The role of interpersonal contingency and self-focused attention in the development of trust in clinical paranoia: a virtual reality study

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

This thesis explores paranoia in clinical populations with psychosis. Part one presents a systematic review and meta-analysis of psychological treatments for psychosis impacting on paranoia. It provides an overview of current interventions, their feasibility and efficacy in reducing paranoia. The review provides preliminary evidence for the acceptability and efficacy of individual cognitive behavioural therapy for psychosis (CBTp) in improving paranoia and associated distress. Results are discussed in the context of potential mechanisms of treatment, limitations in generalisability, and the need for further clinical trials investigating various psychological approaches to treating persecutory delusions and comparisons with active treatment controls.

Part two reports on a jointly conducted empirical virtual reality study investigating the feasibility of interactive virtual reality as a research tool for individuals with psychosis and persecutory delusions. It further investigates the role of interpersonal contingency and self-focused attention in the experience of trust. Eighteen male participants with psychosis and current paranoia interviewed a virtual flatmate whose non-verbal responses were either high or low in contingency to the participants' behaviour. Interactive virtual reality was found to be safe, enjoyable and immersive for this clinical population. Neither the contingency of the avatar's behaviour nor self-focused attention were found to impact on participants' objective trust (i.e. distance kept form the avatar), providing evidence for the employment of interpersonal safety behaviours in individuals with persecutory delusions.

Part three is a critical appraisal of both the empirical study and the literature review. It includes personal reflections on the research processes, including the benefits and challenges of recruiting clinical populations and explores the presence and impact of dissemination biases in clinical research.

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Part 1: Literature Review

Efficacy and feasibility of psychological interventions targeting paranoia in psychosis: a systematic review and meta-analysis

Abstract

Aim: Paranoia is one of the most common distressing experiences reported by people with psychosis. In recent years, persecutory delusions have become the focal point of a number of Cognitive Behavioural Therapy for psychosis (CBTp) interventions emerging in clinical literature. Numerous meta-analytic reviews have assessed the efficacy of psychological interventions in changing symptoms of psychosis, including delusions. However, no review has reviewed the breadth, feasibility and efficacy of psychological interventions that have evaluated their impact on paranoia.

Method: A systematic review identified 23 studies detailing interventions for persecutory delusions, giving an overall synthesis of developments in paranoia interventions and treatment feasibility. Six RCTs (1 group metacognitive training, 5 individual CBTp) were meta-analysed to evaluate treatment efficacy compared to TAU.

Results: The synthesis of studies showed that interventions impacting on paranoia are predominantly individual and from a CBT approach. Many were found to be from the same research group. Meta-analyses found the group intervention to be ineffective. Further meta-analyses of individual CBTp found a significant, small to medium effect size of intervention in improving paranoia at end-of-treatment on two measures: the delusions subscale of the Psychotic Symptoms Rating Scale (PSYRATS-D) (k = 5; *d* = 0.38) and Green et al. Paranoid Thoughts Scale (GPTS) (k = 3; *d* = 0.31), the latter of which was sustained at follow-up (*d* = 0.39). Significant, medium to large effect sizes of individual CBTp were found in improving distress associated with paranoia (k = 3; *d* = 0.62) and well-being (k = 3; *d* = 0.50), predominantly sustained at follow-up (*d* = 0.56 and *d* = 0.42).

Conclusion: There is a promising outlook for the efficacy and feasibility of CBTp for paranoia. Low-intensity CBTp appears to be particularly useful for individuals with persecutory delusions. The application of such interventions in clinical settings could stand to increase service-users access to, and increase their choice of, psychological treatment for psychosis. However, in future research, replication is needed in different settings and from different research groups.

1. Introduction

1.1. The evolution of psychological treatment for delusions

Before the emergence of Cognitive Behavioural Therapy for psychosis (CBTp) in the early 1990s, an assumption was held that psychotic symptoms, such as delusions, were functionally different from 'normal' experiences (Jaspers, 1913). As such, targeting delusions directly in therapy was viewed as either futile or detrimental as it was thought that the patient would not be responsive to typical mechanisms of reason or learning.

The development of psychological therapies that directly target delusional beliefs emerged from research indicating a continuum between normal and psychotic experiences (McGovern and Turkington, 2001; van Os et al., 2009) and emotional and cognitive correlates of psychotic symptoms (Garety et al., 2001). Developed from cognitive therapy, individually tailored formulation-based CBTp combines broader therapeutic features (e.g. psychoeducation, collaboration, guided discovery) with cognitive and behavioural techniques that focus on changing key unhelpful cognitions (e.g. about the self and others) and can also incorporate challenging the delusional belief itself. Research has demonstrated that CBTp is effective in comparison to treatment as usual (TAU) in reducing positive symptoms, negative symptoms, impairments in general functioning and symptoms of depression (Gould, Mueser, Bolton, Mays & Goff, 2001; Rector & Beck, 2001; Zimmerman, Favrod, Trieu & Pomini, 2005; Wykes, Steel, Everitt & Tarrier, 2008; Sarin, Wallin & Widerlöv, 2011). The National Institute of Health and Care Excellence (NICE) guidelines recommend a minimum of sixteen sessions of CBTp as a first-line treatment for psychosis (NICE, 2014). These guidelines were informed by a meta-analysis conducted for the purpose of the 2009 guidelines which included 31 randomised control trials (RCTs) that predominantly delivered CBTp of this length (NICE, 2009). However, there is now a growing body of evidence that briefer, low-intensity CBTp is similarly effective in treating psychosis. Hazell et al. (2016) analysed 10 RCTs and found a moderate effect size of low-intensity

CBTp in reducing symptoms of psychosis compared to TAU (*d* = -0.46, 95%-CI: -0.06, -0.86). Similarly, Naeem et al. (2016) found a moderate effect size of brief CBTp in 6 RCTs compared to TAU (Hedge's *g* = 0.43, 95%-CI: 0.24-0.63) and a small to moderate effect size in comparison to other psychological treatments in 8 RCTs (Hedge's *g* = 0.38, 95%-CI: 0.2-0.57).

Studies investigating the efficacy of CBTp commonly report primary outcome measures as overall symptom reduction, sometimes subdivided into positive and negative symptoms. Thus meta-analyses report pooled estimates of effects for these more general outcomes. For example, Gould, Mueser, Bolton, Mays & Goff (2001) analysed pre- post-intervention change in symptoms of psychosis in 7 clinical trials. The reviewers found a medium to large effect size of cognitive therapy (CT) in reducing overall symptoms (*d* = 0.65, 95%-CI: 0.56-0.71). Jauhar et al. (2014) analysed 34 RCT studies and found that pooled effect sizes were in the 'small' range for all classes of symptoms i.e. overall symptoms (*d* = -0.33, 95%-CI: -0.47, -0.19), positive symptoms (*d* = -0.25, 95%-CI: -0.37, -0.13) and negative symptoms (*d* = -0.13, 95%-CI: -0.25, -0.01) in comparison to TAU. However, this review found high heterogeneity in variance of effect sizes, suggesting a limitation in considering all symptoms of psychosis in the analysis of efficacy of CBTp. A Cochrane review (Jones, Hacker, Cormac, Meaden & Irving, 2012) compared CBTp to other psychosocial interventions for psychosis. They found no significant effect of CBTp in changing global mental state or positive and negative symptoms of schizophrenia in 4 RCTs. Furthermore, the authors commented that very few studies measured impact of interventions on quality of life and social functioning. Against a strong narrative of the benefits of CBTp, they concluded that there is no clear and convincing argument for the advantage of CBTp over other therapies for psychosis.

1.1.1 Effectiveness of psychological Interventions on specific symptoms

A recent meta-analysis investigated the effectiveness of CBTp in specifically reducing delusions and hallucinations, rather than general positive symptoms. Van der Gaag et al. (2014) analysed nine randomised controlled trials (RCTs) from a total of 50 RCTs of CBTp, (identified in a recent review: Naeem, Farooq & Kingdon, 2014) which detailed secondary outcome measures of change in delusions. They found a significant, small to medium effect size of CBTp on delusions (Hedge's *g* = 0.36) and a slightly stronger effect of CBTp on hallucinations (Hedge's *g* = 0.44), but did not report confidence intervals. In addition, CBT for delusions in comparison to active control was non-significant. However, their inclusion criteria of individually tailored formulation-based CBTp meant that studies using other theory-driven approaches to changing delusions such as a worry-reduction CBT intervention (Foster et al., 2010) or a coping skills based training (Cather et al., 2005) were not considered in their review. Mehl, Werner & Lincoln (2015) conducted a meta-analysis to specifically investigate the effect of CBTp on delusions which included both formulation-based CBTp and other theory-driven CBT approaches. Analyses of twelve studies found significant, small to medium effect sizes of CBTp vs. TAU at end-of-therapy (*d* = 0.27, 95%-CI: 0.08, 0.47) and at an average follow-up period of 47 weeks (*d* = 0.25, 95%-CI: 0.07, 0.43). However, no significant effects were found for CBTp in comparison to other interventions.

1.1.2 A New Strategy for Evaluating Psychological Interventions: How is Change Achieved?

In a review and revision of the Medical Research Council (MRC) framework for evaluating complex interventions (Campbell, Fitzpatric, Haines & Kinmonth 2000), Craig et al. (2008) put forward an important point – that there has perhaps been a misled urge to conduct randomised controlled trials (RCTs) without preparatory work in developing the theory of how change is to be achieved. The interventionist-causal model approach (Kendler and Campbell, 2009) suggests that interventions should focus on one of several cognitive and

emotional factors hypothesised to be involved in the formation and maintenance of delusions (Freeman, 2007; Garety, Bebbington, Fowler, Freeman & Kuipers, 2007; Freeman & Garety, 2014).

Several interventions which have been developed to target cognitive and emotional factors such as worry and self-confidence, use cognitive-behavioural techniques to indirectly reduce the prevalence of hypothesised maintenance factors and the impact of the delusion (e.g. Freeman, Waite et al., 2015; Waller et al., 2015). Mehl et al. (2015) compared these causal-interventionist approach therapies (k = 4) with first-generation studies and, at end of treatment, found a small to medium effect in favour of the newer interventions. Furthermore, Mehl et al. (2015) included studies using causal-interventionist therapies specifically tailored to change persecutory delusions but they did not separate these from other forms of delusions in their analyses. To date, no meta-analysis has specifically evaluated CBTp efficacy by delusion type or focused on persecutory delusions alone.

1.2. Clinical relevance and treatment of persecutory delusions

Clinically, paranoia and persecutory delusions are most closely associated with a diagnosis of psychosis, such as a schizophreniform or delusional disorder. In clinical populations, those presenting with paranoid ideation are considered to be at the severe end of the spectrum, with the most extreme form of ideation being persecutory delusions. Persecutory delusions are beliefs held with high conviction that harm is occurring - or will occur - to the individual and that that harm is intended by the persecutor (Freeman and Garety, 2000). Persecutory delusions are one of the most common delusions (Cutting, 1997) and are strongly associated with high levels of distress and with admission to hospital (Castle, Phelan, Wessely & Murray, 1994). Evidence also suggests that at the first episode of psychosis, over 70% of patients have a persecutory delusion (Coid et al., 2013). In the literature, a number of psychological models conceptualise the development and

maintenance of paranoid ideation. Three predominant models of persecutory delusions exist: as a form of psychological self-esteem defence (Bentall et al., 1994; 2008); 'poor-me', 'bad-me' paranoia (Trower and Chadwick, 1995) and the cognitive multi-factorial model (e.g. Freeman et al., 2002). These models have highlighted numerous cognitive and emotional processes relevant to the phenomenon of clinical paranoia and, in doing so, have informed the development of more recent psychological interventions for paranoia.

Freeman and Garety (2014) reviewed recent developments in understanding and treating persecutory delusions. Outside of traditional CBTp given to individuals with persecutory delusions, a number of cognitive therapies have more recently been developed to target causal and maintenance factors such as worry (Foster et al., 2010; Freeman, Dunn et al., 2015), interpersonal sensitivity (Bell and Freeman, 2014; Freeman et al., 2014), insomnia (Freeman, Waite et al., 2015; Myers, Startup and Freeman, 2011), and reasoning biases (Hepworth, Startup and Freeman, 2011; van Oosterhout et al., 2014; Waller et al., 2015). These examples are notably developed from the cognitive multi-factorial model of persecutory delusions, detailed in Figure 1, which focuses on either key emotional processes (worry, interpersonal sensitivity), reasoning biases, or triggers (insomnia). Freeman and Garety (2014) note in their review that pilot and RCT studies show initial promising results for these interventions. However, to date no systematic, quantitative assessment of the efficacy of CBTp for persecutory delusions has been undertaken.

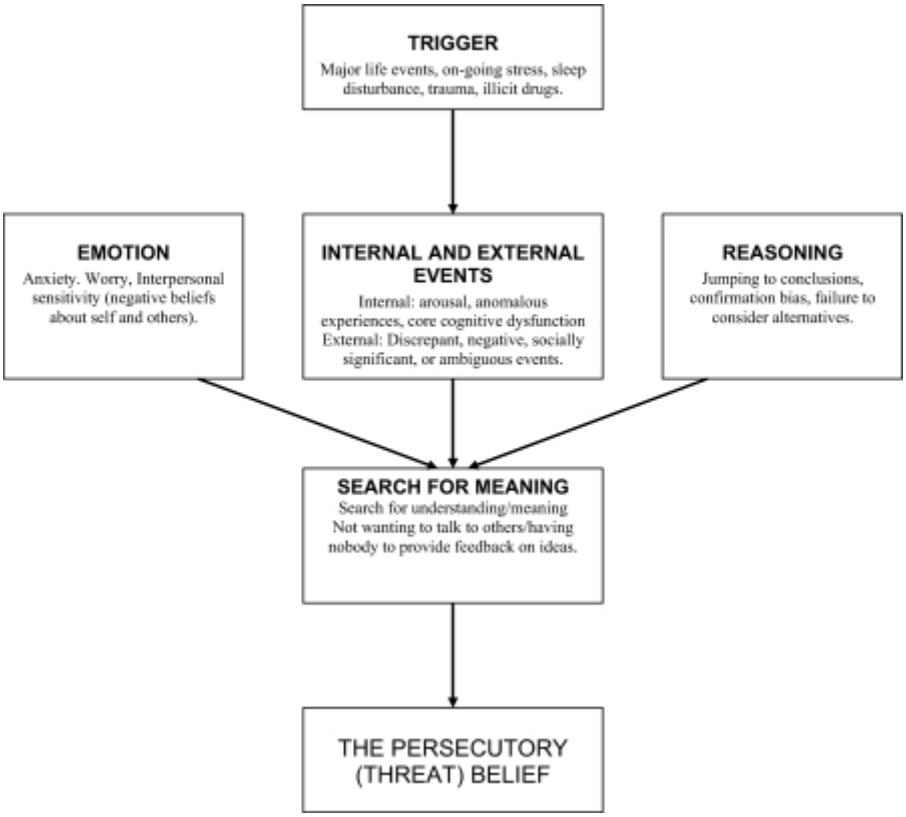


Figure 1: Multifactorial model of the formation of persecutory beliefs (Freeman et al., 2002)

1.3. The importance of treatment feasibility

The challenge of engaging individuals with psychosis in treatment is well-documented in clinical literature (Kreyenbuhl, Nossle & Dixon, 2009; Sainsbury Centre for Mental Health, 1998). Evidence suggests that up to 80% are non-adherent to treatment (Corrigan, Liberman & Engel, 1990) with an average non-compliance of pharmacology of 42% (Cramer & Rosenheck, 1998), albeit such figures may have improved since these studies were conducted. More recent research has found an estimated 24% rate of missed medical appointments for individuals with psychosis (Kreyenbuhl, Nossle & Dixon 2009) and a poor alliance with the therapist in treatment (Lecomte et al., 2008; Priebe, Watts, Chase & Matanov, 2005; Young, Grusky, Jordan & Belin, 2000). However, O'Brien, Fahmy & Singh (2008) found that, relative to other serious mental illnesses, a diagnosis of schizophrenia is associated with lower rates of treatment disengagement. A recent meta-analysis has shown that individuals with schizophrenia spectrum disorders have a better rate of

engagement in psychosocial treatments compared to psychopharmacology adherence (Villeneuve et al., 2010). Analysing 74 RCT studies, they found approximately 13% of participants who had agreed to undergo psychological treatment dropped out prior to or during therapy. Research has indicated that there is a more severe dropout rate among individuals with severe delusions (Lincoln et al., 2014). Although dropout rates were not investigated in relation to persecutory delusions, it is possible that the associated difficulties of holding a persecutory belief (e.g. high anxiety, distrustfulness, social isolation) would contribute to a greater difficulty in engagement. For example, Lawlor, Hall & Ellett (2015) found that individuals with persecutory delusions experienced paranoia towards their therapist, both in and between sessions. Although no participants dropped out of treatment in this study, feelings of paranoia towards a therapist could undeniably disrupt therapeutic engagement, particularly if this is not addressing by the therapist.

1.4. Review objectives

To date, no systematic review has investigated the efficacy and feasibility of psychological treatments in reducing paranoia in psychosis populations. As such, this review has the following research objectives and questions:

1. Provide a synthesis of the characteristics of psychological treatments (e.g. type of intervention, treatment length) impacting on paranoia in psychosis literature to date.
2. What is the feasibility of psychological treatments for paranoia, as measured by treatment dropout rates and ratings of usefulness, satisfaction and interest?
3. What is the efficacy of psychological treatments for paranoia:
    a. At the end-of-treatment and at follow-up?
    b. In terms of overall persecutory delusion severity, frequency and endorsement of paranoid ideas and distress associated with such beliefs?

c. Is general well-being improved?

4. Does the intervention change the targeted factors hypothesised to maintain paranoia?

2. Methods

2.1. Eligibility Criteria

In order to be included in the qualitative review (feasibility and quality), studies needed to meet the following criteria: 1) had to be an evaluation of a psychological intervention, 2) report outcome data specific to persecutory delusions i.e. either the sample is broader psychosis but paranoia change is measured or the sample is homogeneous with people with persecutory delusions, 3) only peer reviewed studies published in the English language were included.

In order for studies to be used in the meta-analysis to investigate efficacy of interventions, studies needed to meet the previously mentioned inclusions criteria (criteria 1-3) and further meet the following inclusion criteria: 4) randomised control trial 5) comparing a psychological therapy intervention (individual or group), 6) treatment as usual (TAU) or another active control intervention (e.g. peer support).

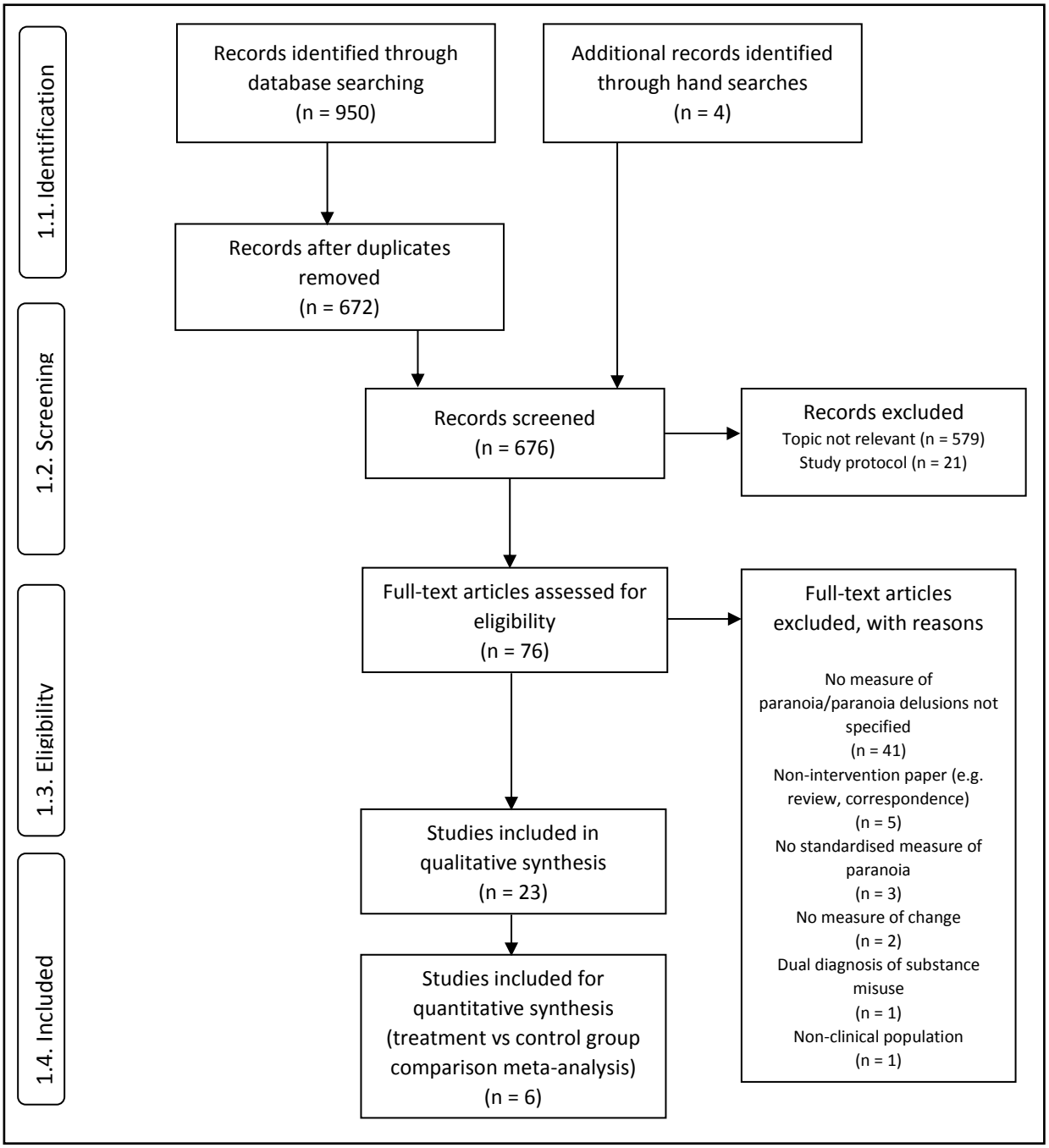
2.2. Information sources

Relevant studies were identified by an electronic database search using three databases: EMBASE, PUBMED and PSYCHinfo from 1987 to 14th December 2015 in English. Published meta-analysis and reviews were also searched. Within each of these databases three searches were conducted and combined.

2.3. Search

The first terms searched in the databases were “psychosis” OR “persecutory delusion*” OR “paranoi*”. Next, databases were searched on the terms “cognitive therapy” OR “cognitive behaviour therapy” OR “cognitive behaviour therapy” OR “cognitive behavioural therapy”

OR “cognitive behavioural therapy” OR “mindfulness” OR “group therapy” OR “group intervention”. Following this, databases were search for the terms “RCT” OR “randomised control trial” OR “randomized control trial” OR “pilot study” OR “case study”. Finally, all three searches were combined using the operator AND, which yielded 950 studies. The



removal of duplicates narrowed the search to 672 studies (see flow chart depicted on Figure 2). Three further studies were added from other sources, resulting in a final total of 675 studies.

Figure 2: Flow chart of selected studies

2.4. Study Selection

All papers were screened on titles and abstracts. Seventy-six full texts were read and assessed for eligibility. Twenty-three studies fulfilled the criteria and were ultimately included for the quantitative synthesis of the review. Of the excluded studies, 41 did not specify delusions as paranoid or use a specific measure of paranoia, 5 were not intervention papers (e.g. correspondence papers), 3 did not use standardised measures to monitor paranoia, 2 did not give a measure of change and 2 did not include participants who met the diagnostic criteria.

Of the 23 eligible studies included in the qualitative review, 6 studies were identified as eligible for meta-analysis (see Table 1c). All studies not included in the meta-analysis were excluded due to a lack of comparison group. It should be noted that one study (Chadwick et al., 2009) was included in the qualitative review as the majority (86%) were identified as suffering from paranoia. However, despite having a comparison group, this study was excluded from the meta-analysis on the basis that the study did not have a follow-up and it reported mean (pre-post) change rather than group means and standard deviations.

2.5 Quality assessment

Quality of treatment and quality of methodology were coded by the author using a quality rating scale developed by Yates et al. (2005) (see Appendix 1). This rating scale was selected as it was specifically designed for assessing quality of randomised controlled trials for psychological treatment and is evidenced to have good reliability and validity (Yates et al., 2005). It also provides two subscales – one of treatment quality and – one of quality of study design and methods. These can be combined to give an overall score of quality. The scale has a maximum total quality score of 35, which is subdivided into a maximum treatment quality score of 9 and a maximum design and methods quality score of 26.

Whilst some of the studies assessed in this review are not randomised controlled trials, the majority of scale items are equally applicable to non-randomised studies and thus the scale was deemed to be a valid comparison tool.

Feasibility of psychological interventions for paranoia was predominantly assessed using the reported dropout rates prior to or during treatment as a measure of engagement in treatment. Where reported, feasibility was also assessed using participants' feedback on the usefulness, and of their interest, enjoyment and satisfaction, of the intervention.

2.6 Assessment of efficacy of treatment

2.6.1. Meta-analyses

Statistical analyses were carried out in Review Manager (Version 5.3). Bias-corrected standardised mean difference (*d*) were calculated on all outcome measures for every intervention-control group comparison using pooled standard deviation as the standardiser (Hedges and Olkin, 1985). A positive sign for *d* indicates that the intervention group showed greater improvement after treatment than the control condition. Effect sizes were calculated based on post-treatment data and follow-up data in order to estimate the long-term effects of treatment.

Homogeneity of effect size was not assumed because the studies differ in various ways (e.g. duration of treatment, format of therapy, measurement tool). Hence, a random-effects model was fitted to the data to allow for variation in the true effect sizes (δ_i). Heterogeneity was calculated using χ^2 tests and the I^2 statistic was reported. When I^2 = 0%, 25%, 50% or 75%, then no, low, moderate and high heterogeneity must be assumed (Higgins, Thompson, Deeks & Altman, 2003).

2.6.1.1. Paranoia assessment

2.6.1.1.1. Overall severity and distress associated with persecutory delusions

The most commonly used measure of paranoia severity was the delusion subscale of the Psychotic Symptom Rating Scale (PSYRATS-D) (Haddock et al., 1999). The scale is largely clinician-led, measuring delusions across six dimensions: amount of preoccupation, duration of preoccupation, conviction, disruption, amount of distress and intensity of distress. Five out of the six studies report a total PSYRATS D score as a primary measure of change in persecutory delusion. Waller et al. (2015) used visual analogue scales (VAS) (scale 1-100) for three dimensions of persecutory delusions: conviction, distress and preoccupation. This data was used for the primary meta-analysis investigating efficacy of psychological treatment in reducing paranoia. Where subscale data was reported, sum scores and pooled variance were calculated. Studies reporting subscale data for distress (Foster et al., 2010; Freeman et al. 2015 and Waller et al., 2015) were used to estimate an effect size of changes in distress.

2.6.1.1.2. Endorsement of persecutory ideation

Three studies also measured change in paranoia using Green et al. Paranoid Thoughts Scale (GPTS) (Green et al., 2008). The GPTS is a self-report tool which measures ideas of social reference, persecutory ideas and associated distress. It has been shown to have good reliability, validity and sensitivity to clinical change and thus warrants inclusion in this review as a secondary measure of change in paranoia. The GPTS differs conceptually from the PSYRATS-D in that it predominantly measures frequency and the endorsement of paranoid ideas held, either in the context of social referencing (part A; e.g. “People have been dropping hints for me”) or persecution (part B; e.g. “Certain individuals have had it in for me”).

2.6.1.2. Causal and maintenance factors

As all studies included in the meta-analysis used interventions designed from a causal-interventionist approach, all interventions targeted a maintenance factor of paranoia. The targeted maintenance factors and associated measuring tools for each study are detailed in Table 1c. These measures were used to calculate the efficacy of interventions in improving the targeted maintenance factors of paranoia. All studies used measures in which a decreasing score indicates improvement with the exception of one study (Waller et al., 2015) which used a measure with an increasing score indicating improvement. To allow for this in the analysis, group means and standard deviations for Waller et al. (2015) were switched between the intervention and control groups in the calculations.

2.6.1.3 Well-being

Three studies included in the meta-analyses measured change in well-being using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) (Tennant et al., 2007). This tool assesses well-being over the past fortnight across fourteen items such as 'I've been feeling cheerful' and 'I've been feeling good about myself'. The scale has high test-retest reliability and criterion validity. Analyses were conducted to evaluate the efficacy of these interventions in improving well-being at end-of-treatment and at follow-up.

2.6.2. Efficacy of pilot and case studies

Studies excluded from the meta-analyses were assessed for observed changes in paranoia and other psychological factors measured within the studies. Observed change was predominantly assessed by comparing scores on pre- and post-intervention measures, factoring in change at follow-up where applicable. In a small number of studies, qualitative evidence of change was found in narrative descriptions of outcomes.

