10,12,14,15, 23,24,26			2,3,9,17,18,19,20
Respon	siveness	Excellent	Good	Fair	Poor
1.	Was the percentage of missing items given?		24,25		
2.	Was there a description of how missing items were handled?	25		24	
3.	Was the sample size used in the analysis adequate?	24		25	
4.	Was a longitudinal design with at least 2 measurements used?	24,25			
5.	Was the time interval stated?	25			24
6.	If anything happened in the interim was this described?	24		25	
7.	Did a proportion of the patients change?	24	25		
8.	Were hypotheses about changes in scores formulated <i>a priori</i> (i.e. before data collection)?			24,25	
9.	Was the expected <i>direction</i> of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	24	25		(continued)

Responsiveness	Excellent	Good	Fair	Poor
10. Were the expected absolute or relative <i>magnitude</i> of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?		25,24		
11. Was an adequate description provided of the comparator instrument(s)?	25			
12. Were the measurement properties of the comparator instrument(s) adequately described?				25
13. Were there any important flaws in the design or methods of the study?	24,25			
<u>Statistical methods</u>14. Were design and statistical methods adequate for the hypotheses to be tested?	24,25			
Design requirements for comparison to gold standard 15. Can the criterion for change be considered as a reasonable gold standard?		25		
16. Were there any important flaws in the design or methods of the study?	25			
17. For continuous scores: were correlations between change scores, or the area under the Receiver Operator Curve (ROC) curve calculated?	25			
18. For dichotomous scales: Were sensitivity and specificity (changed versus not changed) determined?				

Note. Studies were only rated on items if they were applicable, and if information was available in English. ^a could not rate methodologies of some studies on items in these sections, as texts were not available in English; ratings based upon a subset of items. Item 2 of content validity section was rated when questionnaires were validated with new populations (e.g. new language, culture, clinical sample)

Appendix D

Ratings for overall level of psychometric evidence

Table D1

Method used to establish overall levels of evidence for study properties adapted from

Terwee et al. (2011)

Level	Rating	Criteria
Strong	+++ or	Consistent findings in multiple studies of good
		methodological quality OR in one study of
		excellent methodological quality
Moderate	++ or	Consistent findings in multiple studies of fair
		methodological quality OR in one study of good
		methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	+/-	Conflicting findings
Unknown	?	Only studies of poor methodological quality
Indeterminate	Ι	All included studies reported indeterminate
		findings

Note. + = positive rating, and - = negative rating

Section Two

The assessment of paranoid intrusive thoughts: Development and validation of a

self-report questionnaire

Abstract

Aims

This study aimed to develop a reliable and valid self-report questionnaire to assess how commonly paranoid intrusive thoughts (ITs) are experienced across the continuum of psychosis. A further aim was to identify variables associated with how distressing paranoid ITs are experienced as being; particularly focussing upon the role of metacognitive beliefs.

Design

A new self-report measure of paranoid ITs was developed following consultation with experts and piloting of items. Factor analysis informed the selection of final items for the questionnaire. The newly developed Paranoid Intrusive Thoughts Scale (PITS) was distributed to a mixed sample of participants with and without psychosis (N = 339), alongside questionnaires assessing constructs thought to be related to paranoid ITs.

Results

The developed 12-item questionnaire (PITS-12) assessed the frequency of paranoid ITs and their associated distress. A replicable factor structure and good psychometric properties were demonstrated. Eighty-one percent of participants endorsed having at least one paranoid IT in the last 3 months. On average, participants with psychosis had more frequent, distressing intrusions. However, some individuals without psychosis endorsed PITS-12 items to a similar extent. Negative metacognitive beliefs about paranoia were the strongest predictor of more frequent and distressing paranoid ITs.

Conclusions

Although ITs have traditionally been conceptualised as involved in the maintenance of anxiety disorders, findings suggest that they are transdiagnostic

phenomena that also relate to paranoia. Paranoid ITs are commonly experienced nonclinically and may therefore reflect 'normal' cognitive processes. However, factors such as negative metacognitive beliefs are associated with more distressing paranoid ITs.

Practitioner points

- The PITS-12 is a reliable and valid tool appropriate for the assessment of paranoid ITs across the continuum of psychosis.
- Practitioners should assess the frequency and distress associated with paranoid ITs, as well as metacognitive beliefs about paranoid thought processes.
- As ITs are associated with various mental health difficulties (e.g. anxiety, psychosis), transdiagnostic interventions may be appropriate to target the experiences.

Limitations

- While purposive sampling of clinical and non-clinical participants was used to try and reflect the proposed continuum of paranoid ITs, a representative population sample would give a clearer idea of the true prevalence of paranoid ITs.
- The analyses used to establish the psychometric properties of the PITS-12 used data obtained from an earlier version of the PITS, with 20-items. Validation should therefore be replicated using the PITS-12 independently.
- Psychometric properties of the PITS-12 such as responsiveness and crosscultural validity were not assessed in this study and require further validation

Introduction

Intrusive thoughts (ITs) are "repetitive thoughts, images or impulses that are unacceptable and/or unwanted" (Rachman, 1981, p. 89), with research showing that they are experienced by the majority of individuals, across cultures (Radomsky et al., 2014). Nevertheless, some ITs cause distress and are associated with mental health difficulties (Engelhard, Macklin, McNally, Van den Hout & Arntz, 2001; Wenzlaff, 2005). In particular, ITs have been studied extensively in relation to obsessivecompulsive disorder (OCD), in which they are conceptualised as an integral motivator for compulsive behaviours (American Psychiatric Association, 2013). Obsessive intrusive thoughts (OITs) relate to themes such as socially inappropriate behaviour (e.g. sexual/aggressive), issues of cleanliness, and doubts/checking (García-Soriano, Belloch, Morillo, & Clark, 2011). They are thought to exist on a continuum of severity, ranging from infrequent intrusions that cause minimal distress, to persistent intrusions that lead individuals to seek help from services (Clark & Rhyno, 2005).

Like OITs, experiences that reflect psychotic symptoms are also prevalent among the non-clinical population (e.g. voice hearing; Beavan, Read, & Cartwright, 2011; delusions; Freeman, Pugh, Vorontsova, Antley, & Slater, 2010). Experiences associated with psychosis, in fact, have overlapping characteristics with anxiety disorders such as OCD, since in both cases there is often a perceived threat which causes anxiety or worry (Garety & Freeman, 2013). Similar cognitive processes may therefore underlie these two types of difficulties. For example, advocates of a transdiagnostic approach have suggested that ITs may play an important role in in the maintenance both of psychosis and anxiety (Harvey, Watkins, Mansell, & Shafran, 2004). Morrison (2001) has argued that all psychotic experiences are "intrusions into awareness" (p. 257) which can be cognitive, emotional, physiological or external, and are appraised in ways that are not culturally normative. If cognitive intrusions (i.e. ITs) are perceived as being generated by an external source, Morrison, Haddock, and Tarrier (1995) suggest that this could lead to the experience of hearing voices. Supporting this, associations between hearing voices and increases in ITs have been demonstrated (Jones & Fernyhough, 2006; Morrison & Baker, 2000). Voice hearing has also been linked with involuntary semantic memories, described as 'mind pops', and those diagnosed with schizophrenia have more mind pops than do controls (Elua, Laws, & Kvavilashvili., 2012, 2015). Mind pops are described as "fragments of semantic knowledge (words, phrases, images and songs) that unexpectedly pop into mind, often without obvious external/internal triggers" (Elua et al., 2015, p. 503), thus having similar process characteristics to ITs (Kvavilashvili & Mandler, 2004).

Elua et al. (2012, 2015) showed an increased vulnerability to intrusive experiences among those diagnosed with schizophrenia. However, implications were considered only in relation to voice hearing rather than other psychosis-related experiences, such as paranoia and persecutory delusions (PDs). In support of a link between PDs and intrusions, attempts to suppress unwanted paranoid thoughts are subsequently associated with more frequent and distressing persecutory beliefs (Hartley, Haddock, Vasconcelos e Sa, Emsley, & Barrowclough, 2015), particularly when an individual is highly anxious (Jones & Fernyhough, 2008). As thought suppression induces a 'rebound effect', and increases the prevalence of ITs (Wegner, Schneider, Carter, & White, 1987), paranoid ITs may mediate the relationship between suppression and an increased reporting of persecutory beliefs.

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Paranoid Intrusive Thoughts

Paranoia has been linked with experiences such as disrupted attachments due to childhood neglect and social deprivation, which create high levels of perceived injustice, a lack of trust in others, and low self-worth (Cororan et al., 2008; Wickham & Bentall, 2016; Wickham, Taylor, Shevlin, & Bentall, 2014). Paranoid ITs may therefore reflect understandable feelings of being unsafe, vulnerable, and powerless to protect oneself from a potentially dangerous world. However, what might be described as paranoid is not always clearly defined, and 'paranoia' is sometimes used synonymously with 'persecutory', although their meanings differ (McKay, Langdon, & Coltheart, 2006). Freeman and Garety (2000) defined persecutory beliefs as fears that harm is occurring, or will occur to an individual due to the actions of an intentional perpetrator. Alternately, they suggested that paranoia encompasses a broader range of experiences, such as notions that one is being talked about, observed or referred to by others (ideas of reference; Startup & Startup, 2005), which do not explicitly imply harm.

Freeman et al. (2005) conceptualised the range of paranoid experiences as existing in a hierarchy of severity, with social evaluative concerns (e.g. fears of rejection or vulnerability) and ideas of reference being lower down, while persecutory thoughts (subdivided into varying degrees of threat) are placed at the top (Figure 1). Freeman et al. developed their model with a non-clinical sample, and argued that thoughts lower down the hierarchy represent "common emotional concerns" (p. 433) experienced by many in the population, whereas thoughts about 'severe threat' at the top of the hierarchy better reflect clinically-diagnosable PDs, experienced at the upper end of the paranoia continuum. Although the model does not specify the process by which paranoid thoughts arise, thoughts with content from all levels of the hierarchy could feasibly intrude in to awareness in a non-volitional, unexpected way. As with OITs (Rachman, 1981), paranoid intrusions could occur in the form of thoughts, images, or impulses. Paranoid intrusions in the form of *thoughts* are likely to reflect similar themes to those described in the paranoia hierarchy and have already inadvertently been identified in the OIT literature. For example, in their cross-cultural survey of non-clinical participants, Radomsky et al. (2014) were investigating the presence of OITs, but identified ITs that related to fears of becoming a victim of violence. These types of thoughts can be conceptualised as fear-based cognitions associated with paranoia (as described in Freeman et al.'s, 2005 hierarchy), rather than obsessions. Similarly other research has described ITs about harm occurring to oneself or others (Rachman & De Silva, 1978; Parkinson & Rachman, 1981) as OITs, but they could instead be regarded as paranoid ITs.



Figure 1. The hierarchy of paranoia. Reprinted from "Psychological investigation of the structure of paranoia in the general population," by Freeman et al., 2005, *British Journal of Psychiatry*, *186*, p. 427. Copyright 2001 by the Royal College of Psychiatrists. Reprinted with permission via PLSClear.

