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**The relationship between childhood trauma and paranoia: A study
of specificity and underlying theoretical mechanisms.**



THE UNIVERSITY
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Doctorate in Clinical Psychology

The University of Edinburgh

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Name: David Andrew Carmichael

Title: The relationship between childhood trauma and paranoia: A study of specificity and underlying theoretical mechanisms

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Date: 1st March 2019

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Overview of Thesis

This thesis follows a portfolio format and the following information provides a brief overview of each chapter of the thesis:

Chapter 1 is a systematic review and meta-analysis of the literature examining the evidence for specific associations between childhood sexual (CSA), physical (CPA) and emotional abuse (CEA) and physical (CPN) or emotional neglect (CEN) and paranoia across community and clinical samples. Chapter 2 is an empirical research article which aimed to evaluate whether negative self and negative-other core schema mediate the relationship between childhood trauma and paranoia in community (Study 1) and clinical samples (Study 2).

Chapter 1 and Chapter 2 were written for submission to Clinical Psychology Review (Appendix H) and Psychosis: Psychological, Social and Integrated Approaches (Appendix I), respectively.

Word Count: 15,505 (excluding abstracts, figures, tables, references and appendices)

Thesis Abstract

Purpose: While biogenetic theories have traditionally dominated understandings of psychosis, there is now a large body of evidence suggesting a causal relationship between childhood trauma and psychosis. We sought to further study this relationship by adopting a psychotic experience specific approach and applying two of Bradford Hill's causality criteria, namely specificity and underlying theoretical mechanisms, to the relationship between childhood trauma and paranoia.

Method: Chapter 1 was a systematic review and meta-analysis that sought to examine the magnitude of the association between childhood sexual (CSA), physical (CPA) and emotional abuse (CEA) and physical (CPN) or emotional neglect (CEN) and paranoia across community and clinical samples. Chapter 2 is an empirical research study that sought to test whether negative core schema mediated the relationship between childhood trauma and paranoia. Study 1 sought to test these relationships within the general population, whereas Study 2 aimed to test these in a clinical sample of people with persecutory delusions. We also sought to pilot a new measure of negative core schema, The Schema Rating Scale (SCIRATS). Correlation and mediation analysis were utilised to test our empirical study hypothesis.

Results: Our meta-analysis found small associations between all forms of childhood trauma and paranoia examined, however the magnitude of the association may be somewhat greater for CEA and CPA than for the other forms of childhood trauma examined and paranoia. In Study 1, we found that negative-self, negative-other and both negative-self and negative-other core schema mediated the relationship between childhood trauma and paranoia. We found similar results when repeating these analyses with the SCIRATS. In Study 2, we found significant associations between childhood trauma and negative-self core schema that remained significant on the SCIRATS. Negative-self and negative-other core schema were also significantly associated with paranoia however, when we repeated this analysis with the SCIRATS, only negative-self core schema remained significant. We found no significant association between childhood trauma and paranoia. Positive initial feedback on the SCIRATS would suggest participants view this as an acceptable measure.

Conclusions: Whilst acknowledging the limitations associated with our studies, our findings suggest that while there appears to be a general association between the forms of childhood trauma we examined and paranoia, this relationship may be somewhat greater for CEA and CPA and paranoia. They are consistent with cognitive models of psychosis and suggest that negative core schema may be important underlying mechanisms in the relationship between childhood trauma and paranoia. We make recommendations for future research to further examine the evidence for specificity and recommend that individuals with psychosis should be asked about childhood trauma and that future research should further examine the potential benefits of trauma-informed formulation and psychological therapies targeting negative core schema in reducing paranoia.

Lay Summary

Biological theories have typically dominated understandings of psychosis, however in recent years there has been growing awareness that psychosis is likely to develop from a number of interacting factors. One factor that has recently gained prominence within the research literature is the influence of childhood trauma. There is now a significant body of literature suggesting a causal relationship between childhood trauma and psychosis, where it has been claimed this can account for 33% of cases of psychosis.

In light of these findings, researchers have begun to suggest theories to explain this relationship, where a variety of genetic, biological and psychological theories have been proposed. It has been argued however that this approach is problematic because psychosis includes a wide variety of different experiences and that is unlikely one theory has the power to explain all psychotic experiences. This thesis focused on one particular form of psychotic experience, persecutory delusions. Persecutory delusions can be understood as being at the most severe end of a spectrum of paranoia, where mild. Because they are linked, studying paranoia in the general population might help us to understand persecutory delusions.

Part 1 of this thesis is a review of research studies and a meta-analysis. A meta-analysis refers to when multiple studies are entered into one statistical analysis so that we draw conclusions from the existing literature. We examined whether there were bigger relationships between specific types of childhood trauma and paranoia in the general population and in people with persecutory delusions. While we found relationships between all forms of childhood trauma and paranoia examined, the relationship was somewhat greater for childhood emotional abuse and childhood physical abuse. These findings may suggest that experiences of childhood emotional abuse and childhood physical abuse, may be particularly important in the development of paranoia however further research is required before any firm conclusions can be drawn.

Part 2 is a research study that aimed to test theories called ‘cognitive models of psychosis’. These theories suggest that if a person experiences difficult or traumatic experiences during childhood, they are likely to develop negative beliefs about themselves and other people. These negative beliefs are thought to make people more vulnerable to developing paranoia in the future. Study 1 explored if negative beliefs regarding self and others explained some of the relationship between childhood trauma and paranoia in the general population, whereas Study 2 explored this in people with persecutory delusions. Study 1 found that these beliefs did explain some of the relationship between childhood trauma and paranoia. We did not recruit enough people to test this in Study 2, however we found relationships between childhood trauma, negative-beliefs about self and others and paranoia.

We recommend that people experiencing paranoia or persecutory delusions should be asked about childhood trauma, and may benefit from the opportunity to make sense of links between past experiences and paranoia, where experience of emotional or physical abuse during childhood may be worthy of particular consideration. We

also argue that further research should be conducted in order to establish whether working on negative beliefs about self and others through formal psychological therapies reduces paranoia.

Chapter 1: Systematic Review and Meta-Analysis

The evidence for relationships between specific forms of childhood trauma and paranoia: A meta-analytic review

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Abstract

Aims: To examine and synthesise the evidence for specific associations between childhood sexual (CSA), physical (CPA) and emotional abuse (CEA) and physical (CPN) or emotional neglect (CEN) and paranoia.

Method: We conducted a meta-analytic review to examine the magnitude of the association between specific forms of childhood trauma and paranoia across community and clinical samples.

Results: We identified a total of 21 relevant studies. 17, 16, 10, 6 and 6 were entered into meta-analytic calculations for the association between CSA, CPA, CEA, CPN, CEN and paranoia respectively. We found small associations between CSA (N: 19836, $r = 0.16$, 95% CI 0.11 to 0.23, I^2 88%; low quality), CPN (N: 1870, $r = 0.16$, 95% CI 0.04 to 0.27, I^2 76%; very low quality) and CEN (N: 2160, $r = 0.14$, 95% CI 0.02 to 0.25, I^2 80%, very low quality evidence) and paranoia. The magnitude of the relationship between CEA and paranoia (N: 2945, $r = 0.23$, 95% CI 0.12-0.33, I^2 87%; low quality) and CPA and paranoia (N: 16833, $r = 0.19$, 95% CI 0.10 to 0.27, I^2 95%; low quality) was slightly larger than for other forms of childhood trauma.

Conclusions: While the association between CEA and CPA and paranoia initially appeared somewhat greater than for other forms of childhood trauma, methodological limitations result in significant caution being required when assessing the evidence for specificity. We make recommendations for future research in order to address these limitations and to further examine the evidence for a causal relationship between childhood trauma and psychosis.

Keywords: Childhood trauma, psychosis, paranoia, specificity, meta-analysis

1. Introduction

Adverse childhood experiences (ACEs) refer to a number of negative early life events including sexual, physical or emotional abuse, physical or emotional neglect, witnessing domestic violence or living with household members who use substances, have a history of mental health problems or criminality (Ashton, Bellis & Hughes, 2016; Felitti et al, 1998). The concept of childhood adversity is broad however (Trotta, Murray & Fisher, 2015), and alternative definitions include experiences such as bullying, parental loss or separation, war-related trauma, or natural disasters (Butchart, Harvey, Mian, Furniss & Kahane, 2006). ACEs are relatively common; where an estimated 46-50% of the general population have a history of at least one ACE (Ashton et al, 2016; Felitti et al, 1998). Experiencing four or more ACEs however has been found to result in increased risk of a number of negative health and social outcomes. These include physical inactivity, obesity, smoking, substance abuse, sexually transmitted disease, unintended pregnancy, increased risk of intimate partner violence, violence and incarceration, foetal death, heart disease, cancer, COPD, lung disease, mental health difficulties, suicide and premature death (Bellis, Hughes, Leckenby, Perkins & Lowey, 2014; Couper & MacKie, 2016; Felitti et al, 1998). More specific to mental health, childhood adversity has been found to be strongly associated with a history of lifetime mood, anxiety, dissociative, eating and personality disorders (Chen et al, 2010; Green et al, 2010; Kessler et al, 2010; Lange, Kooiman, Huberts & van Oostendorp, 1995; McLaughlin et al, 2010).

Despite the well-established relationship between childhood adversity and mental health difficulties, biogenetic theories have typically dominated understandings of psychosis (Read, van Os, Morrison & Ross, 2005; Read, Bentall & Fosse, 2009). In recent years however, there has been increased recognition that psychosis is likely to develop from a number of interacting factors (Freeman & Fowler, 2009; Garety, Kuipers, Fowler, Freeman & Bebbington, 2001; Garety, Bebbington, Fowler, Freeman & Kuipers, 2007). Perhaps unsurprisingly, one psychological factor that has recently gained prominence within the psychosis research literature is the influence of childhood adversity (Freeman & Fowler, 2009).

Early interest in the potential relationship between childhood adversity and psychosis appears to have arisen following findings of high prevalence rates of childhood adversity amongst individuals with psychosis. In a review of the literature, Read et al (2005) examined the prevalence of childhood sexual (CSA) or physical abuse (CPA) in individuals with psychosis and found rates of approximately 69% for women and 60% for men. The paper acknowledged however these rates were likely to be influenced by under-reporting and stated that when emotional abuse and neglect were also included, the prevalence of a history of childhood adversity increased to approximately 85% of men and 75-100% of women with psychosis. In addition, the review found evidence of significant relationships between a history of childhood adversity and severity of psychosis and early evidence of a possible causal relationship from prospective cohort studies. The authors highlighted that research into a possible relationship between childhood adversity and psychosis is a relatively recent phenomenon and suggest this might be due to a rigid adherence to biological/diagnostic paradigms, concerns regarding reliability of reporting or failing to ask about a history of childhood adversity due to concerns this may result in a deterioration in the individual's mental health (Read et al, 2005). Despite these concerns, disclosures of childhood adversity have been found to be as reliable in individuals with psychosis as in other groups (Read et al, 2005) and there is no evidence to suggest that asking individuals with psychosis about childhood adversity results in any adverse outcomes (Frueh et al, 2009; Lothian & Read, 2002; Mueser et al, 2008; Read, Hammersley & Rudegeair, 2007; van den Berg & van der Gaag, 2012).