3. Results

3.1. Characteristics of psychological treatments impacting on paranoia

Of the 23 studies identified that evaluated psychological interventions treating individuals with paranoia, 10 were case studies or case series, 5 were non-randomised pilot studies and 7 were RCTs (see Tables 1a, 1b and 1c). All interventions were individualised, with the exception of two studies which delivered a mindfulness group intervention and a metacognitive training group programme (Chadwick et al., 2009; van Oosterhout et al., 2014). The majority of the studies were conducted in the UK and almost half (47.8%) were conducted by the same research group (Bell & Freeman, 2014; Freeman et al., 2014; Freeman et al., 2016; Freeman, Dunn et al., 2015; Freeman, Waite et al., 2015; Freeman, Waller et al., 2015; Foster et al., 2010; Hepworth, Startup & Freeman, 2011; Myers, Startup & Freeman, 2011; Waller et al., 2011; Waller et al., 2015).

Across the 23 studies, the number of therapy sessions ranged from 1 to 38 sessions. The average number of sessions was 10.5 (SD 9.61), with a median of 7 sessions and mode of 6 sessions. The length of interventions ranged (in weeks) from 1 (for a one-off intervention) to 78, with an average length of 13.7 weeks (SD 16.76), and a median and mode of 8 weeks.

Seven studies used individually tailored formulation-based therapy. Interventions included four 'classic' CBTp (including normalisation, belief modification and reality testing) (Carden & Jones, 2009; Chadwick & Tower, 1996; Kinderman & Bentall, 1997; Kuller & Björgvinsoon, 2010; Morrison, 2004); a third-wave intervention i.e. acceptance and commitment therapy (ACT) (Bloy, Oliver and Morris, 2011); and a CBT for dog phobia and agoraphobia (Dudley, Dixon and Turkington, 2005).

Sixteen of the interventions were manualised interventions. Two studies were manualised mindfulness interventions (Chadwick et al., 2009; Ellett, 2013). All other studies used interventionist-causal model approaches, targeting a specific causal and maintenance

factor of persecutory delusions. Six studies used variants of metacognitive therapy, specifically targeting reasoning biases associated with persecutory delusions (e.g. jumping to conclusions, belief inflexibility) (Balzan & Gallelty, 2015; Hepworth, Startup and Freeman, 2011; Hutton, Morrison and Wardle, 2014; van Oosterhout et al., 2014; Waller et al., 2011; Waller et al., 2015). Other studies used brief interventions targeting: worry (Foster et al., 2010; Freeman, Dunn et al., 2015); interpersonal sensitivity (Bell and Freeman, 2014); insomnia (Freeman, Waite et al., 2015; Myers, Startup and Freeman, 2011); anxiety in urban environments (Freeman, Waller et al., 2015); and negative self-beliefs (Freeman et al., 2014). The most recent study (Freeman et al., 2016) delivered a lengthier intervention that allowed participants to combine brief modules in improving issues with worry, sleep, self-confidence, reasoning processes and safety behaviours, based on their individual needs.

Eleven of the studies identified come from the same research group: the Oxford Cognitive Approaches to Psychosis (O-CAP), led by Professor Daniel Freeman. Of these, five are RCTs used in the meta-analysis of this review. This research group focus much of their research on investigating their cognitive model of persecutory delusions and developing therapeutic interventions based on hypothesised mechanisms of paranoia (Freeman et al., 2002).

Table 1a: Case studies/series included in the qualitative synthesis of psychological interventions treating paranoia

Author and Year	N/Diagnoses/Age	Type of intervention	Duration of intervention	Number of sessions; session duration	Follow-up	Primary outcome measure
Balzan & Galletly (2015)	2 males Diagnoses: 1 SCZ; 1 DD Age: 25.5 (7.8)	Individual metacognitive therapy (MCT+)	5 weeks	5 sessions; 90-120mins	6 weeks	PSYRATS-D
Bloy, Oliver & Morris (2011)	1 male Diagnosis: POS Age: 32	Individual Acceptance & Commitment Therapy (ACT)	8 months	27 sessions; 60 mins	None	PSYRATS-D
Carden & Jones (2009)	1 male Diagnosis: SCZ Age: 32	Individual CBTp (including normalisation, belief modification, reality testing)	18 months	Not reported	None	PSYRATS-D
Chadwick & Trower (1996)	1 male Diagnosis: SCZ Age:31	CBTp for punishment paranoia (including shared formulation, challenging negative self-evaluative beliefs and challenging delusions)	12 weeks	12 sessions; 60mins	1, 3 and 6 months	Belief conviction and preoccupation (%)
Dudley, Dixon & Turkington (2005)	1 male Diagnosis: SCZ Age: 38	CBT for dog phobia and agoraphobia (including systematic desensitisation)	Not reported	38 sessions	6 months	PSYRATS-D
Ellett (2013)	2 males Diagnoses: DD Age: 41.5 (10.6)	Individual mindfulness intervention for paranoid beliefs based on manual (Chadwick et al., 2005, 2009)	8 weeks	8 sessions; 60 mins	5 weeks	Belief conviction, preoccupation & distress (0-10)
Hutton, Morrison & Wardle (2014)	3 (1 male, 2 female) Diagnoses: SCZ Age: 43.3 (12.6)	Metacognitive Therapy intervention, based on Wells (2009) metacognitive model of GAD, adapted for persecutory delusions.	3 months	11-13 sessions	3 months	PSYRATS-D
Kinderman & Bentall (1997)	1 male Diagnosis: SCZ Age: 33	Attribution therapy: a cognitive-behavioural intervention based on the attribution model of paranoid ideation (Bentall, Kinderman & Kaney, 1994).	8 weeks	9 sessions	None	Paranoia Scale[1]
Kuller & Björgvinsoon (2010)	1 male Diagnosis: Paranoid SCZ Age: 33	Individualised CBTp (including normalisation, belief modification, reality testing)	30 weeks	30 sessions	None	Belief conviction and preoccupation (%)
Morrison (2004)	1 male Diagnosis: DD Age: 30	Individual imagery based cognitive therapy adapted for persecutory delusions	8 weeks	8 sessions	6 weeks	PSYRATS-D

SCZ, Schizophrenia; POS, Psychosis not otherwise specified; DD, Delusional disorder; PSYRATS-D, PSYRATS delusions scale; [1]Fenigstein and Vanable (1992)

Table 1b: Pilot studies (non-randomised) included in the qualitative synthesis of psychological interventions treating paranoia

Author and Year	N/Diagnoses/Mean age (SD)	Inclusion criteria	Type of intervention	Duration of intervention	Number/duration of sessions	Blind?	Follow-up	Intervention dropout rate	Primary outcome measure
Bell & Freeman (2014)	11 Diagnoses: 6 SCZ; 1 DD; 4 POS Age: 38.0 (15.8)	Current persecutory delusion[1]; ≥ 50% delusional belief conviction; reporting interpersonal sensitivity[2]; aged 18-65; 1 month of medication stability	Manualised cognitive-behavioural intervention targeting interpersonal sensitivity	8 weeks	6 sessions	No	4 weeks	8.33%	PSYRATS-D GTPS
Freeman et al. (2016)	11 Diagnoses: 4 SCZ; 5 SA; 1 DD; 1 POS Age: 41.6 (15.2)	Current persecutory delusions[1]; aged 18-70	Individual, modular CBT intervention offering treatment models targeting sleep, worry, self-confidence, reasoning processes and safety behaviours selected preferentially by participant	6 months	20 sessions (average)	No	1 months	8.33%	PSYRATS-D GTPS
Freeman, Waller et al. (2015)	15 Diagnoses: 13 SCZ, 2 SA Age: 41.4 (11.2)	Current persecutory delusions[1], ≥ 50% delusional belief conviction; aged 18-65	One-off computer-based CBT intervention entitled "Getting Out and About". Psychoeducation about anxiety, specifically in urban environments and anxiety management techniques.	2-3 hours	1 session; 2-3 hours duration	No	None	16.67%	Belief conviction and distress (%)
Hepworth, Startup & Freeman (2011)	12 Diagnoses: 10 SCZ, 2 DD Age: 40.3 (11.9)	Current persecutory delusions[1]; aged 18-65	Brief cognitive intervention "Emotional Processing and Metacognitive Awareness (EPMA)". Intervention based on numerous sources[3]	3 weeks	3 sessions, 60 mins durations	No	1 month	29.41%	PSYRATS-D
Myers, Startup & Freeman (2011)	15 Diagnoses: SCZ, SA or DD Age: 45.5 (11.3)	Current persecutory delusions[1]; sleep difficulties lasting for one month or longer; 1 month of medication stability; aged 18-65	Individual insomnia CBT intervention, manual written based on numerous sources[4]	4-8 weeks	4 sessions; 60 mins duration	No	1 month	0.00%	PSYRATS-D
Waller et al. (2011)	13 Diagnoses: 7 SCZ; 4 SA; 1 DD; 1 POS Age: 44.6 (10.2)	Currently persecutory delusions; high delusional conviction (> 75%)	One-off computerised training reasoning biases, termed 'Maudsley Review Training Programme' + 4 CBT sessions	5 weeks	5: 90 mins duration of computer training + 4 sessions CBT	No	1 month	7.14%	Delusional conviction (%)

SD, Standard deviation; SCZ, Schizophrenia; SA, Schizoaffective disorder; POS, Psychosis not otherwise specified; DD, Delusional disorder; PSYRATS-D, PSYRATS delusions scale; GPTS, Green et al. Paranoid Thoughts Scale; [1] defined by Freeman and Garety (2000), present ≥ 6 months; [2] scoring ≥ 95 Interpersonal Sensitivity Measure (IPSM) (Boyce & Parker, 1989); [3] sources include Watkins (2004), Hayes (2005), Segal, Teasdale, Williams & Gemar (2002), and Blackledge (2007); [4]sources included Espie (2006), Freeman & Freeman (2010), Meir & Kryger (2004) and Harvey, Sharpley, Ree, Stinson & Clark (2007).

Table 1c: Randomised Control Trials included in the qualitative synthesis and meta-analyses

Author and Year	N/Diagnoses/ Mean age (SD)	Inclusion criteria	Type of control	Blind?	Type of Intervention	Details of intervention	Duration of intervention	Number/ duration of sessions	Follow up	Intervention dropout rate	ITT?	Measure of Paranoia	Targeted factor	Outcome measure of targeted factor
Chadwick et al. (2009)[1]	22 Diagnoses: 22 SCZ, 19 of which had paranoid beliefs Age: 41.6 (8.1)	Aged 18+ years; diagnosed with a psychotic disorder; prominent, distressing voices for ≥ 6 months; under care of secondary mental health services	Waitlist n = 11	Yes	Group	Group mindfulness intervention for psychosis and voices n = 15	10 weeks (5 weeks bi-weekly session + 5 weeks of practice following intervention)	10 sessions	None	18.18%	No	PSYRATS-D	Mindful response to distressing thoughts and images	SMQ
Foster et al. (2010)	24 Diagnoses: 12 SZ, SA, DD Age: EC: 40.0 (10.5)/ CC: 39.1 (9.2)	Current persecutory delusion[2] for ≥ 6 months; a clinically significant level of worry[2]; aged 18-65.	TAU n = 12	No	Individual	Worry-CBT, Fixed sessions based on a therapy manual (Wells, 1997) n = 12	4 weeks	4 session; 60 mins	4 weeks	8.33%	No	PSYRATS-D GPTS	Worry	PSWQ
Freeman, Dunn et al. (2015)	150 Diagnoses: 111 SZ; 11 SA; 10 DD; 18 POS Age: EC: 40.9 (10.5)/ CC: 42.1 (13.1)	Current persecutory delusion[2] for ≥ 6 months; a clinically significant level of worry[3]; aged 18-65; 1 month medication stability	TAU n = 77	Yes	Individual	Worry-CBT, based on self-help manual (Freeman & Freeman, 2013) n = 73	8 weeks	6 sessions; 60 mins	12 weeks	12.33%	Yes	PSYRATS-D GPTS	Worry	PSWQ
Freeman, Waite et al. (2015)	50 Diagnoses: 33 SCZ; 10 SA; 7 POS Age: EC: 39.6 (11.6)/ CC: 42.4 (13.5)	Current persecutory delusion[2] for ≥ 3 months; a score of at least 2 on the distress items of the PSYRATS-D; sleep difficulties lasting ≥ 1 month; ISI score ≥ 15; aged 18–65; 1 month medication stability	TAU n = 26	Yes	Individual	Individual insomnia CBT intervention, manual written based on numerous sources[8] n = 24	12 weeks	8 sessions; 60 mins duration	12 weeks	4.17%	Yes	PSYRATS-D GPTS	Insomnia	ISI

Table 1c: continued

Author and Year	N/Diagnoses/ Mean age (SD)	Inclusion criteria	Type of control	Blind?	Type of Intervention	Details of intervention	Duration of intervention	Number/ duration of sessions	Follow up	Intervention dropout rate	ITT?	Measure of Paranoia	Targeted factor	Outcome measure of targeted factor
Freeman et al. (2014)	30 Diagnoses: 22 SZ; 6 SA; 1 DD; 1 POS Age: EC: 40.9 (10.5)/ CC: 41.5 (13.1)	Current persecutory delusion[2] for ≥ 3 months; ≥ 50% delusional belief conviction; negative beliefs about the self[4]; aged 18-70; one month medication stability	TAU n = 15	Yes	Individual	Brief CBT targeting negative self-beliefs, based on self-help manual (Freeman & Freeman, 2012) n = 15	8 weeks	6 sessions	12 weeks	0.00%	Yes	PSYRATS-D	Negative self-beliefs	BCSS
van Oosterhout et al. (2014)	154 Diagnoses: EC: 52 SCZ; 9 POS, 3 SA; 11 Others/ CC I: 46 SCZ; 9 POS; 5 SA; 19 Others Age: EC: 38.3 (11.1)/ CC: 35.8 (8.7)	Diagnosed with a psychotic disorder[5]; current paranoia measured by a GPTS score ≥ 50; aged 18–65	TAU n = 79	Yes	Group	Group metacognitive training intervention, manual based on Moritz (2009) n = 75	8 weeks	8 sessions	16 weeks	22.67%	Yes	PSYRATS-D GPTS	Reasoning biases	MCQ-30
Waller et al. (2015)	31 Diagnosis: EC: 16 SCZ; 2 DD; 2 SA/ CC I: SCZ 11 Age: EC: 39.1 (10.5)/ CC: 43.0 (10.7)	A diagnosis of psychosis[6]; a current delusion with persecutory content[7]; ≥ 50% delusional belief conviction; rated as distressing (>0) on a VAS; aged 18-65	TAU n = 11	No	Individual	Brief, focused CBT intervention targeting reasoning biases termed 'Thinking Well (TW)': n = 20	6 weeks	4 sessions	8 weeks	10.00%	Yes	Delusional conviction, distress and preoccupation (%)	Reasoning biases (belief flexibility and jumping to conclusions)	1 item from MADS measuring belief flexibility (%)

SD, Standard deviation; ITT, Intention to treat; EC, Experimental condition; CC, Control condition; SCZ, Schizophrenia; SA, Schizoaffective disorder; POS, Psychosis not otherwise specified; DD, Delusional disorder; VAS, Visual analogue scale; TAU, Treatment as usual; PSYRATS-D, PSYRATS delusions scale; GPTS, Green et al. Paranoid Thoughts Scale; SMQ, Southampton Mindfulness Questionnaire (Chadwick et al., 2008); PSWQ, Penn State Worry Questionnaire (Meyer et al., 1990); ISI, Insomnia Severity Scale (Bastien, Vallières & Morin, 2001); BCSS, Brief Core Schema Scale (Fowler et al., 2006); MCQ-30, Meta-cognitive Questionnaire 30 (Wells & Cartwright-Hatton, 2004); MADS, Maudsley Assessment of Delusions Schedule (Wessely et al., 1993); [1]study excluded from meta-analyses; [2]defined by Freeman and Garety (2000); [3]indicated by a PSWQ score ≥ 45; [4]as indicated by endorsing at least one negative schematic belief on BCSS; [5]according to the DSM-IV schizophrenia spectrum (APA, 2000); [6]according to ICD-10, F20-29 'Schizophrenia Spectrum Psychosis' [7]assessed using Schedules for Clinical Assessment in Neuropsychiatry (SCAN, Wing et al., 1990); [8]Espie (2006), Freeman & Freeman (2010), Meir & Kryger (2004) and Harvey et al. (2007)

3.2. Quality of the included studies

Assessment of the quality of studies included in this review (detailed in Table 2) showed that the overall quality of studies' scores ranged from 10 to 34. The average total quality score of studies was 20.1 (SD 7.57), indicating an overall moderate quality of studies. Quality of treatment was generally high, with an average score of 7.0 (SD 1.45) within a score range of 0 to 9. Quality scores of study design and methods were generally moderate to high, with an average score of 13.1 (SD 6.63) and a range of 6 to 25. In particular, RCTs had good quality of treatment and methodology. This is in comparison to van der Gaag et al. (2013), who used the Clinical Trials Assessment Measure (CTAM; Tarrier & Wykes, 2004), who found three of the ten studies included were of "inferior quality".

More detailed assessment of individual items (see Appendix 2) reveals that treatment quality was generally high across all studies. In particular, studies scored consistently highly in detailing treatment content, quality of therapist training (almost exclusively given by trained clinical psychologists) and evidencing patient engagement. Lower scores in treatment quality were largely due to a lack of manualisation or lack of evidence for adhering to a treatment manual (Bloy, Oliver & Morris, 2014; Chadwick & Torwer, 1996; Carden & Jones, 2009; Dudley, Dixon & Turkington, 2005; Kinderman & Bentall, 1997).

Quality scores for design and methodology approximately grouped studies into RCTs (scoring highest), pilot studies and case studies (scoring lowest), as was to be expected. Understandably, pilot and case studies had low scores for controlling for bias (e.g. randomisation, blinding, allocation bias etc.) and statistical analyses (e.g. power calculations, statistical report etc.). Most studies scored highly for justification and validity of outcomes. The range observed in RCT quality scores was largely due to variation in controlling for bias e.g. blindness (Foster et al., 2010; Waller et al., 2015), and statistical

power (Freeman et al., 2014; Freeman, Waite et al., 2015; Waller et al., 2015). Of particular note, Freeman et al. (2014) and Waller et al. (2015) showed moderate to large effects sizes of their interventions in reducing paranoia but lacked power and Waller et al. (2015) also used un-blinded assessors.

Table 2: Quality scores of included studies (order by total score, highest-lowest)

Author and Year	Type of study	Type of intervention	Treatment Quality Score (0-9)	Quality of study design and methods (0-26)	Total quality score (0-35)
Van Oosterhout et al. (2014)	RCT	Group Metacognitive Training (MCT)	9	25	34
Freeman, Dunn et al. (2015)	RCT	Individual CBT for worry	9	24	33
Freeman, Waite et al. (2015)	RCT	Individual CBT for insomnia	9	22	31
Freeman et al. (2014)	RCT	Individual CBT for self-esteem	8	22	30
Chadwick et al. (2009)	RCT	Group mindfulness	6	20	26
Foster et al. (2010)	RCT	Individual CBT for worry	6	20	26
Waller et al. (2015)	RCT	Individual Computerised + therapist delivered CBT for reasoning biases	8	18	26
Bell & Freeman (2014)	Pilot	Individual IPS CBT	8	15	23
Myers, Startup & Freeman (2010)	Pilot	Individual CBT for insomnia	8	15	23
Freeman et al. (2016)	Pilot	Individual, module CBT	8	13	21
Hepworth, Startup & Freeman (2011)	Pilot	Individual Emotional Processing and Metacogntive Awareness	8	13	21
Freeman, Waller et al. (2015)	Pilot	One-off computer-based psychoeducation + 4 sessions CBT	7	10	17
Hutton, Morrison & Wardle (2014)	Case series	Individual Metacognitive Therapy	7	10	17
Waller et al. (2010)	Pilot	Individual computerised CBT for reasoning biases	6	11	17
Morrison (2010)	Case	Individual Imagery CBTp	7	8	15
Balzan & Galletly (2015)	Case series	Individual MCT CBT	7	7	14
Bloy, Oliver & Morris (2011)	Case	Individual ACT	5	8	14
Ellett (2013)	Case series	Individual mindfulness	8	6	14
Carden & Jones (2009)	Case	Individual CBTp	4	7	11
Chadwick & Trower (1996)	Case	Individual CBTp	6	5	11
Kinderman & Bentall (1997)	Case	Individual Attribution Therapy	6	5	11
Kuller & Björgvinsson (2010)	Case	Individual CBTp	7	4	11
Dudley, Dixon & Turkington (2005)	Case	Individual CBT (systematic desensitization)	4	6	10

3.3. Feasibility

As 10 of the studies were case studies, intervention dropout rates for these studies did not apply and were therefore not included in the evaluation of intervention feasibility. Of the thirteen studies that could be included, the average proportion of individuals who dropped

out of the evaluated intervention was 11.2% (SD 8.59). The range of intervention dropout rates was 0%-29.41%.

Closer inspection of dropout rates highlighted that two of the three studies with the highest intervention dropout rates (van Oosterhout et al., 2014; Chadwick et al., 2009) were the two group interventions, with respective dropout rates of 22.7% and 18.1%. Evaluating the dropout rates of individualised treatments alone suggested an average attrition of 9.5%, skewed by one particular study (Hepworth, Startup and Freeman, 2011) which had a disproportionately high dropout rate of 29.4%. Excluding this study reduces the average attrition rate for individual interventions to 7.5%.

Studies with interventions targeting insomnia (Myers, Startup and Freeman, 2011; Freeman, Waite et al., 2015) had notably low dropout rates of 0.0% and 4.2%, respectively. An intervention targeting negative self-belief (Freeman et al., 2014) also had no participants drop out of treatment. Although studies reporting dropout rates were largely briefer in length, there does not appear to be a distinct relationship between treatment length or number of sessions and attrition in treatment conditions.

Eight studies gave details of patient feedback about the interventions. Feedback was operationalised in various ways, largely categorisable into usefulness of treatment, interest in the intervention, enjoyment of the intervention, and satisfaction with treatment (see Table 3). Feedback was positive in all studies, with satisfaction and usefulness ratings being notable high across numerous interventions. Of note, all studies which reported feedback delivered interventions that either indirectly addressed paranoia or directly addressed paranoia without challenging the delusions (Bloy, Oliver & Morris, 2011). However, no studies report requesting specific recommendations from participants to improve the inventions.

Table 3: Intervention feedback from participants

	Usefulness	Interest	Enjoyment	Satisfaction
Bell & Freeman (2014)	++	NR	NR	++
Bloy, Oliver & Morris (2011)	NR	NR	NR	++
Freeman et al. (2016)	NR	NR	NR	++
Freeman, Dunn et al. (2015)	NR	NR	NR	+
Freeman, Waller et al. (2015)	++	NR	++	++
Van Oosterhout et al. (2014)	NR	NR	+	++
Waller et al. (2010)	++	++	++	NR
Waller et al. (2015)	+	NR	+	NR

++, high ratings reported; + positive feedback reported; NR, not reported

3.3. Efficacy of treatment

3.3.1. Efficacy of pilot and case studies

Across the studies not included in the meta-analyses, Table 4 depicts observed changes in persecutory delusions and other psychological factors. Only a small number of studies evaluated the same outcome with the exception of overall improvements in persecutory delusions and conviction of persecutory belief.

With the exception of two studies (Chadwick et al., 2009; Carden & Jones, 2009), improvements in some aspects (e.g. conviction, preoccupation, distress) if not overall improvement in persecutory delusions were observed. In particular, all studies measuring associated distress reported improvements. Where reported, improvements in other psychological factors were also observed in the majority of studies. This was particularly observed in overall symptoms of psychosis and cognitive factors, albeit the latter factors were largely being targeted by the intervention and hence were reported as outcomes e.g. worry. Observed changes in affect were less consistent – approximately half of the studies measuring affect reported improvements in depression (Bloy, Oliver & Morris, 2011; Chadwick & Trower, 1996; Ellett, 2013; Hepworth, Startup & Freeman, 2010; Myers, Startup & Freeman, 2010) whilst the majority of studies measuring anxiety found no change in outcome (Carden & Jones, 2009; Freeman, Waller et al., 2015; Hepworth, Startup & Freeman, 2011; Hutton, Morrison & Wardle, 2014). Some studies reported

improvements in social functioning and well-being but there was no evidence for improvement in clinical functioning. Notably, no studies reported worsening of persecutory delusions or any other psychological factor.

Table 4: Observed changes in paranoia and other psychological factors in pilot and case studies

		Persecutory Delusions					Symptoms of psychosis						Affect			Cognitive							Functioning			
		Overall	Conviction	Preoccupation	Distress	Impact	Overall	Positive	Negative	General	Hallucinations	Anomalous experiences	Depression	Anxiety	Phobias	Interpersonal sensitivity	Reasoning Biases	Worry	Insight	Rumination	Mind coping	Negative self-belief	Sleep	Social functioning	Clinical functioning	Well-being
Pilot studies	Bell & Freeman (2014)	+														+										
	Chadwick et al. (2009)[1]	=									=										=				=	
	Freeman, Waller et al. (2015)	=	=		+									=												
	Freeman et al. (2016)	+	+		+		+										+	+	+			+	+			+
	Hepworth, Startup & Freeman (2011)	+	=	=	+								+	=				+		=							
	Myers, Startup & Freeman (2010)	+					+					+	+	+									+			
	Waller et al. (2010)		+														=		+							
Case studies	Balzan & Galletly (2015)	+	+	+			+	+	=		+						+		+							
	Bloy, Oliver & Morris (2011)	+											+											+		
	Carden & Jones (2009)	=	=	=									=	=												
	Chadwick & Trower (1996)		+										+													
	Dudley, Dixon & Turkington (2005)	+	+	+	+	+	+				+				+											
	Ellett (2013)		+	+	+	+							+	+							+					
	Hutton, Morrison & Wardle (2014)	+						+	+	=	+		=	=				=							=	
	Kinderman & Bentall (1997)	+															+									
	Kuller & Björgvinsson (2010)		+	+							+													+		
	Morrison (2010)		+	+	+																					

+, observed improvement; =, no change; [1]RCT not included in the meta-analyses due to sample population not all having persecutory delusions and pre-post measures design used rather than control group comparison

3.3.2. Meta-analyses

3.3.2.1. Characteristics of studies included in the meta-analyses

All six studies used manualised interventions that targeted a specific causal or maintenance factor of persecutory delusions (please see Table 1c). Only one study used a group intervention (van Oosterhout et al., 2014). Two studies (Foster et al., 2010; Freeman, Dunn et al., 2015) targeted worry and were a pilot and a larger-scale RCT trial developing the same manual. Two studies (van Oosterhout et al., 2014; Waller et al., 2015) targeted reasoning biases but had quite different intervention approaches e.g. group vs. individual. All studies used treatment as usual (TAU) as their control comparison groups.

Treatment length ranged from 4 to 12 weeks with an average of 7.67 weeks (SD 2.66). Number of sessions in an intervention ranged from 4 to 8 with an average of 6 sessions (SD 1.79). Follow-up periods for studies ranged from 4 to 16 weeks with an average follow-up period of 10.67 weeks (SD 4.13).

3.3.2.2 Efficacy of treatment at reducing paranoia

3.3.2.2.1. Overall severity of persecutory delusions (PSYRATS D)

Intervention vs. TAU at end-of-treatment

Results of the comparison between intervention vs. TAU at end-of-therapy are depicted in Figure 3 in the form of a forest plot. The estimated mean effect size of intervention was non-significant (k = 6, n = 393; *d* = 0.27, 95 % CI [-0.09 – 0.63], z = 1.46, p = 0.14).

The standardised mean difference of groups in most studies favoured intervention, however van Oosterhout et al. (2014) and Freeman, Waite et al. (2015) favoured TAU (*d* = 0.25 and -0.02 respectively). The medium to high value of I^2 = 60% indicates that approximately 60% of the observed variance in effect sizes might be due to heterogeneity. Sensitivity analysis found that one study (van Oosterhout et al., 2014) had an especially large influence on the amount of heterogeneity. If this study is excluded, the proportion of observed variance due to real differences in effect size drops to 14% (I^2 = 14%). Excluding

this study in the model changes the mean effect size to a significant small to medium effect size of intervention (k = 5, n = 265; *d* = 0.38, 95 % CI [0.10 – 0.66], z = 2.62, p = 0.009).

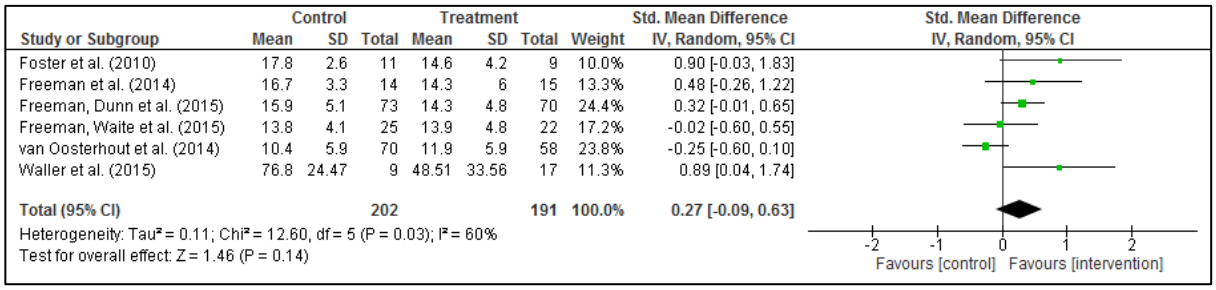


Figure 3: Table and forest plot of effect sizes for the comparison between intervention and TAU at end-of-therapy in reducing paranoia (PSYRATS D)

Intervention vs. TAU at follow-up

Results of the comparison between intervention vs. TAU at follow-up are depicted in Figure 4**.** The estimated mean effect size was also non-significant (k = 6, n = 376; *d* = 0.17, 95 % CI [-0.18 – 0.52], z = 0.95, p = 0.34).