As well as intrusions in the modality of thoughts, there is some evidence to support the existence of paranoid intrusive *images*. Schulze, Freeman, Green, and Kuipers (2013) found that, in a small sample (N = 29), a majority of participants with PDs (73%) experienced paranoia-related intrusive images. OITs can also occur in the form of *impulses*, usually to act in a certain way (e.g. to jump in front of a bus, Rachman & De Silva, 1978). Paranoid impulses could similarly be to take actions as a response to the threat of harm (e.g. impulses to get away or hide). Descriptions of obsessive-intrusive impulses highlight how these types of intrusions are experienced on an embodied level, for example, "I felt an intense urge to leap over the bridge... the impulse was so intense that my knees actually felt weak" (Clark & Rhyno, 2005, p. 2). Intrusive paranoid impulses could therefore reflect a more physiological, 'felt' sense of threat, rather than particular images or thoughts.

Paranoid ITs Across the Psychosis Continuum

There is evidence to suggest that individuals with psychosis-related diagnoses experience more frequent paranoid thoughts (Green et al., 2008), while those with OCD experience more frequent OITs (García-Soriano et al., 2011). Thus, paranoid ITs are also likely to be more frequent among those with psychosis, whose experiences may map on to the severe end of a continuum of paranoid intrusions. DeRosse and Karlsgodt (2015) reported that, for other psychosis-like symptoms, outpatients with schizophrenia diagnoses on average endorse more frequent symptoms than controls. However, they also stress that the distributions of symptom frequency for the two samples were overlapping (Figure 2), and both positively skewed (i.e. most participants endorsed fewer symptoms). As some members of the clinical and non-clinical populations appear to endorse similar rates of psychotic experiences, there must therefore be other factors which increase the likelihood of requiring support from mental health services. Psychosis-like experiences that are associated with increased distress could be conceptualised as better reflecting experiences from the upper end of the psychosis continuum. Indeed, Peters, Joseph, Day, and Garety (2004) identified distress as one marker of the extent to which delusion-like beliefs reflect clinically diagnosable symptoms. Similarly, the distress associated with OITs can be a crucial criterion for an OCD diagnosis (Clark & Rhyno, 2005). For OITs, there is evidence to suggest that intrusions about contamination may be more distressing than intrusions with different obsessive themes (Berry & Laskey, 2012). Similarly, in relation to Freeman et al.'s (2005) hierarchy, Green et al. (2008) found that those with PDs experience more persecutory thoughts than they do socially-driven ideas of reference (e.g. 'I often heard people referring to me'), whereas those without PDs show the opposite endorsement pattern. Thus, paranoid ITs that relate to more extreme threats may be more distressing.



Figure 2. Distribution of positive psychosis-like experiences assessed using the Community Assessment of Psychic experience with both patients with a diagnosis of schizophrenia or schizoaffective disorder. Reprinted from "Examining the Psychosis Continuum," by P. DeRosse and K. Karlsgodt, 2015, *Current Behavioural Neuroscience Reports, 2,* 80-89. Copyright 2015 by Springer. Reprinted with permission.

As well as the content of thoughts, the appraisals that are made about them can influence whether or not they cause distress. Berry and Laskey (2012) reviewed the wide range of appraisals about OITs that have been linked with the development of clinical obsessions, noting that the different appraisal strategies may be triggered by similar "underlying beliefs about mental processes" (p. 128), often described as metacognitive beliefs. Wells and Matthews (1994) argued that the cognitive and attentional strategies that maintain distress stem from an individual's metacognitive beliefs, and their transdiagnostic self-regulatory executive function (S-REF) model has been applied to both OCD (Wells, 1997) and paranoia (Morrison et al., 2011).

Wells and Matthews (1994) proposed that positive beliefs about cognitive events as important and desirable increase the frequency with which they occur, whereas negative beliefs about cognitive events as harmful and uncontrollable increase distress. Some studies have found a relationship between OCD symptoms and negative metacognitive beliefs about worrying thoughts being uncontrollable, dangerous, requiring punishment, and leading to negative actions (Gwilliam, Wells, & Cartwright-Hatton, 2004; Irak & Tosun, 2008; Wells & Papageorgiou, 1998). However, evidence is mixed regarding whether positive metacognitive beliefs about the value of worrying are associated with OCD symptoms (Hermans, Martens, De Cort, Pieters, & Eelen 2003; Wells & Papageorgiou, 1998). In relation to paranoia, positive metacognitive beliefs (e.g. seeing paranoia as a survival strategy) and negative metacognitive beliefs (e.g. seeing paranoia as damaging) were both associated with more frequent paranoid thoughts (Murphy et al., 2017). However, the distress associated with paranoia was found only to be associated with negative metacognitive beliefs (Morrison et al., 2005). Understanding whether metacognition has a similar relationship with paranoid intrusions could therefore provide insight into why some people have these experiences more frequently, and find them more distressing.

Assessing Paranoid Intrusions

To better understand paranoid ITs, an assessment of their prevalence and relationship with other variables is required. Although self-report measures of ITs are perhaps the most common means of assessment, current tools only assess obsessional thought content (e.g. Obsessional Intrusive Thoughts Inventory; García-Soriano et al., 2011), or do not specify the content of thoughts, but rather the general vulnerability to experience them intrusively (e.g. White Bear Suppression Inventory; Wegner & Zanakos, 1994). Furthermore, many measures have been criticised for their poor validity, imprecise definitions of ITs, and lack of significant relationships with clinical obsessions (García-Soriano et al., 2011). The use of existing measures of paranoid thoughts (e.g. Green et al., 2008) is similarly problematic, as there is no way to assess whether these thoughts are perceived as intrusive in nature (e.g. are unwanted, unexpected, and interrupt ongoing thoughts).

A self-report measure of paranoid ITs would build on current understandings of paranoia and the content of existing measures of paranoid thoughts (e.g. The Green Paranoid Thoughts Scale [GPTS]; Green et al., 2008), but allow the assessment of the process of experiencing the thoughts intrusively. The assessment of the frequency and distress of paranoid intrusions among individuals with and without psychosis would produce findings that reflect the proposed continuum of paranoid experiences (van Os, Linscott, Myin-Germeys, Delespaul, & Krabbendam, 2009). Identifying factors that may make paranoid ITs more frequent or distressing, such as metacognitive beliefs, would also have implications for treatment and early intervention in psychosis. Finally, in clinical practice, a self-report measure of paranoid ITs could be used for the assessment of individuals with psychosis, and to identify changes in paranoid IT frequency and distress over the course of therapeutic interventions.

Aims and Hypotheses

This study aimed to develop a Paranoid Intrusive Thoughts Scale (PITS) that was appropriate for use across the continuum of paranoid experience among those with and without psychosis, and thereby to assess the prevalence of paranoid ITs and their distribution across the sample. A further aim was to produce a questionnaire that met requirements specified by Terwee, de Vet, and Mokkink (2011) for evidencing good structural, content, and construct validity, as well as good internal and test-retest reliability (Appendix A). To evidence the construct validity of the scale, several hypotheses were made about the relationship between paranoid ITs and other variables:

- There will be a large, significant, positive correlation (r > .50) between the frequency of paranoid ITs, and the frequency of general paranoid thoughts (convergent validity).
- 2. There will be a large, significant, positive correlation (r > .50) between the distress caused by paranoid ITs, and the distress caused by general paranoid thoughts (convergent validity).
- 3. There will be a positive correlation between the frequency of paranoid ITs, and symptoms of anxiety and depression. However, these correlations will be smaller in size than the correlation between PITS frequency scores and GPTS frequency scores (divergent validity).
- Members of the sample who have psychosis-related diagnoses will experience significantly more frequent, and significantly more distressing, paranoid ITs (known-groups validity).

As well evidencing the psychometric properties of the PITS, another aim of the study was to investigate the relationship between meta-cognitive beliefs about paranoia
with the frequency of paranoid ITs and the distress that they cause. The following experimental hypotheses were therefore made:

- Within a linear regression, having more negative beliefs about paranoia, and more positive beliefs about paranoia as a survival strategy will be associated with more frequent paranoid ITs.
- Within a linear regression, having more negative beliefs about paranoia will be associated with increased paranoid IT-related distress.

Method

This was a cross-sectional, questionnaire-based study comprised of three phases. Phase one involved the generation of a 12-item paranoid intrusive thoughts questionnaire (PITS-12). From a large pool of potential questionnaire items, consultation with experts was used to create an initial 20-item paranoid IT scale (PITS-20). Questionnaires were distributed to participants and subsequent evaluation of the structural validity of the PITS-20 resulted in a reduction of items to create the final PITS-12. Phase two assessed the reliability and validity of the PITS-12. Phase three tested the experimental hypotheses regarding the relationship between paranoid ITs and meta-cognitive beliefs.

Participants

Two main samples were used in the study. Sample 1 included a mix of participants with and without psychosis-related diagnoses (N = 339) to reflect the range in paranoid experience across the continuum of psychosis s (from experiences that do not lead to help-seeking, to those that do). All non-clinical participants were either staff or students at a UK university invited via email invitation, or members of the public recruited via social media. Non-clinical participants were excluded from the study if they disclosed having had a previous episode of psychosis, or were under 18 years old. Clinical participants were recruited by staff working in Early Intervention in Psychosis

teams, or Community Mental Health Teams, in English cities. Participants had either been assessed as having experienced a first episode of psychosis, or had a formal diagnosis with the category of "Schizophrenia Spectrum and other Psychotic Disorders" (American Psychiatric Association, 2013). Clinical participants were not recruited if they had a primary diagnosis of substance misuse, had been assessed by Early Intervention teams as having an 'at risk mental state' (rather than an episode of psychosis), were under 18 years of age, or did not have the capacity to consent to participation.

A further, independent non-clinical sample (Sample 2) was also recruited. This sample consisted solely of non-clinical participants (N = 239); university staff or students at invited via email invitation, or members of the public recruited via social media. The same exclusion criteria as with non-clinical participants from Sample 1 applied.

Table 1 illustrates the demographics of Samples 1 and 2. Overall, in both samples, the majority of participants were White British or Irish and there were more females than males. A small proportion of individuals had other gender identities (Sample 1 = 3%; Sample 2 = 1%). The mean age and age range of individuals in Samples 1 and 2 were also similar.

Within Sample 1 both those who had experienced psychosis and those recruited from the general population were of a similar age, and were largely White British/Irish. However, those from a clinical background were more likely to be male, whereas those from non-clinical backgrounds were more likely to be female.

Fifty percent of non-clinical participants from Sample 1, and 42% of nonclinical participants from Sample 2 had previously received support from a healthcare service for a mental health problem other than psychosis.