Subsequent reviews and meta-analyses have continued to find significant associations between childhood adversity and psychosis, reporting moderate effect sizes for the magnitude of this relationship (Ackner, Skeate, Patterson & Neal, 2013; Bailey et al, 2018; Bendall et al, 2013; Matheson, Shepherd, Pinchbeck, Laurens & Carr, 2012; Trotta et al, 2015; van Dam et al, 2012; Varese et al, 2012). Severity and frequency of childhood adversity have also been found to predict severity of psychosis (Schenkel, Spaulding, DiLillo & Silverstein, 2005). The strength of this association is further supported by findings that significant associations persist even when controlling for other recognised risk factors for psychosis, such as genetic risk,

familial history of psychosis, cannabis use and ethnicity (Gibson, Alloy & Ellman, 2016). A number of prospective cohort studies have also found that childhood adversity predicts the onset of psychosis, highlighting the temporal relationship between these two factors (Arseneault et al 2011; Mäkikyrö et al; 1998; Cutajar et al; 2010; Janssen et al, 2004). In addition, cessation of trauma has been found to predict significant reductions in severity of psychotic experiences (Kelleher et al, 2013). Furthermore, there is evidence of a dose-response relationship, where the number of childhood adversities experienced has been found to predict the subsequent risk and severity of psychosis (Bentall, Wickham, Shevlin & Varese, 2012; Trauelsen et al, 2015; Whitfield, Dube, Felitti & Anda, 2005). In light of the above findings, it has been claimed that the relationship between trauma and psychosis is causal, that childhood adversity can account for 33% of cases of psychosis and that childhood adversity confers approximately the same risk for psychosis as smoking does for lung cancer (Bailey et al, 2018; Bentall et al, 2012; Varese et al, 2012).

Despite the above findings, strength of association, consistency of findings, temporality and dose-response effects are not sufficient alone to demonstrate a causal relationship between childhood adversity and psychosis (Bentall et al, 2012). In a seminal epidemiological paper, Austin Bradford Hill (1965) outlined nine criteria required for establishing causation. In addition to the strength of the association, consistency, temporality and dose-response relationships, Bradford Hill recommended that the specificity of effects, plausibility, coherence, experimentation and analogy are key criterion when evaluating causal relationships between two outcomes. Bentall and colleagues (Bentall & Fernyhough, 2008; Bentall et al, 2012; Bentall et al, 2014) argue that specificity is a key consideration when considering the relationship between childhood trauma and psychosis, where this refers to an association between one form of exposure and outcome, yet not others (Bradford Hill, 1965).

The lack of previous attention to specificity appears to be due to a tendency within the literature to treat individuals with psychosis as a homogenous group and to examine the association between childhood adversity and psychosis based upon odds of a schizophrenia spectrum diagnosis or severity of total positive symptoms (e.g. Alameda et al, 2017; Baudin et al, 2017; see Varese et al, 2012). This approach is

problematic given the heterogenic nature of psychosis, where psychotic experiences may include hallucinations, delusions, thought disorder and negative symptoms such as poor self-care, reduced emotional expression, withdrawal, listlessness, apathy or inability to enjoy previously pleasurable or valued activities. In addition, individuals may experience hallucinations across different sensory modalities or different forms of delusions such as ideas of reference, persecutory or grandiose delusions. As a result, it is likely that while individuals may have a similar diagnosis, the actual experience of psychosis may be highly diverse and individual (British Psychological Society (BPS), 2014; National Institute for Health and Care Excellence (NICE), 2014). These concerns would appear to be supported by the literature, where the experience of psychosis has been found to cluster into three and more recently, five distinct factors (positive symptoms, negative symptoms, cognitive disorganisation + depression and mania) (Demjaha et al, 2009; Liddle, 1987; van Os & Kapur, 2009).

Bentall and colleagues (Bentall & Fernyhough, 2008; Bentall et al, 2012; Bentall et al, 2014) outline some of the difficulties associated with the lack of focus on specificity within the literature. Bentall et al (2014) state that, in light of the evidence for a causal relationship between childhood adversity and psychosis, the attempt to identify underlying mechanisms has focused upon identifying the characteristics shared by different forms of childhood adversity. The authors highlight that this has led to researchers positing mechanisms such as social defeat (Selten & Cantor-Graae, 2005) abnormal dopaminergic functioning (Howes & Murray, 2014) and childhood adversity causing neurodevelopmental changes to the brain (The Traumagenic Neurodevelopmental model; Read, Perry, Moskowitz & Connolly, 2001). These changes are thought to include over-activity of hypothalamic–pituitary (HPA) axis; dopamine, serotonin and norepinephrine abnormalities; and structural differences such as hippocampal damage, cerebral atrophy, ventricular enlargements and reversed cerebral asymmetry as mechanisms linking childhood adversity to psychosis (Read, Fosse, Moskowitz & Perry, 2014). The authors state these models are limited as one underlying mechanism is unlikely to be able to account for all forms of psychotic experience. Furthermore, they argue that different forms of childhood adversity are likely to impact on separate psychological processes, such as attachment representations, self-concept, cognitive styles and coping responses, and

that, while there may be some degree of overlap, different processes are likely to be associated to a lesser or greater extent with different forms of psychotic experience.

Given that a single underlying process is unlikely to be able to account for the relationship between childhood adversity, and that different forms of adversity are likely to impact on different underlying psychological processes and be associated with different psychotic experiences as a result, Bentall and colleagues (Bentall & Fernyhough, 2008; Bentall et al, 2012; Bentall et al, 2014) advocate for further research into specific associations between certain forms of childhood adversity and psychotic experiences, arguing that this will enhance the evidence for a causal relationship by demonstrating specificity, yet also allow for the identification of psychological mechanisms underlying associations between specific forms of childhood adversity and specific psychotic experiences, furthering the effort to meet Bradford Hill's (1965) plausibility criteria. Despite this, Bentall et al (2014) echo Bradford Hill's caution that specificity should not be overemphasised, highlighting that most forms of childhood adversity are likely to have a general effect on psychological processes such as emotional regulation, that childhood adversities are unlikely to have a 'pure' effect on one process but not another (e.g. CSA may impact upon attachment representations in addition to dissociation), that childhood adversities tend to co-occur and that one form of psychotic experience can often give rise to another.

Indeed, Bradford Hill (1965) argued that while there may be multiple causes of a single outcome, if the association between one cause and the outcome is stronger than other factors, then this demonstrates specificity. In support of their arguments, Bentall and colleagues review the literature and highlight evidence of specific relationships between CSA and auditory hallucinations, thought disorder and neglect and victimisation experiences (e.g. bullying, physical abuse) and persecutory delusions (Bentall et al, 2012; Bentall et al 2014).

While it is beyond the scope of this paper to review the literature regarding underlying mechanisms in detail, dissociation has been suggested as the underlying mechanism linking CSA to auditory hallucinations (see Bentall et al 2014; Read et al, 2005), whereas in the case of paranoia, forms of trauma associated with victimisation

or the ‘intention-to-harm’ are thought to disrupted attachment relationships, leading to the development of negative core schema regarding the self and others and subsequently predisposing individuals to the development of persecutory delusions (see Fowler et al, 2006; Garety & Freeman, 2013; Gracie et al, 2007; Read et al, 2005; vanNierop et al, 2014).

This review will focus on the evidence for specific relationships between different forms of childhood adversity and paranoia. The rationale for focusing on paranoia was that it is thought to be one of the most common psychotic experience, occurring in 70% of first-episode, 50% of cases thereafter (Freeman, 2007; Freeman & Garety, 2014) and has been found to be the most likely delusions to be acted upon (Wessely et al, 1993). This review will also adhere to continuum models of paranoia (see Freeman et al, 2005; Freeman & Garety, 2000; Freeman & Garety, 2014) where paranoia is thought to exist on a spectrum ranging from common social evaluative concerns or feelings of vulnerability, to clinically significant persecutory delusions at the most severe range of the spectrum, where these are defined as an unfounded belief that harm is occurring, or is going to occur to them and that the perpetrator has the intention to cause that harm (see Peters et al, 2016). As a result, the term paranoia will be used throughout the review to refer to both paranoid thoughts within the general population and persecutory delusions in individuals with psychosis.

The literature is further complicated by wide variety of childhood adversities studied. Gibson et al (2016) highlight that these adversities can be grouped into those focusing on CSA, CPA, childhood emotional abuse (CEA), childhood physical neglect (CPN) and childhood emotional neglect (CEN), those focusing on life threatening events, those on bullying and those on war exposure. The authors highlight that the majority of studies examine the relationship between childhood abuse and neglect and psychosis. As a result, this review shall focus on the relationship between these forms of childhood adversity and psychosis. A further rationale for focusing on childhood abuse and neglect is derived from the complex trauma literature, where repeated childhood trauma of an interpersonal nature has been found to have a more pervasive effect than single incident traumas (see Cloitre et al, 2009; Courtois, 2008). In an effort to distinguish childhood abuse and neglect

from other forms of childhood adversity, this review shall subsequently refer to these experiences as childhood trauma.

While there does appear to be some evidence for relationships between specific forms of childhood trauma and paranoia, there are conflicting findings within the literature. While CSA is typically associated with auditory hallucinations (see Bentall et al, 2014), a number of clinical and community studies have reported significant associations between CSA and paranoia (Bendall et al, 2013; Dias, Sales, Hessen & Kleber; vanNierop et al, 2014). Conversely, other studies have failed to find significant relationships between CSA and paranoia in community (Boyda, McFetters & Shevlin, 2015) and clinical samples (Ashcroft, Kingdon & Chadwick, 2012; Hardy et al, 2016). A similar pattern of results is evident for the relationship between CPA and paranoia, with community and clinical studies reporting significant results (Fisher, Appiah-Kusi & Grant;, vanNierop et al, 2014; Wickham & Bentall, 2016) and others finding no significant relationship (Colins et al, 2009; Hardy et al, 2016). Results for the relationship between CEA and paranoia appear more consistent, where both community and clinical samples report significant associations (Ashcroft et al, 2012; Fisher et al, 2012; Hardy et al, 2016; Longden, Sampson & Read, 2016; vanNierop et al 2014) however Choi (2011) reported no significant association between CEA and paranoia. In the case of CPN, again a number of community and clinical studies report significant associations with paranoia (Colins et al, 2009; Dias et al, 2015; Wickham & Bentall, 2016), where others report non-significant results (Ashcroft et al 2012). Finally, the same discrepancy in results is found in the case of CEN, where some studies find significant associations (Colins et al, 2009; vanNierop et al, 2014) and others do not (Ashcroft et al, 2012; Dias et al, 2015).