The standardised mean difference for half the studies (Foster et al., 2010; Freeman, Dunn et al., 2015; Waller et al., 2015) favoured intervention groups. The medium to high value of I^2 = 58% indicates that approximately 58% of the observed variance in effect sizes might be due to heterogeneity. Sensitivity analysis found that one study (Freeman, Dunn et al., 2015) had a relatively large influence on the amount of heterogeneity. If this study is excluded, a 30% (I^2 = 28%) change in observed variance is observed. However, the model remains non-significant if this study is excluded and there is no effect of intervention vs. TAU on paranoia found (k = 5, n = 236; *d* = 0.02, 95 % CI [-0.30 – 0.35], z = 0.14, p = 0.89).

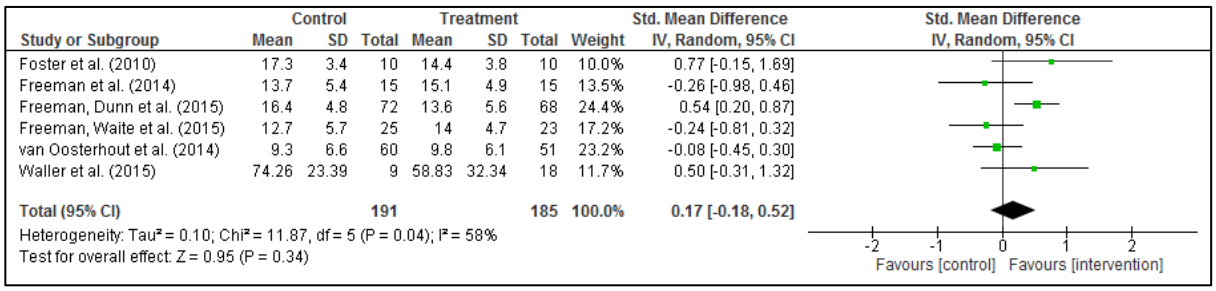


Figure 4: Table and forest plot of effect sizes for the comparison between intervention and TAU at follow-up in reducing paranoia (PSYRATS D)

3.3.2.2.2. Efficacy of reducing distress associated with persecutory delusion

Intervention vs. TAU at end-of-treatment

Analysis of the effect of intervention vs. TAU at end-of-therapy found a significant, medium to large estimated mean effect of intervention in reducing distress (k = 3, n = 187; *d* = 0.62, 95 % CI [0.10 – 1.13], z = 2.74, p = 0.006) (see Figure 5). A low to moderate level of heterogeneity was observed (I^2 = 40%), where approximately 40% of the observed variance in effect sizes may have been due to heterogeneity. Sensitivity analysis found that one study (Waller et al., 2015) had influenced all of the observed heterogeneity in effect sizes. Excluding this study reduces the estimated mean effect size but the model remains significant (k = 2, n = 163; *d* = 0.39, 95 % CI [0.08 – 0.70], z = 2.46, p = 0.01) with no observed heterogeneity of variance (I^2 = 0%). This reflects the picture of improvement, specifically on the distress levels associated with persecutory delusions, which have been observed in non-RCT studies.

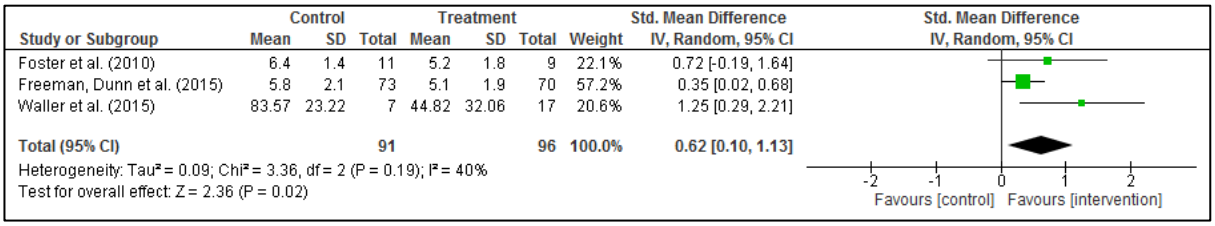


Figure 5: Table and forest plot of effect sizes for the comparison between intervention and TAU at end-of-therapy in reducing distress associated with paranoia

Intervention vs. TAU at follow-up

Comparison of intervention vs. TAU at follow-up found a significant, medium to large mean effect of intervention in reducing distress (k = 3, n = 205; *d* = 0.56, 95 % CI [0.27 – 0.86], z = 3.74, p = 0.0002) (see Figure 6). No heterogeneity in the variance of effect sizes was observed (I^2 = 0%).

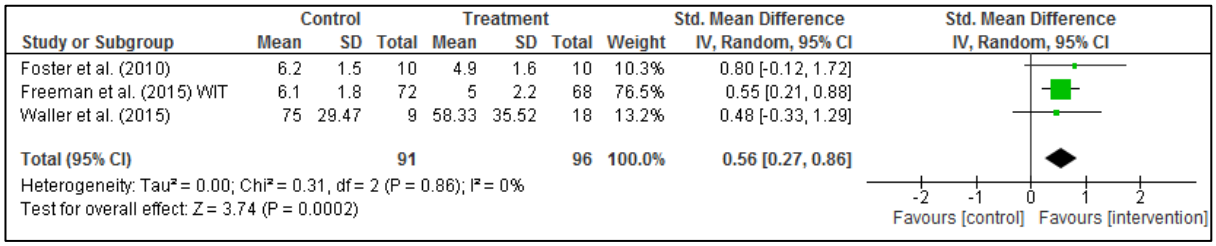


Figure 6: Table and forest plot of effect sizes for the comparison between intervention and TAU at follow-up in reducing distress associated with paranoia

3.3.2.2.3. Endorsement of persecutory ideation (GPTS)

Intervention vs. TAU at end-of-treatment

Results of using the GPTS as a measure of paranoia for a comparison of intervention vs. TAU at end-of-therapy are shown in Figure 7. Analysis found no significant estimated mean effect size (k = 4, n = 336, *d* = 0.09, 95% CI [-0.26 – 0.45], z = 0.52, p = 0.60). A medium to high heterogeneity of variance was found (I^2 = 55%), suggesting 55% of observed variance in effects sizes might be due to heterogeneity. Sensitivity analysis found one study (van Oosterhout et al., 2014) influenced all of the heterogeneity observed. This study also has a standardised mean difference that favoured the control group (*d* = -0.25). Excluding this study in the analysis finds a significant, small to medium estimated mean effect size (k = 3, n = 208; *d* = 0.31, 95 % CI [0.03 – 0.58], z = 2.21, p = 0.03) with no observed heterogeneity in variance of effect sizes (I^2 = 0%).

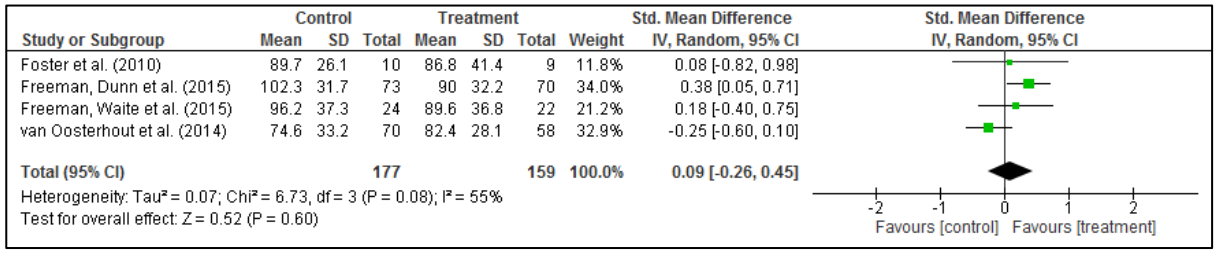


Figure 7: Table and forest plot of effect sizes for the comparison between intervention and TAU at end-of-therapy in reducing paranoia (GPTS)

Intervention vs. TAU at follow-up

The comparison of GPTS scores between intervention vs. TAU at follow-up is shown in Figure 8. The estimated mean effect size found was non-significant (k = 4, n = 317; *d* = 0.18, 95 % CI [-0.22 – 0.58], z = 0.89, p = 0.37). Again, heterogeneity of variance in effect size was found to be medium to high (I^2 = 62%) and sensitivity analysis found the same study (van Oosterhout et al., 2014) to be responsible for all 62% of the heterogeneity of variance and has a standardised mean difference value favouring TAU (*d* = -0.27). Excluding the study finds a significant, small to medium effect size of intervention on reducing paranoia scores (k = 3, n = 205; *d* = 0.39, 95 % CI [0.11 – 0.66], z = 2.74, p = 0.006) with no observed heterogeneity of variance (I^2 = 0%).

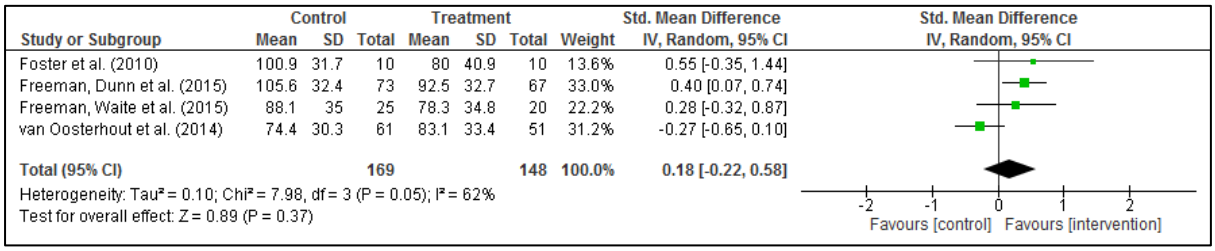


Figure 8: Table and forest plot of effect sizes for the comparison between intervention and TAU at follow-up in reducing paranoia (GPTS)

3.3.2.4. Efficacy of treatment in improving well-being

Intervention vs TAU at end-of-treatment

Analysis of the effect of intervention vs. TAU at end-of-therapy found a significant, medium estimated mean effect of intervention in improving well-being (k = 3, n = 217; *d* = 0.50, 95 % CI [0.16 – 0.84], z = 2.88, p = 0.004) (see Figure 9). A low level of heterogeneity was observed (I^2 = 24%).

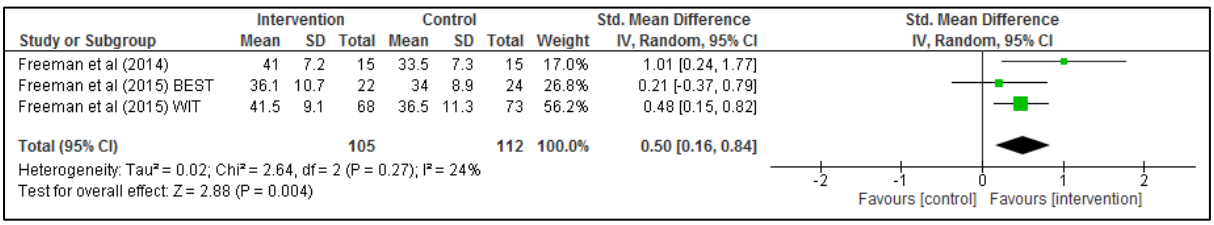


Figure 9: Table and forest plot of effect sizes for the comparison between intervention and TAU at end-of-treatment in changing well-being

Intervention vs TAU at follow-up

Analysis of the effect of intervention vs. TAU at follow-up also found a slightly smaller, significant estimated mean effect of intervention in improving well-being (k = 3, n = 215; *d* = 0.42, 95 % CI [0.15 – 0.69], z = 3.02, p = 0.003) (see Figure 10). A no heterogeneity was observed (I^2 = 0%).

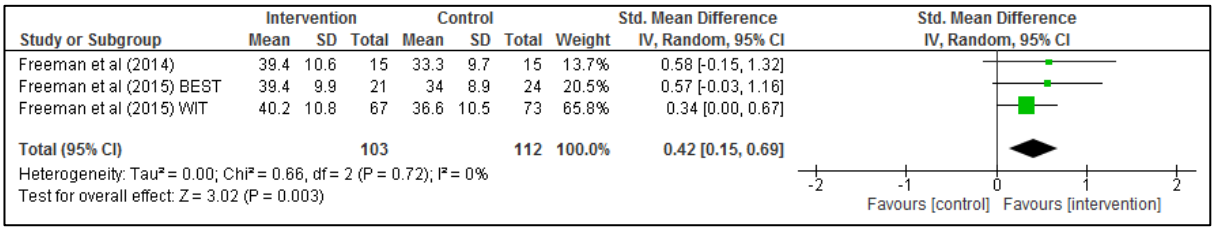


Figure 10: Table and forest plot of effect sizes for the comparison between intervention and TAU at follow-up in changing well-being

3.3.2.5 Efficacy of treatment at reducing maintenance factor of paranoia

Intervention vs. TAU at end-of-treatment

The comparison of change in the maintenance factor of paranoia between intervention and TAU at end-of-therapy found a significant, medium effect (k = 6, n = 391; *d* = 0.50, 95 % CI [0.06 – 0.95], z = 2.21, p = 0.03) (see Figure 11). High heterogeneity of variance was observed in the analysis (I^2 = 74%). However, sensitivity analysis found van Oosterhout et al. (2014) influenced all of the heterogeneity observed. The standardised mean difference observed in this study also favours the control group (*d* = -0.22). Removing this study from the analysis reduced heterogeneity to 0% and increased the size of the significant estimated mean effect (k = 5, n = 263; *d* = 0.65, 95 % CI [0.40 – 0.90], z = 5.07, p < 0.00001).

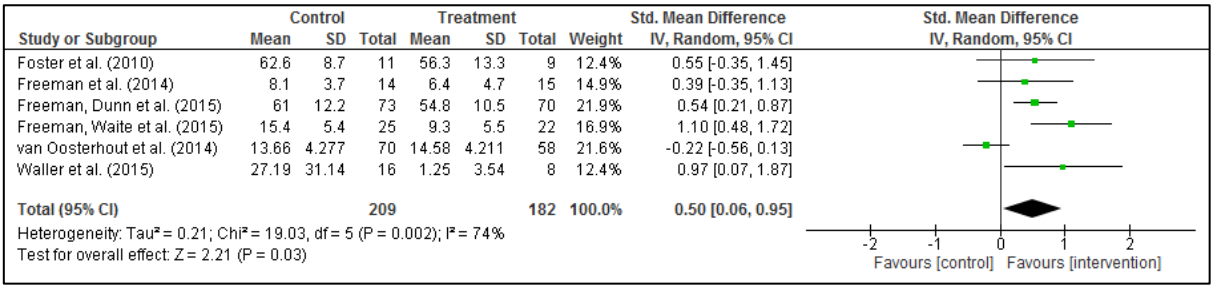


Figure 11: Table and forest plot of effect sizes for the comparison between intervention and TAU at end-of-treatment in changing maintenance factor targeted by the intervention

Intervention vs. TAU at follow-up

Analysis of change in targeted maintenance factors at follow-up found a non-significant estimated mean effect of interventions (k = 6, n = 376; *d* = 0.27, 95 % CI [-0.07 – 0.61], z = 1.56, p = 0.12) (see Figure 12). Moderate heterogeneity of variance in effects sizes was observed (I^2 = 55%) however, similarly to the analysis of maintenance factors at *end-of-treatment*, removing van Oosterhout et al. (2014) from the analysis reduces the value of I^2 to 0%. This study also has a standardised mean difference which favours the control group (*d* = -0.27). The altered estimated mean effect of intervention then becomes a significant, small to medium effect (k = 5, n = 265; *d* = 0.41, 95 % CI [0.17 – 0.66], z = 3.30, p = 0.001).

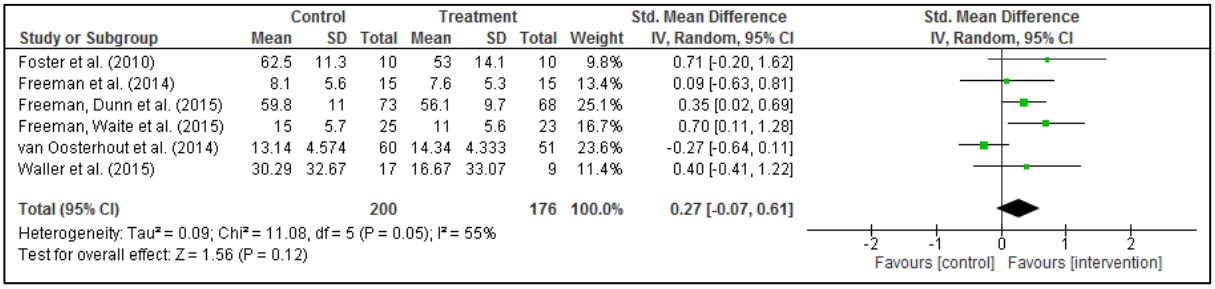


Figure 12: Table and forest plot of effect sizes for the comparison between intervention and TAU at follow-up in changing maintenance factor targeted by the intervention

3.3.2.6. Summary of meta-analysis

Overall, the meta-analyses found that the group intervention (van Oosterhout et al., 2014) was not an effective intervention and had a marked impact on the homogeneity of studies. Analyses of individual psychological therapies (see Table 5) showed small to medium ES improvements across different assessments of paranoia, and most notably with associated distress which improved further at follow-up. Improvements observed in overall severity of delusions were not sustained at follow-up. Medium to large ES improvements were observed in wellbeing and in maintenance factors of paranoia being targeted by interventions.

Table 5: Summary of meta-analyses with homogeneous data

Outcome	ES at end of treatment *d* [95% CI]	ES at follow up *d* [95% CI]
Severity persecutory delusion (PSYRATS-D)	0.38 [0.1 - 0.66]	n.s.
Distress associated with delusion	0.39 [0.08 – 0.70]	0.56 [0.27 – 0.86]
Paranoid ideation endorsement (GPTS)	0.31 [0.03 – 0.58]	0.39 [0.11 – 0.66]
Well-being	0.50 [0.16 – 0.84]	0.42[0.15 – 0.69]
Maintenance factor of paranoia	0.65 [0.40 – 0.90]	0.41 [0.17 – 0.66]

n.s. = non-significant

4. Discussion

4.1. Overview of findings

The current review was the first known systematic review of psychological interventions impacting upon paranoia that also assessed the feasibility and efficacy of treatments. The synthesis of characteristics of psychological treatments found a relatively small number of studies specifically reporting change in paranoia, in comparison to a number of studies in psychosis literature reporting changes in psychotic symptoms, delusions or hallucinations. Almost all interventions were from a CBT approach and individual rather than group treatments. These included longer individually tailored formulation-based interventions and manualised, causal-interventionist approaches which tended to be briefer in length. The assessment of the feasibility of treatments for individuals with paranoia indicated relatively good engagement and satisfaction with treatments, particularly with interventions targeting insomnia and negative self-belief (Myers, Startup and Freeman, 2011; Freeman, Waite et al., 2015; Freeman et al., 2014).

Meta-analyses of the efficacy of psychological treatments in improving paranoia found the group meta-cognitive training intervention to be ineffective (van Oosterhout et al., 2014) and contributing to the vast majority of the heterogeneity observed in analyses. Further analysis with homogeneous data suggests small to medium effects of individual

CBTp in reducing paranoia compared to TAU, however there is mixed evidence for the sustainability of these improvements. The current review found small to medium effects of CBTp in reducing severity of delusions at end-of-treatment but not at follow-up. Studies reporting paranoid ideation endorsement showed small to medium improvements in frequency and endorsement of paranoid beliefs at both end-of-treatment and at follow-up. Importantly, medium to large effects in improving distress associated with persecutory delusions were observed at end-of-treatment and at follow-up.

The current review also aimed to assess the efficacy of psychological treatments in improving factors relevant to, but distinct from, paranoia i.e. maintenance factors and well-being. Analyses found individual CBTp to be significantly more beneficial in improving the targeted maintenance factor of paranoia compared to TAU at both end-of-treatment and at follow-up, implying a relatively good stability in treatment efficacy for these factors. These findings suggest that individual CBTp developed from the interventionist-casual model approach appears to have a dual efficacy in creating change in maintenance factors of persecutory delusions and in reducing paranoia. Individual CBTp was also found to significantly improve the well-being of those involved in psychological treatment compared to those in TAU.

4.2. Psychological interventions acceptable for people with persecutory delusions

The evaluation of the feasibility of current interventions for paranoia suggest promising acceptability, particularly for individual CBTp. The average dropout rate of 11.2% suggests that sustained engagement in psychological treatment for individuals with paranoia and psychosis is similar to psychosocial intervention engagement observed in the general psychosis population (13% dropout rate; Villeneuve et al. 2010). This observed dropout rate is lower than the attrition rate of 15% for individuals with General Anxiety Disorder (GAD) (Hunot, Churchill, Silva de Lima & Teixerira, 2007) and 23% in severe depression

(Arnow et al., 2007). In the current review, engagement appears to be good irrespective of treatment length, albeit the majority of studies offer briefer treatments.

Individual CBTp had a noticeably lower attrition rate in comparison to group interventions, whereby some studies had no individuals decline or dropout of treatment. In general psychotherapy literature, greater dropout rates are observed in group treatments compared to individual therapy, with approximately 20 to 50% of client's terminating group therapy early in the treatment (Stone & Rutan, 1984) and an estimated average dropout rate of 35% (Bostwick, 1987). It is hypothesised that entering a group process with numerous unknown service-users can be extremely threatening for some individuals and lead to premature termination of treatment (MacNair & Corazzini, 1994). It is further hypothesised that premature terminations may impact on meaningful group work (Yalom, 1966; 1985) and precipitate a wave of other dropouts (Stone, Blaze & Bozzuto, 1980). Dynamics such as these may be particularly relevant for individuals with paranoia. Individuals with persecutory delusions are found to have heightened perceptions of social threat (Green & Phillips, 2004), selective attention to threat-stimuli (Bentall & Kaney, 1989), and excessive sensitivity to others' expressions of negative emotions (Bentall, Corcoran, Howard, Blackwood & Kinderman, 2001). It is therefore likely that these individuals will find a group scenario more threatening that one-to-one therapeutic interactions as there is a greater presence of stimuli that may trigger a perception of threat, hence a greater dropout rate is observed.

Considering the aforementioned heightened sensitivity to threat amongst individuals with persecutory delusions, it is perhaps surprising to find a relatively low level of treatment attrition in individual interventions. However, it would seem that individuals with persecutory delusions, considering the inherently distressing nature of the condition, do wish to have access to psychological treatment, equally if not more so than people with other mental health conditions. Research in physical illness has identified a number of key

appraisals that are linked to uptake of treatment (Weinman, Petrie, Moss-Morris & Horne, 1996; Hagger & Orbell, 2003; Petrie, Jago & Devcich, 2007). These include beliefs about the cause of illness, the length of the prognosis, the severity of the consequences and the amount of control the individual has over their illness. Freeman et al. (2013) investigated the impact of these beliefs in the uptake of longer-term CBT in a psychosis population. Conclusions were tentative due to lack of power but it was suggested that a low sense of control and a more biological view of illness was linked with declining therapy, whereas an attribution of illness to their personality or state of mind was linked to better uptake of CBT. As a number of the interventions identified in the current review targeted problems outside of psychosis (e.g. insomnia, worry), it is possible that individuals perceived they had more control over such problems and linked this more with their state of mind in comparison to their perception about their persecutory beliefs. Furthermore, targeting associated difficulties, such as sleep, might facilitate engagement by establishing shared therapeutic goals and collaborative working, which are associated with improved therapeutic engagement and treatment outcomes (Bachelor, 2013).

4.3. Efficacy of treatment on a range of paranoia measures and related factors

Overall, results show that individual CBTp interventions tailored for individuals with paranoia are significantly more beneficial in reducing the severity of persecutory delusions and endorsement of paranoid ideation than TAU immediately following treatment. The mean effect sizes observed are comparable with those seen in other meta-analyses evaluating efficacy of CBTp for all delusions (Van der Gaag et al., 2014; Mehl et al., 2015). Whilst improvements in the endorsement of paranoid ideation (GPTS) were observable at follow-up, improvements in severity of persecutory delusions (PSYRATS-D) were not. Importantly, studies reporting change in distress associated with persecutory delusions found significant and relatively large effects of interventions in reducing distress at both end-of treatment and at follow-up. In keeping with this, significant and sustained

improvement in overall well-being was observed in those receiving treatment compared with TAU. This is a particularly important finding as research has shown that individuals with persecutory delusions have levels of well-being at least one standard deviation below that of the normal population (Freeman, Startup et al., 2014).

The above findings suggest that current interventions targeting paranoia are more effective in reducing the level of general paranoid ideation and distress associated with paranoid beliefs but are less effective in improving overall severity of persecutory delusions. It is possible that the causal-interventionist treatments for paranoia target maintenance factors that are more closely related to general paranoid ideation and distress than those factors more crucial in severe persecutory delusions. For example, it is suggested that the formation and maintenance of persecutory delusions are related to idiosyncratic negative beliefs about the self (Garety, Kuipers, Fowler, Freeman & Bebbington, 2001). There is also evidence in the literature that persecutory delusions serve a defensive explanatory bias which protect an individual from the triggering of negative self-schemas that highlight discrepancies between an individual's ideal-self and actual-self (Bentall, Kinderman & Kaney, 1994). Potentially, other therapeutic approaches, such as longer individually tailored formulation-based CBT or compassion focused therapy, may better address individuals' negative self-schemas and other idiosyncratic maintenance factors that could be contributing to the severity of their persecutory delusions. Further clinical research is needed to determine the efficacy of other treatment approaches in reducing paranoia, particularly outside of causal-interventionist approaches and in comparison to active treatment.

The disparity observed between outcomes in PSYRATS-D and GPTS measures poses a question about the current operationalisation of clinically significant change in paranoia. PSYRATS-D is a measure developed to assess all forms of delusions (e.g. of grandeur, reference, control, persecution etc.) and places an equal importance on the conviction,

preoccupation, distress and functional impact of the delusional belief. The measure is also predominantly clinician-led rather than self-rated and requires focus on a main belief, potentially overlooking whether or not multiple delusions (persecutory or otherwise) are held. In contrast, the GPTS is self-rated and specifically focuses on the endorsement of multiple ideas of social reference and ideas of persecution, incorporating items that also measure associated distress. Whilst this measure may better capture the level of general paranoid ideation in an individual, there is also a potential for response bias and an omission of measurement of the severity and impact of a specific persecutory delusion. This should be considered in future research, and indeed clinical practice, when selecting a tool to measure change in paranoia.

It is important to note that the group meta-cognitive intervention included in the initial analysis (van Oosterhout et al., 2014), consistently showed the intervention to be less effective than TAU and was responsible for the majority of the heterogeneity in observed variance of effect sizes. This was observed despite the study being scored highest on total quality. As such, it is reasonable to deduce that the observed outcomes are more attributable to the psychological mechanisms of the intervention, rather than faults in methodology or treatment quality. Although some evidence exists for the efficacy of MCT for individuals with mild delusions (Ferwerda et al., 2010; Moritz et al., 2011), van Oosterhout et al. (2014) concluded that MCT interventions may not be effective for individuals with moderate to severe delusions. The intervention predominantly uses psychoeducation as a mechanism for change, leading the authors to conclude that MCT may not elicit the necessary emotional arousal needed to create change in core cognitions involved in more severe persecutory delusions. As such, the inefficacy of this intervention is likely to be more attributable to the specific content of the treatment, than the fact that it was a group intervention.

4.4. Strengths and limitations

Strengths of this review include a rigorous search strategy and application of eligibility criteria that allowed for a full picture of the breadth and trends in developments of psychological interventions for paranoia. The inclusion of a meta-analysis is a key strength of the study as it provides an evaluation of treatment efficacy, using large pooled sample sizes, to allow meaningful and statistically viable conclusions to be drawn about the efficacy of treatments delivered in RCTs. The quality of studies included in this review was generally high in both treatment quality and in design and method, particularly those included in the meta-analysis. This allowed more reliable conclusions to be drawn about the efficacy and feasibility of treatments and the mechanisms by which outcomes were achieved. However, there is a discrepancy in the quality ratings of the studies included in the current meta-analysis, which were generally high, compared to those included in van der Gaag et al. (2013), a third of which were scored as inferior in quality. This possibly questions the validity of the quality scoring of the current review. There was no overlap in the studies included in either meta-analysis therefore it is plausible that the studies included in van der Gaag et al. (2013) were, overall, lower in quality than those included in the current meta-analysis. However, the discrepancy could also be a result of the current study using a different quality scoring tool than van der Gaag et al. (2013). Inspection of the two measures shows good consistency between the individual scoring items to assess study design and methodology quality. However, the Yates et al. (2005) measure places particular focus on treatment quality, a rationale for choosing the measure. It is possible that the studies included in the current meta-analysis were comparatively higher in quality as their ratings incorporated scores for factors such as therapist training, description of treatment content and duration, and evidence of treatment engagement.