Table 1

	Age (ye	Age (years) Gender		nder	Ethnicity	
	M (SD)	Range	Male	Female	White/British/Irish	Other
			(%)	(%)	(%)	(%)
Sample 1						
Total (<i>N</i> = 339)	31 (13.12)	18-73	32	65	81	19
Non-clinical participants ($n = 311$)	31 (13.41)	18-73	29	69	80	20
Clinical participants $(n = 28)$	28 (9.10)	19-56	68	29	86	14
Sample 2						
Total (<i>N</i> = 239)	31 (11.81)	18-68	33	66	75	25

Demographic characteristics of the samples

Measures¹

The Paranoid Intrusive Thoughts Scale - 20 (PITS-20; Appendix B). The PITS-20 was developed as part of the study (see Procedure section for further details). The measure consisted of 20-items representing paranoid intrusive thoughts. Each item was rated by marking the appropriate point on a ten-point scale, to show how frequently the intrusion had been experienced in the last three months (0 = never, 10 = all the time), and how much distress it caused (0 = not at all upsetting, 10 = extremelyupsetting).

The Paranoid Intrusive Thoughts Scale - 12 (PITS-12). The PITS-12 was

developed as part of the study and represents a refined, shorter version of the PITS-20. Twelve items form three subscales which assess intrusions of persecution (PITS-12^{PERS}: 5 items), an intrusive sense of threat (PITS-12^{SOT}: 5 items), and social reference intrusions (PITS-12^{SREF}). Ratings for items were the same as for the PITS-20.

Total frequency scores (PITS-12^{FREQ}) were calculated by summing the ratings on frequency scales across all 12 items. Similarly, total distress scores (PITS-12^{DIS})

¹ Copies of all measures used in the study (other than the PITS versions which were created by the authors) have been removed from Appendices for copyright reasons

were calculated by summing all available distress ratings. Total scores on the PITS-12^{PERS}, PITS-12^{SOT}, and PITS-12^{SREF} were calculated by summing frequency scores for only items on that particular subscale. As all participants, from all samples, completed the PITS-20, in analyses using the PITS-12, data pertaining to the relevant 12 items was extracted from this longer measure.

The Green Paranoid Thoughts Scale (GPTS; Green et al., 2008). The GPTS is a 32-item measure of paranoid thinking that has been validated with clinical and nonclinical samples (Green et al., 2008). Respondents indicate the frequency with which they have had the experiences described over the last month, ranging from 1 (not at all) to 5 (totally). Two studies have confirmed that the measure has a 2-factor structure (Green et al., 2008; Ibáñez-Casas et al., 2015), although item to participant sample size ratios were below optimal. The GPTS subscales assess thoughts of persecution (GPTS^{PERS}) and thoughts of social reference (GPTS^{REF}). The distress (GPTS^{DIS}), preoccupation (GPTS^{PRE}), and conviction (GPTS^{CONV}) associated with paranoid thoughts are also assessed. Green et al. (2008) and Ibáñez-Casas et al. (2015) report good internal consistency ($\alpha > .7$) for the total scale and subscales, and provide evidence of construct validity. Green et al. (2008) also found the measure to have good test-retest reliability (intraclass correlation coefficient [ICC] = .88). In the current study the scale had good internal consistency: GPTS^{TOTAL} ($\alpha = .97$), GPTS^{PER} ($\alpha = .97$), and GPTS^{REF} ($\alpha = .95$)

The Generalized Anxiety Disorder Scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is a 7-item questionnaire used to measure symptoms of anxiety. Respondents rate how often they have had the symptoms described within the last two weeks, ranging from 0 (not at all) to 3 (nearly every day). Spitzer et al. (2006) evidenced a unidimensional structure, with good internal consistency ($\alpha = .92$), test-retest reliability (ICC = .83), construct validity, and accurate

identification of those with anxiety disorders. The GAD-7 has been validated with both clinical (Spitzer et al., 2006) and non-clinical samples (Löwe et al., 2008). In the current study the scale had good internal consistency ($\alpha = .91$).

The Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, & Williams, 1999). The PHQ-9 is a 9-item questionnaire used to measure symptoms of depression. Respondents rate how often they have had the symptoms described within the last two weeks, ranging from 0 (not at all) to 3 (nearly every day). Kroenke, Spitzer, and Williams (2001) evidenced a unidimensional scale, with good internal consistency (α = .89), test-retest reliability (r = .84), construct validity, and accurate identification of those with depression. The measure has been validated with clinical (Kroenke et al., 2001) and non-clinical participants (Martin, Rief, Klaiberg & Braehler, 2006). In the current study the scale had good internal consistency (α = .91).

The Beliefs about Paranoia Scale - Short Form (BaPS-short form; Gumley, Gillan, Morrison, & Schwannauer, 2011). The BaPS (short form) is an 18-item selfreport measure of meta-cognitive beliefs about paranoia. Respondents indicate their agreement with different statements about paranoia, ranging from 1 (not at all) to 4 (very much). The measure was developed with a non-clinical sample (Gumley et al., 2011), but its 3-factor structure has been replicated among participants with psychosisrelated diagnoses (Morrison et al., 2011; Murphy et al., 2017). The BaPS subscales assess negative beliefs about paranoia (e.g. BaPS^{NB}; 'my paranoia distresses me'), positive beliefs about paranoia as a survival strategy (e.g. BaPS^{SS}; 'my paranoia protects me'), and normalising beliefs (e.g. BaPS^{NORM}; 'paranoia is normal'). Gumley et al. (2011) and Morrison et al. (2011) evidenced all subscales' good internal consistency ($\alpha > 0.7$), and this was replicated in the current study: BaPS^{NB} ($\alpha = .91$), BaPS^{SS} ($\alpha = .90$), and BaPS^{NORM} ($\alpha = .92$).

Procedure

Generation of PITS items. A large pool of PITS items were generated by the researcher and supervisors drawing on content from existing paranoia questionnaires (e.g. Paranoia Scale; Fenigstein & Vanable, 1992; GPTS; Green et al., 2008) and theoretical understandings of paranoia (e.g. Freeman & Garety, 2014). In line with research associating paranoia with low self-esteem, trust, and a reduced sense of fairness (Cororan et al., 2008; Wickham et al., 2014; Wickham & Bentall, 2016), items reflected related themes thought to be central to paranoid experience, such as perceived vulnerability, unsafeness, powerlessness, and a lack of ability to protect oneself.

Items were developed to reflect a range of paranoid thoughts from the levels of Freeman et al.'s (2005) paranoia hierarchy. The upper hierarchy represents persecutory thoughts, and thus some items were phrased to reflect Freeman and Garety's (2000) identified elements of persecutory beliefs. For example, some items related to present or ongoing threats of harm (e.g. *I am being* targeted), and some made reference to an intentional agent behind the threat (e.g. *people* are out to get me). To reflect the lower hierarchy, items were generated to represent ideas of reference (i.e. thoughts that neutral happenings refer to an individual personally, or have personal significance; Startup & Startup, 2005). Items that reflected strong, intrusive urges to complete an action when feeling under threat were also generated (e.g. *I need to hide from people*), or an intrusive 'felt' sense of threat (e.g. *I am not safe*).

Previous definitions of ITs (Clark & Rhyno, 2005; García-Soriano et al., 2011; Rachman, 1981; Rachman & de Silva, 1978) informed the phrasing of items and initial description of paranoid intrusive thoughts (Appendix C). The description explained that items could be experienced in the form of intrusive thoughts, images, and impulses. Items were also phrased to reinforce the intrusive nature thoughts (i.e. how often thoughts "*popped in to your head*" '*without you trying*"). **Consultation.** Fifty-nine PITS items (Appendix D) were circulated to four academics (two experts in paranoia, two experts in intrusive thoughts), three clinical psychologists working in the NHS with clients experiencing psychosis, and two experts with lived experience of paranoia and/or anxiety, working for mental health services. Experts rated items on a scale of 0 to 10, where, 0 indicated a very poor example of a paranoid IT and 10 indicated an excellent example. They also commented on the description of intrusive thoughts, the format of the questionnaire, and the scale used to record responses.

Twenty of the top-rated items by experts were retained to create the PITS-20 (Appendix B). Based upon expert feedback, items were retained that were applicable across various, idiosyncratic paranoid experiences. For example, some items were rephrased so that rather than specifying that *people* were the perpetrators of harm, other agents could be implicated (e.g. extra-terrestrial beings, God). Although more persecutory ITs reflecting the upper hierarchy were rated highly, it was ensured that some highly rated items from the lower hierarchy were also included for breadth. Finally, following advice, the frequency and distress PITs scales were designed as 0 to 10 scales, with only the start and end points labelled, to ensure a true interval scale.

Pilot. The 20-item PITS was piloted in paper format with a group of individuals from a local mental health charity who had a range of psychiatric diagnoses, including those relating to psychosis and OCD. Participants in the pilot described the measure as relevant to their experiences and generally easy to understand. However, changes to the wording and proposed scoring system were made based upon feedback. The questionnaire was also piloted in an online format with two individuals from the general population to ensure that it could be understood without any difficulties.

Distribution of questionnaires. The PITS-20 along with the GPTS, GAD-7, PHQ-9 and BaPS-short form was distributed to members of Sample 1. The battery of

questionnaires included an information sheet at the beginning (Appendix E), which described what the study would entail and asked for consent for participation. There was also a debrief sheet at the end with further information about the study and researcher contact details (Appendix F). Non-clinical participants completed all questionnaires online, whereas clinical participants had the option of completing paper or online versions.

Non-clinical participants from Sample 1 who consented to be contacted again were emailed two weeks after their initial completion of the measures (Time 2) with a link to the online version of the PITS-20, which they were asked to complete. The PITS-20 was presented as the first questionnaire in the battery at Time 1 to ensure similarity of administration at Time 2, where this was the only questionnaire completed.

The PITS-20, along with information and debriefing sheets was also distributed to a further independent sample (Sample 2) to obtain data for use in a confirmatory factor analysis.

Ethical Issues

The study received ethical approval from the National Health Service (NHS) Research and Ethics Committee (Appendix G). Anonymity of questionnaire responses was ensured through the use of anonymous codes, rather than linking personal details to responses. Participants were informed of their right to withdraw their data (Appendix E). Data were also stored securely. Finally, in the study debriefing information participants were advised where they could access support if they were distressed by the study (Appendix F).

Analyses

All data analyses were performed using SPSS (Version 22). Figure 3 illustrates the different samples used for different stages of the analyses.



Figure 3. A flow chart to demonstrate which samples were used at each stage of the analysis

Phase One: Development of the PITS-12. The structural validity of the PITS-20 was assessed using exploratory (EFA) and confirmatory (CFA) factor analyses. An EFA was conducted using PITS-20 data from the mixed clinical and non-clinical sample (Sample 1) and a subsequent CFA was conducted using data from solely nonclinical participants (Sample 2). All participants from Sample 2 completed the 20-item PITS. However, only data relating to the developed PITS-12 items were used in the CFA.

Mokkink et al. (2012) recommend that to assess the structural validity of a questionnaire, the sample size should be greater than the number of items multiplied by 7. The sizes of Samples 1 & 2 were both larger than this recommended value (7 x 20 = 140).