As is evident from the above results, there is significant discrepancy in findings in the literature examining specificity of associations between different forms of childhood trauma and paranoia. Bonoldi et al (2013) address these conflicting results, suggesting these may be due to high levels of methodological heterogeneity across published studies, where a wide variety of assessment measures, definitions and sampling techniques have been utilised. In light of these contrasting results, this meta-analysis aims to measure the magnitude of the association between different

forms of childhood trauma and paranoia. While a number of systematic reviews and meta-analysis exist within the literature, to the author's knowledge none of these address the specific associations between different forms of childhood trauma and paranoia.

2. Method

This study adhered to the statement of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA; Moher, Liberati, Tetzlaff & Altman, 2009). The completed PRISMA checklist is available in Appendix H.

2.1 Registration of Review Protocol and Subsequent Changes

The review protocol was pre-registered with the PROSPERO International Prospective Register of Systematic Reviews (registration number: CRD4201708186, see Appendix A). Subsequent changes to the original protocol are outlined in Appendix B.

2.2 Search Strategy

Provisional searches of the literature identified seven previous systematic reviews or meta-analyses relevant to the research question and records from these papers were first identified (Ackner et al., 2013; Bailey et al., 2018; Gibson et al., 2016; Matheson et al., 2013; Read et al., 2005; Trotta et al., 2015; Varese et al., 2012). The search strategy was subsequently informed by previous reviews and developed in consultation with a research librarian. Electronic databases (EMBASE, MEDLINE, PsychINFO and Web of Science) were searched from January 1980. Search terms included: 'Child* trauma OR child* advers* OR child* maltreat* OR physical abuse OR sexual abuse OR emotional abuse OR psychological abuse OR physical neglect OR emotional neglect AND Psychosis OR psychotic* OR schizo* OR delusion OR persecut* delusion OR paranoi* delusion OR paranoi*'. The reference lists of all included full-text studies were subsequently reviewed in order to identify any studies omitted from the initial search. All posters and conference abstracts were checked for usable data or accompany journal articles. Where studies appeared to examine the relationship between a specific form of childhood trauma and paranoia, but did not report this in results, the authors were contacted for further information.

2.3. Study Selection

Studies were eligible for inclusion if they reported case-control, cross-sectional or prospective cohort data examining the relationship between either CSA, CPA, CEA, CPN or CEN and paranoia in clinical psychosis, clinical non-psychosis and community samples. Baseline data from experimental and intervention studies were also included however data that had been manipulated in these types of studies, including outcome data, was excluded. Clinical samples were defined as studies where >50% of participants had first episode psychosis (FEP) or an established diagnosis of non-affective psychosis (e.g. schizophrenia, schizoaffective disorder, delusional disorder, psychosis NOS). Clinical Non-Psychosis studies were defined as sample where <50% of participants had a diagnosis of FEP or an established diagnosis of non-affective psychosis. Community samples were those examining the relationship between specific forms of childhood trauma and paranoia or persecutory delusions in the general population.

Studies were excluded where 1) Over half the sample had a co-morbid diagnosis of intellectual disability, bipolar disorder, substance-induced psychosis or psychosis due to an organic cause, 2) The association between specific forms of childhood trauma and paranoia was examined in an at risk mental state sample (given the ongoing debate around how to define this group, see Yung & Nelson, 2013), 3) Over 25% of the sample were under the age of 16, 4) The study only reported the association between paranoia/persecutory delusions and an alternative form of adverse childhood experience (e.g. bullying, death of a parent, being brought up in institutional care), 5) The study did not report specific associations between the above forms of childhood trauma and paranoia (e.g. only reports a total childhood trauma score or total PANSS positive symptoms score) or 6) The study only reported the association between trauma experienced in adulthood and paranoia/persecutory delusions. Only studies reported in English language were included. Selection of studies was conducted by DC against inclusion/exclusion criteria and in consultation with PH.

2.4. Outcome Measures and Data Extraction

The outcomes examined were the magnitude of the associations between severity of 1) CSA, 2) CPA, 3) CEA, 4) CPN and 5) CEN and severity of paranoia. A wide variety of measures have been used to assess the severity of childhood trauma and paranoia. Severity of childhood trauma has been assessed through case note reviews (see Schenkel et al., 2005), bespoke questionnaires (see Bentall et al., 2012), structured/unstructured clinical interviews (see Arseneault et al., 2011) and validated questionnaires (e.g. Bernstein & Fink, 1998). Similarly, a wide range of measures have been used to measure severity of paranoia, including symptom specific measures (e.g. Green Paranoia Thoughts Scale; Green et al., 2008), combining items on more generic measures of positive symptoms of psychosis (e.g. PANSS delusions and suspiciousness items; Kay, Opler & Fiszbein, 1986; see Bendall et al., 2013) and case note reviews for evidence of symptoms (see Read, Agar, Argyle & Aderhold, 2003). Data were extracted from studies employing any of the above methods to measure the magnitude of the association between specific forms of childhood trauma and paranoia, however the measures employed were reflected in study quality ratings (see Appendix C for further details).

Data were extracted by DC, in consultation with PH. Where available, Pearson's correlation coefficients were extracted for the magnitude of the association between specific forms of childhood trauma and paranoia. Alternatively, Odds Ratios or Cohen's *d* were extracted when effect sizes were reported in this format. Where effect sizes were not reported, any usable data (e.g. means, SDs, 2x2 frequency tables, t-test *p* values) were extracted and entered into the Campbell Collaboration effect size calculator (Wilson, 2017) in order to calculate Cohen's *d*. A critical F value calculator (Soper, 2018) was used to convert F value to t-test *p* values where necessary and these were subsequently used to calculate Cohen's *d* (Wilson, 2017). Regression coefficients were converted to correlation coefficients using the formula outlined in Peterson & Brown (2005). Odds Ratios and Cohen's *d* were subsequently converted to *r* using formulae outlined in Borenstein et al (2009).

2.5. Risk of Bias and Study Quality

In line with previous meta-analyses (e.g. Murphy, Bentall, Freeman, O'Rourke & Hutton, 2018; Woodrow et al, 2018), the methodological quality of studies included in the meta-analyses was assessed using an adapted version of the Agency for Healthcare Research and Quality Assessment Tool (AHRQ; Viswanathan et al, 2010). This tool allows for the consistent and transparent assessment of a number of quality domains, including participant selection, a-prior sample size calculations, validity of assessment measures, controlling for confounds and handling of missing data. See Appendix C for further details regarding the rating of each quality criterion. Quality ratings are organised by studies entered into each separate meta-analysis in Appendix D.

The overall quality of meta-analytic outcomes was rated through an adapted version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt et al, 2008). The GRADE ratings, either high, moderate, low or very low, were based upon the study limitations, imprecision of results, inconsistency of results, level of publication bias and the quality of the evidence. Further details of the GRADE assessment criteria can be found in Appendix E.

2.6. Meta-Analytic Calculations

Meta-analyses were conducted using Version 3 of Comprehensive Meta-Analysis (CMA; Borenstein, Hedges, Higgins & Rothstein, 2013). For each meta-analysis of the magnitude of the association between a specific form of childhood trauma and paranoia, correlation coefficients and sample size were used to calculate pooled correlation coefficients and 95% CIs. CMA converts Pearson's correlations into Fisher's Z and 95% CIs and subsequently back-transforms these estimates to Pearson's correlations to allow interpretation against Cohen's (1992) effect size conventions, where 0.1 indicates a small correlation, 0.3 indicates a moderate correlation and 0.5 represents a large correlation.

DerSimonian and Laird (1986) random effects meta-analyses models were used for all outcomes as it was expected that the true effect would vary across samples due to factors such as sample size, assessment measures, population etc. and to ensure that

sample size did not unduly influence the weight assigned to each sample within the analysis (Borenstein et al., 2009). Heterogeneity was assessed using the I^2 statistic, where $I^2 < 40\%$ was viewed as low and 75-100% is viewed as considerable (Higgins & Green, 2011). The Doi plot and LFK index (see Furuya-Kanamori, Barendregt & Doi, 2018) were used to assess publication bias for outcomes with at least 10 studies, (LFK index > 2 indicates major asymmetry) and if publication bias was potentially indicated, this was adjusted for using the ‘trim and fill’ method (Duval & Tweedie, 2000).

2.7. Moderator Analysis

Study population, measure of childhood trauma and measure of paranoia were identified as pre-specified moderators of effect size across outcomes. Univariate meta-regressions were conducted when there were 10 or more studies in the analysis using the CMA software in order to determine whether 1) clinical psychosis, clinical non-psychosis or community study populations, 2) quality of trauma measure (Low vs. Acceptable vs. ‘Good’ quality) and 3) quality of paranoia measure (Low vs. Acceptable vs. Good quality rating), individually moderated the magnitude of the association between each form of childhood trauma and paranoia. Study population, quality of trauma measure and quality of paranoia measure were subsequently re-entered into meta-regression for multivariate moderator analysis.

3. Results

As shown in the PRISMA flowchart (Fig.1), the search returned 6335 articles. Manual searches of previous systematic reviews and meta-analyses returned a further 130 articles, resulting in a total of 6,465 results. 4165 results remained after removal of duplicates. A large number of studies examined genetic factors as potential mediators of the relationship between childhood trauma and positive symptoms and were removed at the title and abstract screening stage if they contained no usable data. The full-text papers of 288 articles were examined, and a further 267 studies were excluded. The main reason for exclusion was that the paper did not examine specific associations between the forms of childhood trauma in question and paranoia. Instead, many papers reported associations between total childhood trauma scores and total PANSS positive symptoms, associations between specific forms of

childhood trauma and PANSS positive symptoms or associations between total childhood trauma scores and paranoia/persecutory delusions only. Reviews of posters and conference abstracts did not reveal any additional usable data.

Of the 21 studies included in the analysis, 17 were entered in analysis for the relationship between CSA and paranoia, 16 for CPA and paranoia, 10 for CEA and paranoia, 6 for CPN and paranoia and 6 for CEN and paranoia. Where studies appeared to examine the relationship between a specific form of childhood trauma and paranoia, but did not report this in results, the authors were contacted for further information. No additional data was received from authors. We had concerns regarding extracting ORs derived from a modelling analysis with multiple outcome variables from Bentall et al (2012) as these were not felt to be comparable to other effect sizes reported in the literature. The authors of this paper were contacted for further information and provided ORs derived from more standard analytic approaches in an earlier draft of their paper. The majority of studies took place in the UK ($k = 8$), followed by the USA ($k = 5$), New Zealand ($k = 3$) and one study took place in Australia, Belgium, Portugal, India and The Netherlands respectively ($k = 5$). Dates of publication ranged from 1998 to 2016. Characteristics of included studies are outlined in Table 1.