A limitation in the meta-analysis was the combining of group and individual interventions in the analysis. High heterogeneity in the variance of effects sizes was

observed in analyses that included the group intervention RCT (van Oosterhout et al., 2014). The heterogeneity observed may be due to the dynamics of group intervention differing from the dynamics of individual therapy, impacting on treatment outcomes. Furthermore, the study population was from a different country (the Netherlands) compared to UK populations in the other RCTs. It is likely that some of the heterogeneity observed is due to this study being the only RCT conducted outside of the Oxford Cognitive Approaches to Psychosis (O-CAP) research group.

Following this point, it is important to note that almost half of the studies included in this review were from the O-CAP research group, led by Professor Daniel Freeman. This research group is based in the UK and focus much of their research on investigating their cognitive model of persecutory delusions and developing therapeutic interventions based on hypothesised mechanisms of paranoia. The majority of the studies from this research group use methodology to reduce potential bias (e.g. blinding, study protocols and analysis published a priori) and use sample populations from both inner city and rural settings. However, this limits the generalisability of findings to other settings and cross-culturally.

Further limitations also exist when considering the generalisability of conclusions drawn. The number of RCTs in the literature was relatively small and all comparison groups were TAU. This prevents conclusions being drawn about the specific effects of CBTp for paranoia, separate from non-specific effects e.g. therapist attention, expectation of benefits. Future research would benefit from more RCTs in CBTp for paranoia that also included active control conditions to allow for the efficacy of specific CBTp effects to be evaluated. Although studies included sample populations with moderate to severe paranoia, it is difficult to entirely generalise findings from controlled clinical trials to routine clinical practice when one considers the resources and efforts available in trials to retain participation, and the training required for the therapist. Although the manualisation may facilitate the application of such interventions in true clinical settings, establishing the

effectiveness of these interventions in routine clinical practice will require further investigation.

Finally, it is important to note that many studies were excluded from this review because no direct measure of paranoia was given in studies delivering psychological therapies for psychosis. Considering that persecutory delusions are present for many individuals with psychosis (Freeman & Garety, 2014), routinely measuring change in persecutory delusions as an outcome in psychosis treatment trials could elucidate a broader understanding of the efficacy of treatment for paranoia in psychosis.

4.5. Clinical implications

This review reflects a movement in psychological treatment for paranoia away from more traditional individually tailored formulation-based CBTp and towards briefer, manualised CBT interventions that target specific causal and maintenance factors of paranoia. This is arguably driven by the ongoing development of psychological models of persecutory delusions, such as the cognitive multi-factorial model (Freeman et al., 2002) and the fact that the research group behind this model have conducted a large proportion of the treatment trials in the literature.

The relatively high number of case studies and pilot trials, particularly those published in more recent years, suggests that psychological treatments for paranoia are still in the early stages compared to other mental health disorders e.g. depression. Perhaps this is, at least in part, driven by a movement away from purely diagnosis-based interventions (e.g. CBT for social anxiety, reliving for PTSD) and towards interventions for mental health phenomena that either transcend or are not consistently present within diagnoses. This seems a particularly important shift in the field of schizophrenia, long-since debated to be a heterogeneous condition (e.g. Tsuang, Lyons and Toomey, 1975) with specifically identified differences between paranoid and non-paranoid sub-types (Potkin et al., 1978; McGuffin, Farmer & Yonace, 1981).

The movement towards briefer, manualised therapy for paranoia observed in this review may reflect a wider movement in the delivery of CBT in the UK. Considered to have progressed in two phases, the original phase saw specialist practitioners deliver bespoked CBT to individuals experiencing complex, longer-lasting problems, characterised by high-quality services delivered to a few, with long waiting lists. Accordingly, a number of the older case studies in this review reflect this style of treatment. In order to increase service-users access to CBT, a second phase has introduced a stepped-care approach that separates 'high' and 'low' intensity CBT, provided by practitioners with various levels of training. Lower intensity interventions generally target mild to moderate severities of mental health disorders; they are briefer and delivered in many formats (e.g. individual, self-help, computerised, group interventions) in order to similarly increase both access and choice (Williams and Martinez, 2008). A considerable number of studies in this review, particularly those that are more recent, are showing attempts to develop these types of low-intensity interventions for complex, severe and enduring mental health disorders (i.e. persecutory delusions), perhaps suggesting that a third phase in CBT delivery may be emerging.

The findings of this review provide a tentative but hopeful outlook for the successful delivery of CBTp for paranoia in true clinical settings. As previously discussed, persecutory delusions are considered one of the most debilitating yet common disorders in psychosis populations. Evidence for effective treatments with which such individuals engage well is a promising development within clinical psychology and could potential have wider, positive implications on mental health services e.g. reduced hospital admissions, reduced reliance on community-based services. It could also stand to improve current treatments available for individuals experiencing paranoia outside of schizophreniform disorders e.g. borderline personality disorder (Zanarini, Gunderson & Frankenburg, 1990), PTSD (Sautter et al., 2005). The apparent efficacy and feasibility of numerous shorter,

manualised CBTp interventions could stand to increase the availability and choice service-users suffering with paranoia have with regards to psychological interventions.

Finally, there are also implications on the current NICE guidelines (NICE, 2014) which recommend a minimum of 16 sessions of individually-tailored CBTp for service-users with psychosis. Currently, these guidelines do not make any specific recommendation for the treatment of persecutory delusions. In time, a revision to the guidelines to specify treatments for paranoia may be warranted. For this to occur justifiably, future research would need to concentrate on further establishing the efficacy of CBTp for paranoia, to clarify the operationalisation of 'recovery' from paranoia and to tighten our understanding of the mechanisms that underpin it. The more general growing body of evidence for low-intensity CBTp may also warrant its inclusion as a recommended treatment for psychosis in the near future. However, replication of studies in different settings and by independent research groups is needed in order to confirm the efficacy of brief CBTp, particularly for persecutory delusions. Future research in CBTp for paranoia should also consider the implementation of interventions (e.g. low-intensity, manualised vs longer, individualised CBT) and the feasibility of their application in mental health services.

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Part 2: Empirical Paper

The role of interpersonal contingency and self-focused attention in the development of trust in clinical paranoia: a virtual reality study.

Abstract

Aims: Research into interpersonal processes involved in paranoia remains limited. This study aimed to assess the feasibility of using interactive virtual reality in a clinical sample with psychosis and persecutory delusions. The study aimed to replicate an experiment which found healthy individuals high in paranoia showed a hypersensitivity to contingent behaviour which increased their perceived trust towards the avatar. A further aim was to investigate the impact of self-focused attention on the perception of interpersonal contingency and trust.

Method: Eighteen male participants with psychosis and paranoia completed the virtual reality exercise. Participants entered a virtual flat and interviewed a virtual flatmate whose non-verbal responses were either high or low in contingency in relation to the participant. Trust towards the avatar was measured by self-report and behaviour towards the virtual flatmate, operationalised as interpersonal distance. Focus of attention, affect and immersion in the virtual reality scenario were assessed.

Results: Overall, participants enjoyed and were immersed in the interactive virtual reality environment. Interpersonal distance was predicted by severity of persecutory delusions and negative affect. Exploratory graphic analyses showed no evidence of hypersensitivity to avatar contingency or moderating effect of self-focus attention. Persecutory delusion severity was associated with other-focus attention, which in turn, unexpectedly, predicted higher self-focused attention.

Conclusions: Interactive virtual reality is a safe and feasibility research tool for individuals with clinical paranoia. Severity of persecutory delusions, rather than environmental manipulation, predicted trust. However, the lack of power in the current study prevents clear conclusions about the impact of interpersonal contingency on trust in clinical paranoia from being drawn. Replication is required with a larger sample and a more ambiguous scenario.

1. Introduction

1.1. Paranoia

Paranoid thinking is a phenomenon shown to occur in both general and clinical populations (e.g. Freeman et al., 2005). Whilst previously perceived to be limited to delusional presentations seen in psychiatric services, a growing body of literature supports the conceptualisation of paranoia as a continuum (e.g. Chapman & Chapman, 1980; Claridge, 1997; van Os et al., 2009). In non-clinical populations, suspicious thoughts are found to be a relatively common occurrence, particularly with regards to social evaluative concerns e.g. fears of rejection (Freeman et al., 2005). In clinical populations, those presenting with paranoid ideation are considered to be at the severe end of the spectrum, the most extreme form being persecutory delusions. Persecutory delusions are strongly held beliefs that harm is occurring, or will occur, to the individual and that harm is intended by the persecutor (Freeman & Garety, 2000).

Persecutory delusions are one of the most common delusions (Cutting, 1997), strongly associated with high levels of distress and admission to hospital (Castle et al., 1994). Given the clinical relevance of researching paranoia, a number of psychological models conceptualising paranoia have been put forward. The cognitive model of persecutory delusions (Freeman, Garety, Kuipers, Fowler & Bebbington, 2002) proposes that a number of key mechanisms contribute to the formation and maintenance of paranoid ideation including negative beliefs about the self and others, self-esteem, jumping to conclusions data gathering bias and safety behaviours which prevent disconfirmation of persecutory beliefs. Attributional biases (Kaney & Bentall, 1989; Kinderman & Bentall, 1994) and Theory of Mind (ToM) deficits (Corcoran & Frith, 1996) have also been long linked to paranoia. An investigation using structural equation modelling revealed that paranoid delusions were predicted by a wide range of hypothesised cognitive and emotional processes (Bentall et al, 2009). Since, in parallel with proposals for interpersonal conceptualisation of psychosis

(Berry, Barrowclough & Wearden, 2007; Bentall et al., 2014), growing evidence is building for the role of social anxiety (e.g. Birchwood et al., 2007; Michail & Birchwood, 2009; Michail & Birchwood, 2013; Rietdijk et al., 2009; Voges & Addington, 2005).

1.2. Social anxiety and paranoia

Epidemiological studies have found the rate of co-morbid social anxiety disorder in individuals with schizophrenia to range between 13%-39% (Kendler et al., 1995*b*; Cosoff & Hafner, 1998; Cassano et al., 1999; Bermanzohn et al., 2000). This is compared to a notably lower 6.8% prevalence of social anxiety found in the general population (Kessler et al., 2005b). A key feature of social anxiety is the expectation of embarrassment and negative appraisals from others. Several studies have indicated that intense social anxiety can lead to the anticipation of catastrophic loss of social status, resulting in the conviction that others mean harm (Michail & Birchwood, 2009; Birchwood et al., 2007). As such, theories have emerged to suggest that social anxiety may be an independent route to paranoia or it may interact with other mechanistic pathways such as deficits in theory of mind (Lysaker et al., 2010; Brüne, 2005). Whilst Lysaker et al. (2010) do not suggest that all cases of clinical paranoia are a product of social anxiety, they propose that a subset of this clinical population have significant levels of social anxiety which contributes to the occurrence of their paranoid ideation.

1.3. Social anxiety, self-focused attention and interpersonal experiences

Defined as “an awareness of self-relevant, internally generated information”, self-focused attention is proposed to play an important role in numerous pathological conditions including social anxiety and schizophrenia (Ingram, 1990). The subject of self-focus can include physiological information, thoughts, emotions, personal beliefs and attitudes and has been shown to be exacerbated by physiological arousal and negative mood states (Wegner & Giuliano, 1980; Hackman, Clark & McManus, 2000). Clark & Wells’ (1995) model

of social anxiety theorises that self-focused attention is a maintenance factor in the condition as it increases access to negative thoughts and affect, interferes with performance and prevents individuals from focusing on external information that might disconfirm their beliefs driving the distress. Research has shown that high socially anxious and socially phobic individuals, while in a social situation, display higher levels of self-reported self-focused attention than participants scoring lower on these measures (Bögels & Lamers, 2002, Bögels et al., 2002). Experimental studies have shown that greater self-focused attention correlates with higher levels of state anxiety in social situations for both clinical and non-clinical populations (Woody & Rodriguez, 2000; Woody, 1996). Self-focused attention also influences an individual's information processing in social interactions as shown by the association between high social anxiety correlates, greater self-focused attention and poorer memory for details of recent social interactions (Daly et al, 1989; Hope, Heimberg & Klein, 1990; Kimble & Zehr, 1982). This suggests that self-focused attention creates a deficit in the processing of external social information, resulting in lower other-focused attention, and therefore individuals are less able to utilise objective feedback in an interpersonal experience.

1.4. Interpersonal contingency

Interpersonal contingency is considered to be an important feature in the experience of interpersonal encounters. The concept of interpersonal contingency is defined as the general responsiveness to another person's actions during an interaction, including mimicry and synchrony. Its presence during an interaction is theorised to influence the positive appraisal of others, including trust between individuals (Kendon, 1970) and experience of empathy (Van Baaren, Decety, Dijksterhuis, van der Leij, & van Leeuwen, 2009). A virtual reality study has shown that the presence of mimicry positively influences the evaluation of an avatar in participants from a non-clinical population (Bailenson & Yee, 2007). However, the same positive effects of mimicry have not been observed in socially

anxious individuals (Vrijsen et al., 2010), hypothesised to be influenced by self-focused attention interrupting the processing of the avatar's responsiveness. The role of interpersonal contingency in persecutory delusions has not yet been investigated. However, research has found that clinical populations with persecutory delusions have a tendency to perceive intentional contingency between animate shapes with random movement (Blakemore, Sarfati, Bazin & Decety, 2003), suggesting a bias in over-attributing behavioural contingency.

1.5. Virtual reality research in paranoia

In more recent years, virtual reality (VR) has been used as a method to study the phenomenon of paranoia (e.g. Freeman et al., 2003, 2008; Freeman et al., 2005; Freeman, Pugh, Vorontsova, Antley & Slater, 2010; Fornells-Ambrojo, Barker, Swapp, Slater, Antley & Freeman, 2008; Valmaggia et al., 2007). The benefit of using this technology is that it allows for a controlled environment in which avatars are consistent and neutral, thus interpersonal behaviour and appraisals can be better attributed to the individual's own biases in interpretation rather than the reality of someone's character. Virtual reality studies have shown that participants, including those from clinical populations, demonstrate paranoid ideation in relation to avatars (Freeman et al., 2010). The same study also showed that factors hypothesised to be related to paranoia, including affective processes (anxiety, worry), interpersonal sensitivity and trauma history, were predictive of paranoid ideation across the spectrum. A recently published study has shown that that virtual reality can be used therapeutically with individuals with persecutory delusions to test threat predictions in paranoia-inducing situations (e.g. public transport) with the dropping of safety behaviours (Freeman et al., 2016). However, little research has been conducted to investigate how individuals with paranoia experience interpersonal interactions and the interpersonal processes associated with paranoid thinking is these VR environments.

1.6. Paranoia, interpersonal contingency and interpersonal distance

A recent VR study investigated the influence of contingency on experiences of interpersonal trust in individuals with high paranoia in a non-clinical population (Fornells-Ambrojo et al., 2016). Participants were randomly allocated to high or low contingency conditions in a brief, friendly interaction with an avatar programmed either to be highly responsive or less responsive (high/low contingency). Higher paranoia was associated with larger interpersonal distance kept from the avatar and was independent of actual avatar responsiveness. This interpersonal distance was considered to be an avoidant safety behaviour employed by those with high paranoia in order to protect against anticipated threat, in accordance with safety behaviours being a key maintenance factor of paranoia (Freeman et al., 2002). Similar safety behaviours of greater interpersonal distance have also been observed in relation to avatars amongst socially anxious individuals (Rinck et al, 2010).

Unexpectedly, Fornells-Ambrojo et al. (2016) found that individuals with high levels of paranoia (90th percentile) were the only group to show susceptibility to contingency manipulation, experiencing the highly responsive avatar as more trustworthy than the low contingency avatar. It was concluded that extreme paranoia may be associated with hypersensitivity and preference for contingent behaviour in others which, in turn, could explain experiences of mistrust in everyday social situations when others are not highly responsive.

As yet, no research has been conducted to investigate the interpersonal processes relevant to paranoia in a clinical population, principally in those with psychosis. Although paranoia is hypothesised to exist on a continuum, a number of cognitive deficits have been found to exist in clinical populations of psychosis compared to non-clinical populations e.g. attentional deficits (Fioravanti et al., 2005; Neuchterlein et al., 1991) and deficits in theory of mind (Brüne, 2005; Sprong et al., 2007). It is therefore important to investigate whether

the hypersensitivity to interpersonal contingency observed in Fornells-Ambrojo et al. (2016) is also found in a psychosis population with clinical paranoia.

Virtual reality research in clinical populations predominantly uses paradigms that are observational and non-verbal i.e. whilst avatars might be present in the scenarios, the participant does not verbally communicate with them (e.g. Freeman et al., 2010; Freeman et al., 2016). To date, no virtual reality study of clinical paranoia uses a scenario that involves an interpersonal interaction with an avatar. Moreover, most studies using virtual reality to investigate paranoia have used either ambiguous or anxiety-eliciting situations (e.g. Fornells-Ambrojo et al., 2008; Freeman et al., 2010; Freeman et al., 2016; Valmaggia et al., 2007), whereas the use of positive interactions would allow parallels to be drawn between processes that occur in friendly social encounters in everyday life (e.g. brief chat with a peer). Furthermore, considering evidence that individuals with persecutory delusions experience paranoia towards their therapist, both within and between sessions (Lawlor, Hall & Ellett, 2015), the current study stands to inform clinical interactions in therapeutic contexts.

1.7. Study aims and hypotheses

1.7.1. Feasibility of interactive VR scenario:

As this study is the first of its kind to use an interpersonal interaction with an avatar to investigate factors relevant to a clinically paranoid population, this study aims to evaluate the feasibility of using interactive virtual reality with this population. In particular, participants' levels of distress, sense of presence and feedback about the VR scenario will be evaluated.

1.7.2. Paranoia, contingency and trust:

The primary aim of this study is to investigate the impact of interpersonal contingency on trust (subjective and objective) in a clinical population of individuals with paranoia.

- Hypothesis 1: People with persecutory delusions are hypothesised to keep a safe distance from the avatar regardless of his behaviour. Severity of paranoia will predict objective trust (distance) as shown by Fornells-Ambrojo et al. (2016) but not subjective trustworthiness.
- Hypothesis 2: Whereas trusting behaviour is hypothesised to be unaffected by the contingency manipulation, it is predicted that greater subjective trust will be experienced by clinically paranoid individuals interacting with the high contingency avatar compared to the low contingency avatar, replicating Fornells-Ambrojo et al. (2016) with a sample of non-clinical highly paranoid individuals.

1.7.3. Self-focussed attention: a moderator of contingency sensitivity?

- Hypothesis 3: However, it is predicted that self-focused attention will moderate the impact of contingent behaviour on subjective trust. Participants with higher levels of self-focused attention will not show susceptibility to the contingency manipulation (whereas those with low levels of self- focussed attention will do as stated in hypothesis 1). This will be due to their internal attentional focus impairing their processing of the avatar's behaviour.

1.7.4. Self-focussed attention: Additional hypotheses

- In line with the reviewed literature, we hypothesise that higher self-focussed attention will be associated with higher social anxiety.
- Self-focus and other-focus attention will be negatively associated. Clark & Wells (1995) propose that self-focused attention prevents the processing of external social information therefore one would expect lower levels of other-focused attention in those with high levels of self-focused attention.

2. Method

2.1. Design

The study was jointly conducted with another trainee clinical psychologist (HR) (see Appendix 3). A mixed-method, quantitative and qualitative design was employed to investigate all hypotheses. A group-comparison design with randomised assignment to two conditions, high versus low contingency, was used. The independent variables of paranoia, social anxiety and self-focused attention were treated as continuous. The dependent variables of trust, measured both subjectively (self-rated) and objectively (behaviourally) were also treated as continuous.

Feasibility of the methodology and participants' views of the scenario were assessed using qualitative data collected using a semi-structured interview and quantitative measures of participants' attention and sense of presence during the VR scenario.

2.1.1. Participants

Male participants[1] aged 18 and above were recruited from four Early Intervention in Psychosis services across three London NHS trusts. Inclusion criteria were a diagnosis of psychosis, schizophrenia or schizoaffective disorder and currently experiencing paranoia. Exclusion criteria were a history of epilepsy (due to associated potentially adverse effects of virtual reality) or a current clinical presentation (e.g. thought disorder, acutely psychotic state) that prevented them from being able to engage in the VR exercise and complete primary measures. Individuals under section were also excluded.

2.1.2. Sample size and power analysis

The sample needed to evaluate the feasibility of virtual reality as a methodology for researching paranoia and interpersonal sensitivity was deemed to be ten or more

[1] An all-male sample was chosen in an attempt to minimise the impact of gender differences shown to exist in sense of presence in virtual reality (Felnhofer et al. 2012), and taking into account the VR interaction was with a male avatar.

participants. This sample size would also permit exploratory data analysis of emerging trends in the quantitative data along with a thematic analysis of the qualitative interview.

Power analyses were conducted using G*Power3 (Faul, Erdfelder, Lang & Buchner, 2007). Using the data from Fornells-Ambrojo et al. (2016), a sample size of 26 per group (high/low contingency) was calculated based on a large effect size ($d = 0.8$, $\alpha = 0.05$, $\beta = 0.80$) to detect an effect of contingency condition on trust. No studies currently investigate the effect of self-focused attention on trust or paranoia using the same methodology. As a result, the sample size needed to detect a moderating effect of self-focussed attention was unknown. It was felt that a sample size of 60 participants (30 per condition) would be sufficient. The achieved sample fell considerably short of this. A total of 18 participants completed the study and nine participants were randomly allocated to each condition. The power of the current study for the detection of contingency sensitivity is 35.8% ($\beta = 0.358$).

2.1.3. Ethics

The study was giving favourable ethical opinion from Camberwell St Giles NRES Committee (see Appendix 4) and R&D approval from all NHS trusts.

Prior to taking part, participants were fully informed about the study's procedure and their right to withdraw from participation. They were told that the rationale for undertaking the research was to help develop therapeutic tools for mental health service users. Written informed consent was obtained from all participants prior to taking part in the study.

Due to the nature of the participants' clinical presentation, the researchers expected high levels of anxiety in some prospective participants around travelling to and from the research location. Researchers accompanied participants to and from the location where necessary. Further considerations were made to minimise the likelihood of worsening paranoia or distress during the experiment. Recent VR research has found that patients with paranoia can feel engaged in VR scenes and experience persecutory thought

without experiencing raised levels of distress, anxiety or simulator sickness (Fornells-Ambrojo et al., 2008). The VR paradigm was designed to be a pleasant experience that is non-intrusive and non-threatening. Participants were informed prior to taking part that they could discontinue at any time. All participants were debriefed following completing the experiment, including monitoring current distress or adverse experiences.

2.2. Procedure

2.2.1. Participant recruitment

Participants were referred by their Early Intervention in Psychosis teams following presentations to the teams and further correspondence. Initial screening was conducted during discussion with care co-ordinators at the point of referral. All potential participants were approached by their care co-ordinators with the participant information sheet (see Appendix 5). Care co-ordinators sought permission from interested service-users for the researchers to contact them to arrange a further screening and verbal consent, either over the phone or in person.

Participants were screened using the Green et al. Paranoid Thoughts Scale (GTPS; Green et al., 2008) as a measure of current paranoia (see appendix 6). A cut-off score of 33 and above on part A (ideas of social reference) or part B (ideas of persecution) was used to meet the paranoia inclusion criterion. As no current measure of paranoia has a validated clinical cut-off score, the use of this screening criteria was based upon a current clinical trial using this cut-off score on the GTPS to recruit a population with psychosis and paranoia (Hardy, 2016).

Successfully screened participants were then invited to take part in the one-off virtual reality experiment. To minimise the risk that an individual's level of paranoia would fluctuate below the threshold for participation in the study, the maximum time between screening and testing was one week. There was one exception to this, however the

participant was re-screened immediately before participating in the study to confirm they still met inclusion criteria.

In total, sixty-eight potential participants were referred by the EIS teams. Of these referrals, forty-one were successfully approached by their care coordinators about the study. Thirty service-users agreed to be contacted by the researchers. Of those contacted by the researchers, the following reasons were given (largely before screening) for non-participation: lack of interest in the study or a feeling that the study did not apply to them (n = 5); inability to travel to the testing location (n = 3); lack of availability during the opening hours of the testing facility (n = 2); inability to make contact following successful screening and recruitment (n = 1). One participant expressed interest but fell below the cut-off score for paranoia. Eighteen participants were recruited and completed the study.

2.2.2. Overview of experimental procedure

All participants were either escorted to or met at the Virtual Reality Lab with the researchers. Written consent was obtained at the start (see Appendix 6). Participants were informed that the study was investigating how people interact with virtual environments and the impressions people have of the virtual reality avatar. It was explained to participants that they would complete a series of questionnaires about themselves before taking part in the virtual reality exercise. Participants then entered the virtual reality environment and completed the exercise. Following this, participants completed a series of measures and a semi-structured interview about their experience in the virtual reality exercise. After a final debrief, participants were paid £12.50 and reimbursed for any travel expenses. The experiment took approximately 90 minutes. See Table 1 for overview of procedure including measures used by both researchers.

Table 1: Overview of experiment procedure

Pre-VR	VR exercise	Post-VR
Randomisation to high or low contingency condition	Instructions to VR exercise	Completion of following measures:
Written Consent	Brief rehearsal of questions to ask the avatar	Post-VR PANAS*
Demographic details (age, ethnicity, occupation, previous experience of flat sharing)	Participant interviews virtual flatmate (four questions)	FAQ*
GPTS*	Avatar moves towards the window and invites participant to follow him	1-item trustworthy scale* TICR
PSYRATS-D*	Distance between avatar and participant recorded*	Detection of contingency check*
SIAS*		Attention check*
UCLA Loneliness Scale		Sense of Presence Questionnaire*
RG-UK		Semi-structured interview about avatar and the VR experience and debrief*
RQ		
FESFS		
CAPE-42		
PS		
Baseline PANAS questionnaire*		

Note: * = measures used by the author; CAPE = Community Assessment of Psychic Experiences-42 (Konings, Bak, Hanssen, Van Os, & Krabbendam, 2006); FAQ = Focus of Attention Questionnaire (Woody, 1996); TICR = Trust in Close Relationships Scale (Rempel, Holmes & Zanna, 1985); FESFS = First Episode Social Functioning Scale (Lecomte et al., 2014); GPTS = Green et al. Paranoid Thoughts Scale (Green, Freeman, Kuipers, Bebbington, Fowler, Dunn & Garety, 2008); PANAS = Positive and Negative Affect Schedule (Watson, Clark & Tellegen, 1988); PSYRATS-D = Psychotic Symptoms Rating Scale - Delusions (Haddock, McCarron, Tarrier & Faragher, 1999); PS = Paranoia Scale (Fenigstein & Vanable, 1992); RG-UK = Resource Generator UK (Webber & Huxley, 2007); RQ = Relationship Questionnaire (Bartholomew & Horowitz, 1991); SIAS = Social Interaction Anxiety Scale (Mattick & Clarke, 1998); Sense of Presence Questionnaire (Slater, Steed, McCarthy & Maringelli, 1998); SOS = Significant Others Scale (Power, Champion, & Aris, 1988);; UCLA Loneliness Scale (Russell, 1996).

2.2.3. Virtual reality exercise

Before entering the virtual reality environment, participants were informed that they would be entering a virtual flat that was available to rent, in which they would meet a virtual flatmate called Mark. Participants were given a set of four printed questions with which to interview Mark to find out more about the flat. Participants were instructed to ask the avatar the scripted questions in order (e.g. '*What makes a good flatmate?*') and that

they should ask the first question when the avatar told them he was 'ready'. Participants were given time to read the questions and remember them as best as they could and were also provided with a prompt sheet to take into the virtual reality environment (see Appendix 8). To increase the spontaneity of the interaction, participants were told that the avatar would introduce himself and may ask their name. Participants were told that they could move around the virtual flat as much as they wanted during the exercise but that the main aim was to find out how the virtual character comes across and ask to try to pay as much attention as possible to what Mark told them. They were further informed that the avatar would indicate to them when the interview was over.

On entering the virtual reality environment, participants were instructed about the stereo glasses and allowed to look around the virtual flat to acclimatise to the environment. When participants were ready and confirmed they could see in 3D they were instructed to stand on a designated spot so that all participants began the exercise in-line with the avatar and at approximately the same distance (200cm). Participants were instructed they should move as naturally as possible once the scenario started, as they would in a normal interaction. The researchers then drew a curtain, informing participants they would stay on the other side for the duration of the exercise, and on a final signal from participants that they were ready, the scenario was started. The scenario lasted approximately two and a half minutes. On exiting the virtual reality scenario, researchers verbally checked whether the participant was experiencing any ill-effects.

2.2.3.1. Virtual reality apparatus

The visuals of the VR exercise were displayed in an immersive projection system. High-resolution images were projected in real-time onto three back-projected wall screens (3m x 2.2m) and a floor screen (3m x 3m). A stereo presentation of the virtual world was delivered using Lightweight CrystalEyes shutter-glasses worn by participants. These glasses present separate images to the left and right eyes, producing the illusions of 3D objects

within and beyond the walls of the laboratory. An inertial/ultrasonic head-tracking device was mounted on the glasses, which enabled images to be presented in reference to the participants' physical orientation and viewpoint. This technology provides almost natural sensorimotor contingencies for visual perception i.e. as participants move around, the environment projected perspective-correct information. Spatialised audio was delivered through four corner speakers.