For the EFA, a principal components analysis (PCA) method was used, as it was expected that there would be high correlations between scores on items, and PCA is effective even in the case of multicollinearity (Field, 2009). An oblique rotation (Direct Oblimin) was applied, as factors were also expected to be correlated (Field, 2009).

Assumptions of the factor analysis were examined in line with recommendations by Field (2009), i.e. that there was adequate sampling adequacy (Kaiser-Meyer-Olkin measure > .7), and sufficiently large correlations for PCA (p < .05 for Bartlett's test of Sphericity).

When deciding upon the numbers of factors to retain, those with eigenvalues > 1 were examined (according to Kaiser's criteria; Kaiser, 1960), along with Monte Carlo parallel analysis using 150 repetitions and examination of the scree plot (Cattell, 1966). In line with Field (2009), items were considered for exclusion if their largest loading on a factor was small (approximately < .4), if they cross-loaded across factors, or if their presence hindered the establishment of conceptually clear subscales.

For the CFA factor analysis the same steps as for the EFA were completed, but with a specified number of factors extracted as identified in the previous analyses.

Phase Two: Questionnaire Validation. Validation analyses were conducted on data from the mixed clinical and non-clinical sample (Sample 1; N = 339). For test-retest analyses data from a subset of participants from this sample were used (n = 96). All participants had completed the PITS-20 within the original questionnaire battery. However, data pertaining to the PITS-12 were extracted from responses and used in validation analyses.

Mokkink et al. (2012) advise that the methodologies of studies assessing internal consistency, test-retest reliability, and hypotheses related to construct validity, can be described as 'excellent' if the sample size used is \geq 100. This criterion was met for all validation analyses aside from test-retest reliability (n = 96), where Mokkink et al. would describe the sample size used as 'good' (50-99 participants).

Normality tests. The normality of data relating to ratings paranoid IT frequency and distress was assessed using Kolmogrov-Smirnov tests. If distributions were significantly different from normal, non-parametric tests were employed. The amount of missing data was reported and Mann-Whitney U tests used to examine any differences in the characteristics of participants with and without missing data.

Endorsement of measures and relationships with demographic factors. Mean scores on the PITS-12 and other measures used to assess validity (GPTS, GAD-7, & PHQ-9) were calculated. To assist with the interpretation of the pattern of PITS-12 scoring, a histogram to show the distribution of the frequency of paranoid ITs within the sample was examined. The relationship between demographic variables and PITS-12 scoring was also assessed. Spearman's correlation coefficients between participant age and the frequency and distress scores on the PITS-12 were calculated. Mann-Whitney U

tests were used to examine differences in PITS-12 scoring between males and females, and those with or without minority ethnic status.

Internal and test-retest reliability. For all PITS-12 subscales, Cronbach's alphas were calculated to assess internal consistency and average measures ICCs were calculated to assess test-retest reliability. A two-way mixed effects ICC model was applied, as consistency in scores from the same individuals was being assessed (Koo & Li, 2016). Terwee et al. (2011) recommend that to evidence acceptable psychometric properties, Cronbach's alpha and ICCs should be > .70.

Construct validity. Next, the hypotheses relating to the construct validity of the PITS-12 were tested. Terwee et al. (2011) recommend that when validating a questionnaire, correlations with related measures should be \geq .50, and at least 75% of the hypotheses about construct validity should be supported. Spearman's correlation coefficients were used to examine the relationship between frequency scores on the PITS-12 with frequency scores on the GPTS, PHQ-9 total scores, and GAD-7 total scores. Correlations between the distress scales of the PITS-12 and GPTS were also calculated. Correlation sizes (e.g. small, large) were interpreted according to guidance from Cohen (1992).

Mean scores for all PITS-12 subscales were reported separately for members of the sample who did, or did not, have a psychosis-related diagnosis. As the subscales assessing intrusions of persecution and an intrusive sense of threat had 5-items, while the social reference intrusions subscale only had 2-items, the mean total score on the latter subscale was transformed to represent a mean obtained from a 5-item scale. This enabled a face value comparison of subscale scores and was achieved by multiplying the mean score from the social reference intrusions subscale by the proportion 5/2, to scale it up. To assess known-groups validity, Mann-Whitney U tests were used to compare the frequency and distress scores on the PITS-12, and its individual subscales, between clinical and non-clinical participants. The distribution of the frequency of paranoid ITs was also compared between clinical and non-clinical participants using histograms.

Phase Three: Paranoid ITs and meta-cognitive beliefs. To test the experimental hypotheses relating to meta-cognitive beliefs, data from mixed clinical and non-clinical participants was used (Sample 1, N = 339). Although participants completed the PITS-20, data for the PITS-12 was extracted and used in analyses during this phase.

An *a priori* power analysis determined the sample size needed to prevent type II errors when conducting multiple linear regressions to predict scores on the frequency and distress scores from the PITS-12. Assuming a medium effect size of $R^2 = .13$, a significance level of alpha = .05, and six predictors, a sample size of 98 was required to achieve 80% power. Thus, the sample size used for these analyses provided adequate power.

Spearman's correlations coefficients between the different types of beliefs about paranoia measured by the BaPS (positive, negative, normalising) and the frequency and distress scores from the PITS-12 were calculated.

Multiple linear regressions were conducted to see which variables were predictive of firstly PITS-12^{FREQ} scores, and secondly PITS-12^{DIS} scores. Age, anxiety, and depression were significantly correlated with PITS-12^{FREQ} and PITS-12^{DIS} scores in phase two of the study, and were therefore entered in to the regression as control variables, followed by any BaPS subscales that significantly correlated with the dependent variables.

Assumptions of the regression were tested against Field's (2009) recommendations. Case to variable ratio should be > 10:1, and to meet the assumption

of independent errors, Durbin-Watson statistic should be close to 2. The absence of multicollinearity was assumed if predictor variables were not too highly correlated (r < .90), Tolerance was > 0.2, and VIF was close to 1. Residuals were examined to see if they showed evidence of homoscedasticity and a normal distribution. Casewise diagnostics were also examined to determine if over 5% of cases had standardised residuals greater than 2 and may therefore be unduly influencing model. Cases were deemed as potentially problematic if Cook's distance was greater than 1, leverage values were 3 times greater than the average leverage (i.e. > .0531), and Mahalanobis distance was < 20.

Results

Phase One: Development of the PITS-12. No participants had any missing data on the PITS-20.

Exploratory factor analysis. Sampling adequacy was acceptable (Kaiser-Meyer-Olkin measure = .93), and there was evidence of significant correlations between variables, $X^2(190) = 4031.06$, p < .001.

Kaiser's criteria recommended that a 3-factor solution should be retained, which explained 60% of the variance in scores. Monte Carlo parallel analysis suggested a 2factor structure (explaining 54% of the variance), although the difference between the actual Eigenvalue for the third component and the value generated using parallel analysis was minimal (Table 2). Examination of the scree plot (Appendix H) and item loadings (Table 3) also suggested that the 3-factor solution was a better fit to the data. Table 2

Eigenvalues extracted for each component and those generated using parallel analysis

Component	Eigenvalues extracted for	Eigenvalues generated using Monte
	components	Carlo parallel analysis
1	9.282	1.459
2	1.512	1.374
3	1.275	1.309
4	0.973	1.255

Table 3 shows that six items had high loadings on factor 1 (> .68) with minimal cross loading (< .3). Of these, five were related clearly related to persecutory thinking, whereas item 20 was more related to ideas of reference and was therefore excluded. On factor 2 there were five items with high loadings (> .66) and minimal cross loading (< 0.3). Finally, for factor 3 there were two items with high positive loadings (> .73) and minimal cross loading (< .2). The remaining items were excluded due to having lower loadings on their primary factor, cross-loading on other factors, and/or not being conceptually related to other items in the subscales (items 16, 8, 19, 18, 4, 11 & 6). The exclusions led to the creation of a 3-factor PITS with 12 items (PITS-12, items emboldened in Table 3). Factor 1 was labelled, 'intrusions of persecution', factor 2 was labelled 'intrusive sense of threat', and factor 3 was labelled, 'social reference intrusions'.

Table 3

Pattern matrix from the EFA of the PITS-20

		Component	
	1	2	3
13 - I am being targeted	0.938	0.099	-0.91
10 - People are after me	0.882	-0.036	-0.078
17 - There is a plot against me	0.829	-0.015	-0.035
3 - People are out to get me	0.811	0.049	0.147
12 - People want to hurt me	0.689	-0.241	-0.032
20 - Messages on the TV or internet are just for me	0.675	-0.116	0.009
16 - People want to kill me	0.538	-0.334	-0.221
19 - People know what I am thinking	0.534	-0.040	0.257
8 - I am being watched	0.532	-0.079	0.256
18 - People are trying to control me	0.526	-0.034	0.204
4 - Other people are a threat	0.423	-0.343	0.159
7 - I am not safe	-0.103	-0.898	0.030
14 - I am at risk of harm	0.162	-0.732	-0.055
5 - I need to keep myself safe	-0.103	-0.723	0.175
9 - I don't feel safe anywhere	0.038	-0.719	0.007
15 - My life is in danger	0.227	-0.657	-0.151
11 - I need to hide from people	0.197	-0.335	0.229
2 - I know what other people think about me	-0.036	-0.059	0.811
1 - People are talking about me behind my back	0.124	-0.105	0.736
6 - People are against me	0.456	0.033	0.500

Note. Emboldened items represent those retained for the final PITS measure and their highest loadings on a particular factor.

Component 1 = Intrusions of persecution

Component 2 = Intrusive felt sense of threat

Component 3 = Social reference intrusions

Confirmatory Factor Analysis. Scores from Sample 2 on the PITS-12 were used in a subsequent CFA. Sampling adequacy (Kaiser-Meyer-Olkin measure = .89), and the significant correlations between variables, $X^2(66) = 1859.83$, p < .001), suggested that assumptions for factor analysis had been met.

Table 4 illustrates that all items loaded highly (> .5) on the same factors as was shown in the previous EFA. While some items cross-loaded across factors (e.g. items 5, 10, 13), the size of these loadings was generally small (< .4). Item 12 was the only item which cross-loaded to a greater extent, loading upon the 'intrusions of persecution' factor by .57, and but also cross-loaded on the 'intrusive sense of threat' factor by .45. However, as the item was highly weighted on its primary factor, and the overall factor structure was accurately replicated, it was included within the final measure.

Table 4

		Component	
	1	2	3
7 - I am not safe	0.879	-0.098	0.170
14 - I am at risk of harm	0.867	0.105	-0.108
9 - I don't feel safe anywhere	0.767	0.126	-0.020
15 - My life is in danger	0.745	0.225	-0.157
5 - I need to keep myself safe	0.731	-0.217	0.390
17 - There is a plot against me	-0.165	0.893	0.131
13 - I am being targeted	0.193	0.799	0.045
10 - People are after me	0.361	0.663	-0.012
3 - People are out to get me	0.021	0.659	0.363
12 - People want to hurt me	0.453	0.570	-0.064
2 - I know what other people think about me	0.036	0.094	0.827
1 - People are talking about me behind my back	0.019	0.215	0.772

Pattern matrix from the CFA of the PITS-12

Note. Emboldened scores indicate largest loading on a single factor

Component 1 = Intrusive felt sense of threat

Component 2 = Intrusions of persecution

Component 3 = Social reference intrusions

Phase Two: Questionnaire Validation.