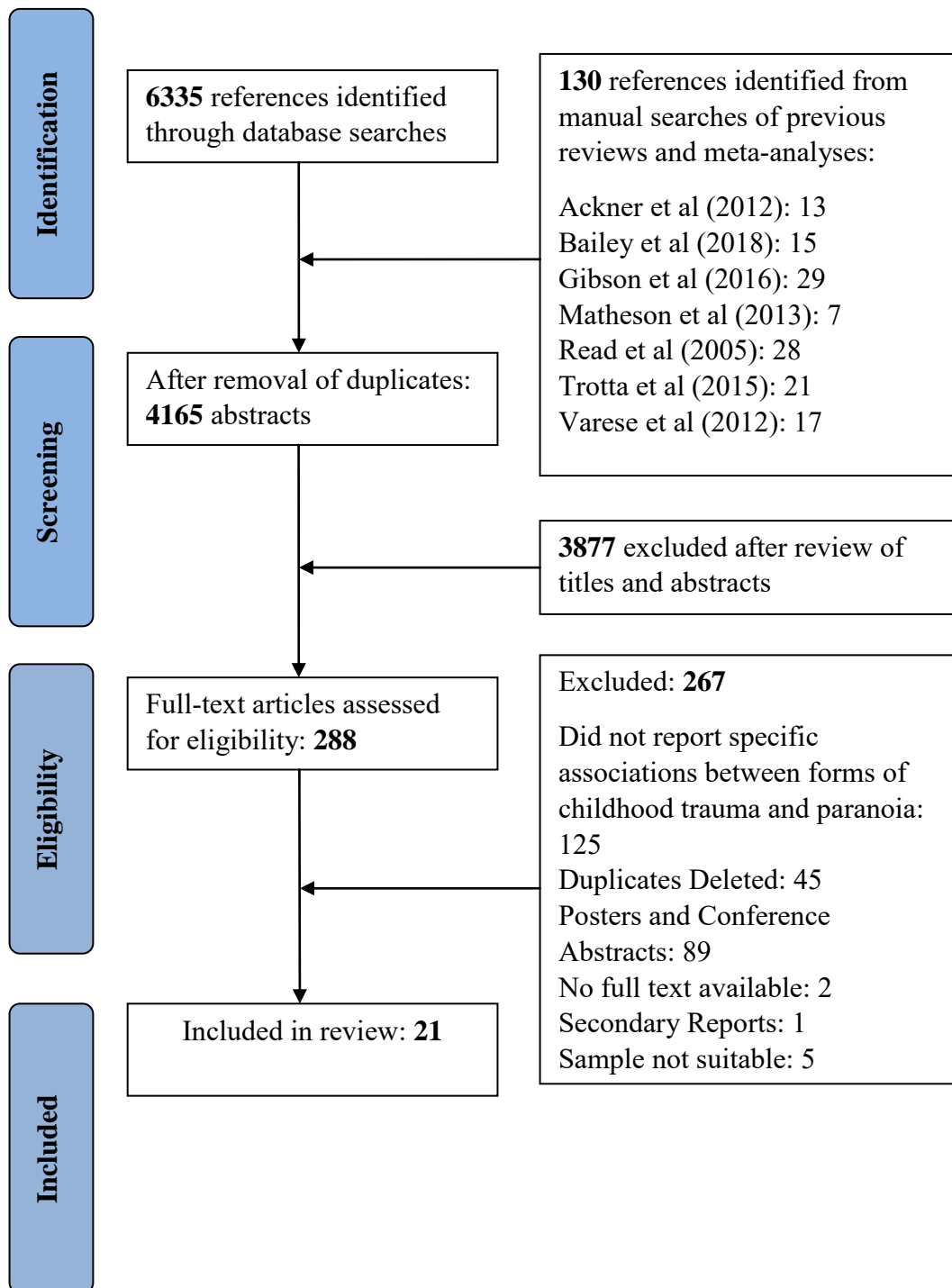


Figure 1. PRISMA Flowchart of Included Studies

Table 1. Characteristics of Included Studies

Study Ref (First Author, Year)	Design	Sample Size ^a	Participant Group(s) (Group: N)	Assessment of Dx/Paranoia	Age Mean (SD)	Gender (% Male)	Measure of CT	Forms of CT Examined	Measure of Paranoia
Clinical Psychosis Samples									
Ashcroft, 2012	Case- control	59	PD present: 36 PD absent: 23	SCID-I	42.6 (10.9) 36.4 (9.6)	66% 70%	CTQ-SF	CSA CPA CEA CPN CEN	Presence of SCID-I PD
Bendall, 2013	Case- control	49	Controls: 21 FEP with CSA: 13 FEP without CT: 15	SCID-I	21.19 (2.52) 20.62 (3.10) 22.07 (3.20)	43% 46% 60%	CTQ-SF	CSA	Sum of PANSS delusions & suspiciousness items
Choi, 2011	Cross- sectional	94	Schizophrenia: 90 Schizoaffective: 58 Bipolar: 20 Psychosis NOS: 3	Chart Diagnosis	37.04 (12.11)	50.3%	Child Abuse Rating System	CSA CPA CEA ^b CPN ^c	BPRS- Hostility/ Suspicion Factor
Hardy, 2016	Cross- sectional	228	Schizophrenia: 195 Schizoaffective: 29 Delusional Disorder: 4	Chart Diagnosis & PANSS rating of >4 on delusions, hallucinations, grandiosity or suspiciousness/ persecution items	38.24 (11.11)	72%	THQ	CSA CPA CEA	SAPs PD item

Study Ref (First Author, Year)	Design	Sample Size ^a	Participant Group(s) (Group: N)	Assessment of Dx/Paranoia	Age Mean (SD)	Gender (% Male)	Measure of CT	Forms of CT Examined	Measure of Paranoia
Lysaker, 2005	Cross- sectional	43	Schizophrenia: 49 Schizoaffective: 26	SCID-I	46 (9)	100%	CEQ	CSA	PANSS Suspiciousness item
Rajkumar, 2015	Cross- sectional	62	Schizophrenia: 62	Chart Diagnosis	35.3 (8.5)	50%	CTQ-SF	CSA ^d CPA CEA ^d CPN ^d CEN ^d	PANSS delusions (specified PD sub-type)
Shahar, 2004	Cross- sectional	109	Schizophrenia or schizoaffective: 67 Bipolar Disorder: 30 Other Psychosis: 4 Personality disorder: 8	Chart Diagnosis	39.9 (9.74)	58%	PSAS	CSA CPA	BSI paranoid ideation sub-scale
vanNierop, 2014	Cross- sectional	384	Sub-sample of NEMESIS-1 and NEMESIS-2 (N: 13, 772) reporting at least one validated Psychotic Experience	Self-reported Psychotic Experiences on CIDI & SCID-I	Not reported	Not reported	BQ	CSA CPA CEA CEN	SCID-I
Wickham, 2016	Case- control	144	Schizophrenia: 57 Schizoaffective: 10 Substance-induced psychosis: 3 Psychosis NOS: 1 72 healthy controls	Chart Diagnosis & consistency check with PANSS symptom ratings	Cases: 43.36 (11.17) Controls: 39.94 (12.07)	Cases: 64% Controls: 43%	CTQ-SF	CSA CPA CEA CPN CEN	PANSS suspicious-ness & persecution items

Study Ref (First Author, Year)	Design	Sample Size ^a	Participant Group(s) (Group: N)	Assessment of Dx/Paranoia	Age Mean (SD)	Gender (% Male)	Measure of CT	Forms of CT Examined	Measure of Paranoia
Clinical Non-Psychosis Samples									
Allen, 1998	Cross- sectional	142	Specialist Trauma Centre PTSD: 175 Psychosis: 0	Chart Diagnosis	37.3 (9.42)	0%	CTQ	CSA CPA CEA CPN CEN	BSI Paranoid Ideation Scale
Longden, 2016 ^c	Cross- sectional	251	Psychosis: 58 Mood Disorders: 114 Anxiety Disorders: 19 Other Disorders: 35 No Diagnosis: 25	Chart Diagnosis	35.66 (12.36)	51.4%	Medical records reviewed	CSA ^d CPA ^d CEA CEN ^d CPN ^d	Medical records reviewed for PD
Read, 2003 ^c	Cross- sectional	200	Psychosis: 42 Bipolar Disorder: 15 Depression: 85 Adjustment Disorder: 7 PTSD/Other Anxiety: 16 Substance Abuse: 20 Personality Disorder: 10	Chart Diagnosis	36.36 (Not reported)	43%	Medical records reviewed	CSA CPA	Medical records reviewed for DSM-IV-TR symptoms of schizophrenia
Community Samples									
Barker-Collo, 2011	Cross- sectional	338	General Population	N/A	37.2 (17.11)	26.9%	'Yes/No' response to interview question	CSA CPA	SCL-90-R Paranoid Ideation scale

Study Ref (First Author, Year)	Design	Sample Size ^a	Participant Group(s) (Group: N)	Assessment of Dx/Paranoia	Age Mean (SD)	Gender (% Male)	Measure of CT	Forms of CT Examined	Measure of Paranoia
Bentall, 2012 & Boyda, 2015 ^f	Cross- sectional	7403	General Population: Adult Psychiatric Morbidity Survey 2007	N/A	51 (18.5)	43%	BQ	CSA ^g CPA ^g	PSQ
<i>Same Sample</i>									
Colins, 2009	Cross- sectional	231	Juvenile Offenders	N/A	15.99 (Not reported)	100%	CTQ-SF	CSA CPA CEA CPN CEN	Schizophrenia section of DISC-IV
Dias, 2015	Cross- sectional	1200	General Population	N/A	37.43 (16.95)	54%	CTQ-SF	CSA CPA CEA CPN CEN	BSI Paranoid Ideation Scale
Fisher, 2012	Cross- sectional	212	General Population	N/A	27 (8.4)	34.6%	CTQ-SF	CSA ^d CPN CEA CPN ^d CEN ^d	PSQ
Freeman, 2009	Case- control	200	General Population Paranoia Present: 115 Paranoia Absent: 85	N/A	37.5 (13.3)	50%	LSC	CSA CPA	GPTS- Part B scores dichotomised to Paranoia present vs absent

Study Ref (First Author, Year)	Design	Sample Size ^a	Participant Group(s) (Group: N)	Assessment of Dx/Paranoia	Age Mean (SD)	Gender (% Male)	Measure of CT	Forms of CT Examined	Measure of Paranoia
Shevlin, 2015	Cross- sectional	3135	General Population: Survey of Psychiatric Morbidity among Prisoners in England and Wales	N/A	Not reported	75.5%	LoLTE	CSA	PSQ
Sitko, 2014	Cross- sectional	5877	General Population: National Co- morbidity Survey 1994	N/A	Not reported	Not reported	Life Event History Module of UM- CIDI	CSA ^h CPA	'Beliefs and Experiences' Module of UM- CIDI

List of abbreviations: BPRS: The Brief Psychotic Rating Scale, BSI: The Brief Symptom Inventory, BQ: Bespoke Questionnaire, CEA: Childhood Emotional Abuse, CEN: Childhood Emotional Neglect, CEQ: The Childhood Experiences Questionnaire, CIDI: The Composite International Diagnostic Interview, CPA: Childhood Physical Abuse, CPN: Childhood Physical Neglect, CSA: Childhood Sexual Abuse, CT: Childhood Trauma, CTQ: Childhood Trauma Questionnaire, CTQ-SF: Childhood Trauma Questionnaire- Short Form, FEP: First Episode Psychosis, GPTS-Part B: Green et al. Paranoia Thoughts Scale-Part B, LoLTE: List of Life Threatening Experiences, LSC: Life Stressors Checklist, NEMESIS: The Netherlands Mental Health Survey and Incidence Study, NOS: Not Otherwise Specified, PANSS: Positive and Negative Syndrome Scale, PD: Persecutory Delusions, PSAS: The Physical/Sexual Abuse Survey, PSQ: The Psychosis Screening Questionnaire, SAPS: The Scales for the Assessment of Positive Symptoms, SCID-I: The Structured Clinical Interview for DSM-IV-TR Axis I Disorders, SCL-90-R: Symptom Checklist-90- Revised, THQ: The Trauma History Questionnaire, UM-CIDI: The University of Michigan Composite International Diagnostic Interview.