The majority of the avatar's verbal and non-verbal responses were controlled via button presses on a wireless hand-held device. One button cued the avatar's nodding response when the participant spoke or nodded themselves while a second button was used to cue the avatar's next answer to the participants' questions. The researchers used the device whilst observing each trial to allow for speed and ease of response cuing.

2.2.3.2. The virtual reality scenario

The virtual reality scenario was designed specifically for Fornells-Ambrojo et al. (2016) and future follow-up studies, programmed by collaborators at the Department of Computer Science at UCL and the University of Barcelona. It was designed to be a neutral, non-threatening or anxiety-provoking and naturalistic (see Figure 1 for images of the scenario in sequence). The scenario represented a modern student flat which featured a seating area to the left and was decorated to resemble a tidy living room. To the right, there was a French window which looked out onto a large sunny window with a barbecue.

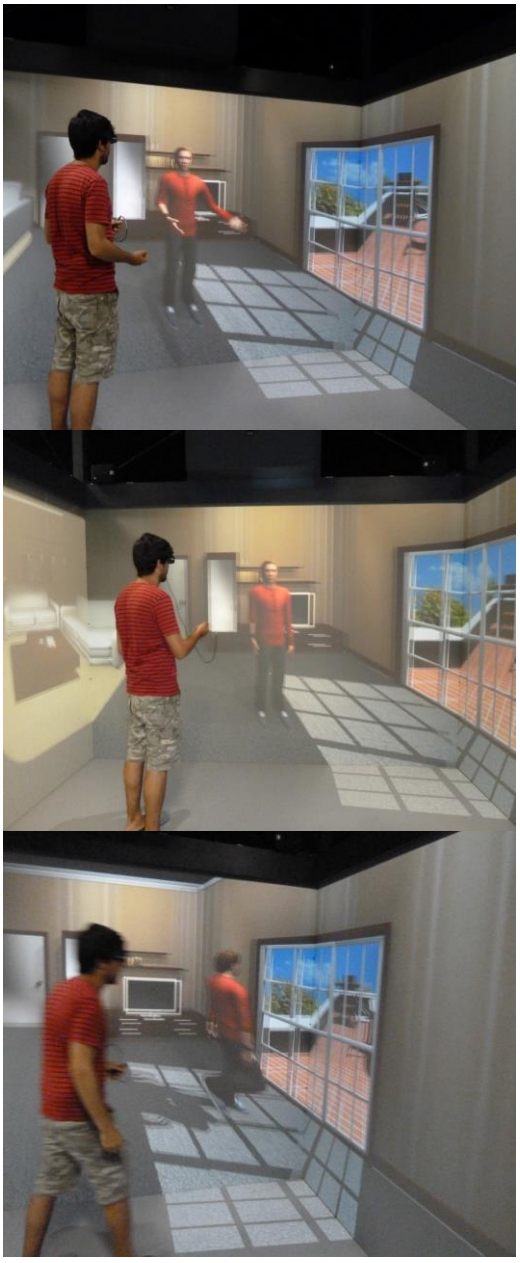


Figure 1: Images of the virtual reality scenario in sequence

2.2.3.3. The avatar

The virtual flatmate, 'Mark', was present in the virtual flat from the beginning of the scenario. He was stood in the centre of the virtual flat which was projected onto the back wall of the virtual reality environment. Mark was designed to be a young, casually dressed White male in his early twenties. His voice and movement were pre-recorded by a male actor and mapped onto the avatar. A head tracker fitted to the virtual reality glasses worn

by participants allowed programming of the avatar's gaze to always be in the direction of the participant. The avatar was also programmed to blink regularly to make his appearance more realistic. Throughout the scenario, Mark was programmed to make gestures with his arms during conversation and display subtle baseline ambient body movements when 'listening'.

2.2.3.4. Contingency manipulation

The avatar's body movements were programmed to either be at either a low or high level of contingency with the participant. See Table 2 for an overview of the contingency mapping between participant and avatar responses in low and high contingency conditions.

In the high contingency condition, the avatar subtly tilted his head when the participant tilted their head to either side, in the same direction, with a 1.5 second delay. When a participant moved their head in any other way, Mark was programmed to subtly move his body either from side to side (swaying) or back and forth. The virtual flatmate also nodded to the participant after the participant introduced himself to the avatar as well as after every time the participant spoke to the avatar. The slight delay and mixture of responses from the avatar were chosen to reduce the likelihood that the participant would experience Mark as directly mimicking their actions. This was based on previous research that indicated that detection of mimicry may adversely affect individuals' liking towards another (Bailenson, Yee, Patel & Beall, 2008).

In the low contingency condition, the avatar was programmed to give the same responses (head tilts, body movements and nodding), but instead with a 20 second time delay. Delayed contingent responses were used in the low contingency condition to control for the effects of overall amount of avatar movement on the dependent variables of trust, as has been done using different methodology in studies investigating mimicry (e.g. Vrijsen et al., 2010). The delay time of 20 seconds was chosen in order for sufficient time to have elapsed between participant movement and avatar response so that the participant would

not perceive the virtual flatmate's movements as directly related to their own behaviours. Pilot trials run by Fornells-Ambrojo et al. (2016) ensured these two conditions were sufficiently different from one another, but subtle enough for manipulations to go undetected by participants. Due to the programming of the virtual flatmate, only head tilts were executed by the programme throughout the scenario. It was not possible for avatar nodding or avatar body movements to be triggered whilst another avatar response was 'queued' to be executed or when the avatar was speaking.

Table 2: Contingency mapping participant behaviour and avatar responses

Participant behaviour	Avatar responses
Participant moves head side to side (tilt)	Avatar tilts head in the same direction and returns head to original centre after participant has done so
Participant moves head in any other direction (back/front, up/down)	Avatar moves his body (random choice of back to front or side to side (sway)
Participant speaks	Avatar nods

2.2.3.5. Virtual scenario script

The script consisted of 4 main parts:

- Greetings
- Participant asks and avatar responds to questions about flat sharing
- Avatar moves to the terrace and invites participant to look
- Avatar received unexpected phone call and ends the meeting

At the start of the scenario, Mark introduced himself to the participant and asks the participant their name. After a pause for the participant to respond, Mark then stated that he was 'ready'. This was the cue for participants to ask the virtual flatmate the scripted questions about his flat. Participants were unaware that the avatar was unable to respond to any unexpected questions.

When participants asked the last question, the avatar invited the participant to come to have a look at the terrace, gesturing with his arms as he spoke. See Table 3 for an extract of the conversation between participant and avatar. For the full script of the conversation, see Appendix 9. Shortly after being invited to and shown the terrace by Mark, Mark's mobile phone rang and Mark took the call. He turned slightly away from the participant and spoke briefly and discreetly on his phone. Mark then made his apologies to the participant and explained that he had to go. Mark asked the participant if they could continue the interview at another time and, after pausing for the participant's response, the scenario faded out to signify the end of the virtual reality exercise.

Table 3: Extract from the conversation between participant and avatar

Participant question	Avatar verbal response
[Asks third question]	
Who makes a good flatmate?	Mhm... Good question... don't know... I'm trying to think.... Someone who is easy-going, friendly and fun but who also can give you space. It is also good to have something in common with them, like love for sport, or music. It's hard to answer because I think it really depends on the person... I've got on with people who were completely different from me… sometimes it just works.
[Asks fourth and final question]	
And what would you say is the best thing about this flat?	The terrace, and the view! Come and have a look! *[Avatar moves to window and gazes outside before turning back to face participant].* It's amazing to have all this outside space, in the summer we practically live outside! We have great barbecues.

2.2.4. Measures

2.2.4.1. Pre-VR measures

Before entering the virtual reality environment, participants were asked to complete a number of baseline measures. These measures were as follows:

Paranoia: The *Green et al. Paranoia Thoughts Scale (GPTS; Green et al., 2008)* was used both as a screening tool and an experimental measure of paranoia. The GPTS consists of two scales of 16-items: Part A assesses endorsement of ideas of social reference (e.g. *People have definitely laughed at me behind my back*) and Part B assesses ideas of persecution (e.g. *I was convinced there was a conspiracy against me*). Items are rated from 1 = not at all, 3 = somewhat, 5 = extremely, to the extent to which participants have experiences these feelings over the past month. Scores on each subscale can range from 16 to 80, with higher scores indicating a greater degree of paranoid thinking. The internal consistency of the GPTS is good, with a Cronbach's $\alpha = .90$ in the original clinical sample, and the test is considered valid and sensitive to change (Green et al., 2008).

Severity of persecutory delusion: *The Psychotic Symptoms Rating Scale – Delusions* (PSYRATS-D; Haddock et al., 1999) was used as a measure of persecutory delusions severity (see Appendix 10). Delusions are assessed by 6 items measuring preoccupation, duration, conviction, distress, intensity of distress and disruption. The items are clinician-rated in a structured interview. The total score ranges from 0 to 24, with higher scores indicating a greater delusional experience. The scale has good internal consistency ($\alpha = .90$) (Haddock et al., 1999) and has been shown to have validity when used in first-episode psychosis (Drake et al., 2007).

Social anxiety: Trait levels of social anxiety were measured using the *Social Interaction Anxiety Scale* (SIAS; Mattick & Clarke, 1998) *(*see Appendix 11). The SIAS is a 20-item self-report scale assessing anxiety in interpersonal encounters (e.g. *I feel I'll say something embarrassing when talking*). Items are rated on a 5-point Likert scale of how characteristic each item is for the person (from 0 = 'Not at all' to 4 = 'Extremely'). The total score ranges from 0 to 60, with a higher score indicating greater experiences of social anxiety. It is widely used in social phobia literature and has received extensive validation (Peters, 2000). The SIAS uses a cut-off score of 34 to indicate the presence of social anxiety. It has been shown to discriminate between social anxiety and other anxiety disorders and community samples, with a sensitivity of 0.93 and a specificity of 0.66 (Peters, 2000). The measure also has good internal consistency (α = .94) (Mattick & Clarke, 1998).

State affect: To measure change in positive and negative affect during the virtual reality exercise, the *Positive and Negative Affect Schedule (*PANAS; Watson, Clark & Tellegen, 1988) was completed by participants immediately prior to entering the VR environment and immediate after completing the exercise. The PANAS is a 20-item self-report questionnaire that assesses positive and negative affect on two independent subscales. Participants were asked to rate the extent to which each word applies to how they feel 'right at this present moment' (e.g. '*scared*', '*enthusiastic*') on a 5-point Likert scale (from 1 = 'Very slightly or not at all' to 5 = 'Extremely'). The PANAS has good reliability and validity (Crawford & Henry, 2004).

2.2.4.2. Virtual reality measure

Distance kept from avatar: The distance participants kept from the avatar was automatically recorded (in metres) throughout the participants' time in the virtual environment. For each animation frame, the 3D positions of both the avatar's head and the

participant's head were recorded. The distance was calculated using the horizontal Pythagorean distance so that difference in height between participant and avatar were ignored. Minimum or shortest distance kept by the participant from the avatar during the scene when they are invited by Mark to view the terrace was used as an objective behavioural measure of trust. Minimum distance rather than average distance was chosen as this is a traditional measure used by proximity (interpersonal space) researchers (Hayduk, 1983) and is commonly used in virtual reality proxemics research in this way (e.g. Bailenson et al., 2001; Bailenson et al., 2003; Burgoon, Buller, Dillman & Walther, 1995).

2.2.4.3. Post-VR measures

Subjective Trust: As used by Fornells-Ambrojo et al. (2016), participants' feelings of trust towards the avatar were assessed with a Likert-scale item. Participants were asked to rate how trustworthy they felt Mark the avatar seemed ('*How trustworthy did Mark come across?*') on a 7-point scale (from 1 = 'Not at al' to 7 = 'Very much') (see Appendix 12).

Focus of Attention: In order to measure the extent of participants' self-focused attention and other-focused attention, the *Focus of Attention Questionnaire* (FAQ; Woody, 1996) was used (see Appendix 13). The FAQ has two 5-item subscales: self-focused attention (FAQ_{self}) e.g. '*I was focusing on what I would say or do next'* and other-focused attention (FAQ_{other}) e.g. '*I was focusing on the other person's appearance or dress*'. Each item is rated on a 5-point scale (from 1 = 'Not at all' to 5 = 'Very much'). For each subscale, the average item score is taken as a measure of self- and other-focused attention, with a higher mean score indicating a greater level of attentional focus. Research suggests that the two scales are independent and they display distinct patterns of correlations (Woody, Chambless & Glass, 1997). High internal consistency has been reported for the scale (Woody et al., 1997).

Scenario feedback and checks: In order to ascertain whether participants had consciously perceived the contingency of the avatar's body movements (head tilts and nods), participants were asked whether they had noticed any relationship between what they did and what Mark the avatar did (*detection of avatar contingency*) (see Appendix 14). Participants who responded 'yes' to this question were asked to give details of what they noticed. To assess whether participants were directing sufficient attention to the virtual flatmate during the scenario, participants were asked two 'true or false' questions about what the virtual flatmate had told them during their conversation about flat-sharing (e.g. 'One reason that Mark the virtual flatmate gave for why he likes flat sharing is that he has made new friends').

Sense of presence: The *Sense of Presence Questionnaire* (Slater, Steed, McCarthy & Maringelli, 1998, Appendix 15) assessed the extent to which participants felt present in the virtual world, as opposed to their physical location (e.g. '*During the experience, which was strongest on the whole, your sense of being in the virtual flat, or being in the real world of the laboratory*'). Participants rated each item on a 7-point Likert scale with a higher score indicating a greater sense of presence in the virtual flat.

Qualitative feedback: In order to elicit richer information about participant's experience in the virtual reality environment, a brief, semi-structured qualitative interview was administered at the end of the experiment. The interview invited participants to share their thoughts about the virtual flatmate and the virtual environment in general. The interview was conducted by one of the researchers while the other researcher wrote down the participant's answers verbatim. See Appendix 16 for the full interview structure.

2.3. Planned Data Analysis

All quantitative data analyses were conducted using SPSS (Version 21).

2.3.1. Feasibility of interactive VR scenario

Affect change: To assess the impact of the virtual reality scenario on participants' affect states, differences between baseline and post-VR positive and negative affect scores as measured by the PANAS were assessed. To assess if the virtual reality experience was a predominantly positive experience, differences in mean positive and negative affect scores were compared pre-VR and post-VR with related-sample t-tests. The post-VR comparison used a non-parametric Wilcoxon signed rank test as assumptions of normality could not be assumed for the post-VR negative PANAS variable. To assess whether there was a significant change in positive or negative affect during the virtual reality scenario, related-sample t-tests compared pre- and post-VR PANAS scores for positive affect (parametric test) and negative affect (non-parametric test).

Detection of contingency manipulation: A non-parametric equivalent of chi-squared (Fisher's exact test) was used to identify whether group differences in perception of contingency were observed.

Participant feedback: Participants' responses about their overall experience in the virtual reality exercise were analysed to evaluate the feasibility of the methodology in a clinically paranoid population. Responses were predominantly from the final question '*What did you think of the VR environment? Do you have any feedback on the VR experience?*' but all responses were assessed.

A generic thematic analysis approach (Braun & Clarke, 2006; 2016) was used to analyse responses. Four distinct categories arose as a coding framework from familiarisation with the data relevant to the broader concept of interactive virtual reality feasibility: safety, enjoyment, immersion in the environment and engagement in the avatar interaction. Themes were then searched for by the researcher within the coding framework and reviewed in the context of the full data set. The qualitative 'essence' of each theme

was reported with data extracts. Participant responses were then triangulated with relevant quantitative measures to assess whether verbal responses were concordant with responses given on self-report measures.

2.3.2. Paranoia, contingency and trust

Associations between the two measures of severity of paranoid ideation and objective trust (distance) were to be analysed using non-parametric correlation analysis (Spearman's rho).

The originally planned data analysis for subjective trust analyses was based on the study reaching sufficient power (β = .80) based on a sample size of n = 26 in each contingency group. In this instance, participants' sensitivity to contingency manipulation was to be analysed (if normality assumptions were met) with two independent t-tests assessing the difference in trust measures (subjective and objective) between high and low contingency groups. Regression analysis was planned to analyse the moderating effects of self-focused attention on subjective trust towards the avatar and susceptibility to contingency. However, the study did not obtain a sample size large enough to adequately evaluate the effects of interpersonal contingency and self-focus attention on trust toward the avatar with statistics alone (β = .067; n = 9 per condition).

Exploratory Data Analysis (EDA; Tukey, 1977) was also used to systematically explore the data and assess hypotheses. This method of analysis emphasises displaying the data graphically and its use in research in clinical psychology is well supported (Barker, Pistrang & Elliott, 2016). The distribution and normality of all variables were explored using univariate non-graphical EDA (e.g. inspection of mean, range and skewedness) and univariate graphical EDA (e.g. histograms and box and whisker plots). Comparisons of trust between contingency conditions were explored using side-by-side boxplots.

Correlates of trust measures were also explored using Pearson's correlation coefficient where assumptions of normality could be assumed and non-parametric

equivalent correlational analyses where assumptions of normality were not met by variables.

2.3.3. Self-focused attention: moderation of contingency sensitivity and additional analysis

The moderator of focus of attention was investigated using graphical EDA, namely multivariate scatterplots with R^2 values calculated (i.e. the proportion of the variation in one variable explained by another variable) to assess the strength of the relationship.

Correlation analyses were used to assess whether self-focused attention was associated with either social anxiety or other-focused attention. Non-parametric equivalent correlational analyses (Spearman's rank correlation coefficient) were used where assumptions of normality were not met by variables.

2.4. Data screening

2.4.1. Missing data

All primary measures were completed fully by participants with the exception of one participant who did not complete the PSYRATS-D due to his emerging distress during the completion of the GPTS relevant to discussing his paranoid experiences. One participant gave a double response on the PANAS. To correct for the double scored items, the more conservative of the double score was chosen. One participant did not complete the qualitative interview due to time constraints and participant fatigue.

2.4.2. Normality of distributions

All data was screened for normality and outliers. Inspection of histograms, distributions of variances, significance levels on the Kolmogorov-Smirnov test and values of skewedness and kurtosis indicated that most measures were found to be normally distributed. No clear outliers were detected in any measure.

Kolmogorov-Smirnov tests of normality were found to be significant for the FAQ_{self} ($p = .001$), measure of objective trust ($p = .036$) and the post-VR negative affect PANAS ($p =$

.019). Inspection of skewedness and kurtosis did not reveal any obvious abnormalities in the spread of distributions. Non-parametric analyses were used for these measures to minimise the likelihood of type I errors.

3. Results

3.1. Descriptives

3.1.1. Demographics

Please see Table 4**.** Eighteen male participants completed the virtual reality paradigm. Nine participants were randomly allocated to the high contingency condition and nine to the low contingency condition. The sample had a mean age of 26.3 (SD = 5.57). Participants self-described as a variety of ethnicities, most frequently as White British (44.4%).

Mental health diagnoses consisted of F20-F29 diagnoses of schizophrenia, schizotypal and delusional disorders. The sample comprised mostly of individuals who were in some form of employment or education (76.5%).

Table 4: Key demographics of sample

Demographic	Summary Statistic
Age, *mean (SD)*	26.3 (5.57)
Ethnicity, *n (%)*	
White British	8 (44.4%)
Other	10 (55.6%)
Employment, *n (%)*	
In education	6 (35.3%)
Employed	7 (41.2%)
Unemployed	4 (23.5%)

3.1.2. Symptom measures

3.1.2.1. Paranoia

The present sample had an average PSYRATS-D score (severity of persecutory delusion) of 13.1 (SD = 4.33), which is comparable but slightly lower than other VR studies using clinical

populations with paranoia e.g. Freeman et al. (2016) mean score of 17.3 (SD = 2.70). The sample's mean overall score for paranoid thinking (using the GTPS) was 94.9 (SD = 28.9). Mean scores for ideas of social reference (part A) and ideas of persecution (part B) were similar: 45.8 (SD = 13.97) and 49.2 (SD = 16.62) respectively. No current VR paranoia study uses the GPTS as a measure of comparison however these scores are comparable to other large-scale studies using clinical populations with persecutory delusions e.g. van Oosterhout et al. (2014) (N = 150) had a mean overall score of 96.8 (SD = 22.98), mean part A score of 49.2 (SD = 11.0) and a mean part B score of 47.7 (SD = 14.05). In the current study, PSYRATS-D scores were closely associated with overall GPTS scores (see Table 5).

3.1.2.2. Social anxiety

The present sample had a relatively large proportion of individuals scoring above the clinical cut-off score on the SIAS. Fifty percent of participants scored 34 or above on the SIAS, compared to 36% of individuals with psychosis having a co-morbid diagnosis of social anxiety in the community (Pallanti, Quercioli and Hollander, 2004). The average SIAS score for this sample was 33.4 (SD = 14.09) which is comparable to clinical populations with social phobia e.g. Mattick & Clarke (1998) mean score of 34.6 (SD = 16.4). This average is lower than mean scores observed in psychosis populations co-morbid with social anxiety e.g. Birchwood et al. (2007) mean score of 51.9 (SD = 11.9).

3.1.3. Self-focused attention

In the present sample, six participants reported high levels of self-focused attention (i.e. with an average FAQ_{self} score ≥ 3) during the virtual reality exercise. This suggests that the majority of participants (66.7%) had moderate to low levels of self-focused attention.

Table 5 shows the non-parametric correlations between focus of attention measures and symptom measures. Against the hypothesis, informed by Clark & Wells (1995) model, self- and other-focus of attention were positively correlated (r_s = .702, p = .001) (see Figure 2). Also against the predictions by Clark & Wells' (1995) model, self-focus of attention and social anxiety (SIAS) were not significantly correlated (r_s = .433, p = .073).

Figure 2: Relationship between self- and other-focus of attention

Outside of predicted observations, other-focus of attention was positively correlated with PSYRATS-D scores (r = .526, p = .03), suggesting that greater external focus of attention was associated with greater severity of persecutory delusion. However, neither self-focused attention nor other-focused attention were associated with ideas of social reference (GPTS A), ideas of persecution (GPTS B) or overall paranoid ideas (GPTS Total).

Table 5: Correlations between focus of attention variables and symptom measures

Measures Correlation coefficient	1. r_s *p*	2. r *p*	3. r *p*	4. r *p*	5. r *p*	6. r *p*
1. FAQ_{self}	-					
2. FAQ_{other}	.702** *.001*	-				
3. SIAS	0.433 *.073*	0.615 *.628*	-			
4. PSYRATS-D	0.283 *.272*	.526* *.03*	0.184 *.479*	-		
5. GPTS Total	0.175 *.487*	0.177 *.482*	0.289 *.245*	0.48 *.051*	-	
6. GPTS Social reference	0.1 *.694*	0.127 *.615*	0.358 *.145*	0.467 *.059*	.910** *>.0001*	-
7. GPTS Persecution	0.023 *.926*	0.194 *.440*	0.188 *.455*	0.434 *.082*	.938** *>.0001*	.710** *.0009*

*p < .01; **p < .001

Note: As the assumption of normal distribution of FAQ_{self} was not met, Spearman's rank correlation coefficents (r_s) are reported. As assumptions of normality were met for all other measure, Pearsons correlation coefficients (r) are reported.

3.2. Feasibility of the virtual reality scenario

3.2.1. Sense of presence, attention and contingency perception checks

Participants' mean score of their sense of presence in the virtual scenario (24.9, SD = 9.77, range 8-39) was similar to that of the non-clinical group mean (25.47) found by Fornells-Ambrojo et al. (2016).

Post-VR attention checks indicated that the majority of participants (66.7%) had paid good attention to the virtual avatar and the conversation. Five participants (33.3%) had answered one or both questions incorrectly. Compared to Fornells-Ambrojo et al. (2016), in which only 9.8% of the sample of healthy participants answered one or both questions incorrectly, the current sample showed lower levels of attention.

In the highly contingent condition, post-VR responses to the contingency perception check indicated that seven of the nine participants (77.8%) said there was a relationship between what they did and what the avatar did. In comparison, three of the nine participants (33.3%) in the low contingency condition reported a relationship between their actions and that of the avatar, albeit this difference was non-significant (Fisher's Exact

test $Chi^2 = 3.60$, $p = .153$). Further inspection of verbatim responses suggests that three participants clearly confirmed detection of the contingency. Other comments were less specific or ambiguous (e.g. "*The virtual flatmate came too close to me*"; "*He was looking at me, body language a little bit accurate*", "*He responded to the scripted questions and seemed to follow my gaze*"), indicating possible but not definite detection of the contingency. Fornells-Ambrojo et al. (2016) (n = 63) similarly found a greater number of participants in the high contingency condition detecting a possible contingency relationship compared to those in the low contingency condition (33.3% vs. 4.9%; Fisher's Exact test $Chi^2 = 4.50$, $p = .034$).

3.2.2. Safety

At the end of the VR scenario all participants were asked if they had or were experiencing any adverse effects e.g. nausea, dizziness etc. One participant experienced nausea due to flickering glasses but this passed within ten minutes of the virtual reality scenario ending.

3.2.2.1. Positive and negative affect

Overall, the amount of positive affect reported by participants both before and after the virtual reality environment was significantly greater than the amount of negative affect reported pre- and post-VR ($t_{(17)} = 6.528$, $p < .001$; $Z = -3.664$, $p < .001$) (see Figure 3). Non-parametric comparison of means found a significant reduction in mean total negative emotion scores ($Z = -2.612$, $p = .009$). There was no significant change found in positive affect scores ($Z = -.906$, $p = .365$).

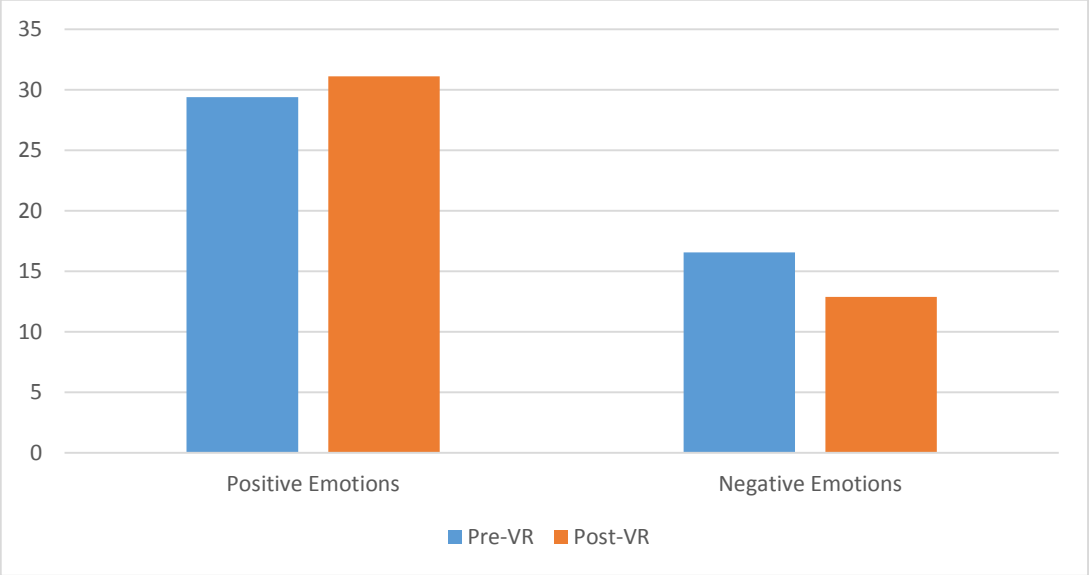


Figure 3: Change in total positive and negative affect

Scores from the positive affect items on the PANAS indicate that participants were experiencing moderate levels of a range of positive emotions before the VR scenario (average total 29.4, SD = 5.14, range = 21.0 – 38.0) and this positive affect largely increased or stayed the same after the VR scenario (average total 31.1, SD = 8.74, range 13.0 – 48.0) (see Figure 4). Scores from the negative affect items on the PANAS indicate that participants were experiencing some negative emotions at relatively low levels before the VR scenario (average total 16.6, SD = 5.51, range = 10 – 27) and that these had all decreased immediately after completing the VR scenario (average total 12.9, SD = 3.19, range = 10 – 20) (see Figure 5). The trends seen in pre-VR and post-VR positive and negative affect in this sample are similar to those found in Fornells-Ambrojo et al. (2016), as can be seen in Table 6.

Table 6: Comparison of pre-VR and post-VR PANAS scores for current study and the high paranoia group in Elenbaas (2013)

	Pre-VR positive affect	Post-VR positive affect			Pre-VR negative affect	Post-VR negative affect		
	Mean (SD)	Mean (SD)	Z	p	Mean (SD)	Mean (SD)	Z	p
Current study	29.38 (5.14)	31.11 (8.74)	-0.906	0.365	16.56 (5.51)	12.89 (3.20)	-2.612	.009
Fornells-Ambrojo et al. (2016) High paranoia group	31.17 (5.13)	31.42 (4.81)	-0.1	0.947	13.25	11.92	-2.14	0.045

Further inspection of individual items of positive affect show high levels of interest before and after the VR scenario and a noticeable increase in excitement (see Figure 4). Content analysis of participant responses in the qualitative interview support this finding, with a number of participants expressing interest and enjoyment during the scenario (see Table 7). Inspection of individual items of negative affect show noticeable reductions in participants' experiences of distress, nervousness and feeling scared (see Figure 5). This is also supported by the responses identified in the content analysis (see Table 7), in which only a small minority of participants reported experiencing anxiety during the scenario.