Normality tests. Kolmogorov-Smirnov tests found the distribution of PITS-

$$12^{\text{FREQ}}$$
 scores, $D(339) = .234$, $p < .001$, and PITS- 12^{DIS} scores, $D(339) = .226$, $p < .001$

to be significantly different from normal. Thus all analyses involving these variables

were conducted using non-parametric tests.

Missing data. No participants had missing data on the PITS-12. However, 8.5% of participants had missing data on other study measures. Due to the relatively large sample size and small proportion of missing data, in line with Howell (2008) casewise deletion was employed, with participants being excluded from any analyses where they had missing data. Mann-Whitney U tests showed that those with missing data (n = 29) did not significantly differ from the rest of the sample in their age, U = 4388.5, p = .833, frequency of paranoid ITs, U = 4347, p = .769, and distress caused by paranoid ITs, U = 4256.5, p = .635. Chi-squared tests also found no differences between those with and without missing data in the number of participants identifying as male or female, $X^2(1, N = 331) = 3.26$, p = .071, or the number of participants from a minority ethnic background, $X^2(1, N = 339) = 1.68$, p = .194.

Endorsement of the PITS-12. Mean scores on the subscales of the PITS-12 are presented in Table 5, along with mean scores on the other validation measures. The transformed mean value suggested that social reference intrusions were the most common type of IT. The majority of participants (81%) endorsed having had at least one paranoid IT. However, the frequency distribution of paranoid ITs (Figure 4) was positively skewed, indicating that many people had infrequent paranoid ITs, and few people had very regular paranoid ITs.

Table 5

Scales	# items	М	SD
PITS-12 ^{FREQ}	20	13.35	18.40
PITS-12 ^{DIS}	20	15.00	19.90
PITS-12 ^{PERS}	5	2.94	8.23
PITS-12 ^{SOT}	5	5.20	8.88
PITS-12 ^{SREF}	Scaled to $5(2)$	13.05 (5.22)	13.28 (5.31)
GPTS ^{FREQ}	32	48.49	23.90
GPTS ^{DIS}	8	11.74	6.25
GAD-7	7	7.54	5.66
PHQ-9	9	8.18	6.68

Mean values obtained on scales from self-report questionnaires

Relationship between PITS-12 scoring and demographic variables.

Spearman's correlation coefficients suggested that being younger was moderately associated with more frequent (r = -.35, p < .001) and distressing (r = -.34, p < .001) paranoid ITs. No significant differences in PITS- 12^{FREQ} or PITS- 12^{DIS} scores were found between men and women (PITS- 12^{FREQ} ; U = 11169, p = .227; PITS- 12^{DIS} ; U = 10701.5, p = .075), or between those who were, or were not, White British/Irish (PITS- 12^{FREQ} ; U = 8576.5, p = .543; PITS- 12^{DIS} ; U = 8869.5, p = .844).





Internal consistency. The internal consistency for the social reference PITS-12

subscale ($\alpha = .69$) was slightly below recommended levels. However, all other PITS-12

subscales demonstrated good internal consistency (Table 6).

Table 6

Subscale	Cronbach's alpha (α)
PITS-12 ^{FREQ}	.89
PITS-12 ^{DIS}	.94
PITS-12 ^{PERS}	.91
PITS-12 ^{SOT}	.82
PITS-12 ^{SREF}	.69

Test-retest reliability. All PITS-12 subscales demonstrated temporal stability

over a two week period (Table 7).

Table 7

Test-retest reliability of all PITS-12 subscales

Subscale	Average measures ICC
PITS-12 ^{FREQ}	.87**
PITS-12 ^{DIS}	.83**
PITS-12 ^{PERS}	.80**
PITS-12 ^{SOT}	.87**
PITS-12 ^{SREF}	.90**

Note . **p < .001.

Construct validity. Spearman's correlation coefficients between PITS-12 scores and the variables used to assess construct validity are displayed in Table 8. There was a large, significant correlation between the frequency of paranoid ITs (PITS-12^{FREQ}) and paranoid thoughts generally (GPTS^{FREQ}), thus illustrating that the PITS-12 has good convergent validity (Hypothesis 1). Similarly, there was a large, significant correlation between the distress caused by paranoid ITs (PITS-12^{DIS}) and the distress caused by paranoid thoughts generally (GPTS^{DIS}), again providing evidence of convergent validity (Hypothesis 2). There was also a very large correlation between frequency and distress scores on the PITS-12, which was of a similar size to the correlation between the frequency and distress subscales of the GPTS.

Table 8

	PITS-12 ^{FREQ}	PITS-12 ^{DIS}	GPTS ^{FREQ}	GPTS ^{DIS}	GAD-7	PHQ-9	
PITS-12 ^{FREQ}	1						
PITS-12 ^{DIS}	.94**	1					
GPTS ^{FREQ}	.69**	.69**	1				
GPTS ^{DIS}	.66**	.68**	.89**	1			
GAD-7	.61**	.62**	.62**	.60**	1		
PHQ-9	.56**	.56**	.62**	.57**	.79**	1	
	0.1						

Correlations between measures used to assess the construct validity of the PITS-12

Note. ***p* < .001.

There was a large, significant correlation between the frequency of paranoid ITs and levels of anxiety and depression. The correlation between the frequency of paranoid ITs (PITS-12^{FREQ}) and paranoid thoughts generally (GPTS^{FREQ}), was larger than the

correlations between paranoid ITs and measures of depression and anxiety (Hypothesis 3), illustrating divergent validity.

Table 9 shows that members of the sample who had a psychosis-related diagnoses obtained higher mean scores on all subscales. Mann-Whitney U tests confirmed that differences between clinical and non-clinical participants were statistically significant, illustrating known-groups validity, and providing further evidence for the construct validity of the PITS-12 (Hypothesis 4). The mean values obtained on subscales suggested that social reference intrusions were the most common ITs for clinical participants, whereas for clinical participants intrusions of persecution were just as frequent as social reference intrusions.

Table 9

Mean scores and Mann-Whitney U tests comparing PITS-12 subscales between clinical and non-clinical participants

	# items	<u>Non-c</u> partic	linical ipants 211)	Clinical pa (N =	articipants = 28)	
		M $(N - M)$	STT) SD	М	SD	U
PITS-12 ^{FREQ}	12	10.47	12.38	45.39	36.29	1790.5**
PITS-12 ^{DIS}	12	12.08	14.59	47.32	36.52	1757.5**
PITS-12 ^{PERS}	5	1.29	3.81	21.18	17.47	991**
PITS-12 ^{SOT}	5	4.26	7.38	15.61	15.44	2260.5**
PITS-12 ^{SREF}	Scaled to 5	12.77	12.60	21.53	21.53	3057*
	(2)	(4.91)	(5.04)	(8.61)	(7.03)	

*p < .05, p < .001

Figures 5 illustrates that the distribution of PITS-12 scoring was positively skewed for both clinical and non-clinical participants. The distributions are overlapping, showing that although those with psychosis-related diagnoses generally had higher mean scores on the PITS-12^{FREQ}, some non-clinical participants had more frequent paranoid ITs than some clinical participants.



Figure 5. Histogram to show the distribution of PITS-12^{FREQ} among clinical, compared with non-clinical, participants

Phase Three: Paranoid ITs and meta-cognitive beliefs. Phase three of the study tested the hypothesised relationships between meta-cognitive beliefs about paranoia and the frequency and distress associated with paranoid ITs.

Missing data. Casewise deletion (Howell, 2008) was employed if participants

had missing data on any of the measures used in phase three analyses.

Correlations between PITS-12 subscales and meta-cognitive beliefs about

paranoia. Table 10 shows that there was a positive, significant relationship between all of the different types of meta-cognitive beliefs about paranoia (BaPS subscales) with both the frequency and distress scores on the PITS-12. Negative beliefs about paranoia had the largest association with more frequent and distressing paranoid ITs.

	PITS-12 ^{FREQ}	PITS-12 ^{DIS}	BaPS ^{NB}	BaPS ^{SS}	BaPS ^{NORM}	
PITS-12 ^{FREQ}	1					
PITS-12 ^{DIS}	.94**	1				
BaPS ^{NB}	.65**	.68**	1			
BaPS ^{SS}	.59**	.56**	.55**	1		
BaPS ^{NORM}	.39**	.38**	.40**	.52**	1	

Spearman's correlation coefficients between PITS-12 subscales and BaPS subscales

Note. ***p* < .001

Multiple linear regressions. For both hierarchal regressions, age was entered into the first block, followed by anxiety and depression in the second block, and then each BaPS subscale was entered into a separate block. All BaPS subscales were entered in to the regression due to their significant correlations with the dependent variables.

Both regressions met the following assumptions: adequate case to variable ratio (324:5), no evidence of multicollinearity, and independence of errors. However, for both regressions, the residuals were not normally distributed and there was evidence of heteroscedasicity within the data, which suggested that the assumption of homogeneity of variance may have been violated.

From the PITS-12^{FREQ} regression, 16 cases had standardized residuals above 2, which is less than 5% of the total sample size (16.7). For the PITS-12^{DIS} regression 17 cases had standardized residuals above 2, which is slightly greater than 5% of the total sample size. The majority of these outliers were participants with a diagnosis of psychosis. This suggested that they did not represent errors in the data, as some clinical participants would be expected to have higher scores than the rest of the sample, which mainly consisted of non-clinical participants. Further examination of the cases confirmed that the majority did not have a large impact upon the regression models.

All five regression models predicted PITS-12^{FREQ} scores significantly better than the constant only model, and adding each block of variables significantly improved the model. The change statistics reported in Table 11 illustrate that, of the BaPS subscales, the addition of the negative beliefs about paranoia scale resulted in the largest 88 improvement in the model. The final model, F(6,312) = 57.92, p < .001, accounted for

52% of the variance in the frequency of paranoid ITs.

Table 11

Model summary for the PITS^{FREQ} regression

Model	R^2 adjusted	ΔR^2	F change	df
1.Age	.04	.04	14.14**	1, 311
2.Age, GAD-7 & PHQ-9	.35	.31	74.83**	2, 309
3. Age, GAD-7, PHQ-9 & BAPS ^{NORM}	.36	.01	5.53*	1, 308
4. Age, GAD-7, PHQ-9, BAPS ^{NORM} & BAPS ^{SS}	.43	.07	38.62**	1,307
5. Age, GAD-7, PHQ-9, BAPS ^{NORM} , BAPS ^{SS} & BAPS ^{NB}	.52	.09	61.48**	1,306

Note. ***p* < .001, **p* < .05

Table 12 displays the final model's coefficients. Age, anxiety, depression, and normalizing beliefs about paranoia were not significantly associated with PITS^{FREQ} scores. Negative beliefs about paranoia had the strongest association with paranoid IT frequency, followed by positive beliefs about paranoia as a survival strategy (Hypothesis 5).