Notes:

^a Final sample size may be lower than participant groups total N due to missing data or excluded participants.

^b CEA referred to as Emotional Maltreatment in paper.

^c CPN referred to as Failure to Provide in paper.

^d Results not reported. Author contacted for further information.

^e There may be an overlap in sample between Longden (2016) and Read (2003). This was deemed unproblematic as only results for each paper were entered into separate meta-analyses (i.e. CSA & CPA from Read, 2003; CEA only from Longden, 2016).

^f Sample characteristics reported refer to those reported in Boyda (2015).

^g While Bentall (2012) and Boyda (2015) are the same sample, this was considered unproblematic as effect sizes for CSA and paranoia were extracted from Boyda (2015) only and for CPA are paranoia were extracted from Bentall (2012). These effect sizes were subsequently entered into separate analyses.

^h Sitko (2014) reported effect sizes for both the association between rape and paranoia and sexual molestation and paranoia. CSA effect sizes reported later in this paper refer to those reported for the association between rape and paranoia.

3.1 Risk of Bias and Study Methodological Quality Ratings

AHRQ risk of bias and study methodological quality ratings are presented in Table 2. Quality ratings organised by studies entered into each separate meta-analysis are available in Appendix D.

Strengths associated with the literature were the unbiased selection of cohorts across the majority of studies (90% of studies received a 'Yes' or 'Partial' AHRQ rating), appropriate descriptions of study cohorts (only three studies received a 'No' AHRQ rating) and the handling of missing data (only one study included in the review received a 'No' AHRQ rating).

While 81% of studies received a 'Yes' or 'Partial' AHRQ rating for the validity of method used to assess the severity of childhood trauma, only 52% used a validated assessment questionnaire, where the remainder used bespoke questionnaires, Yes/No interview questions or review of medical records. In addition, while 10% of studies received a 'No' AHRQ for the validity of method used to assess paranoia, only 48% of studies included in review used a validated, symptom specific, measure of paranoia. Further methodological limitations common in the literature included the failure to minimize baseline differences in prognostic factors (where all studies in this review received 'No' or 'Unclear' AHRQ ratings), the lack of a-priori sample size calculations (where these were reported in none of the studies included in the review), the lack of valid methods for assessing the presence of a schizophrenia spectrum diagnosis in clinical samples (where only 46% of studies received a 'Yes' or 'Partial' AHRQ rating), the lack of controlling for confounding variables in analysis (62% of studies received a 'No' AHRQ rating) and the lack of blinding outcome assessments to the presence of childhood trauma exposure (only one study reported blinding to the presence or absence of a history of childhood trauma when assessing paranoia severity).

3.2. Meta-Analytic Outcomes

A summary of meta-analytic outcomes is outlined in Table 3. GRADE ratings for the quality of the evidence in each meta-analytic outcome are presented in the right-hand column of Table 3. Meta-regression scatterplots for moderator analysis in the case of the association between CSA and paranoia, CPA and paranoia and CEA and paranoia are available in Appendix F.

Table 2. Study Methodological Quality Ratings

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Clinical Psychosis Samples										
Ashcroft, 2012	Partial	No	No	Partial	Yes	Yes	Yes	No	No	Partial
Bendall, 2013	Yes	No	No	Partial	Yes	Yes	Partial	No	Unclear	Yes
Choi, 2011	Yes	-	No	Yes	No	No	Partial	No	Yes	Partial
Hardy, 2016	Partial	-	No	Yes	Partial	Yes	Yes	Yes	No	Yes
Lysaker, 2005	Partial	Unclear	No	No	Yes	Partial	Partial	No	No	Yes
Rajkumar, 2015	Yes	-	No	Yes	No	Yes	Partial	No	No	Partial
Shahar, 2004	Partial	-	No	No	No	Partial	Yes	Yes	No	Partial
vanNierop, 2014	No	-	No	Yes	Yes	Partial	Partial	Yes	No	Partial
Wickham, 2016	Partial	No	No	Yes	Partial	Yes	Partial	Yes	No	Yes
Clinical Non-Psychosis Samples										
Allen, 1998	Yes	-	No	Partial	-	Yes	Yes	No	No	Yes
Longden, 2016	Yes	-	No	Yes	No	No	No	No	No	Yes
Read, 2003	Yes	-	No	Partial	No	No	No	No	No	Yes

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Community Samples										
Barker- Collo, 2011	Partial	-	No	Yes	-	No	Yes	No	No	Yes
Bentall, 2012	Yes	-	No	No	-	No	Yes	Yes	No	Partial
Boyda, 2015	Yes	-	No	Partial	-	No	Yes	No	No	Partial
Colins, 2009	Yes	-	No	Partial	-	Yes	Yes	Partial	No	Yes
Dias, 2015	Partial	-	No	Partial	-	Yes	Yes	No	No	Yes
Fisher, 2012	No	-	No	Partial	-	Yes	Partial	No	No	Partial
Freeman, 2009	Partial	-	No	Yes	-	Yes	Yes	Yes	No	No
Shevlin, 2015	Yes	-	No	Partial	-	Yes	Partial	Yes	No	Yes
Sitko, 2014	Yes	-	No	No	-	Partial	Yes	No	No	Partial

Note: ^a Relevant to Case-control studies only

Table 3. Summary of Meta-Analytic Outcomes

Meta-Analytic Outcome	N Included Studies	Total Sample N	r (95% CI)	Heterogeneity <i>I</i>², Chi² P-value	Publication Bias: LFK Index	Quality: GRADE Rating
Association between CSA and Paranoia	17	19,836	0.16 (0.11-0.23)	88%, p < 0.001	5.17 (major asymmetry)	Low -1 quality (lack of a-priori sample size calculations, controlling for confounds and blinding to childhood trauma exposure) -1 inconsistency
Association between CPA and Paranoia	16	16,833	0.19 (0.10-0.27)	95%, p < 0.001	-0.59 (no asymmetry)	Low -1 quality (lack of a-priori sample size calculations, controlling for confounds and blinding to childhood trauma exposure) -1 inconsistency
Association between CEA and Paranoia	10	2,945	0.23 (0.12-0.33)	87%, p < 0.001	-2.37 (major asymmetry)	Low -1 quality (lack of a-priori sample size calculations, controlling for confounds and blinding to childhood trauma exposure) -1 inconsistency
Association between CPN and Paranoia	6	1870	0.16 (0.04-0.27)	76%, p < 0.001	0.56 (no asymmetry)	Very Low -1 quality (lack of a-priori sample size calculations, controlling for confounds and blinding to childhood trauma exposure) -1 imprecision -1 inconsistency
Association between CEN and Paranoia	6	2160	0.14 (0.02-0.25)	80%, p < 0.001	3.75 (major asymmetry)	Very Low -1 quality (lack of a-priori sample size calculations, controlling for confounds and blinding to childhood trauma exposure) -1 imprecision -1 inconsistency -1 publication bias

3.2.1. Association between CSA and Paranoia

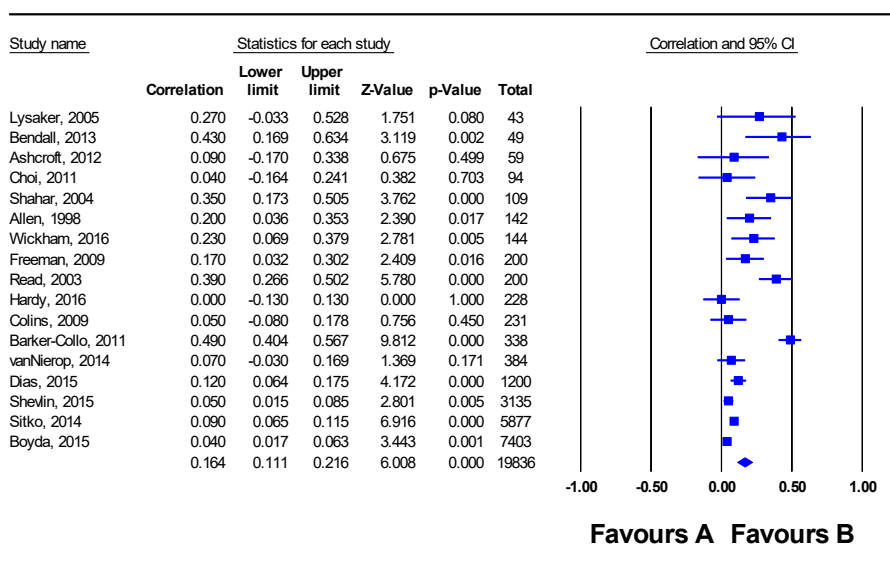


Figure 2. Forest Plot for the Association between CSA and Paranoia

As shown in Figure 2, meta-analysis of 17 studies found a small effect for the association between CSA and paranoia (N: 19836, $r = 0.16$, 95% CI 0.11 to 0.23, I^2 88%; low quality). The overall quality of the meta-analytic outcome was low, where the quality was downgraded by one point for quality of studies and 1 point for inconsistency due to considerable heterogeneity. The LFK index suggested major publication bias, however when this was adjusted for using the ‘trim and fill’ method, the magnitude of the effect did not change. As outlined in Table 4 and Table 5, study population, quality of childhood trauma measure and quality of paranoia measure were entered into uni- and multivariate meta-regression, however none of these factors emerged as significant moderators of the magnitude of the effect. While study population initially appeared to explain 14% of the variance, this reduced to 0% when quality of childhood trauma measure was entered into the model. The overall multivariate meta-regression model explained 0% of the variance in the magnitude of effect size estimates.