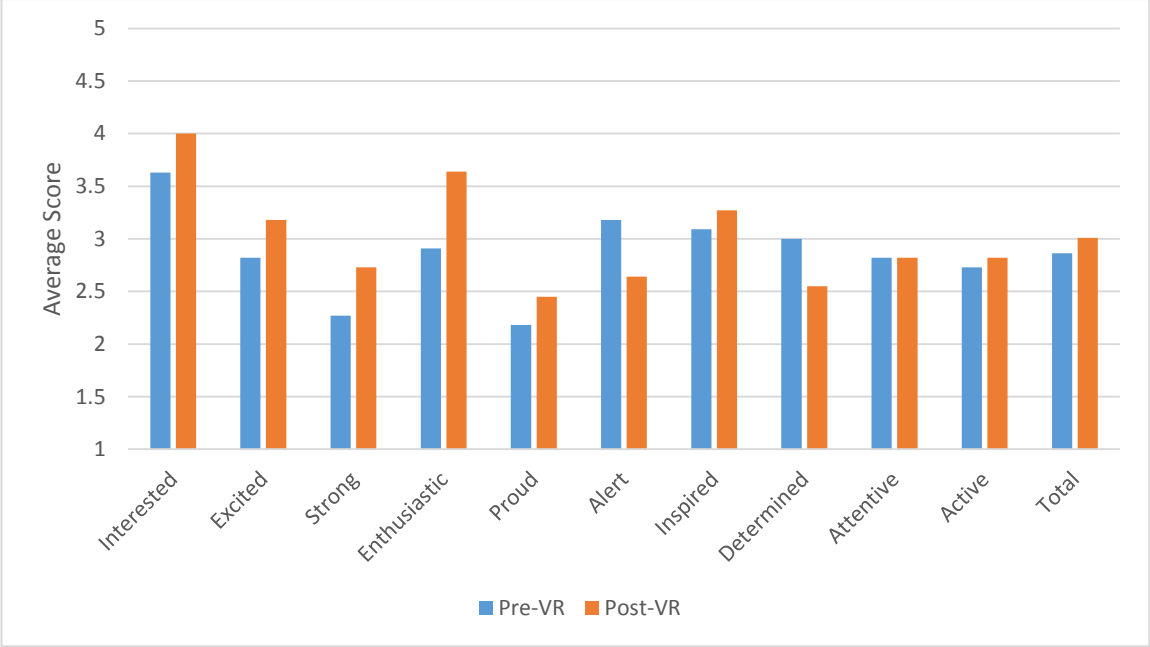


Figure 4: Average positive affect scores pre- and post-VR scenario

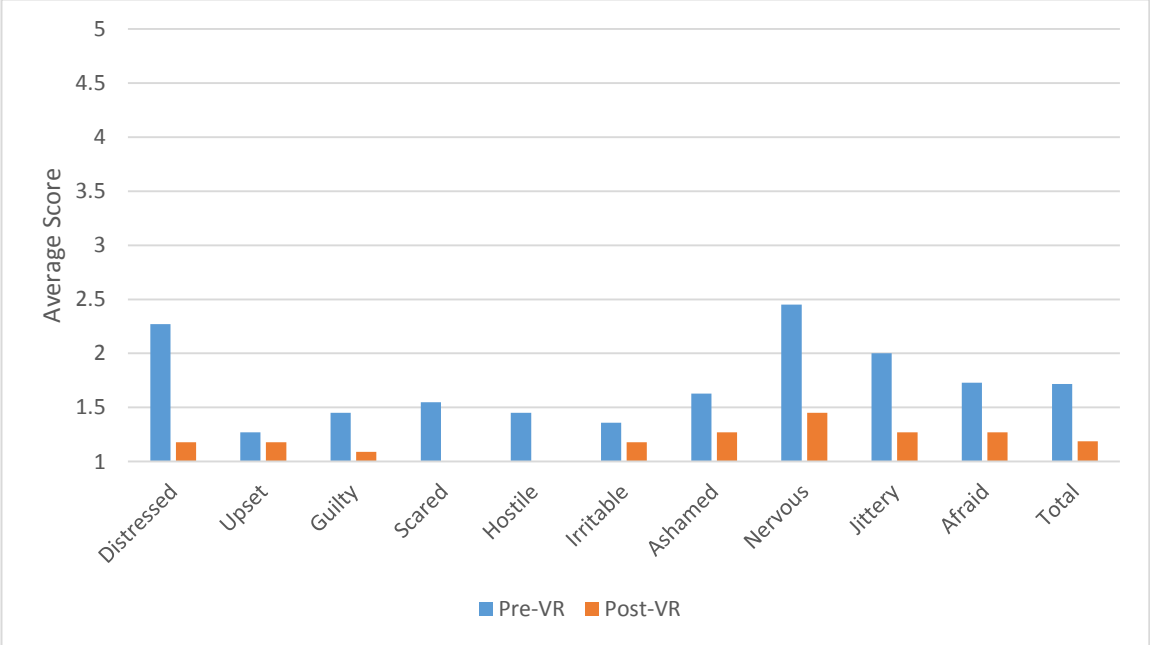


Figure 5: Average negative affect scores pre- and post-VR scenario

3.2.3. Qualitative feedback about VR scenario

Table 7 gives an overview of the content analysis of the feasibility of the virtual reality scenario based on participant responses in the qualitative interview. In the category of safety, only two participants reported possible adverse physical effects which were relatively minor and only one was clearly related to the virtual reality environment. Four

participants reported some level of anxiety during the experiment, one participant expressed brief, low-level annoyance and one reported a brief experience of aggression. Triangulation of these participants using the post-VR negative affect PANAS revealed that only one participant reporting anxiety (ppt 17) gave a high post-VR response for nervousness. All other participants reporting negative affect during the VR indicated no, or very little, experience of related emotions on the post-VR PANAS.

In the category of enjoyment, eight participants gave clearly positive feedback about their overall virtual reality experience, indicating enjoyment. Six participants specifically commented that they felt relaxed and comfortable. Post-VR positive affect scores support these responses, with these participants scoring relatively highly on overall positive affect following the virtual reality environment. However, other participants with similarly high post-VR positive affect did not make reference to this in their verbal feedback. The seven participants specifying positive affect experienced during the scenario gave scores for related emotions on the post-VR PANAS which corroborated their verbal feedback e.g. high score on 'excited' (ppt 16), 'strong' (ppt 18).

Analysis of participants' level of immersion in the virtual reality environment found ten participants (58.8%) reporting the virtual reality environment immersive or realistic. One participant specifically stated that he thought the scenario would be clinically useful for people with mental health problems. The predominant element of the scenario which detracted from participants' immersion in the environment was the graphics, with seven participants critiquing the quality of the visuals. Mixed opinions were found about using the prompts during the interaction, with three participants finding the prompts useful and adding to their sense of comfort in the environment and two participants commenting that the prompts detracted from their immersion in the scenario.

Analysis of participants' engagement in the interaction with the avatar found that 11 participants (64.7%) gave responses indicative of good engagement or immersion in the

interaction with the avatar. Analysis of responses revealed a predominant theme of participants likening the interaction to that of a real interaction with another person. Nine participants commented that they experienced their interaction with the avatar as similar to a real-life interaction. Only one participant (ppt 11) reported finding the interaction artificial. Four participants reported that the avatar's behaviour during the scenario was realistic and aided immersion in the interaction. Three participants directly commented on their interest in the avatar, indicative of good engagement in the interaction. Participants' critique of the interaction was largely centred on the content of the verbal interaction. Five participants commented that the content of their conversation with the avatar was a limiting factor in their immersion in the interaction e.g. being less restricted in the questions they could ask the avatar, having a longer introduction period to get to know each other better.

Table 7: Content analysis of feasibility of virtual reality scenario

Category	Description	Themes	N (%)	Quotes
Safety	An absence of an increase in level of anxiety, distress or paranoia and no triggering of significant levels of simulator sickness. Simulator sickness refers to symptoms similar to motion sickness (e.g. nausea, dizziness) that can sometimes be caused by virtual environments (Fornells-Ambrojo et al., 2008).	Experience of adverse physical effects	2 (11.8%)	"I had a stomach ache" (ppt 5); "Felt ok in there but now I have tension in my forehead and feel weird, dry mouth. It's getting better though" (ppt 13)
		Anxiety	4 (23.5%)	"At the beginning I was a bit anxious but when I kept talking my anxiety went away and I was more calm" (ppt 14); "[I felt] a bit agitated" (ppt 17)
		Other negative emotions	2 (11.8%)	"When his mobile set off… it annoyed me a bit" (ppt 14) "I felt aggressive when he asked me to look at the window" (ppt 1);
Enjoyment	Experiencing positive emotions as a direct result of being in the virtual reality environment e.g. excitement, comfort. Positive feedback of the scenario which is indicative of enjoyment e.g. "cool", "brilliant" etc.	Positive evaluations of participants experience	8 (47.1%)	"It was cool" (ppt 5); "Amazing" (ppt 8); "It was perfect" (ppt 8); "Really good… really interesting" (ppt 15);
		Positive emotions	7 (41.2%)	"[I felt] relaxed and comfortable" (ppt 1); "It's fun and exciting… that's what I felt" (ppt 16); "[I felt] better and stronger because he was friendly and open, not hostile" (ppt 18)
		Clinical usefulness	1 (5.9%)	"The technology is impressive, in two years tech will be able to be used for mental health to help people that can't get out of the house. They can use it to gradually get out, talk to people. It could be used therapeutically, would be really helpful." (ppt 8)
Immersion in the environment	A subjective experience of being immersed in the virtual reality environment so that is it experience as 'real' as opposed to a virtual reality scenario. This includes experiences of being in a real flat, comments of realisticness of the virtual reality environment. Also includes aspects of the experience which aided or limited immersion in the scenario.	Immersion	4 (23.5%)	"It felt like I was in a different place" (ppt 5); "I felt immersed and part of the flat" (ppt 12); "[the environment] absorbs and attracts you" (ppt 18)
		Realistic	6 Yes (35.3%) 1 No (5.9%)	"[it was] realistic, it felt like a home" (ppt 9); "It was realistic" (ppt 14) "It didn't feel realistic but that was because I was worrying about the paper and questions and not walking into the wall" (ppt 13);

Table 7 continued

Category	Description	Themes		Quotes
Immersion in the environment	A subjective experience of being immersed in the virtual reality environment so that is it experience as 'real' as opposed to a virtual reality scenario. This includes experiences of being in a real flat, comments of realisticness of the virtual reality environment. Also includes aspects of the experience which aided or limited immersion in the scenario.	Graphics	4 Good (23.5%)	"The graphics were good" (ppt 12); "; "The graphics were good... the 3D was good and immersive" (ppt 15)
			7 Critique (41.2%)	"Better graphics would have made it more realistic" (ppt 1); "The flat itself was not that realistic. I knew from the visuals that I couldn't keep walking" (ppt 7)
		Digital interface: high quality	2 (11.8%)	"Going to the terrace and looking out and the environment moves with you [made it realistic]" (ppt 8); "I like the way that, the interface of it, the wall the walls changed as you moved, responding to my movement" (ppt 16)
		Lab equipment and environment awareness	4 (23.5%)	"Glasses weighed me down, almost slid off when I looked down, goggles would be better" (ppt 1); "the top corners of the environment could be blocked out, but I might have been paying more attention to them because I am tall" (ppt 10)
Immersion in the environment	A subjective experience of being immersed in the virtual reality environment so that is it experience as 'real' as opposed to a virtual reality scenario. This includes experiences of being in a real flat, comments of realisticness of the virtual reality environment. Also includes aspects of the experience which aided or limited immersion in the scenario.	Appearance of the virtual flat	2 Good (11.8%)	"Felt real, the features in the flat (TV, balcony), when you walk you can see it clearly, see it like looking out the window" (ppt 9)
			4 Critique (23.5%)	"There could be more detail like adding a carpet... He could have had photos of other flatmates to add detail to him as a character" (ppt 12); "the flat wasn't very detailed. The 'skin' – is that the word – the texture of the environment like the sofa was quite plain, and the walls could have had had texture, the textures could have been improved" (ppt 15);
		Length of scenario	1 Good (5.9%)	" It could have been longer" (ppt 5); "too short, should be longer" (ppt 9);
			4 Critique (23.5%)	"It was a good length, not too long or short" (ppt 12)
		Prompts	3 Good (17.6%)	"Liked having the prompts, knowing that I didn't have to talk too much was helpful" (ppt 1); "It felt safer with the question prompts" (ppt 5)
			2 Critique (11.8%)	"I would have preferred not to have had the [prompt] sheet but then I would have forgotten the questions!" (ppt 13); "Asking the questions on the sheet made me remember that I was in VR" (ppt 8)

Table 7 continued

Category	Description	Themes		Quotes
Engagement in the interaction	Evidence of attention to the verbal interaction with the avatar and reports of realisticness or immersion in the interaction. Aspects of the avatar which aided or limited the engagement in the interaction	Avatar behaviour	4 (23.5%)	"Mark's behaviour was very on point, even though he didn't look that realistic, that made it more so" (ppt 10); "His response was quick, it was a good response time, which added to the level of immersion and feeling real" (ppt 15); "The way Mark shows you the terrace, makes it more realistic with his movement" (ppt 18)
		Avatar voice	1 (5.9%)	"Some bits were realistic, the human voice" (ppt 7)
Engagement in the interaction	Evidence of attention to the verbal interaction with the avatar and reports of realisticness or immersion in the interaction. Aspects of the avatar which aided or limited the engagement in the interaction	Content of verbal interaction	5 (29.4%)	"It would be better to have a list of vague questions, he expanded on some of them, if the prompts were more vague he could expand more and it would seem like a conversation with a person" (ppt 7); "If the responses had felt more real and less rehearsed. As time went on it was stilted, it felt like he had given pre-planned answers a million times over, not fluid" (ppt 11)
		Likeness to a real interaction	9 Good (52.9%)	"Like talking to a person… He answered questions in real time, seconds after" (ppt 8); "Interaction was good, balcony situation felt like I was walking with a real person" (ppt 14); "It was the same as speaking to someone for the first time" (ppt 16);
			1 Critique (5.9%)	"He was artificial, he was obviously pre-programmed so it was hard to know what he was going to say before the questions" (ppt 11)
		Interest in avatar	3 (17.6%)	"He kept me interested" (ppt 5); "he was as neutral as he could be but still sparked my interest" (ppt 15)

3.3. Virtual reality outcomes

3.3.1. Subjective and objective trust

The average minimum distance kept by participants from the avatar during the terrace scene (objective trust) was 1.02m (SD = .42), a slightly larger distance than that observed in the non-clinical sample (M (SD) = .92 (.23)) by Elenbaas (2013). Participants average avatar trustworthiness score was 4.7 (SD = 1.67), similar to the average trustworthy score of 4.9 (SD = 1.07) found in the non-clinical sample.

Correlational analysis of the subjective measure of trust and objective trust behaviour showed no relationship between these variables (r_s = -.184, p = .464). Similarly, Fornells-Ambrojo et al. (2016) found no significant relationship between their objective and subjective measures of trust (r = -.05, p = .418).

3.3.1.1. Trusting behaviour and paranoia (Hypothesis 1)

Keeping a larger distance from the avatar (objective trust) was predicted by higher severity of persecutory delusions (PSYRATS-D) (Spearman's r = 0.52, p = .034) but not by general endorsement of paranoid ideas (Spearman's r = -0.17, p = .490) showing partial support for hypothesis 1 (see Table 8).

Table 8: Correlations and associated p-values between objective and subjective trust and symptom measures, affect and focus of attention outcomes

TRUST OUTCOME VARIABLES	PARANOIA SEVERITY		SOCIAL ANXIETY PROCESSES			AFFECT CHANGE			
	PSYRATS	GPTS Total	SIAS	SFA	OFA	Positive affect Post-VR	Positive affect pre-post change	Negative affect Post-VR	Negative affect pre-post change
Objective Trust									
Spearman's r	.515*	-.174	.405	.319	.150	-.207	-.170	.590**	-.093
p-value	.034	.490	.095	.197	.552	.410	.500	.010	.714
Subjective Trust									
Pearson's r	-.417	-.030	.172	.129	-.023	.428	.539*	.016[1]	.176
p-value	.096	.905	.495	.609	.927	.076	.021	.949	.486

*p < .01; **p < .001

[1]Spearman's rank correlation co-efficient (r_s) reported as assumptions of normality are not met for this variable

3.3.1.2. Other predictors of trust

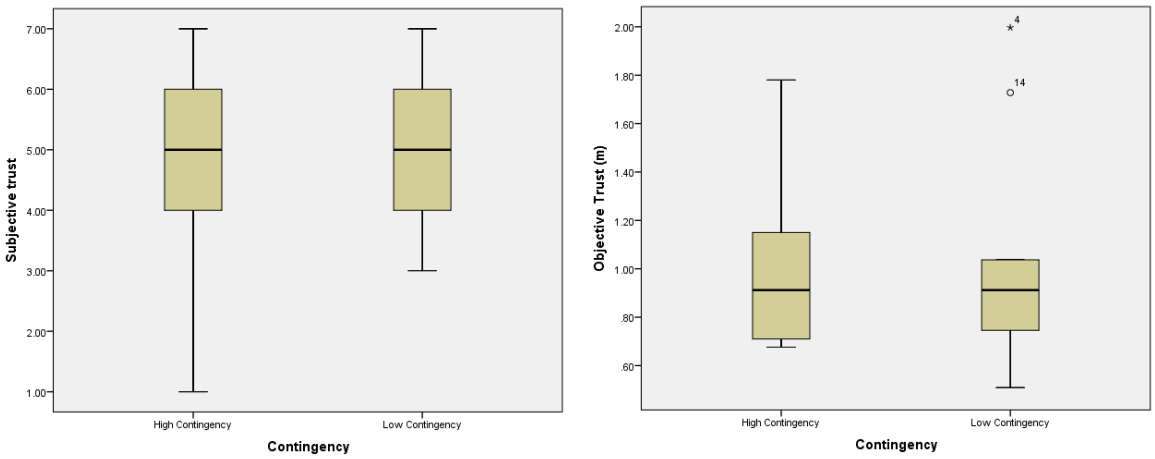
Correlational analyses were conducted to investigate if social anxiety processes and affect predicted subjective or objective trust (see Table 8). Participants experiencing a higher degree of negative affect during the virtual reality scenario kept a greater distance from the avatar during the terrace scene, whereas an increase in positive affect during the virtual interpersonal exchange was associated with experiencing the avatar as more subjectively trustworthy. Neither social anxiety nor focus of attention predicted any of the trust outcome variables.

3.3.2. Avatar contingency and trust (hypotheses 1 & 2)

Hypothesis 2 predicted that participants in the high contingency condition would rate the avatar as significantly more trustworthy than in the low contingency group, as can be seen in Table 9 and Figure 6 there is no indication that the contingency manipulation had an impact on subjective trust, against the prediction, or objective trust, as predicted.

Table 9: Trust measure for high and low contingency conditions

	High contingency	Low contingency
Mean subjective trust (SD)	4.56 (2.07)	4.89 (1.27)
Mean objective trust (min. distance (m)) (SD)	1.00 (.36)	1.05 (.49)



Figures 6a & 6b: Boxplots of subjective trust and objective trust outcomes between groups

3.3.3. Self-focused attention and trust (hypothesis 3)

The third experimental hypothesis stated that self-focused attention would moderate the impact of contingent behaviour on subjective trust as high levels of attention paid to the self would prevent the processing of avatar interpersonal contingency, thus this information would not contribute to feelings of trust towards the avatar. Lack of power prevents statistical investigation of this hypothesis. Graphical exploratory data analysis shows no clear evidence of a moderation of trust by self-focus attention (see Figure 7a). Figure 7a suggests that in the low contingency condition, the higher the level of self-focused attention, the higher the perception of trust. The R^2 value of 0.57 in the high contingency condition suggests that 57% of the variance in subjective trust is explained by self-focused attention. No impact of self-focused attention is apparent in the high contingency condition. A similar trend is observed in graphical EDA of other-focused attention and subjective trust (see Figure 7b). Figure 7b suggests that in the low contingency condition, the higher the level of other-focused attention, the higher the perception of trust. However, the R^2 value (0.23) suggests that only 23% of the variance in subjective trust is attributable to other-focused attention. Again, there is no impact of other-focused attention on subjective trust in the high contingency condition.

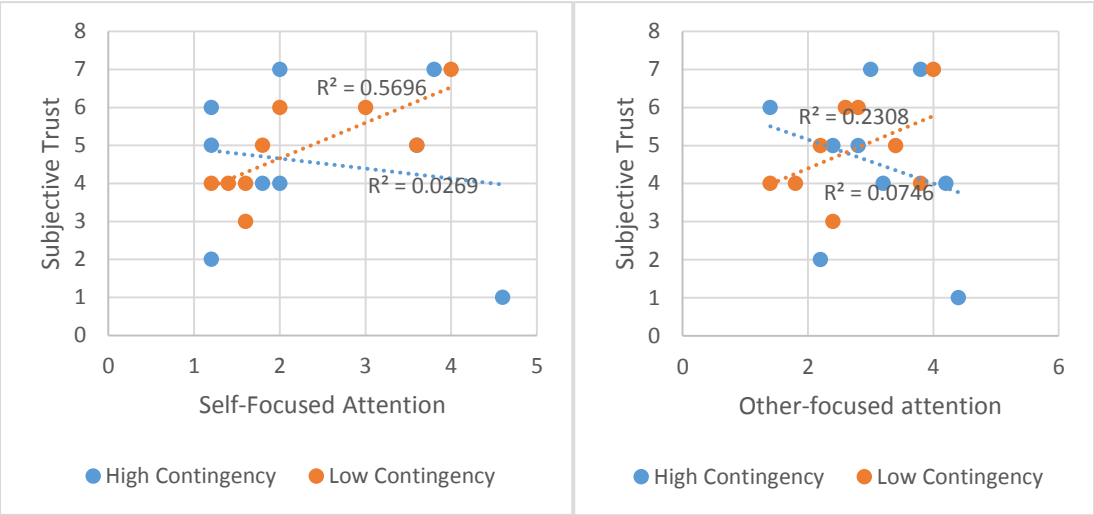


Figure 7a & b: Scatterplots (with trend lines and R^2 values) of subjective trust and self-focused attention and subjective trust and other-focused attention in high and low contingency groups

4. Discussion

4.1. Summary of findings

The present study investigated the safety and feasibility of interpersonally interactive virtual reality in a clinical population with psychosis and paranoia. Both quantitative and qualitative data suggest that this methodology is not only safe and immersive but also enjoyable for individuals with clinical paranoia. Furthermore, findings indicate that interactive virtual reality is a potentially useful tool for experimental research in paranoia and give provisional implications for future therapeutic use.

The objective trust measure of interpersonal distance kept from the avatar was associated with severity of persecutory delusions, as predicted, and negative affect experienced during the virtual reality scenario. Subjective trust ratings towards the avatar did not show a hypersensitivity to contingent behaviour in the avatar, as was predicted from the findings in a highly paranoid, non-clinical population (Fornells-Ambrojo et al.,

2016). Considering the lack of power in the current study, and the lack of correcting for multiple comparisons, only tentative conclusions can be drawn from this observation.

The present study also investigated the potential role of state focus of attention in clinical paranoia and its impact on interpersonal experiences. The study's findings of a positive association with self- and other-focus of attention and a lack of influence of self-focused attention on trust may highlight a complexity in the process of self-focused attention and its role in clinical phenomena such as paranoia.

4.1.1. Interactive VR: a viable tool for people with psychosis who experience paranoia

Similar to conclusions drawn by Fornells-Ambrojo et al. (2008), the current study's virtual reality scenario was shown to be a safe research tool to use with individuals with clinical paranoia. Only one participant reported brief effects of simulator sickness and only a small minority of participants verbally reported low-level experiences of anxiety during the scenario.

Overall, positive affect was found to be significantly higher than negative affect experienced by participants. Furthermore, a significant reduction in post-VR negative affect was also found. This supports the proposal that virtual reality does not create discomfort, including anxiety, in participants with clinical paranoia (Fornells-Ambrojo et al., 2008). In fact, the observed increases in positive affect, particularly excitement, and the positive feedback given indicates that the large majority of participants enjoyed their virtual reality experience.

The feasibility of interactive virtual reality as a research tool in clinical paranoia is also supported by the study's findings. Participants experienced a sense of presence in the virtual reality world, comparable to clinical populations with paranoia in non-interactive virtual reality paradigms (Fornells-Ambrojo et al., 2008) and non-clinical participants in the same scenario (Fornells-Ambrojo et al., 2016). Participants also reported finding the overall experience "*realistic*" and "*immersive*". Of particular importance, thematic analysis of

interview responses showed good evidence for participant's engagement and immersion in the interaction with the avatar. Numerous participants likened their interaction with the avatar to a real-life interpersonal encounter, with some commenting that the avatar's body language and behaviour particularly added to their immersion in the interaction. This gives promise for its future use as a tool to investigate potential trait and '*in situ*' factors impacting on interpersonal experiences in paranoia.

The current clinical sample were shown to pay less attention to the content of the conversation with the avatar compared to the non-clinical sample, albeit the majority still evidenced good attention. Lower levels of attention is arguably expected from a clinical population, considering impaired attention is proposed to be a fundamental cognitive deficit in patients with schizophrenia (Fioravanti et al., 2005; Neuchterlein et al., 1991). The indication of reduced attention in the current clinical sample is also supported by research showing that paranoid delusions are associated with impaired cognitive performance i.e. executive functioning, tendency to jump to conclusions and theory of mind (ToM) deficits (Bentall et al., 2009). This highlights a possible issue in the future use of verbally interactive virtual reality in clinical populations with paranoia, as it requires a degree of both attention (executive function) and reasoning about the mental state of others (ToM). It also highlights that individuals with clinical paranoia may have reduced attention to verbal content during therapeutic interactions and this should be considered by clinicians during therapy.

Some participants reported that the quality of the graphics of the virtual reality scenario detracted from their immersion in the environment, as did wearing the visual equipment. Constant development of virtual reality technology, primarily for the gaming industry, gives great promise for future developments of virtual reality as a clinical research and therapeutic tool. For example, the newly developed Oculus Rift is an inexpensive, consumer headset that can be used with a high-end computer, rather than the elaborate

and expensive virtual reality laboratories currently used. This technology has been shown to enable enhanced visual graphics and a superior immersive experience in virtual environments (Desai et al., 2014). In future, this could provide a more immersive experience in interactive virtual reality and improve the validity of interpersonal responses elicited by avatars in virtual reality scenarios.

4.1.2. No evidence of hypersensitivity to contingency in a clinically paranoid sample

Based on the findings by Fornells-Ambrojo et al. (2016) and the assumption that paranoia exists on a continuum (Chapman & Chapman, 1980; Claridge, 1997; van Os et al., 2009), the current study hypothesised that a hypersensitivity to the highly contingent avatar would be observed in the self-report measures of trust in the clinical sample but not in distance kept from the avatar. Exploratory data analysis gave no evidence that the contingency manipulation influenced subjective or trust behaviour.

4.1.2.1 Safety behaviours and interpersonal distance

People with persecutory delusions keep a "safe" distance from the avatar regardless of avatar responsiveness level i.e. they maintain a distance from the avatar that minimises feelings of discomfort or prevents the activation of a threat response. Interestingly, this is in line with Fornells-Ambrojo et al (2016) non-clinical study but also with data from naturalistic settings, such as an experience sampling study in which paranoid thinking was found to be immune to social context (familiarity) in people with high paranoia (Collip et al., 2011). Furthermore, a recent study found that state paranoid experiences in people with schizophrenia predicted greater interpersonal distance in a stop-distance paradigm compared to individuals with schizophrenia and low paranoia and non-clinical controls (Schoretsanitis, Kutynia, Stegmayer, Strik & Walther, 2016).

The minimum distance kept from the avatar was significantly associated with severity of delusion and post-VR negative affect, indicative of the employment of greater

interpersonal safety behaviours in individuals with more severe persecutory delusions and those experiencing greater emotional discomfort. Safety behaviours, such as interpersonal distance kept during a verbal exchange, are performed with the aim of protecting against a feared threat, and not only prevent disconfirmation of paranoid beliefs (Freeman et al., 2007), but also are likely to elicit confirmatory evidence, for example by giving the interlocutor the impression that one is less trusting or interested in them as signalled by keeping farther away during the communicative exchange. Further research could investigate the role of contingency in more ambiguous or threatening environments given that Veling et al (2016) reported increased paranoia in virtual reality scenarios showing higher levels of hostility, population and ethnic density in comparison to less socially stressful scenes. However, it is also possible that more subtle environmental cues, such as interpersonal responsiveness, do not influence trusting behaviour.

4.1.2.2 Subjective trust

No hypersensitivity was found towards the highly contingent avatar based on self-report trust towards the virtual flatmate in a clinical sample with persecutory delusions. A number of possible explanations are now considered.