(Hypothesis 5

Table 12

Final model coefficients for the PITS-12^{FREQ} regression

	<i>v</i>	U		
	В	SE B	В	CIs
Constant	-20.46	3.80		[-27.93,-12.98]
Age	-0.04	0.06	03	[-0.08,0.17]
GAD-7	0.43	0.24	.13	[-0.05,0.91]
PHQ-9	0.29	0.19	.11	[-0.09,0.67]
BaPS ^{NORM}	-0.07	0.18	02	[-0.43,0.29]
BaPS ^{SS}	1.06	0.26	0.21**	[0.55,1.58]
BaPS ^{NB}	1.75	0.22	0.43**	[1.31,2.18]
$N_{-4-} ** - < 0.01$	*** < 05			

Note. ** *p* < .001, *p < .05

When the same independent variables were entered into regression to predict the distress associated with paranoid ITs, all five regression models predicted PITS-12^{DIS} scores significantly better than the constant only model, and adding each block of variables significantly improved the model.

The change statistics reported in Table 13 illustrate that of the BaPS subscales, the addition of the negative beliefs about paranoia scale resulted in the biggest improvement in the model. The final model, F(6,312) = 66.33, p < .001, accounted for

56% of the variance in distress levels associated with paranoid ITs.

Table 13

model summer y jor me 1115	regression			
Model	R^2 adjusted	ΔR^2	F change	df
1.Age	.04	.05	15.48**	1, 311
2.Age, GAD-7 & PHQ-9	.36	.32	78.24**	2, 309
3. Age, GAD-7, PHQ-9 &	.37	.01	4.70*	1, 308
BAPS ^{NORM}				
4. Age, GAD-7, PHQ-9, BAPS ^{NORM}	.42	.05	27.32**	1,307
& BAPS ^{SS}				
5. Age, GAD-7, PHQ-9, BAPS ^{NORM} ,	.56	.14	96.65**	1,306
BAPS ^{SS} & BAPS ^{NB}				
<i>Note</i> **p < .001, *p < .05				

Model summary for the PITS^{DIS} regression

Table 14 displays the coefficients for the final model. Age, anxiety, depression, and normalizing beliefs about paranoia were not significantly associated with the distress caused by paranoid ITs. Again, standardized betas suggested that negative beliefs about paranoia were associated with the largest increase in distress, followed by having positive meta-cognitive beliefs about paranoia. Hypothesis 6 was therefore partially supported, as it was not expected that positive meta-cognitive beliefs would be a significant predictor of the distress caused by paranoid ITs.

Table 14

Final model coefficients for the PITS-12^{DIS} regression

1 mai model coefficie		regression		
	В	SE B	В	CIs
Constant	-22.31	3.98		[-30.12,-14.48]
Age	0.04	0.07	.03	[-0.85,0.17]
GAD-7	0.42	0.26	.12	[-0.09,0.92]
PHQ-9	0.32	0.20	.10	[-0.08,0.71]
BaPS ^{NORM}	-0.03	0.19	01	[-0.41,0.35]
BaPS ^{SS}	0.73	0.28	.14*	[0.19,1.27]
BaPS ^{NB}	2.29	0.23	.52**	[1.83,2.75]

Note. ***p* < .001, **p* < .05

Discussion

This study aimed to design and validate a new self-report questionnaire to measure paranoid ITs. In phase one, a 20-item questionnaire (PITS-20) was developed, with items grounded in relevant literature and endorsed by experts. After assessing the

measure's structural validity, eight items were excluded to create a 12-item scale (PITS-12) with a replicable factor structure. In phase two, the PITS-12 was shown to be a reliable and valid measure of paranoid ITs. Finally, during phase three, PITS-12 data provided evidence of a relationship between positive and negative metacognitive beliefs about paranoia with the frequency of paranoid ITs and their associated distress.

The endorsement of PITS-12 items suggest that, as with thoughts of an obsessive nature, paranoid thoughts can arise into awareness in an unexpected, non-volitional, intrusive way. Furthermore, similarly to OITs, paranoid intrusions were experienced commonly among the general population. Indeed, 80.5% of participants had experienced at least one paranoid IT recently. Findings therefore suggest that paranoid ITs are not solely part of diagnosable 'disorders', but exist on a continuum. As suggestions that paranoid experiences occur as intrusions have been largely theoretical (Morrison, 2001), this study has provided further encouragement that paranoid ITs are a genuine phenomenon, worthy of further investigation. As distressing paranoia can be associated with receiving a diagnosis of psychosis, the study findings also support the transdiagnostic model of ITs, and suggest that intrusions are associated with mental health difficulties aside from anxiety.

The 3-factor structure of the PITS-12, which accounted for an adequate proportion of the variance in scores (Terwee et al., 2011; > 50%), provides subscales to assess different types of paranoid intrusions. Two subscales clearly map onto parts of Freeman et al.'s (2005) proposed hierarchy of paranoid thought. The hierarchy model suggests that paranoid thoughts relate to threats of varying severity, ranging from commonly experienced social evaluative concerns and ideas of reference at the bottom, to thoughts that one is at risk of harm at the top. Thoughts from the upper hierarchy can be described as 'persecutory', and within the PITS-12 a subscale assessing 'intrusions of persecution' was identified. A second 'social reference intrusions' subscale assessed intrusions that one was being thought or talked about in social situations, reflecting thoughts from the lower end of the hierarchy. The factor-analytic findings support Freeman et al.'s suggestions that distinguishable types of paranoid thoughts exist, that relate to varying degrees of harm. The PITS-12 demonstrates adequate breadth to assess these different types of paranoia. Findings also suggest that the paranoid thoughts from the hierarchy may arise as intrusions in to awareness, something not currently explored by the model.

The final PITS-12 subscale was thought to measure an intrusive sense of threat, consisting of intrusions that were self-focussed and emphasised a sense of threat or danger. These intrusions were conceptualised similarly to 'impulse' intrusions outlined in the OIT literature, described as a strong urge or feeling, sometimes with accompanying somatic sensations (Clark & Rhyno, 2005). Assessing paranoid experiences with an impulse-like character has not been done, with research focusing upon thoughts and beliefs (e.g. Freeman et al., 2005). However, Morrison (2001) proposed that psychotic symptoms may stem from emotional and physiological intrusions, rather than just cognitive ones. Conceptualising paranoid experiences as intrusions therefore has advantages in allowing the assessment of a 'felt' sense of paranoia, perhaps experienced on a more emotional and physiological level. The PITS-12 is currently the only paranoia questionnaire designed to assess these types of experience, and individuals with and without psychosis endorsed items from this subscale, suggesting that the phenomenon is worthy of further investigation.

The PITS-12 subscales had good content validity, as items were grounded in literature and rated highly by experts in the field. Considering previous criticisms of IT questionnaires (García-Soriano et al., 2011), a comprehensive description of an intrusion was developed, which is likely to have improved the PITS-12 ability to measure paranoid intrusions, rather than paranoia more generally. Accordingly,

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feedback from piloting the measure with mental health service users and members of the public suggested that the IT definition was effective and easily understandable.

Evidence of acceptable test-retest reliability was found for all PITS-12 subscales and internal consistency was acceptable for the majority, only being marginally less than recommended (Terwee et al. 2011; $\alpha > .70$) for the social reference intrusions subscale ($\alpha = .69$). Hypotheses regarding the construct validity of the PITS-12 were also supported, as those with psychosis-related diagnoses had significantly higher scores on the measure, and there was a larger correlation between the frequency of paranoid ITs with GPTS^{FREQ} scores (Green et al., 2008) than with assessments of anxiety and depression. Correlations between paranoid IT frequency and distress with anxiety and depression were still large, although these variables were not significant predictors in the final regressions. However, the large correlation with anxiety (r = .61) could reflect the fact that both difficulties are associated with threat-based intrusions. Indeed, previous studies have emphasised the overlap between anxiety and paranoia, with Freeman et al. (2008) proposing that "paranoia can be conceptualised as a type of anxious fear" (p. 1130). Although the correlation between PITS-12^{FREQ} and GPTS^{FREQ} scores (Green et al., 2008) was large (r = .69) its size still allowed room for differences between the constructs of the two measures, which is again supportive of the PITS-12 ability to measure *intrusive* paranoid thoughts, rather than paranoid thoughts more generally.

Using a mixed clinical and non-clinical sample in the development of the PITS-12 has ensured that it can assess paranoid ITs across the continuum of psychotic experience. Those with a psychosis-related diagnosis did on average have significantly more paranoid ITs, which they found significantly more distressing. However, the overlapping frequency distributions of the two populations (Figure 5) suggest that some participants with psychosis-related diagnoses had fewer paranoid ITs than individuals without a psychosis diagnosis. The distributions replicate those found for other psychotic-like symptoms (DeRosee & Karlsgodt, 2015) and their overlap suggests that there will be factors other than solely the frequency of paranoid ITs that lead to increased levels of impairment and help-seeking.

Paranoid ITs did have different predominant themes for the clinical and nonclinical participants. For example, intrusions of persecution were highly endorsed by participants with psychosis, whereas those without psychosis had few of these thoughts. In contrast, non-clinical participants endorsed social reference intrusions more frequently, and for both groups these experiences were relatively prevalent. These findings were similar to those shown for general paranoid thoughts (Green et al., 2008) and may be used to support Freeman et al.'s (2005) proposal that persecutory thoughts are more common among clinical populations, and represent more extreme fears that build upon commonplace experiences from lower down the paranoia hierarchy.

Positive and negative metacognitive beliefs about paranoia significantly predicted both the frequency of paranoid ITs and their associated distress. In both multiple linear regressions, negative beliefs about paranoia as dangerous and uncontrollable were the strongest predictor of PITS-12 scores. Findings support metacognitive theories of paranoia (Morrison et al., 2011), which suggest that beliefs about paranoid thought processes can lead to unhelpful appraisals, causing distress and resulting in attempts to control paranoia (e.g. avoidance, thought suppression) that inadvertently maintain the problem. These theoretical implications also illustrate similarities between our understanding of psychosis and anxiety disorders; as in OCD, metacognitive beliefs are similarly thought to drive unhelpful appraisals of OITs, consequently leading to compulsive behaviours and increased distress (Wells, 1997).