Table 4. Univariate Moderator Analysis: Association between CSA and Paranoia

Moderator	N Samples	Groups (No Samples) ^a	Coefficient	Q-value	R ²	p-value	Effects per Group
Study Population <i>General population vs. clinical non-psychosis and clinical psychosis</i>	17	General Population (7) Clinical: Non-Psychosis (2) Clinical Psychosis (8)	+ 0.177 if Clinical: Non Psychosis Population + 0.020 if Clinical: Psychosis Population	4.09	14%	p = 0.129	No clear association between effect size and study population group
Quality of Childhood Trauma Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	17	Low Quality (4) Acceptable Quality (4) Good Quality (9)	- 0.084 if Acceptable Quality -0.123 if Good Quality	1.57	0%	p = 0.455	No clear association between effect size and Quality of Childhood Trauma Measure
Quality of Paranoia Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	17	Low Quality (1) Acceptable Quality (6) Good Quality (10)	-0.274 if Acceptable Quality -0.254 if Good Quality	4.71	0%	p = 0.095	No clear association between effect size and quality of paranoia measure

Note: ^a Subgroups for quality of childhood trauma measure and quality of paranoia measure were based on AHRQ quality ratings. Low Quality refers to studies assigned a 'No' AHRQ rating, Acceptable Quality refers to those assigned a partial rating and Good Quality refers to those assigned a 'Yes' rating. Please see Appendix C for further details.

Table 5. Multivariate Moderator Analysis: Association between CSA and Paranoia

Moderator	N Samples	Groups (No Samples) ^a	Coefficient	R ²	p-value	Narrative Description
Study Population <i>General population vs. clinical non-psychosis and clinical psychosis</i>	17	General Population (7) Clinical: Non-Psychosis (2) Clinical Psychosis (8)	+ 0.830 if Clinical: Non Psychosis +0.040 if Clinical: Psychosis	15% (Clinical: Non Psychosis population) 14% (Clinical: Psychosis population)	p = 0.129	Study Population initially appeared to explain 14% of the variance between effect sizes however this result was non-significant
Quality of Childhood Trauma Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	17	Low Quality (4) Acceptable Quality (4) Good Quality (9)	-0.043 if Acceptable Quality -0.084 if Good Quality	-14% (Acceptable Quality) 0% (Good Quality)	p = 0.530	Quality of childhood trauma measure is not significant associated with effect size
Quality of Paranoia Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	17	Low Quality (1) Acceptable Quality (6) Good Quality (10)	-0.138 if Acceptable Quality -0.126 if Good Quality	0% (Acceptable Quality) 0% (Good Quality)	p = 0.194	Quality is paranoia measure is not significantly associated with effect size
Overall Model	-	-	-	R ² = 0%	p = 0.980	The model did not explain any of the variance in effect size

Note: ^a Subgroups for quality of childhood trauma measure and quality of paranoia measure were based on AHRQ quality ratings. Low Quality refers to studies assigned a ‘No’ AHRQ rating, Acceptable Quality refers to those assigned a partial rating and Good Quality refers to those assigned a ‘Yes’ rating. Please see Appendix C for further details.

3.2.2. Association between CPA and Paranoia

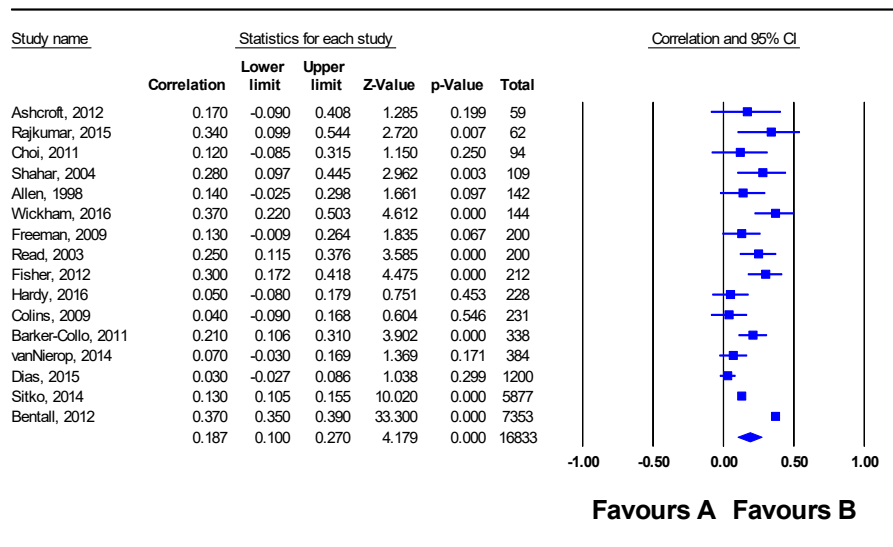


Figure 3. Forest Plot for the Association between CPA and Paranoia

As shown in Figure 3, the meta-analysis for the relationship between CPA and paranoia included 16 studies and found a small association (N: 16833, $r = 0.19$, 95% CI 0.10 to 0.27, I^2 95%; low quality). The overall quality of the meta-analytic outcome was low, where the GRADE rating was reduced by one point for the quality of studies and a further point due to considerable heterogeneity among estimates of the magnitude of the effect. The LFK index did not indicate publication bias. Table 6 and Table 7 detail the results of uni- and multivariate moderator analysis. Study population, quality of childhood trauma measure and quality of paranoia measure were not found to be significant moderators of the overall magnitude of effect. In multivariate meta-regression, the model was found to explain 44% of the variance in effect size estimates however this result was non-significant.

Table 6. Univariate Moderator Analysis: Association between CPA and Paranoia

Moderator	N Samples	Groups (No Samples) ^a	Coefficient	Q-value	R ²	p-value	Effects per Group
Study Population <i>General population vs. clinical non-psychosis and clinical psychosis</i>	16	General Population (7) Clinical: Non-Psychosis (2) Clinical Psychosis (7)	+0.021 if Clinical Non-Psychosis population +0.020 if Clinical Psychosis population	0.05	0	p = 0.977	No clear association between effect size and study population
Quality of Childhood Trauma Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	16	Low Quality (4) Acceptable Quality (3) Good Quality (9)	-0.120 if Acceptable Quality - 0.106 if Good Quality	2.37	59%	p = 0.307	No clear association between effect size and quality of childhood trauma measure
Quality of Paranoia Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	16	Low Quality (1) Acceptable Quality (5) Good Quality (10)	- 0.013 if Acceptable Quality -0.097 if Good Quality	0.79	0	p = 0.673	No clear association between effect size and quality of paranoia measure

Note: ^a Subgroups for quality of childhood trauma measure and quality of paranoia measure were based on AHRQ quality ratings. Low Quality refers to studies assigned a ‘No’ AHRQ rating, Acceptable Quality refers to those assigned a partial rating and Good Quality refers to those assigned a ‘Yes’ rating. Please see Appendix C for further details.

Table 7. Multivariate Moderator Analysis: Association between CPA and Paranoia

Moderator	N Samples	Groups (No Samples) ^a	Coefficient	R ²	p-value	Narrative Description
Study Population <i>General population vs. clinical non-psychosis and clinical psychosis</i>	16	General Population (7) Clinical: Non-Psychosis (2) Clinical Psychosis (7)	+ 0.001 if Clinical: Non Psychosis -0.007 if Clinical Psychosis	0% (Clinical: Non-Psychosis) 0% (Clinical Psychosis)	p = 0.997	Study population was not significantly associated with effect size
Quality of Childhood Trauma Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	16	Low Quality (4) Acceptable Quality (3) Good Quality (9)	-0.121 if Acceptable Quality -0.103 if Good Quality	0% (Acceptable Quality) 48% (Good Quality)	p = 0.497	Higher quality trauma measures appeared to explain 48% of the variance in effect sizes, however this result was non-significant
Quality of Paranoia Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	16	Low Quality (1) Acceptable Quality (5) Good Quality (10)	+ 0.079 if Acceptable Quality -0.011 if Good Quality	-1% (Acceptable Quality) -3% (Good Quality)	p = 0.621	Quality of paranoia measures was not significantly associated with effect size but did account for 4% of the variance
Overall Model	-	-	-	44%	p = 0.839	The model did not significantly explain any of the variance in effect sizes

Note: ^a Subgroups for quality of childhood trauma measure and quality of paranoia measure were based on AHRQ quality ratings. Low Quality refers to studies assigned a ‘No’ AHRQ rating, Acceptable Quality refers to those assigned a partial rating and Good Quality refers to those assigned a ‘Yes’ rating. Please see Appendix C for further details.

3.2.3. Association between CEA and Paranoia

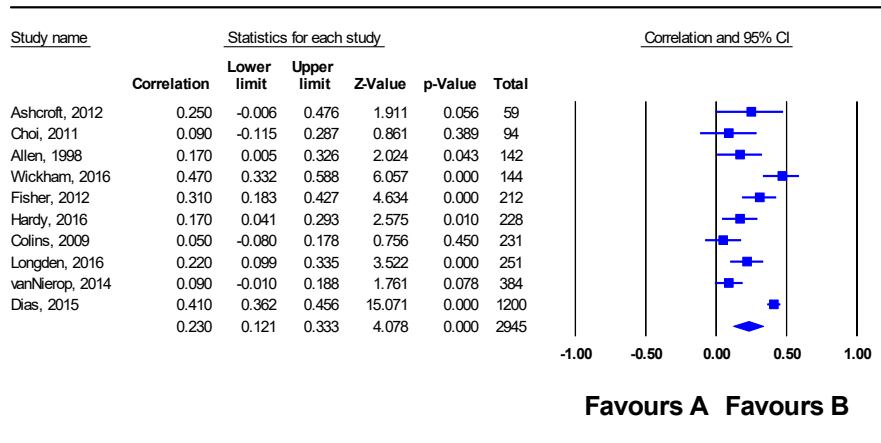


Figure 4. Forest Plot for the Association between CEA and Paranoia

As shown in Figure 4, meta-analysis of 10 studies found a small effect for the magnitude of the association between CEA and paranoia (N: 2945, $r = 0.23$, 95% CI 0.12-0.33, I^2 87%; low quality). The overall quality of the meta-analytic outcome was low, where the GRADE rating was reduced by two points for quality of studies and inconsistency due to considerable heterogeneity amongst estimates. The LFK index indicated major publication bias however the magnitude of the effect size did not change after adjusting through the trim and fill method. As outlined in Tables 8 and 9, study population, quality of childhood trauma measure and quality of paranoia measure were entered into univariate and multivariate meta-regression, however none of these moderators were found to be significant. The overall meta-regression model explained 0% of the variance in effect size estimates.