It is possible that a type II error has occurred in the current study due to lack of power and a true hypersensitivity to contingency has not been detected. However, it is also plausible that the previous findings by Fornells-Ambrojo et al. (2016) are not true for a clinical population with paranoia. It is important to consider that not all processes relevant to paranoid ideation may exist on the entire paranoia spectrum and factors specific to clinical populations may further influence the formation of persecutory delusions. For example, attribution biases and ToM deficits are predominantly reported in populations with acute paranoid delusions compared to remitted, other clinical and non-clinical populations; and there is mixed evidence for their presence along the paranoia continuum (e.g. Kettle, O'Brien-Simpson & Allen, 2008; Mehl et al., 2010; McKay, Langdon & Coltheart,

2005; Diez-Alegría et al., 2006; Lincoln et al., 2010). This is perhaps why correlations were observed between severity of persecutory delusions (PSYRATS-D) and outcome measures of objective trust and other-focused attention, but not between the amount of paranoid delusions reported (GPTS). The PSYRATS-D measures the severity of delusions across a number of dimensions, including distress and disruption to daily living, whereas the GPTS measures frequency and endorsement of paranoia beliefs. It is plausible that the PSYRATS-D is more sensitive to the presence of mechanisms relevant to persecutory delusions in comparison to the GPTS. Principally, the PSYRATS-D may be more sensitive to the presence of safety behaviours associated with interpersonal distance kept from the avatar, and hypervigilance to external threat, an associated phenomenon in persecutory delusions (Freeman, Garety & Phillips, 2000; Freeman et al., 2002), which may explain the observed association with other-focused attention.

Blakemore et al. (2003) proposed that clinical individuals with paranoia over-attribute contingent behaviour. It is possible that a misperception of contingent behaviour in the low contingency condition therefore levelled the perceptions of subjective trust across the two conditions. The non-significant difference in participants' detection of contingency in the high and low contingency groups potentially supports this theory, but the sample size is too small to clearly establish if a misperception of contingency existed in the clinical sample.

Another explanation is that reasoning biases present in a clinical population were influencing subjective appraisals of trust towards the avatar, irrespective of the avatar's behavioural contingency. A reasoning bias identified as a contributory factor in the occurrence of paranoid delusions is jumping to conclusions (JTC) (Bentall et al., 2009; Garety & Freeman, 1999; Garety et al., 2013). Associated with working memory (Freeman et al., 2014; Garety et al., 2013; Lunt et al., 2012), JTC is the process of limited information gathering before reaching a conclusion. The positive relationship found between subjective

trust and positive emotions experienced in the virtual reality environment may be indicative of participants basing their perceptions of trust on their affective state during the virtual interaction, without using further interpersonal information (i.e. contingency) to reach their conclusion. This is further supported by the literature that suggests that attribution biases are present in individuals with persecutory delusions during both positive and negative events (Lincoln, Mehl, Exner, Lindenmeyer & Rief, 2010).

4.1.3. Social anxiety and self-focussed attention in people with paranoia: a complex story

The clinical literature suggests that a subset of individuals with persecutory delusions have significant levels of social anxiety and that this may contribute to the occurrence of paranoid ideation (Lysaker et al., 2010). As self-focused attention has been implicated as a key process in social anxiety and, to a lesser extent, psychosis, it was hypothesised that higher self-focus attention would be associated with higher social anxiety in the current sample. Despite half of the current sample self-reporting clinical levels of social anxiety, only a minority of individuals reported high levels of self-focused attention during the virtual reality scenario and the relationship between social anxiety and self-focused attention was non-significant. Consideration of the pleasant nature and low level of subjective distress observed during the virtual reality environment provides some explanation for this finding. Glick et al. (2011) found that the relationship between social anxiety and state self-focused attention was partially mediated by experiential distress in a non-clinical population high in social anxiety. Furthermore, Clark & Wells (1995) propose that the relevant processes of self-focused attention are activated when an individual enters a “feared social situation”. It is therefore plausible that the current sample, particularly those scoring high in social anxiety, were not experiencing levels of distress intense enough to trigger heightened levels of self-focused attention during the virtual reality scenario, hence no association was found. The findings that the virtual reality scenario was a mostly positive experience with minimal levels of negative affect reported,

and the significant reduction in negative affect by the end of the scenario, supports this hypothesis. In addition, participants were instructed to 'speak' with the avatar (using the question prompts). This forced contact may have prevented participants fully engaging in attention directed towards the self.

Based on Clark & Wells' (1995) model of social anxiety that proposed that self-focused attention limits the processing of external socially relevant information and supportive empirical evidence, it was hypothesised that self-focused attention would be negatively associated with other-focused attention. However, the data contradicted this prediction, showing instead the participants who paid greater attention to themselves also reported paying greater attention to their external environment, including the avatar. Further inspection of the literature on self-focused attention reveals inconsistencies between whether self-focused attention does, in fact, limited other-focused attention. For example, Panayiotou & Vrana (1998) found that self-focused manipulation in a socially anxious group did not decrease attention to the environment but may have enhanced it. Holzman & Valentiner (2016) found that high socially anxious individuals demonstrated higher levels of both self- and other-focused attention compared to those low in social anxiety. Both studies contradict the assertion that focus of attention is one-directional.

Spurr & Stopa (2002) highlight the complexity of self-focused attention in their review of the literature. The authors emphasised that the mechanistic function of self-focused attention in social anxiety cannot be explained simply by the presence of attention to the self. The content of self-focused attention is highlighted to play a crucial role in influencing appraisals of social situations. In Carver & Scheier's (1982; 2012) cybernetic theory of self-regulation, a distinction is made between two types of self-focused attention based on content: private self-consciousness (i.e. focus on psychological aspects of themselves, such as thoughts, feelings and attitudes) and public self-consciousness (i.e. awareness of themselves being processed as social objects, such as the impression they are

making on another). Public self-consciousness has been shown to be a strong predictor of social anxiety (Darvill, Johnson & Danko, 1992).

As it would seem that the mechanism by which self-focused attention impacts upon social anxiety is complex, it is fair to assume that a similar complexity exists in its role in clinical paranoia. Rietdijk et al. (2009) reflect on the complexities of the relationship between social phobia and paranoid ideation in the general population. They propose the two phenomena may share psychological mechanisms i.e. subject of attention, heightened self-consciousness, scanning the environment, overestimating the impact of behaviour and self-reference and confirmation biases. However, the shared mechanisms are driven by different motives: fear of rejection versus fear of persecution, which lead to different psychological outcomes.

Should a positive relationship between self- and other-focus of attention truly exist in clinically paranoid populations, this might suggest a more general state of higher awareness (both to self and others) experienced by some in social interactions, influenced by factors specific to processes of paranoid ideation e.g. hypervigilance to threat. The significant positive correlation found between other-focused attention and severity of delusion may suggest that other-focus of attention is driven by factors more relevant to delusional processes than those of social anxiety. Furthermore, the literature on self-focused attention places great emphasis on its influence on self-perception, rather than perceptions of another. It is important for future research to further investigate the relationship between self- and other-focus of attention in social interactions in individuals with clinical paranoia and how this might impact on their interpersonal experiences.

4.1.4. Lack of influence of self-focused attention in trust perception

Against hypotheses, no influence of self-focused attention in trust perception was found. Again, this finding is possibly due to lack of power. However, possible explanations could be drawn from considering the content of self- and other-focused attention.

Carver & Scheier's (1982; 2012) cybernetic theory of self-regulation proposes that self-focus attention may provide a feedback cycle which allows a person to become aware of processes towards a goal and take appropriate action, effecting changes if there is a discrepancy between the perceived standard of behaviour and actual behaviour. The greater the discrepancy, the greater the distress experienced in a social interaction. Furthermore, the extent to which self-focused attention negatively impacts on perceptions of a social interaction is dependent on whether the content of self-consciousness is positive or negative. It is plausible that the pleasantness of the interaction with the avatar, and the fact that the avatar would not respond to any nervousness in the participants, was incorporated into a feedback loop of social performance that minimised *negative* self-focused attention assessed in the FAQ e.g. anxiety, memories of past social failures. Further investigation into the content of participants' focus of attention (e.g. positive or negative, public or private self-consciousness) might give further insight into the role of self- and other-focused attention in interpersonal experiences in paranoia.

Graphical exploratory data analysis (EDA) of focus of attention and subjective trust suggested that there is potentially a link between focus of attention and trust in the low contingency condition. Conclusions drawn from this must be very tentative due to the small sample. However, Fornells-Ambrojo et al. (2016) found that dismissive attachment predicted greater subjective trust in the non-clinical sample. Potentially, the low contingency condition was more likely to elicit an insecure attachment response to the avatar, hence the greater attention paid to the self (private self-consciousness) and the other, the greater the subjective trust rating.

4.2. Limitations

The current findings must be interpreted in the context of a number of limitations. Whilst the sample size allowed for adequate exploration of the feasibility of the interactive virtual reality environment in a clinical population with paranoia and overall associations with

paranoia, a clear limitation of the study is a sample size without enough statistical power to detect effects of contingency manipulation or self-focused attention. Therefore any conclusions drawn about contingency and focus of attention in clinical paranoia can only be very tentative. Exploratory data analysis (EDA) was employed to allow a more exploratory approach to potential trends emerging from the data. However, small-n EDA remains susceptible to biases in the data from outliers.

The current study also used multiple statistical tests to explore correlations between outcome measures. This will have increased the likelihood that a type I error may have occurred in the analysis i.e. rejecting a null hypothesis (H_0) when it is true. Applying Bonferroni corrections (Cabin & Mitchell, 2000) would have minimised the chance of type I errors occurring, yet applying these corrections would have rendered most of the significant tests non-significant. There is no formal consensus for when Bonferroni corrections should be used (Perneger, 1998) and it is noted that applying Bonferonni corrections increases the likelihood of type II errors (i.e. accepting H_0 when it is false), thus reducing the power of a study (Nakagawa, 2004). Hence, the decision was made not to use these corrections in the current study.

The qualitative feedback from participants helped enrich findings from this study, particularly enabling firmer conclusions to be drawn about the feasibility of interactive virtual reality. However, a comment must be made about the potential for response bias. The interview was conducted by the researchers with whom participants had conducted all other research tasks. This may have influenced greater positive feedback about their experience or a with-holding of negative feedback about their experience.

The pleasant nature of the scenario, reflected by the PANAS and participant feedback, could be considered to limit the generalisability of findings. It is proposed that social cognitive biases are greatly exacerbated in clinical individuals with paranoia when there is a perceived threat to self or under conditions of stress (Bentall et al., 2001; Lincoln,

Lange, Burau, Exner & Moritz, 2010; Lincoln, Peter, Schäfer & Moritz, 2009). Similarly, research has found that the impact of self-focused attention on social appraisals is mediated by experiential distress (Glick et al. 2011). It is difficult to determine the impact of interpersonal contingency or self-focused attention on trust if the virtual reality scenario was more ambiguous or anxiety provoking. Virtual reality experiments that have used more ambiguous paradigms have found clinical participants with paranoia experience paranoid ideation towards avatars (Fornells-Ambrojo et al., 2008). It may be that if a threshold of experiential discomfort is reached, cognitive factors relevant to clinical paranoia become more influential on subjective interpersonal experiences, such as trust.

Clearly, the study's all-male sample contributes to limitations in the studies generalizability. Significant gender differences have been found in sense of presence experienced in virtual reality, with men experiencing a higher sense of spatial presence, perceived realism and sense of immersion in the environment (Felnhofer et al., 2012). This limits the assertion that interactive virtual reality is a feasible research methodology for both men and women with clinical paranoia, particularly with regards to a sense of presence in the environment and interaction. Furthermore, the salience of paranoid ideation may vary between clinical individuals with paranoia, both in the current sample and wider population, based on the dissonance between their idiosyncratic belief system and the presence of a Caucasian, male avatar.

4.3. Future research and clinical implications

In the current study, one participant was quoted saying "*The technology is impressive, in two years tech will be able to be used for mental health to help people that can't get out of the house. They can use it to gradually get out, talk to people. It could be used therapeutically, would be really helpful.*" Although this is perhaps a distant future implication for interactive virtual reality as a therapeutic tool in paranoia, it coincides with the emergence of exposure-based virtual reality being effectively used as a therapeutic tool

with individuals with persecutory delusions (Freeman et al., 2016) and other mental health conditions such as social phobia (Klinger et al., 2005). Interpersonally interactive virtual reality may prove to be a useful therapeutic tool in addition to exposure-based interventions for individuals with clinical paranoia, particularly those with very limited social contact.

However, future research needs to expand on the feasibility of interactive virtual reality in clinical populations with paranoia. Addressing possible gender differences in senses of presence needs to be explored with a mixed gender clinical sample. Furthermore, as attention to content was highlighted as a potential issue to the feasibility of the interaction, future research should aim to further investigate the impact of severity and chronicity of psychotic illness on engagement in the virtual reality interaction including psychosis populations other than that of just first-episode.

The role of interpersonal contingency in perceptions of trust in paranoia remains unclear. To truly investigate whether hypersensitivity to interpersonal contingency does exist in clinical individuals with paranoia, the current study needs to be replicated with a sample size large enough to reach satisfactory power. Particular focus should be given to evidence that either supports paranoia processes on a continuum or suggests that there are features of paranoid delusions that are exclusive to clinical populations. Similarly, the role of interpersonal contingency and trust needs further exploration in a more ambiguous or anxiety-provoking social interaction. This would potentially allow for further conclusions to be drawn about the impact of affective state on cognitive processes related to paranoid such as self-focused attention and reasoning biases.

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Part 3: Critical Appraisal

1. Introduction

This critical appraisal will review observations made during the processes of this research, both in the empirical study and in conducting the systematic review. The appraisal will also incorporate personal reflections. Firstly, it will consider observations of potential biases that exist in clinical literature, particularly those relevant to the dissemination of clinical research. Secondly, the benefits and challenges of recruiting from clinical populations are explored. Reflections are made about the positive impact of involving service users in research. Further reflections explore the impact recruitment challenges may have on encouraging research with clinical populations and thus the development of clinical knowledge. Finally, the concept of statistical power is considered. The possible restrictions that more orthodox methods of statistics may have on developing our knowledge of 'harder to reach' populations are explored.

2. A reflection on biases in clinical research

My pre-training research experience had been in contributing to the cognitive model of persecutory delusions (Freeman et al., 2002). As a result, I was dedicated to pursuing a doctoral thesis project that investigated mechanisms of paranoia and involved researching a clinical population. Having been given the opportunity to do this, I noticed from early on in the research process that my personal experience had created a bias in my wish to investigate paranoia within the context of the aforementioned cognitive model. Despite a more open-minded approach to my clinical practice, I became aware that in research I was perhaps more wedded to a particular model than I should be. I observed that even with the insight of having this potential bias, it was at times difficult to remove myself from the wish to provide evidence for a model I had previously been invested in. This led to an overall reflection about the biases that can arise in clinical psychology, even with the best intentions to remain neutral.

The process of conducting a systematic literature review evoked particular reflections on publication bias. Publication bias is originally defined as the selective publishing of studies with a particularly outcome, usually favouring significant results over those accepting a null hypothesis. In mental health research, particular focus has been given to selective publication of positive outcomes in clinical trials investigating the efficacy of anti-depressants (Robinson, 2008; Turner, Matthews, Linardatos, Tell & Rosenthal, 2008). Whilst this research highlighted the potential for corruption of research due to the economic incentives of pharmaceutical companies, it also indicated that publication biases throughout mental health research may be distorting scientific and public knowledge about the mechanisms and treatment of clinical conditions (Rothstein, Sutton & Borenstein, 2005).

Further conceptualisation of publication biases highlights numerous potential mechanisms of information suppression beyond the original definition. These include language bias (selective inclusion of studies published in English); familiarity bias (selective inclusion of studies from one's own discipline) and outcome bias (selective reporting of some outcomes but not others in clinical studies) (Rothstein, Sutton & Borenstein, 2005). The broader term of 'dissemination bias' has been suggested to encapsulate all of these potential biases (Song et al., 2010). Holding these biases in mind, as well as potential personal biases, proved useful when conducting the systematic literature review.

A clear observation from the literature review was the dominance of a particular research group in clinical trials of psychological treatments impacting on paranoia. The original intent of the literature review was to only be a meta-analysis. However, it was clear from conducting preliminary literature searches to form the research question that a meta-analysis in isolation would limit the broader picture of treatments for paranoia. Yet, even with a wider synthesis, a dissemination bias towards this research group continued to exist. This promoted a reflection on the impact of research resources and the narrative in clinical

research that the gold standard of randomised controlled trails (RCTs) overshadows smaller-scale research in the same field. It would seem that larger research groups have the resources to conduct larger scale research with methodology (e.g. multi-site RCTs) that is viewed as superior to other studies (e.g. pilots and case-studies) by authors who do not have access to the same resources, particularly financial. Whilst RCTs included in the literature review predominantly used unbiased methodology e.g. blinding, preplanned analysis etc., there remains a clear potential for the suppression of research of other therapeutic interventions for paranoia.

This observation drew a number of parallels with the experience of recruiting a clinical sample for the current empirical study. Whilst the importance of conducting research on clinical populations, particularly those considered 'hard to reach', is clear, there were many challenges involved in recruiting from a population of individuals with psychosis and paranoia within a NHS setting.

3. The highs and lows of conducting research with clinical populations

3.1. The need to engage clinical populations in experimental research

The benefits of conducting research in clinical populations are clear. As was reflected in parts of the empirical study and literature review, there are only so many conclusions that can be drawn from investigating non-clinical samples with sub-clinical threshold symptoms. There are many factors both within and beyond mental health diagnoses that can be specific to individuals from a clinical population, such as cognitive deficits associated with schizophrenia (Heinrichs, Walter, Zakzanis & Konstantine, 1998), the experience and impact of societal stigma (Corrigan, Druss & Perlick, 2014) and an increased likelihood of having experience childhood adversity or trauma (e.g. Edwards, Holden, Felitti & Anda, 2003). The conclusions drawn in both the systematic review and empirical study of this thesis suggest that there are psychological factors which are exclusive to persecutory delusions. Whilst

such conclusions in no way disregard the hypothesis of a continuum of paranoia (e.g. Chapman & Chapman, 1980; Claridge, 1997; van Os et al., 2009), they call for greater empirical research on the understanding of the similarities and differences between sub-clinical and clinical paranoia. This, of course, requires recruiting from a clinical population.

3.2. The barriers to recruiting clinical participants

Problems with recruitment in psychiatric populations are well documented, both anecdotally and in the literature (Patel, Doku & Tennakoon, 2003). They have been shown to disrupt schedules for research projects, preoccupy staff, reduce the ability to detect therapeutic differences and can result in a trial being abandoned (Ashery & McAuliffe, 1992). Furthermore, factors such as non-response and selection biases can mean that eligible participants entering studies influence the validity of the representativeness of the clinical population being studied (Woods, Ziedonis, Sernyak, Diaz & Rosenheck, 2000; Hulley, Cummings, Browner, Grady & Newman, 2001). This is principally based on the concept that those who do not respond after being contacted are different from people who do participate. Armstrong et al. (1992) explored characteristics associated with poor response rate in clinical populations and found that some main factors adversely affecting response rates were: older age, male gender, non-Caucasian ethnicity, urban residence, unemployment or low education/occupation status, low family income, smoker and high use of medical care. Perhaps with some exceptions, these characteristics capture a significant proportion of individuals with psychosis (Castle & Murray, 1991; Marwaha & Johnson, 2004; Ruhrmann et al., 2010; Sundquist, Frank & Sundquist, 2004).

However, from the experience of conducting the current research, there were a number of challenges and barriers to recruitment that were not directly related to the service users themselves. In the early stages of the study, ethical and NHS Research and Development (R&D) approval, for obvious and appropriate reasons, was a lengthy procedure that required specific restrictions on recruitment strategies. Participants could

only be recruited from Early Intervention in Psychosis services (EIS) pre-named in the ethical application. Experience from a previous role as a research assistant had highlighted the critical importance of engaging service team members. It was similarly apparent for the current project that recruitment hinged on the engagement of service team members in approaching their service users to suggest the research to them. Furthermore, it became clear that the presence of the researchers in the clinical teams was an important factor in the number of referrals received. This highlighted a critical learning point in conducting research: efforts to engage health care professions in clinical research are as important as engaging the service users. Furthermore, engagement of either takes time - time that is not always available to health care professionals attempting to conduct research whilst also balancing clinical caseloads.

Two distinct barriers in engaging health care professionals became apparent. Recent re-structuring of many EIS teams has seen dramatic increases in the caseloads, and therefore workloads, of care coordinators (Belling et al., 2011). Although efforts were made on the researchers' behalf to minimise any work required of care coordinators to aid recruitment, it was clear that holding our research in mind and approaching service users was burdensome for many health care professionals. In addition, differences were experienced in care coordinators perceptions of the usefulness of research. Understandably, those who viewed research as less integral to clinical care were less inclined to refer service uses or encourage their clients to engage in the research. A greater presence of the researchers in the teams enabled a greater alliance to be formed with team members. This alliance became helpful in combatting negative views about research in certain team members and thus improved recruitment. However, time constraints for the project and the researchers meant resources to fully engage many of the EIS teams were not possible, highlighting the time resources necessary to reach recruitment targets in quantitative research in clinical populations.

Many clinical research trials employ junior researchers to undertake recruitment in order to meet necessary targets for statistical power (Dowling & Weiner, 1997). However, this is not a widely available option for many clinical psychologists wishing to conduct research in clinical populations. Without these resources, researchers can run the risk of under-recruitment and therefore under-powered findings. This then impacts upon the acceptability and generalisability of conclusions and the wider dissemination of knowledge within clinical psychology (e.g. publications). It is barriers such as these that stand to potentially discourage researchers from attempting to conduct research in clinical populations unless they have the resources more commonly seen in larger, well-establish research groups. This arguably contributes to dissemination biases and impoverished knowledge, particularly in populations considered "hard-to-reach".

3.3. The benefits of recruiting clinical populations

As previously discussed, it is important to investigate the continuum of psychological phenomena and whether there are distinct features of clinical conditions that set individuals who suffer from these conditions apart from non-clinical populations. However, there are other benefits of recruiting from clinical populations that were experienced during this research that warrant specific reflections.

As the researcher, I was overwhelmed by the enthusiasm and effort participants showed to take part in our research. Some travelled for over an hour and were quite insistent that they did not wish to be paid for participation; the opportunity to try virtual reality was incentive enough. Others informed us that they very rarely left the house or socialised with others, but were motivated to be involved in something that might not only help them but would also help other people who use mental health services. Some also used the experiment as a space to talk about current serious difficulties that we were able to feed back to the care coordinators and promote more support for that individual during a time of need. Overall, my sense as a researcher during the experiments was that engaging

this clinical population was providing them with an opportunity to do something 'out of the ordinary' and altruistic – something that was clearly meaningful to them.

There is some research that explores the importance of people with mental health difficulties having the opportunity to help others. The helper-therapy principle (Reissman, 1965; 1990) proposes; assuming an individual has a worthwhile contribution to make, a greater sense of self-efficacy and capability can be promoted. Furthermore, the theory suggests that when individuals are put in an active role, rather than a passive recipient role they can: impact on wellbeing (Mead & Copeland, 2000), combat feelings of dependence, engender a sense of status in an individual, and encourage a greater sense of positive self-identity (Reissman, 1990; Salzer & Shear, 2002; Skovholt, 1974). This feels particularly relevant in a group of individuals who can experience some of the more severe forms of stigma amongst mental health difficulties (Brohan, Elgie, Sartorius & Thornicroft, 2010). Engagement in activities of value in young people with psychosis has also been found to have a positive impact on their wellbeing (Lal et al., 2013). Qualitative analysis found the key factors which made activities meaningful were a sense of making a contribution, expressing thoughts and emotions and additionally, connecting and belonging.

For numerous reasons, research might not be an enjoyable or meaningful activity for all individuals with psychosis or, indeed, other mental health conditions. However, my experience of conducting research with individuals that are perhaps more difficult to engage is that, selection biases aside, the majority of individuals from clinical populations who take part will enjoy the process. Furthermore, this did not feel like a narrative that was shared by the healthcare professionals. Many were reluctant to approach their clients to suggest the research, assuming it would be burdensome, distressing or disinteresting for the person. In order to amend the common consensus amongst researchers and clinicians that recruiting from clinical populations has many challenges; a step should be taken in clinical psychology to understand the dynamics of these difficulties from three key

perspectives: the participants, the referring clinicians and the researchers. It may well be that there are misunderstandings and miscommunications than can be reduced or avoided in the future. With hope, a greater understanding of the benefits and barriers of engaging clinical populations in research will improve recruitment and therefore increase the likelihood and frequency of clinical research from many, independent researchers.

4. The issue of power – Baseyian vs Orthodox statistics in 'hard to reach' populations

Whether recruiting from a non-clinical or clinical population, the importance of achieving a sample size with enough power to reliably detect an effect becomes a prominent, if not overwhelming, concern in a researcher's mind. The emphasis on achieving power in a sample is largely driven by the logic of orthodox statistics, as developed by Jerzy Neyman and Egon Pearson in the 1930s. Orthodox statistics primarily function from the assumption that probabilities are long-run relative frequencies (Dienes, 2008), which in turn require an indefinitely large series of events that constitutes as a 'collective' (von Mises, 1957). These collectives are often populations (e.g. gender, culture, specified clinical diagnosis) that can be used to predict the likelihood that an observed event (e.g. a study's finding) would occur in that collective and in comparison to other collectives (e.g. a non-clinical population), thus allowing for the accepting or rejection of a null hypothesis. It is an incredibly useful mathematical and theoretical application that strengthens the certainty with which we can understand and treat psychological phenomena.

In orthodox statistics, the concept of statistical power proposes that with prior knowledge of the effect size of an observable phenomenon and defined parameters to reduce type I and type II error (α and β), a researcher can determine the sample size needed to reliably reject the null hypothesis in the event of statistically significant results (Ellet, 2010). Reflections on this process during the empirical research began to pose questions about whether an emphasis on statistical power becomes overly restrictive when

researching ‘hard to reach’ populations or when exploring hypotheses with little prior research from which to estimate an effect size. Arguably, if one cannot know the a priori effect size or whether it exists in a relatively unknown ‘collective’, one cannot accurately assume the sample size calculation is correct. This then places an arbitrary restriction on the interpretation of findings.

Bayesian statistics suggest a slightly different approach can be taken within quantitative research which minimizes the importance of power. Barker, Pistrang & Elliott (2016) remark than the there is some merit in the application of Bayesian thought in clinical psychology research as it proposes that any data is useful and that small-N studies should not be avoided. However, Bayesian theories also concede that the larger the sample size, the more the study will add to prior knowledge (Dienes, 2011; 2014; Edwards, Lilford, Braunholtz & Jackson, 1997). Whilst both Bayesian and Orthodox statistics have their merits and limitations, the latter is a far more widely accepted approach in clinical psychology. This poses the question of how much research defined as underpowered has either gone unpublished or received minimal attention in literature, despite it plausibly adding to valuable knowledge. Furthermore, a fixation on statistical power is arguably limiting our knowledge of ‘harder-to-reach’ clinical or societal populations. This could be compounding the difficulties and discouragements faced by researchers attempting to recruit from these populations, contributing to a wider dissemination bias in clinical psychology.

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Appendices

Appendix 1: Quality Rating Scale (Yates et al., 2005)

Quality Rating Scale – Scoring Sheet

Rater: _____

Author/Year: _____

Title: _____

____

TREATMENT QUALITY

Please circle the appropriate score

Item #	Question	Item	Response
1	Has a clear rationale for the treatment been given and an adequate description of its content?	Treatment content / setting	**0 1 2**
2	Has the total treatment duration been reported? If so: No. sessions_____ Duration _____ Total (hrs)____	Treatment duration	**0 1**
3 2 parts	Is there a treatment manual that describes the active components of treatment?	Manualisation	**0 1 2**
		Adherence to manual	**0 1**
4	Have the therapists been appropriately trained in the relevant procedures for this trial?	Therapist training	**0 1 2**
5	Is there evidence that the patients have actively engaged in the treatment?	Patient engagement	**0 1**

Total score for section: _____

QUALITY OF STUDY DESIGN AND METHODS

Please circle the appropriate score.