Findings from the current study differ slightly from previous research, which has found that positive beliefs about paranoia (e.g. my paranoia protects me) have predicted

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more frequent paranoid thoughts, but not how distressing they are (Morrison et al., 2005). In this study, positive beliefs about paranoia were also predictive of paranoid ITrelated distress, albeit to a lesser extent than negative metacognitive beliefs. In the OCD literature, some research has found significant correlations between the frequency of OITs and positive beliefs about the importance of worry (Wells & Papageorgiou, 1998). There could therefore be a slightly different relationship between metacognitive beliefs and intrusive, as opposed to non-intrusive thoughts. It may be that the belief that paranoid thoughts are helpful for survival involves an assumption that the thoughts reflect real threats. When these thoughts therefore appear in a seemingly involuntary and uncontrollable manner, those with positive beliefs about paranoia may be less able to dismiss them and become more distressed about the potential threat. An alternative explanation could relate to findings by Murphy et al. (2017) that positive metacognitive beliefs only predict the distress caused by paranoid thoughts when they occur alongside negative metacognitive beliefs, as this leads to dissonance and internal conflict. The impact of the co-occurrence of positive and negative metacognitive beliefs upon paranoid ITs was not explored in this study, but could be an avenue for further research.

Limitations and Avenues for Future Research

This study recruited individuals with and without psychosis-related diagnoses, to assess a full continuum of paranoid experience. However, many non-clinical participants were students, and self-reported higher rates of mental health difficulties than might be seen in a more representative population sample (Freeman et al., 2005). This study may therefore have reported a particularly high prevalence of paranoid ITs, considering the proposed overlap between paranoia and other mental health difficulties (Freeman et al., 2008). Individuals with psychosis were recruited to reflect the upper continuum. However, as a psychosis diagnosis can be given for various experiences (e.g. voice hearing, negative symptoms), paranoia may not have been a primary

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difficulty for some of these participants. Future research could involve individuals who are experiencing PDs, to more specifically examine paranoid ITs at the severe end of the paranoia continuum. This would also follow recommendations to study different psychotic symptoms separately, as they may have different causal mechanisms (Bentall et al., 2014).

There were limitations to some analyses in the study. While scaling up scores on the social reference intrusions subscale allowed a rudimentary comparison with other subscale scores, there are more statistically valid ways to do this (Colman, Norris, & Preston, 1997). Furthermore, some assumptions were not met for multiple linear regressions (e.g. homoscedasticity of residuals), decreasing the generalisability of findings (Field, 2009). The psychometric validation for the PITS-12 was based on data extracted from the PITS-20 that participants completed. Thus, validation analyses should ideally be replicated following an administration of the PITS-12 itself. The EFA and CFA were also performed on different samples, one with mixed clinical and nonclinical participants, and another solely of non-clinical participants. Kilne (1994) recommends that heterogeneous samples are generally better for EFA and increase variance, providing they do not reflect two completely distinguishable groups. As only a small number of participants were recruited to reflect the upper part of the paranoia continuum, Sample 1 arguably better reflected the spread of paranoia across the population, rather than two completely different groups. The replication of the factor structure in a solely non-clinical sample also illustrates the measure's applicability to different populations.

Although the PITS-12 had generally good psychometric properties, the internal consistency of the social reference intrusions subscale was marginally below recommended levels. If the PITS-12 was to be further developed, additional social reference items could be created to improve the reliability of this subscale. The

questionnaire could also be developed to include assessments of appraisal and coping strategies that increase the distress associated with ITs (e.g. dismissability; Salkovskis & Harrison, 1984) and paranoid thoughts generally (e.g. pre-occupation/conviction, Peters et al., 2004). Finally, future studies could validate psychometric properties such as responsiveness to change and cross-cultural validity, which were not addressed in this study.

PITS-12 items were phrased in a way that could represent thoughts, and there is a subscale conceptualised as relating to intrusive impulses. Despite PITS-12 instructions stating that items could be experienced as intrusive imagery, it is unclear how successfully participants could apply images to the items. Researchers using the PITS-12 may wish to investigate how well it can assess the different modalities of intrusions. For example, by asking participants to rate PITS-12 items on whether they are experienced as a thought, sensation/impulse, or image. This would also affirm the construct of the intrusive sense of threat subscale.

One could question how accurately questionnaires can distinguish the assessment of intrusive, rather than non-intrusive thoughts. However, for OITs, questionnaires are regularly used and have advanced understanding in this field. In this study the comprehensive description of an intrusion may have assisted participants to report specifically intrusive thoughts. The less-than-perfect correlation between GPTS (Green et al., 2008) and PITS-12 subscales could also reflect that the PITS-12 assessed thoughts with different process characteristics. Future research could use interviews to ask more in-depth questions about the intrusive process characteristics of paranoid thoughts. Alternatively, experimental priming of ITs, or experience sampling methods which ask participants questions at random daily time intervals (Myin-Germeys, Nicolson, & Delespaul, 2001), could be used to assess whether 'in the moment' paranoid intrusions occur as thoughts, impulses and images. The PITS-12 could be

correlated with data obtained using these methods, to further evidence its construct validity.

Clinical Implications

Paranoid intrusions were more common among clinical participants, suggesting that clinicians should assess for the presence of these experiences among individuals diagnosed with psychosis. The PITS-12 is a potential means with which to do this. The fact that high levels of paranoid ITs were associated with increasing distress also suggests that the experiences could be targets of psychological interventions. Study findings suggest that interventions which seek to target metacognitive beliefs (e.g. metacognitive therapy; Wells, 2008) could be useful to address paranoid ITs. In particular, addressing negative beliefs about paranoia should be prioritised, as these were associated with the most frequent and distressing intrusions. The PITS-12 could also be used to assess any changes in paranoid ITs over the course of an intervention.

Study findings support the idea that paranoid IT exist on a continuum. Clinicians may therefore wish to assess these experiences among those that are suspected of having an at risk mental state to develop psychosis. Findings from this study also suggest that certain metacognitive beliefs and intrusions of a persecutory nature could be particularly useful to identify at the assessment phase, as these variables were either linked to increased distress or a more clinical presentation. More broadly, raising awareness that paranoid intrusions are common may help to normalise the experiences and increase the ease with which people will approach services if their paranoia is becoming distressing. Interventions that seek to prevent the development of psychosis could also focus upon promoting helpful metacognitive beliefs (e.g. that thoughts do not necessarily represent absolute truths).

This current study illustrates that ITs are common among individuals with diagnoses other than anxiety. The identification of common cognitive processes in

maintaining different forms of distress supports the relevance of transdiagnostic treatments such as metacognitive therapy (Wells, 2008), which may be useful for targeting both paranoid and obsessive ITs. Clinicians should seek to evaluate the effectiveness of such interventions, to develop the evidence base in this area.

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Appendix A

Evidence required for good psychometric properties

Domain	Appraisal criteria
Reliability	
Internal	P: Cronbach's alpha(s) $\geq .7$
	I: No Cronbach's alphas, or dimensions undetermined
	N: Cronbach's $alpha(s) < .7$
Test-retest	P: Intra-class correlation/weighted Kappa \geq .7, or Pearson's r \geq .8
	I: Neither of the above analyses reported
	N: Intra-class correlation/weighted Kappa $< .7$, or Pearson's r $< .8$
Validity	
Criterion	P: Criterion variable is a 'gold standard' assessment of the construct.
	Correlation $\geq .7$
	I: No information. No arguments that criterion variable is 'gold standard' N: Correlation with gold standard < 7
	N. Conclution with gold standard < ./
Content	P: Itams relevant to construct and target population, and questionneirs is
Content	comprehensive
	I:Not enough information
	N: Some items irrelevant to construct, or for target population, or
	questionnaire is not comprehensive
Construct Validity	
Hypothesis testing	P: Correlations with associated measures $\geq .5$, or at least 75% results are in
	accordance with hypotheses and correlations with related constructs are higher
	than with unrelated constructs
	I: No information, or correlations solely with unrelated constructs presented
	N: Correlations with associated measures < .5, or less than 75% of hypotheses
	accepted
Cross-cultural validity	P. No difference in factor structure or important differential item functioning
	(DIF) between versions
	I: Factor analysis not applied and DIF not assessed
	N: Differences in factor structure of DIF between languages
Star strand and idita	D: Eastern combinent locat 500/ af the continues
Structural validity	P: Factors explain at least 50% of the variance
	N: Explained variance not mentioned, of factor analysis not completed. N: Eactors explain $< 50\%$ variance
	N. Factors explain < 50% variance
Responsiveness	P. Correlation with changes on instruments measuring the same construct >
responsiveness	0.5 OR at least 75% of results in accordance with hypotheses OR area under
	the curve ≥ 0.7 and correlations with changes in related constructs are higher
	than unrelated constructs
	I: Appropriate analyses not conducted, or solely correlations determined with
	unrelated constructs.
	N: Responsiveness analyses conducted but criteria not met

 Table A1

 Appraisal criteria for good psychometric properties (Terwee et al., 2011)

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Appendix B

The 20-item Paranoid Intrusive Thoughts Scale (PITS-20)

Intrusive thoughts are UNWANTED thoughts that pop into our heads at UNEXPECTED times, AGAINST OUR WILL. Intrusive thoughts INTERRUPT what we were thinking about or what we were doing and grab our attention. The thoughts might be about things that we do not want to think about and can be UNPLEASANT, causing us to feel worried or upset. While we might try to dismiss these thoughts or avoid thinking about them, they can be HARD TO GET RID OF and to prevent from coming back into our minds. They are therefore DIFFICULT TO CONTROL and may enter our minds REPEATEDLY.

As well as thoughts, people may experience intrusive IMAGES. These can appear like a PICTURE in the mind's eye. People may also experience an INTRUSIVE FEELING or SENSE THAT THEY ARE UNDER THREAT.

This example describes what an intrusive thought might be like:

Mary is hanging out washing in her garden and thinking about her plans for the rest of the day. Suddenly, Mary has the thought that her neighbours are watching her and plotting against her. This interrupts Mary's train of thought and she stops hanging up the washing. Mary does not want to think about this and tries to tell herself that it is a silly idea, but she struggles to get it out of her mind. Mary now starts to feel uncomfortable and goes back inside.

Listed below are some more intrusive thoughts that people might sometimes experience. Please circle YES or NO to show whether you have had each intrusive thought.

Remember, you might also experience the examples as intrusive IMAGES or FEELINGS.

If you circle YES, please also rate HOW OFTEN this thought pops into your head, without you trying, and how UPSETTING this thought is for you. Please circle the point on each line that represents your answer

PLEASE DO NOT RATE ANY EXPERIENCES THAT YOU HAVE HAD UNDER THE INFLUENCE OF DRUGS

1. People are talking about me behind my back



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



2. I know what other people think about me



If you have circled YES then please rate the thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



3. People are out to get me



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?





4. Other people are a threat



If you have circled YES then please rate the thought on the following scales





5. I need to keep myself safe



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



6. People are against me



If you have circled YES then please rate the thought on the following scales



How upsetting do you find this intrusive thought?



7. I am not safe



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?



8. I am being watched



If you have circled YES then please rate the thought on the following scales







9. I don't feel safe anywhere



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?







10. People are after me



If you have circled YES then please rate the thought on the following scales



How upsetting do you find this intrusive thought?



11. I need to hide from people



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?







If you have circled YES then please rate the thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



13. I am being targeted



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?





upsetting

14. I am at risk of harm



If you have circled YES then please rate the thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



Extremely

upsetting

15. My life is in danger



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?