Table 8. Univariate Moderator Analysis: Association between CEA and Paranoia

Moderator	N Samples	Groups (No Samples) ^a	Coefficient	Q-value	R ²	p-value	Effects per Group
Study Population							
<i>General population vs. clinical non-psychosis and clinical psychosis</i>	10	General Population (3) Clinical: Non-Psychosis (2) Clinical Psychosis (5)	-0.076 if Clinical: Non Psychosis -0.055 if Clinical Psychosis	0.27	0%	p = 0.874	No clear association between Study Population and effect size
Quality of Childhood Trauma Measure							
<i>Low Quality vs. Acceptable Quality and Good Quality</i>	10	Low Quality (2) Acceptable Quality (2) Good Quality (6)	-0.036 if Acceptable Quality +0.130 if Good Quality	2.08	23%	p = 0.353	No clear association between quality of childhood trauma measure and effect size
Quality of Paranoia Measure							
<i>Low Quality vs. Acceptable Quality and Good Quality</i>	10	Low Quality (1) Acceptable Quality (4) Good Quality (5)	+0.029 if Acceptable Quality -0.004 if Good Quality	0.06	0%	p = 0.971	No clear association between quality of paranoia measure and effect size

Note: ^a Subgroups for quality of childhood trauma measure and quality of paranoia measure were based on AHRQ quality ratings. Low Quality refers to studies assigned a 'No' AHRQ rating, Acceptable Quality refers to those assigned a partial rating and Good Quality refers to those assigned a 'Yes' rating. Please see Appendix C for further details.

Table 9. Multivariate Moderator Analysis: Association between CEA and Paranoia

Moderator	N Samples	Groups (No Samples) ^a	Coefficient	R ²	p-value	Narrative Description
Study Population <i>General population vs. clinical non-psychosis and clinical psychosis</i>	10	General Population (3) Clinical: Non-Psychosis (2) Clinical Psychosis (5)	-0.080 (Clinical: Non Psychosis) +0.107 (Clinical Psychosis)	0% (Clinical: Non-Psychosis) 0% (Clinical Psychosis)	p = 0.778	No clear association between study population and effect size
Quality of Childhood Trauma Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	10	Low Quality (2) Acceptable Quality (2) Good Quality (6)	+0.074 (Acceptable Quality) +0.337 (Good Quality)	5% (Acceptable Quality) -5% (Good Quality)	p = 0.343	The impact of Acceptable Quality childhood trauma measures disappeared when accounting for Good Quality measures. No clear association between quality of childhood trauma measure and effect size
Quality of Paranoia Measure <i>Low Quality vs. Acceptable Quality and Good Quality</i>	10	Low Quality (1) Acceptable Quality (4) Good Quality (5)	-0.320 (Acceptable Quality) -0.390 (Good Quality)	0% (Acceptable Quality) 0% (Good Quality)	p = 0.607	No clear association between quality of paranoia measure and effect size
Overall Model	-	-	-	0%	p = 0.876	The model did not explain any of the variance in effect sizes

Note: ^a Subgroups for quality of childhood trauma measure and quality of paranoia measure were based on AHRQ quality ratings. Low Quality refers to studies assigned a ‘No’ AHRQ rating, Acceptable Quality refers to those assigned a partial rating and Good Quality refers to those assigned a ‘Yes’ rating. Please see Appendix C for further details.

3.2.4. Association between CPN and Paranoia

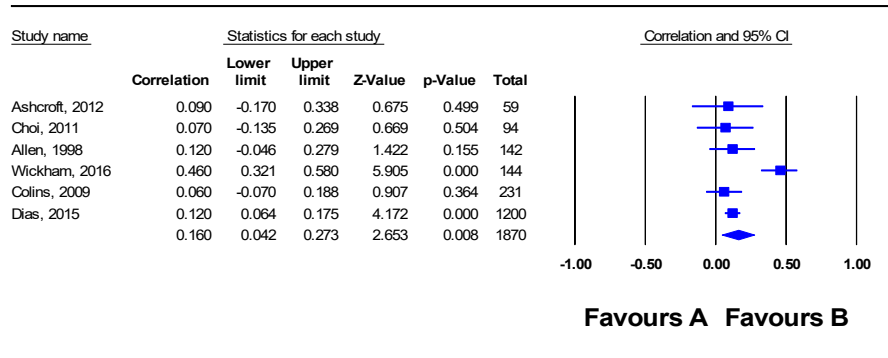


Figure 5. Forest Plot for the Association between CPN and Paranoia

As shown in Figure 5, a total of 6 studies were entered into the meta-analysis for the relationship between CPN and paranoia and found a small association (N: 1870, $r = 0.16$, 95% CI 0.04 to 0.27, I^2 76%; very low quality). The overall quality of the meta-analytic outcome was very low, where the GRADE rating was reduced by three points for study quality, imprecision and inconsistency. The LFK index did not indicate publication bias. Moderator analysis was not possible as there were less than 10 studies included in the meta-analysis (Higgins & Green, 2011).

3.2.5 Association between CEN and Paranoia

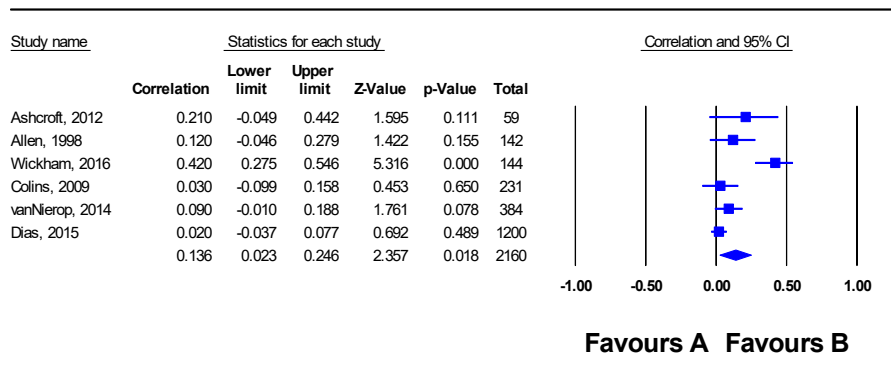


Figure 6. Forest Plot for the Association between CEN and Paranoia

As shown in Figure 6, meta-analysis of 6 studies found a small association for the relationship between CEN and paranoia (N: 2160, $r = 0.14$, 95% CI 0.02 to 0.25, I^2 80%, very low quality evidence). The overall quality of the meta-analytic outcome was very low, where the GRADE rating was reduced for four points for study quality, imprecision, inconsistency and publication bias. The LFK index indicated major publication bias and this could not be adjusted for using the ‘trim and fill’ method as there were less than 10 studies included in the meta-analytic outcome. Moderator analysis was also not possible for the same reason (Higgins & Green, 2011).

4. Discussion

4.1. Summary of Findings

To our knowledge, this study is the first meta-analytic review of the magnitude of the association between specific forms of childhood trauma and paranoia. We conducted five separate meta-analytic calculations. 17 studies were entered into the meta-analysis to examine the magnitude of the association between CSA and paranoia, 16 for the association between CPA and paranoia, 10 for the association between CEA and paranoia, 6 for the association between CPN and paranoia and 6 for the association between CEN and paranoia.

We found evidence of associations between each form of childhood trauma examined and paranoia. Meta-analysis of 17 studies found a small effect for the association between CSA and paranoia (N: 19,836, $r = 0.16$, 95% CI 0.11 to 0.23, I^2 88%; low quality). Meta-analysis of 16 studies found a small association between CPA and paranoia (N: 16,833, $r = 0.19$, 95% CI 0.10 to 0.27, I^2 95%; low quality). In the case of the magnitude of the association between CEA and paranoia, meta-analysis of 10 studies found a small effect (N: 2945, $r = 0.23$, 95% CI 0.12 to 0.33, I^2 87%; low quality). Again, the magnitude of the association between CPN and paranoia was found to be small in meta-analysis of 6 studies (N: 1870, $r = 0.16$, 95% CI 0.04 to 0.27, I^2 76%; very low quality). Finally, meta-analysis of 6 studies found a small effect for the magnitude of the association between CEN and paranoia (N: 2160, $r = 0.14$, 95% CI 0.02 to 0.25, I^2 80%, very low quality).

Heterogeneity was high across all meta-analytic calculations. Study population, quality of childhood trauma measure and quality of paranoia measure were not found to be significant moderators of the magnitude of the effect in either uni- or multivariate meta-regression analysis across all meta-analytic calculations were moderator analysis was possible. Publication bias was found to be high for the association between CSA and paranoia, CEA and paranoia and CEN and paranoia. Whilst recognising the limitations associated with detecting and adjusting for publication bias (see Renkewitz & Keiner, 2018), we found that the ‘trim and fill’ method (Duval & Tweedie, 2000) did not influence the magnitude of the effect size estimate for the association between CSA and paranoia or CEA and paranoia. It was

not possible to adjust for publication bias in the case of the association between CEN and paranoia as the meta-analysis contained less than 10 studies (Higgins & Green, 2011).

4.2. Discussion of Findings

While our findings would initially appear to support specificity in the relationship between childhood trauma and paranoia, caution is required when interpreting our results. While it may be tempting upon initial inspection to conclude that our findings of slightly larger associations between CEA and paranoia ($r = 0.23$) and CPA and paranoia ($r = 0.19$) than for other forms of childhood trauma and paranoia ($r = 0.14-0.16$) are evidence of specificity, significant caution is required when interpreting our results. The overall quality of the meta-analytic outcomes ranged from Low (CSA and paranoia; CPA and paranoia; CEA and paranoia) to Very Low (CPN and paranoia). If we were to accept the lower limits of the confidence intervals for the association between each form of childhood trauma and paranoia, the magnitude effect for the association between CSA and paranoia, CPA and paranoia, CEA and paranoia, CPN and paranoia and CEN and paranoia would be $r = 0.11$, $r = 0.10$, $r = 0.12$, $r = 0.04$ and $r = 0.02$ respectively. Conversely, if we were to accept the upper limit of the confidence interval, small associations between most of the forms of childhood trauma and paranoia we examined would remain, yet the magnitude of the relationship between CEA and paranoia would increase from a small to medium effect ($r=0.23$ vs $r= 0.33$). In addition, childhood traumas tend to co-occur (see Ashton et al, 2016; Bellis et al, 2014; Bentall et al, 2014; Felitti et al, 1998), yet we did not control for the presence of other forms of childhood trauma within each of our meta-analytic outcomes. Furthermore, we were unable to conduct analysis to ascertain whether differences in the magnitude of the association between each form of childhood trauma examined and paranoia were statistically significant. While Bradford Hill (1965) does not require statistically significant differences in the magnitude of effect sizes for there to be evidence of specificity, our results must be interpreted within this context. Finally, in order to make rigorous claims regarding specificity, we would have to have controlled for all other risk factors for psychosis, such as genetic risk, cannabis use, ethnicity etc. (see Gibson et al, 2016) within each of our meta-analytic outcomes.

Our findings of high levels of heterogeneity are also of note, particularly given that our univariate and multivariate meta-regression analyses found that study population, quality of childhood trauma measure and quality of paranoia measure were not significant moderators of the magnitude of the association between CSA and paranoia, CPA and paranoia and CEA and paranoia. As noted above, it was not possible to conduct moderator analysis for the magnitude of the association between CPN and paranoia and CEN and paranoia. In light of our non-significant moderator analyses, the high levels of heterogeneity we found across all meta-analytic outcomes become more difficult to explain. As noted above, we wondered however if this might be associated with the fact that very few studies (Bentall et al, 2012; Shevlin, McAnee, Bentall & Murphy, 2015; Wickham et al, 2016) controlled for the presence of other forms of childhood trauma when reporting associations between specific forms of childhood trauma and paranoia. We also considered that this heterogeneity could be the result of a number of studies with large samples producing different estimates of the magnitude of the association between forms of childhood trauma and paranoia, resulting in wider confidence intervals when these studies were synthesised into meta-analytic outcomes. Subgroup analysis may have been more appropriate than the meta-regression analyses we performed in allowing us to explore heterogeneity in further detail.