Item #	Question	Item	Response
1 2 parts	Are the inclusion and exclusion criteria clearly specified?	Sample criteria	**0 1**
		Evidence criteria met	**0 1**
2 2 parts	Is there evidence that CONSORT guidelines for reporting attrition have been followed?	Attrition	**0 1 2**
		Rates of attrition	**0 1**
3 2 parts	Is there a good description of the sample in the trial?	Sample characteristics	**0 1**
		Group equivalence	**0 1**
4 4 parts	Have adequate steps been taken to minimise biases?	Randomisation	**0 1 2**
		Allocation Bias	**0 1**
		Measurement Bias	**0 1**
		Treatment expectations	**0 1**
5 3 parts	Are the outcomes that have been chosen justified, valid and reliable?	Justification of outcomes	**0 1 2**
		Validity of outcomes for context	**0 1 2**
		Reliability and sensitivity to change	**0 1 2**
6	Has there been a measure of any sustainable chance between the treatment and control groups?	Follow up	**0 1**
7 5 parts	Are the statistical analyses adequate for the trial?	Power calculation	**0 1**
		Sufficient sample size	**0 1**
		Planned data analysis	**0 1**
		Statistics reporting	**0 1**
		Intention to treat analysis	**0 1**
8	Has a good, well-matched alternative treatment group been used?	Control Group	**0 1 2**

Total score for section: _____

Total Score: _____

Comments:

Appendix 2: Table of individual item quality rating scores for included studies

		Treatment Quality							Quality of design and methods																				Grand Total
		Treatment Content/Setting	Treatment duration	Manualisation	Adherence to manual	Therapist training	Patient Engagement	Total	Sample criteria	Evidence criteria met	CONSORT attrition	CONSORT rates of attrition	Sample characteristics	Group equivalence	Randomisation	Allocation bias	Measurement bias	Treatment expectations	Justification of outcomes	Validity of outcome for context	Reliability and sensitivity to change	Follow-up	Power calculation	Sufficient sample size	Planned data anlaysis	Statistics reporting	Intention to treat analysis	Control group	Total	
RCTs	Van Oosterhout et al. (2014)	2	1	2	1	2	1	**9**	1	1	2	1	1	1	2	1	1	1	2	2	2	1	1	1	1	1	1	1	**25**	**34**
	Freeman, Dunn et al. (2015)	2	1	2	1	2	1	**9**	1	1	2	1	1	1	2	1	1	1	1	2	2	1	1	1	1	1	1	1	**24**	**33**
	Freeman, Waite et al. (2015)	2	1	2	1	2	1	**9**	1	1	2	1	1	1	2	1	1	1	1	2	2	1	0	0	1	1	1	1	**22**	**31**
	Freeman et al. (2014)	2	1	2	0	2	1	**8**	1	1	2	0	1	1	2	1	1	1	2	2	2	1	0	0	1	1	1	1	**22**	**30**
	Foster et al. (2010)	1	1	1	0	2	1	**6**	1	1	2	1	1	2	0	0	0	2	2	2	1	1	1	1	1	1	0	1	**22**	**28**
	Chadwick et al. (2009)	1	1	1	0	2	1	**6**	1	1	2	0	1	0	2	1	1	0	2	2	2	0	1	1	1	1	0	1	**20**	**26**
	Waller et al. (2015)	2	1	2	0	2	1	**8**	1	1	2	0	1	1	2	0	0	0	2	2	1	1	0	0	1	1	1	1	**18**	**26**
Pilot studies	Bell & Freeman (2014)	2	1	2	0	2	1	**8**	1	1	2	1	1	0	0	0	0	0	2	2	2	1	0	0	1	1	0	0	**15**	**23**
	Myers, Startup & Freeman (2010)	2	1	2	0	2	1	**8**	1	1	2	0	1	0	0	0	0	0	2	2	2	1	0	1	1	1	0	0	**15**	**23**
	Hepworth, Startup & Freeman (2(	2	1	2	0	2	1	**8**	1	1	1	0	1	0	0	0	0	0	2	2	2	1	0	0	1	1	0	0	**13**	**21**
	Freeman et al. (2016)	2	1	2	0	2	1	**8**	1	1	1	0	1	0	0	0	0	0	1	2	2	1	0	0	1	1	0	0	**12**	**20**
	Freeman, Waller et al. (2015)	2	1	1	1	1	1	**7**	1	1	1	0	1	0	0	0	1	0	1	1	1	0	0	0	1	1	0	0	**10**	**17**
	Waller et al. (2010)	2	1	1	1	1	0	**6**	1	0	1	0	0	0	0	0	0	0	2	2	2	1	0	0	1	1	0	0	**11**	**17**
Case studies	Balzan & Galletly (2015)	2	1	2	0	1	1	**7**	0	0	0	0	1	0	0	0	1	0	2	1	1	1	0	0	0	0	0	0	**14**	**21**
	Hutton, Morrison & Wardle (201(	2	1	1	0	2	1	**7**	1	1	0	0	1	0	0	0	0	0	1	2	2	1	0	0	0	1	0	0	**10**	**17**
	Morrison (2010)	2	1	1	0	2	1	**7**	0	0	0	0	1	0	0	0	0	2	2	2	0	0	0	0	0	1	0	0	**8**	**15**
	Bloy, Oliver & Morris (2011)	2	1	0	0	1	1	**5**	0	0	0	0	1	0	0	0	1	1	2	2	1	1	0	0	0	0	0	0	**9**	**14**
	Ellett (2013)	2	1	2	0	2	1	**8**	0	0	0	0	1	0	0	0	1	0	1	1	1	1	0	0	0	0	0	0	**6**	**14**
	Carden & Jones (2009)	2	0	0	0	1	1	**4**	0	0	0	0	1	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	**7**	**11**
	Chadwick & Trower (1996)	1	1	1	0	2	1	**6**	0	0	0	1	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	**5**	**11**
	Kinderman & Bentall (1997)	2	0	1	0	2	1	**6**	0	0	0	0	1	0	0	0	0	0	1	1	1	0	0	0	0	1	0	0	**5**	**11**
	Kuller & Björgvinsson (2010)	2	1	2	0	1	1	**7**	0	0	0	0	1	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	**4**	**11**
	Dudley, Dixon & Turkington (200	1	1	0	0	1	1	**4**	0	0	0	0	1	0	0	0	0	0	0	2	2	1	0	0	0	0	0	0	**6**	**10**

Appendix 3: Summary of Joint Project and Each Researcher's Contribution

The virtual reality paradigm was developed and used in a previous doctoral thesis project by Dr Maikke Elenbaas, submitted in 2013. The two researchers on this joint thesis project were Gail Wingham (author) and Hannah Reidy, both supervised by Dr Miriam Fornells-Ambrojo and Professor Chris Barker. The current author's project focused on virtual reality feasibility and contingency manipulation (two conditions: high vs low contingency) and self-focused attention in the development of trust in paranoia. The joint researcher (HR) focused on the impact of social capital and social connectedness in the development of trust in paranoia, treating the high and low contingency conditions as one condition.

In designing the experiment, researchers independently selected measures that were related to their separate experimental hypotheses. The only measures shared by the researchers in their independent projects were the objective measure of trust (distance kept from avatar), Sense of Presence questionnaire (Slater et al., 1998) and attention checks (Elenbass, 2014; Fornells-Ambrojo et al., 2016). The semi-structure interview and debrief was designed by both researchers but there was no overlap of the data used from this measure in the separate empirical papers. The order of the experiment measures and procedures was collaborative decided upon by both researchers.

Both researchers collective designed all project documents, including information sheets, consent forms and posters. Ethical and R&D approval was also a joint effort between the researchers.

For recruitment, researchers each targeted two Early Intervention in Psychosis (EIS) teams in order to promote the research study and gain referrals from as wider scope as possible. Screening of referrals was largely shared between researchers, or dictated by prior engagement with a care coordinator or service-user. Researchers shared the responsibility of escorting participants to and from the testing location when needed and jointly conducted each experiment.

Each empirical paper was written independent by the respective authors.

Appendix 4: Ethical Approval

NHS
Health Research Authority
NRES Committee London - Camberwell St Giles
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT
[redacted]

10 August 2015

Dr. Miriam Fornells-Ambrojo
Clinical Psychologist, Step Team
South London and Maudsley NHS Foundation Trust
Step Team, 12 Windsor Walk,
Denmark Hill
London
SE5 8BB

Dear Dr. Fornells-Ambrojo

Study title:	**Investigating social factors and affective processes in individuals with clinical paranoia: a virtual reality study.**
REC reference:	**15/LO/1197**
IRAS project ID:	**172018**

Thank you for your letter of 6th August 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC at a meeting held on 10th August 2015. A list of the Sub-Committee members is attached.

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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Tina Cavaliere, [redacted]. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

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 approvals 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. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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 request a deferral for study registration within the required timeframe, they should contact [redacted] The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

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).

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 [Research Poster]	3	03 August 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Certificate]	1	12 June 2015
GP/consultant information sheets or letters [HCP Information Sheet]	1	15 January 2015
Interview schedules or topic guides for participants [Qual interview qus]	2	01 July 2015
IRAS Checklist XML [Checklist_18062015]		18 June 2015
IRAS Checklist XML [Checklist_01072015]		01 July 2015
IRAS Checklist XML [Checklist_06082015]		06 August 2015
IRAS Checklist XML [Checklist_06082015]		06 August 2015
Letter from sponsor [Letter from Sponsor]	1	12 June 2015
Non-validated questionnaire [Sense of Presence non-validated]	2	01 July 2015
Non-validated questionnaire [TICR non-validated]	2	01 July 2015
Non-validated questionnaire [Detection of Contingency and Attention Checks]	2	01 July 2015
Non-validated questionnaire [Reading the Eyes non-validated]	2	01 July 2015
Participant consent form [Participant consent form]	2	03 August 2015
Participant information sheet (PIS) [Participant Information Sheet]	3	03 August 2015
REC Application Form [REC_Form_18062015]		18 June 2015
REC Application Form [REC_Form_06082015]		06 August 2015
Research protocol or project proposal [Research Protocol]	3	06 May 2015
Summary CV for Chief Investigator (CI) [CI CV]	1	13 March 2015
Summary CV for student [CV Gail Wingham and Hannah Reidy merged]	1	12 June 2015
Summary CV for supervisor (student research) [Chris Barker CV]	1	01 July 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Research Flow Chart]	1	01 April 2015
Validated questionnaire [RQ]	1	12 June 2015
Validated questionnaire [CAPE 42 item]	2	01 July 2015
Validated questionnaire [FAQ validated]	2	01 July 2015
Validated questionnaire [FESFS-2013 validated]	2	01 July 2015
Validated questionnaire [GPTS validated]	2	01 July 2015
Validated questionnaire [PANAS Validated]	2	01 July 2015
Validated questionnaire [PSYRATS-D validated]	2	01 July 2015

Validated questionnaire [RG UK]	1	01 July 2015
Validated questionnaire [SIAS validated]	1	01 July 2015
Validated questionnaire [SNI validated]	2	01 July 2015
Validated questionnaire [SOS validated]	2	01 July 2015
Validated questionnaire [UCLA loneliness validated]	2	01 July 2015
Validated questionnaire [SEAT validated]	1	01 July 2015

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

Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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/

15/LO/1197	**Please quote this number on all correspondence**

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

Yours sincerely

Pp [redacted]

Mr John Richardson
Chair

[redacted]

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Mr Dave Wilson*
Mrs Angela Williams, NoCLOR

NRES Committee London - Camberwell St Giles

Attendance at Sub-Committee of the REC meeting on 14 August 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Jennifer Bostock	Philosopher of Psychiatry	Yes	
Mr John Richardson (Chair)	Retired Director of COREC: former Ecumenical Officer for Churches Together in South London	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Claudia Harrison	REC Assistant

Appendix 5: Participant Information Sheet

South West London and St George's NHS
Mental Health NHS Trust

PARTICIPANT INFORMATION SHEET

PROJECT TITLE: UNDERSTANDING SOCIAL INTERACTIONS IN CLINICAL POPULATIONS: AN EVALUATION OF A VIRTUAL FLATMATE

We would like to invite you to take part in a study looking at people's reactions to virtual environments. This project is part of two doctorate research projects. Please take time to read the following information carefully and ask us if there is anything that is not clear to you or if you would like more information. Alternatively, one of our team will go through the information sheet with you and answer any questions you have.

Why have I been invited to take part in the study?
You have been invited to take part in the study because we are looking for volunteers who are 18 years old or above. We are specifically looking for individuals who are currently involved with community mental health services. We hope to involve 60 participants for this study.

Do I have to take part?
It is up to you to decide whether or not to take part. We will describe the study and go through this information sheet. If you do decide to take part you will be given this information sheet to keep, and be asked to sign a consent form. In this consent for we will ask to have access your medical notes. This is only because relevant sections of your medical notes may be required to be looked at by the research team should my care coordinator not be able to access this information on the researcher's behalf. This is optional and your participation does not depend on it. You are still free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

What will happen if I decide to take part?
If you decide to take part in this study, we will invite you to visit our virtual reality suite at University College London for a one-off appointment. We expect that this appointment will take a maximum of 2 hours and you will be reimbursed for your time. Our researchers can meet you on any part of your journey to assist you with travelling to the location.

The main thing you will be asked to do will be to explore a virtual environment. Brief questionnaires will be used to assess how realistic the environment is. You will be asked to complete the following steps:

Part 1 - Questionnaires: Prior to entering the virtual environment you will be asked to complete a number of brief questionnaires about your feelings at the time and some background information.

Part 2 - Virtual Reality: After completion of the questionnaire, we will invite you to enter the virtual reality room representing a student flat. You will be given instructions in the use of virtual reality before you start. You will be asked to wear glasses that produce three-dimensional images and you will be invited to remain in the student flat for a brief time and

interact with a virtual flatmate character. The whole scenario will last 3 minutes. There will be another researcher directly outside the virtual suite at all times to ensure that you feel comfortable during the exercise. During your time in the virtual environment your interaction with the virtual flatmate character will be video recorded by an unobtrusive camera in the ceiling to help us review how you and the virtual character move around the room. The video footage will not be shown to anyone outside the research team and will be destroyed when the research project has been completed.

Part 3 – Questionnaires: Following the virtual reality exercise, we will ask you to complete some final questionnaires about your feelings at that time and to provide feedback on the quality of the virtual interaction with a flat mate avatar.

Part 4 – Interview: A brief interview will as about your experience of the virtual environment.

Will I be paid for my participation?
All participants will be paid £12.50 to thank them for their time. Any travel expenses will be reimbursed.

Are there any disadvantages to taking part?
When people use virtual reality systems they occasionally experience a degree of nausea. If at any time you wish to stop taking part in the study due to this or any other reason, please just say so and we will stop.

There has been some research that suggests that people using virtual reality might experience some disturbance in vision afterwards. No long term studies are known to us, but the studies which have conducted testing after about 30 minutes, and have found that the effect is still sometimes there. It is advised that you do not drive a car, motorcycle, or operate complicated machinery in the four hours following virtual reality. There have been various reported side effects of using virtual reality equipment, such as 'flashbacks'. With any type of video equipment there is a possibility that an epileptic episode may be generated. This, for example, has been reported for computer video games. **If you have epilepsy, please tell us. We would not want you to take part in study in this case.**

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get from the study will help improve understanding of social interactions for people under the care of mental health services and could help inform better practices and treatments for the future.

What if there is a problem?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Miriam Fornells-Ambrojo who is

the Chief Investigator for the research and is based at the Department of Clinical, Educational and Health Psychology, University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Will my taking part in the study be kept confidential?
All the information obtained will be kept strictly confidential and you will not be identified. This is done by allocating you an anonymous participant number under which to collect data in the experiment. All data will be collected and stored in accordance with the Data Protection Act 1998.

What will happen if I don't want to carry on with the study?
If you withdraw from the study, we will destroy all your identifiable information e.g. name, contact number, care coordinator etc. However, we may use non-identifiable data that we have collected up until your withdrawal e.g. data from questionnaires that are assigned an anonymous participant number.

What will happen to the results of the research study?
The results of the research will be analysed in order to complete a doctorate in clinical psychology and the findings will be published in a scientific journal and may be presented at conferences. You will not be identified in any report or publication. Please inform Hannah Reidy or Gail Wingham if you would like a copy of the study's findings.

Who is organising this study?
The research is being organised and funded by UCL.

Who has reviewed the study?
All research in the NHS is looked at by an independent group people, called a Research Ethics Committee, to protect your interests. The study has been reviewed and given favourable opinion by Camberwell St Giles Research Ethics Committee (Project ID 15/LO/1197).

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

Research Team Members:

Hannah Reidy, Trainee Clinical Psychologist, Department of Clinical, Educational and Health Psychology, University College London. [redacted]

Gail Wingham, Trainee Clinical Psychologist, Department of Clinical, Educational and Health Psychology, University College London. [redacted]

Dr Miriam Fornells-Ambrojo, Lecturer in Clinical Psychology, Department of Clinical, Educational and Health Psychology, University College London. [redacted]

Appendix 6: Participant Consent Form

Consent Form
Version 3: 17.06.15
THIS STUDY HAS BEEN APPROVED BY
CAMBERWELL ST-GILES NRES COMMITTEE LONDON
Project ID 15/LO/1107

Patient Identification Number:
Date:

CONSENT FORM

PROJECT TITLE: UNDERSTANDING SOCIAL INTERACTIONS IN CLINICAL POPULATIONS: AN EVALUATION OF A VIRTUAL FLATMATE

Name of Researchers: Hannah Reidy & Gail Wingham

Thank you for your interest in taking part in this research. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to take part. You will be given a copy of this Consent Form to keep and refer to at any time.

1. I confirm that I have read and understand the information sheet dated 15.01.15 (Version 1) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that if I decide to withdraw from the study, any identifiable data collected up to this point will be destroyed but non-identifiable data may be used for the research. ☐
4. I understand that I must not take part in the study if I have epilepsy. ☐
5. I understand that the information I have submitted will be published as a report and I will be sent a copy if I request this. Confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications. ☐
6. I understand that data collected during the study may be looked at by individuals from University College London, from regulatory authorities such as external auditors checking how the research is being run, or from the NHS Trust where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records. ☐
7. *Optional:* I understand that relevant sections of my medical notes may be required to be looked at by the research team should my care coordinator not be able to access this information on the researcher's behalf. I give permission for the research to have access to my medical notes, only for the duration that I am involved in the research. ☐
8. I agree that the research project named above has been explained to me to my satisfaction and I agree to take part in this study. ☐

Name of Participant:.....

Signature:.....
Date:.....

Name of researcher
taking consent :.....

Signature:.....
Date:.....

If you would like to receive a copy of the research findings once the study is complete please tick here: ☐

When completed: 1 for participant, 1 for researcher, 1 for documenting in medical notes

Appendix 7: Green et al. Paranoid Thoughts Scale

(Green et al., 2008)

Version 2 01.07.15

GPTS

Participant no:

Instructions: Please read each of the statements carefully.
They refer to thoughts and feelings you may have had about others **over the last month**.
Think about the last month and **indicate the extent of these feelings** from 1 (Not at all) to 5 (Totally).
Please complete both **Part A and Part B**.
(N.B. Please do not rate items according to any experiences you may have had under the influence of drugs.)

Part A

Statement	Not at all		Somewhat		Extremely
1. I spent time thinking about friends gossiping about me	1	2	3	4	5
2. I often heard people referring to me	1	2	3	4	5
3. I have been upset by friends and colleagues judging me critically	1	2	3	4	5
4. People definitely laughed at me behind my back	1	2	3	4	5
5. I have been thinking a lot about people avoiding me	1	2	3	4	5
6. People have been dropping hints for me	1	2	3	4	5
7. I believed that certain people were not what they seemed	1	2	3	4	5
8. People talking about me behind my back upset me	1	2	3	4	5
9. I was convinced that people were singling me out	1	2	3	4	5
10. I was certain that people have followed me	1	2	3	4	5
11. Certain people were hostile towards me personally	1	2	3	4	5
12. People have been checking up on me	1	2	3	4	5
13. I was stressed out by people watching me	1	2	3	4	5
14. I was frustrated by people laughing at me	1	2	3	4	5
15. I was worried by people's undue interest in me	1	2	3	4	5
16. It was hard to stop thinking about people talking about me behind my back	1	2	3	4	5

Part B

Statement	Not at all		Somewhat		Extremely
1. Certain individuals have had it in for me	1	2	3	4	5
2. I have definitely been persecuted	1	2	3	4	5
3. People have intended me harm	1	2	3	4	5
4. People wanted me to feel threatened, so they stared at me	1	2	3	4	5
5. I was sure certain people did things in order to annoy me	1	2	3	4	5
6. I was convinced there was a conspiracy against me	1	2	3	4	5
7. I was sure someone wanted to hurt me	1	2	3	4	5
8. I was distressed by people wanting to harm me in some way	1	2	3	4	5
9. I was preoccupied with thoughts of people trying to upset me deliberately	1	2	3	4	5
10. I couldn't stop thinking about people wanting to confuse me	1	2	3	4	5
11. I was distressed by being persecuted	1	2	3	4	5
12. I was annoyed because others wanted to deliberately upset me	1	2	3	4	5
13. The thought that people were persecuting me played on my mind	1	2	3	4	5
14. It was difficult to stop thinking about people wanting to make me feel bad	1	2	3	4	5
15. People have been hostile towards me on purpose	1	2	3	4	5
16. I was angry that someone wanted to hurt me	1	2	3	4	5

Appendix 8: Prompt sheet for virtual reality scenario

1. What do you like about flat sharing?

2. How do you choose flatmates?

3. What makes a good flatmate?

4. What's the best thing about this flat?

Appendix 9: Full script of conversation with avatar

A=Avatar

P=Participant

A: Hi my name is Mark thanks for coming. What’ s your name?”

P: (Tells avatar their name)

A: Thanks, OK I’ m ready!

P: **What do you like about flat sharing**?

A: I enjoy meeting new people... I have made new friends this way...its great getting to know them, have a laugh... mhm... and it helps to keep the cost of living low so you can live in a better area!

P: **What do you ask potential flatmates before going ahead?**

A: Well, I always meet them in person and get a sense of what they are like... I ask them what they are looking for in a shared flat, what is a typical day like for them, what music they like, if they smoke, if they are lazy about house chores... mhm.. If they like having friends around ... Oh, yeah it is also good to ask them what has been their best and worse experience of flat sharing!

P: In your experience... who makes a great flatmate?

A: Mhm... good question... don’ t know... I’ m trying to think ....someone how is easygoing, friendly and fun but who also can give you space... It is also good to have something in common with them, like love for sport, or music...It’ s hard to answer because I think it really depends on the person... I’ ve got on with people who were completely different from me, sometimes it just works.

P: **What is the best thing about your flat?**

A: The terrace and the view! Come and have a look! (moves to the window)

A: It’ s amazing to have all this outside space, in the summer we practically live outside! We have great BBQs....

(Phone rings – avatar answers and speaks discreetly on the phone)

A: Hello? Okay..yeah I can be there!okay bye.

A: Oh, sorry but I need to go now... anyway thank you for coming and maybe we can continue the interview some other time?

P: (Answers)

SCENARIO ENDS

Appendix 10: The Psychotic Symptoms Rating Scale – Delusions (PSYRATS-D; Haddock et al., 1999)

1 Amount of preoccupation with delusions

0 No delusions, or delusions which the subject thinks about less than once a week
1 Subject thinks about beliefs at least once a week
2 Subject thinks about beliefs at least once a day
3 Subject thinks about beliefs at least once an hour
4 Subject thinks about delusions continuously or almost continuously

2 Duration of preoccupation with delusions

0 No delusions
1 Thoughts about beliefs last for a few seconds, fleeting thoughts
2 Thoughts about delusions last for several minutes
3 Thoughts about delusions last for at least 1 hour
4 Thoughts about delusions usually last for hours at a time

3 Conviction

0 No conviction at all
1 Very little conviction in reality of beliefs, < 10%
2 Some doubts relating to conviction in beliefs, between 10-49%
3 Conviction in belief is very strong, between 50-99 %
4 Conviction is 100 %

4 Amount of distress

0 Beliefs never cause distress
1 Beliefs cause distress on the minority of occasions
2 Beliefs cause distress on < 50% of occasions
3 Beliefs cause distress on the majority of occasions when they occur between 50-99% of time
4 Beliefs always cause distress when they occur

5 Intensity of distress

0 No distress
1 Beliefs cause slight distress
2 Beliefs cause moderate distress
3 Beliefs cause marked distress
4 Beliefs cause extreme distress, could not be worse

6 Disruption to life caused by beliefs

0 No disruption to life, able to maintain independent living with no problems in daily living skills. Able to maintain social and family relationships (if present)
1 Beliefs cause minimal amount of disruption to life, e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support
2 Beliefs cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The patient is not in hospital although may live in supported accommodation or receive additional help with daily living skills
3 Beliefs cause severe disruption to life so that hospitalisation is usually necessary. The patient is able to maintain some daily activities, self-care and relationships while in hospital. The patient may be also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships
4 Beliefs cause complete disruption of daily life requiring hospitalization. The patient is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted

Appendix 11: Social Interaction Anxiety Scale

(SIAS; Mattick & Clarke, 1998)

Instructions: For each item, please circle the number to indicate the degree to which you feel the statement is characteristic or true for you. The rating scale is as follows:

0 = **Not at all** characteristic or true of me
1 = **Slightly** characteristic or true of me
2 = **Moderately** characteristic or true of me
3 = **Very** characteristic or true of me
4 = **Extremely** characteristic or true of me

Characteristic	Not at all	Slightly	Moderately	Very	Extremely
1. I get nervous if I have to speak with someone in authority (teacher, boss, etc.)	0	1	2	3	4
2. I have difficulty making eye contact with others	0	1	2	3	4
3. I become tense if I have to talk about myself or my feelings	0	1	2	3	4
4. I find it difficult to mix comfortably with the people I work with	0	1	2	3	4
5. I find it easy to make friends my own age	0	1	2	3	4
6. I tense up if I meet an acquaintance in the street	0	1	2	3	4
7. When mixing socially, I am uncomfortable	0	1	2	3	4
8. I feel tense if I am alone with just one other person	0	1	2	3	4
9. I am at ease meeting people at parties, etc	0	1	2	3	4
10. I have difficulty talking with other people	0	1	2	3	4
11. I find it easy to think of things to talk about	0	1	2	3	4
12. I worry about expressing myself in case I appear awkward	0	1	2	3	4
13. I find it difficult to disagree with another's point of view	0	1	2	3	4
14. I have difficulty talking to attractive persons of the opposite sex	0	1	2	3	4
15. I find myself worrying that I won't know what to say in social situations	0	1	2	3	4
16. I am nervous mixing with people I don't know well	0	1	2	3	4
17. I feel I'll say something embarrassing when talking	0	1	2	3	4
18. When mixing in a group, I find myself worrying I will be ignored	0	1	2	3	4
19. I am tense mixing in a group.	0	1	2	3	4
20. I am unsure whether to greet someone I know only slightly	0	1	2	3	4

Appendix 12: Subjective Measure of Trust

How TRUSTWORTHY did Mark come across?

Not at all						Very much
1	2	3	4	5	6	7

Appendix 13: Focus of Attention Questionnaire

(FAQ; Woody, 1996)

Rate each answer between 1 and 5.

1 = not at all, 5 = very much

Self-focus	**Not at all**		**Somewhat**		**Very much**
1. I was focusing on what I would say or do next	1	2	3	4	5
2. I was focusing on the impression I was making on the other person	1	2	3	4	5
3. I was focusing on my level of anxiety	1	2	3	4	5
4. I was focusing on my internal bodily reactions (for example, heart rate)	1	2	3	4	5
5. I was focusing on past social failures	1	2	3	4	5
Other-focus	**Not at all**		**Somewhat**		**Very much**
1. I was focusing on the other person's appearance or dress	1	2	3	4	5
2. I was focusing on the features of conditions of the physical surroundings (e.g. appearance, temperature)	1	2	3	4	5
3. I was focusing on how the other person might be feeling about himself/herself	1	2	3	4	5
4. I was focusing on what I thought of the other person	1	2	3	4	5
5. I was focusing on what the other person was saying or doing.	1	2	3	4	5

Appendix 14: Detection of Contingency and Attention Checks

Scenario Feedback and Checks

1. In your experience of your interaction with the virtual flatmate, was there any relationship between what you did and the virtual flatmate's actions? Please Circle

   Yes No

2. If you experience any relationship between what you did and the virtual flatmates actions, what did you notice? Please write your comments in the space below.

Please circle whether the following statements are true or false

1. One reason that Mark the virtual flatmate gave for why he likes flat sharing is that he has made new friends

   True False

2. When asked who makes a good flatmate, Mark mentioned that the most important thing is that they are tidy.

   True False

Appendix 15: Sense of Presence Questionnaire

(Slater et al., 1998)

The following questions relate to your recent virtual reality experience. Please read each question and answer as you are instructed in each one.

1. Please rate the sense of actually being in the flat

Abnormal of being Experience	1	2	3	4	5	6	7	Normal experience in a flat

2. To what extent were there times during the experience when the virtual flat became "reality" for you, and you almost forgot about the "real world" of the laboratory in which the whole experience was actually taking place?

At no time	1	2	3	4	5	6	7	Almost all the time

3. When you think back about your experience, do you think of the virtual flat more as "images that you saw", or more as "somewhere you visited"?

Images that I saw	1	2	3	4	5	6	7	Somewhere that I visited

4. During the experience, which was strongest on the whole, your sense of being in the virtual flat, or being in the real world of the laboratory

Laboratory	1	2	3	4	5	6	7	Virtual flat

5. Consider your memory of being in the flat. How similar is the memory of the virtual reality experience to other memories of "real places" in terms of: visual quality, size, colour and how realistic and vivid it seems in your imagination?

Not at all Similar	1	2	3	4	5	6	7	Very similar

6. During the experience, did you think to yourself that you were actually "just standing in a room wearing equipment" or did the virtual flat "overwhelm" you? The virtual flat overwhelmed me…

Not at all	1	2	3	4	5	6	7	All of the time

Appendix 16: Semi-Structured Qualitative Interview

Qualitative Interview

Q1. What did you think of Mark?

Q2. Based on you experience of talking to Mark, what kind of impression did you have of him? How did he make you feel?

Q3. Did you feel (instinctively) you could trust him? What kind of things made you feel that you could or couldn't trust him?

Q4. How did you feel about Mark as your interaction went along? Did you feel that he was honest and trustworthy? Why/Why not?

Q5. What impressions do you think Mark may have got of you? Why?

Q8. What did you think of the VR environment? Do you have any feedback on the VR experience?