If you have circled YES then please rate the thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



17. There is a plot against me



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



18. People are trying to control me



If you have circled YES then please rate the thought on the following scales



How upsetting do you find this intrusive thought?



19. People know what I'm thinking



If you have circled YES then please rate this thought on the following scales

How often does this thought pop in to your head, without you trying?



Not at all upsetting

20. Messages on the TV or internet are just for me



If you have circled YES then please rate the thought on the following scales

upsetting

How often does this thought pop in to your head, without you trying?



How upsetting do you find this intrusive thought?



Appendix C

Process characteristics of intrusive thoughts described in the literature

Table E1

Process Characteristics of Intrusive Thoughts

Process Characteristics Unwanted Something to be avoided Non-volitional entry to awareness/spontaneous/no wilful control/unintended Thoughts, images, impulses Recurrent/repetitive/perseverative Discordant with train of thought/ego-alien/ego-dystonic Irrational or not plausible Interrupt goal directed behaviour/ongoing activity/interferes in task performance Interfere with ability to engage in productive thought/interrupt train of thought Interfere with ongoing cognitive/behavioural activity Difficult to supress/distract from/grab attention/difficult to control/hard to dispel/captures attentional resources/distracting/intrusive/take attentional priority/hard to ignore Requires suppressive effort/impels an action to control or reduce distress Attributed to an internal origin Associated with negative affect/subjective discomfort e.g. anxiety, guilt/negative mood

Appendix D

59-items initial PITS items

People don't like me/I am not liked People are criticising me/I am being criticised/I am being judged critically/negatively People are talking about me behind my back/I am being talked about behind my back People are talking negatively about me People are avoiding me There are rumours about me People are trying to irritate me People are mocking me/making fun of me/laughing at me /I am being mocked/made fun of/laughed at People are being unfriendly towards me on purpose People want to embarrass me People are going out of their way to get at me I need to be on guard/I need to protect myself People want to be mean to me Everybody/people hate me People are bullying me/I am being bullied I am being targeted People are saying nasty things about me/talking badly about me People are trying to humiliate me/I am being humiliated People are trying to provoke me People are trying to drive me away People are being hostile towards me People want to trick me/I am being tricked I am being lied to 122

People have it in for me/are after me

People are trying to drive me mad

People are against me/everybody is against me/the whole world is

against me

People are trying to sabotage my relationships/friendships

Other people are a threat

I am not safe

People/others are out to get me

I can't trust anybody

The world is dangerous

People are evil

I am being followed

I am in danger

Something bad/terrible is about to happen

Something is not right here

I am at risk of harm

I am being watched

I need to get away/need to escape/get out of here/I need to leave right now

It is not safe to be here/I'm not safe anywhere

Nobody is safe

I am being harassed

I am being punished

People want to hurt me

I have to make sure nobody hurts me

People will harm me if I let them

I am at risk of harm/violence

People are going to attack me/I might be attacked Others are preventing me from succeeding People want to kill me My life is in danger I need to stay away from people/hide I am being persecuted There is a conspiracy against me/there is a plot against me People are trying to control me/my thoughts/My thoughts are being controlled People can read my mind/know what I'm thinking/people can read my body language I know what other people are thinking about me People are communicating to me via the TV, books, magazine

Appendix E

Participant study information sheet



Study title: Research investigating the experience of paranoid, intrusive thoughts

Invitation and brief summary

You have been invited to take part in a research project. Your participation is entirely voluntary. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, then please contact somebody from the research team overseeing this project (contact details are provided at the end of this sheet). Please take time to decide whether or not you wish to take part. If you are unsure, we would suggest taking at least 15 minutes to read and consider the following information. This is a minimum recommended time and you are welcome to take as long as you wish to decide whether to participate, or come back to the study at a later date.

This study is investigating the experience of INTRUSIVE THOUGHTS which relate to themes of paranoia or suspiciousness. Thoughts are described as intrusive if they "intrude" in to our awareness and interrupt ongoing thought processes, without us wanting them to. Intrusions can also be difficult to control or stop from re-appearing. They are often felt to be unwanted, unpleasant and unacceptable. This study will hope to investigate the experience of paranoid intrusive thoughts among a range of people, with and without mental health difficulties. It is hoped that your participation may help us to understand why some people find intrusive thoughts upsetting.

What's involved?

You will be asked to answer a range of questions which should take around 20 minutes. To develop some of the questions, members of the public with experience of paranoid thinking were asked for their opinions.

We do not collect any identifying information from you other than your email address. This will be used to invite you to complete a small part of the questionnaire again in 7 days' time. Results will remain completely anonymous and nobody will link your responses to the email address that you provide. Email address information will be deleted after use and you will not be identified in any research write-ups or publications. Your information will only be accessed by the research team and will be stored in a password protected spreadsheet.

Your data will be stored for 6 years and then destroyed. You have the right to ask the research team for your data to be removed from the study. Please keep a note of your participant ID which you will generate at the beginning of the questionnaire, as we will need this to find your data and remove it. It is possible to stop the questionnaire at any stage and ask for data to be removed, as long as you know your participant ID.

The questionnaire is not designed to be upsetting; however, it will ask questions about your mental wellbeing and patterns of thinking. If you do feel distressed by any of the questions then contact numbers for agencies who can provide support will be provided at the end of the questionnaire. If you have any complaints about this research or require further advice then please contact: *contact details provided*

). If you are a mental health service user you can also make a complaint or ask for further information from your local Patient Advise and Liaison Service (see below). Please contact the researcher if you would like to obtain a copy of the study findings when they have been collected.

Further information and contact details

This research is sponsored by Sheffield University. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Research Ethics Committee. The IRAS Project ID for this study is **196353**

Researcher: contact details provided

Research supervisors: contact details provided

The researcher and research supervisors are based at: contact details provided

For complaints please contact: contact details provided

Consent to begin study

By clicking the link to begin the questionnaire you are confirming that:

- You have read the information sheet, had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- You understand that your participation is voluntary and that you are free to exit the questionnaire at any time without giving any reason.
- You understand that you can ask to withdraw your data from the study by contacting the researcher and providing your participant ID

Appendix F

Debriefing information

Thank you for participating in this research and answering questions about intrusive thoughts that relate to paranoia and suspiciousness. There has not been previous any research to investigate whether people have intrusive thoughts of this kind. This study will therefore hope to see how commonly people have these experiences. The study will also compare paranoid intrusive thoughts between people who have - and have not experienced psychosis. We are also hoping to see whether the questions that we have used to ask about paranoid intrusive thoughts are able to produce reliable findings.

Please remember that if you no longer wish to have your answers included in the research then it is possible to contact the researcher with your anonymous code and ask for your data to be removed.

If you have found completing this questionnaire upsetting or it has left you feeling concerned about your mental wellbeing, then there are agencies that you can contact to obtain support and advice. You might wish to:

- Contact a confidential helpline such as the Samaritans (call **116 124**, 24 hours a day) or Mind (call **0300 123 3393**, Monday to Friday 9am to 6pm). These services will give free advice and have experience in issues relating to mental health.
- If you are worried about feeling paranoid then Mind also provide a helpful information pack online (<u>http://www.mind.org.uk/information-support/types-of-mental-health-problems/paranoia/#.VmhTEUqLTIU</u>) which explains what paranoia is and how you can get help.
- If you are worried about your mental health and are not currently receiving any support, then it might be advisable to book an appointment with your GP to discuss this. If you are already receiving support from a mental health service you should contact a member of your care team.

Details of the research team are provided below in case you require any further information. If you wish to be informed about the findings of this study, then please contact the lead researcher.

Lead researcher: contact details provided

Research supervisors: contact details provided

The research team are based at: contact details provided

If you have any complaints about the research process then we would advise you to contact: *contact details provided*

Thank you again for the time to complete this questionnaire, your participation is appreciated.

Ethical approval

2nd Re issue 02 August 2016 - To add and correct all versions



West Midlands - Solihull Research Ethics Committee The Old Chapel Royal Standard Piace Notlingham NG1 6FS

<u>Please note</u>: 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

27 June 2016

Miss Verity Statham 23 Vicarage Street Kirkstall Leeds LS5 3HQ

Dear Miss Statham

Study title:	Research investigating the experience of paranoid, intrusive thoughts	
REC reference:	16/WM/0224	
Protocol number:	149128	
IRAS project ID:	196353	

Thank you for your letter, responding to the Committee's 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.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Miss Vic Strutt, NRESCommittee.WestMidlands-Solihull@nhs.net.

2nd Re issue 02 August 2016 - To add and correct all versions

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.

Conditions of the favourable opinion

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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 NHS permission for research is available in the Integrated Research Application System, <u>www.hra.nhs.uk</u> or at <u>http://www.rdforum.nhs.uk</u>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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 clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (<u>catherineblewett@nhs.net</u>), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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).

2nd Re issue 02 August 2016 - To add and correct all versions

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission 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 sites

Approved documents

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

Document	Version	Date
Copies of advertisement materials for research participants [Email, facebook and twitter invitations for non-clinical participants. invitation cards for clinical participants]	3	20 April 2016
Covering letter on headed paper [Response]		20 June 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		16 December 2015
IRAS Checklist XML [Checklist_17062016]		17 June 2016
Non-validated questionnaire [The Paranoid Intrusive Thoughts Scale (developed by the researcher)]	2	26 April 2016
Other [Second supervisor's CV]		27 January 2016
Other [Provisional opinion changes]	1	11 June 2016
Participant information sheet (PIS) [Debriefing after time 2]	3	20 April 2016
Participant information sheet (PIS) [Debriefing after time 1]	3	20 April 2016
Participant information sheet (PIS) [Online participant information sheet]	6	01 July 2016
Participant information sheet (PIS) [Paper information sheet (clinical participants)]	6	01 July 2016
REC Application Form [REC_Form_06062016]		06 June 2016
Referee's report or other scientific critique report		01 February 2016
Research protocol or project proposal	3	26 April 2016
Summary CV for Chief Investigator (CI)		06 February 2016
Summary CV for supervisor (student research)		06 February 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language		06 February 2016
Validated questionnaire		

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.

After ethical review

2nd Re issue 02 August 2016 - To add and correct all versions

Reporting requirements

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

 Image: Notifying substantial amendments

 Image: Adding new sites and investigators

Notification of serious breaches of the protocol

Progress and safety reports

Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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 Training

We are pleased to welcome researchers and R&D staff at our training days - see details at http://www.hra.nhs.uk/hra-training/

16/WM/0224		Please quote this number on all correspondence			
	With the Committee's best wishes for the success of this project.				
	Yours sincerely				

PP. V. Suut

Dr Rex J Polson Chair

NRESCommittee.WestMidlands-Solihull@nhs.net

Enclosures:

"After ethical review – guidance for researchers" [SL-AR2]

Copy to:

Email:

Mr Dan Last, Sheffield Health and Social Care Trust

Appendix H





Figure H-1. Scree plot to determine number of factors from the PITS-20 to retain