Notwithstanding the need for future research to address the methodological limitations outlined above, the most conservative interpretation of our results is that, while there appears to be a general association across the forms of childhood trauma and paranoia we examined, this association may be somewhat greater for CEA and paranoia and CPA and paranoia. CSA, CPA and CEA are often grouped together and referred to as childhood traumas associated with the intention to harm (Gibson et al, 2016; vanNierop et al, 2014). Given the similarities between each of these forms of trauma, it might initially be considered surprising that the association between CSA and paranoia was not more similar in magnitude to that between CEA and paranoia and CPA and paranoia. As outlined in our introduction however, CSA appears to be more associated with voices than paranoia (Bentall et al, 2014). It has been claimed that relationships may differ between specific forms of psychotic experiences due to individuals having to resort to different coping strategies to

manage different forms of childhood trauma (Bentall et al, 2014). Indeed Bentall et al (2014) suggest that these different coping strategies may predispose individuals to the different psychological processes, where voices and thought to be linked to dissociation, whereas negative core schema regarding self and others are thought to underlie paranoia. The reasons an individual may have to resort to different coping mechanisms in the face of alternative forms of trauma and how these might impact or influence the psychological process through to underlie different psychotic experiences however remain poorly described.

We tentatively offer some initial thoughts as to why different forms of childhood trauma might have specific relationships with different psychotic experiences. Perry, Pollard, Blakely, Baker and Vigilante (1995), describe how humans have developed two possible systems for responding to threat, including the ‘hyperarousal/fight or flight’ system or the ‘dissociative/freeze or surrender’ system. It has been argued that when the fight or flight response is not available to escape or avoid threat, then freeze or dissociating may be an adaptive response in order to ‘escape’ from the physical, psychological and emotional distress associated with the threat (Hagenaars, Stins & Roelofs, 2012; Schalinski & Teicher, 2015). As children may not have the physical ability to utilise fight or flight in certain situations, they may be more likely to respond to some threats by freezing or dissociating (Schalinski & Teicher, 2015). This might be particularly true in the case of CSA, where a child unable to utilise fight or flight to cope with this trauma might have to resort to a freeze or dissociative response to survive the physical, psychological and emotional distress of this experience (see Heidt, Max & Forsyth, 2005). We wondered therefore if CSA might be more associated with voices as individuals might be more likely to engage in a freeze/ dissociative coping response, whereas CEA and CPA might be more associated with paranoia due to the potential repeated utilisation of the fight or flight response and the influence this may have on core schema regarding self and others. While we offer these tentative thoughts, significant further research is required to test these links.

4.3. Strengths and Limitations

There were a number of strengths associated with this review. First, to our knowledge this is the first meta-analysis to adopt a psychotic experience specific approach and synthesise the evidence of relationships between specific forms of childhood trauma and paranoia. Secondly, we pre-registered our review protocol to ensure academic transparency (Appendix A). In addition, we made significant efforts to provide clarity regarding the definitions and theoretical assumptions underlying our review and saw this as a strength given the multiple definitions present in the literature. Furthermore, our meta-analytic outcomes included large total sample sizes, particularly in the case of the association between CSA and paranoia and CPA and paranoia (CSA N: 19836, CPA N: 16833, CEA N: 2945, CPN N: 1870, CEN N: 2160). Finally, we felt the inclusion of robust uni- and multivariate moderator analysis where this was possible was a significant strength.

Despite significant strengths, we must also highlight the limitations associated with our review. First, we only had the ability to include English language studies due to a lack of available translation software and this may introduce some degree of bias in our results. In addition, the quality of the evidence in each of our methodological outcomes ranged from Low to Very Low and as a result, caution is required when interpreting our results. Furthermore, some caution is required regarding the association between CPN and CEN given the small number of studies available for entry into these meta-analytic outcomes.

We are aware that our findings must be considered within the context of the fact we did not examine alternative forms of childhood adversity such as life threatening events, parental separation, witnessing domestic violence or living with household members who use substances, have a history of mental health problems or criminality. More specifically, not including bullying/peer-victimisation could be considered a further limitation. While bullying is often categorised separately from the forms of childhood trauma we examined in our review, it could be claimed that this form of adversity is similar to CSA, CEA and CPA as they all involve the intention-to-harm by another and therefore could involve potentially similar underlying psychological mechanisms. While a number of meta-analyses have

examined the relationship between bullying and psychosis (Cunningham, Hoy & Shannon, 2016; van Dam et al, 2012), to our knowledge none have examined the specific association between bullying and paranoia.

To our mind, the most significant limitations however are that we were unable to control for the presence of other forms of childhood trauma within each separate meta-analytic outcome and that we were unable to statistically compare differences in the magnitude of effect size estimates across different forms of childhood trauma and paranoia to establish whether these were statistically significant.

4.4. Theoretical Implications and Recommendations for Future Research

As noted above, while our findings of slightly larger effects for the magnitude of the association between CEA and paranoia and CPA and paranoia than for other forms of childhood trauma and paranoia could initially be seen as supporting arguments for specificity, significant caution is required in making this interpretation due to a number of methodological limitations. The most conservative interpretation of our results is that while there does appear to be a general association between the forms of childhood trauma we examined and paranoia, the association between CEA and paranoia and CPA and paranoia may be slightly larger, possibly indicating specificity in the relationship between childhood trauma and paranoia.

We make a number of recommendations for future research in order to address the methodological limitations associated with our review and to further examine the evidence for specificity in the relationship between childhood trauma and paranoia. As the overall quality of our meta-analytic outcomes ranged from Low to Very Low, our recommendations focus on strategies that would boost the overall quality of the literature for each meta-analytic outcome. Future studies in the area would be of higher methodological quality if they included a-prior sample size calculations, if their analysis controls for cofounds and if they reduced the risk of bias by blinding the assessment of paranoia to childhood trauma exposure. While the majority of studies received a 'Yes' or 'Partial' AHRQ quality rating for their choice of childhood trauma and paranoia measures, only 52% of studies included in our review used a standardised and psychometrically valid questionnaire to assess the severity of

childhood trauma and only 48% of studies used a validated, 'symptom-specific' measure of paranoia.

While we would recommend that future research controls for confounds in any statistical analysis in order to improve the wider quality of the literature. In order to make robust claims regarding specificity, future cross-sectional studies would be required to control for as many identified risk factors for psychosis as possible, where genetic risk, cannabis use and ethnicity should be viewed as particularly important (see Gibson et al, 2016). We were somewhat cautious however about recommending that analysis focusing on associations between one form of childhood trauma and paranoia controls for other forms of childhood trauma. While controlling for the presence of other forms of childhood trauma would improve the theoretical and methodological quality of the study, given than childhood traumas tend to co-occur (Bentall et al, 2014), to do so may reduce the ecological validity of any results.

We would also recommend that future research in the area employs a standardised and validated measure of childhood trauma, such as the Childhood Trauma Questionnaire (CTQ, Bernstein & Fink, 1998), where this is often considered the 'gold-standard' measure of childhood trauma (Bendall et al, 2007). We did not view case note reviews as a robust measure of childhood trauma history given findings that individuals with psychosis are rarely asked if they have experienced childhood trauma (Lothian & Read, 2002; Read et al, 2005). In the case of paranoia, we would recommend the use of the Green Paranoia Thoughts Scales- Part A and B (GPTS, Green et al, 2008), where a recent systematic review found this measure to be most robust and reliable for assessing paranoia across community and clinical samples (Statham, Emerson & Rowse, 2018). Furthermore, we would recommend future studies further examine the relationship between CEA, CPN and CEN given the limited number of studies available for the association between these forms of childhood trauma and paranoia. Finally, given that negative core schema (see Fowler et al, 2006; Garety & Freeman, 2013; Gracie et al, 2007; Read et al, 2005; vanNierop et al, 2014) have been proposed as possible underlying mechanisms for the relationship between childhood trauma and paranoia, we would recommend further research examine to what extent negative core schema mediate the relationship between childhood trauma and paranoia. This avenue of research key as, if we can

robustly conclude specific underlying mechanisms mediate the relationship between childhood trauma and paranoia, then psychological therapies can be refined or developed to target these mechanisms with the hope of improving outcomes (Bentall et al, 2014).

4.5. Implications for Clinical Practice

Our findings suggest that while there appears to be a general association between the forms of childhood trauma examined and paranoia, that experiences of CEA and CPA may be worthy of particular consideration. Our first recommendation is that individuals with psychosis should be asked about a history of childhood trauma (Lothian & Read, 2002; Read et al, 2007). There is no evidence to suggest that asking about childhood trauma results in any adverse effects (Frueh et al, 2009; Lothian & Read, 2002; Mueser et al, 2008; Read et al, 2007; van der Berg & van der Gaag, 2012), rather, the evidence suggests that individuals with psychosis who have experienced childhood trauma, yet have not been asked about this, are more likely to doubt their diagnosis, have a negative experience of, and subsequently disengage from treatment (Lothian & Read, 2002; Read et al, 2007). Should individuals experiencing paranoia within the context of psychosis disclose a history of childhood trauma, then clinicians should consider working with the individual to develop a collaborative, trauma-informed formulation of their experience of psychosis (BPS, 2014; NICE, 2014). When developing these formulations, however, clinicians should be mindful that while the available evidence suggests that there may be specific relationships between CEA and CPA and paranoia, that traumas rarely occur in isolation and that individuals may likely have experience other forms of childhood trauma or adverse early life experiences (Bentall et al, 2014). Furthermore, it should not be assumed that all individuals experiencing paranoia within the context of psychosis have a history of childhood trauma, where it has been found that childhood trauma accounts for approximately 33% of cases with psychosis (Varese et al, 2012).

Access to a trauma-informed psychological formulation of paranoia and psychosis may be particularly relevant to individuals receiving acute inpatient care. Individuals receiving care in these settings often present with high levels of distress, and in some circumstances this distress may manifest in the form of violence and aggression

(NICE, 2015). Clinicians working in these settings should consider developed a trauma-informed, team-based formulation of an individual's experience of paranoia, as it has been found that psychological formulations that involve all members of the individual's care team have a positive impact on care, where increased understanding of an individual's difficulties results in increased empathy, strengthens the therapeutic alliance, helps to avoid iatrogenic trauma and ensure a consistent approach to care and treatment (BPS, 2011).

While our findings suggest the above clinical implications, we are mindful that the specific intervention trials regarding the benefits of trauma-informed formulation specifically for psychosis are lacking. We note however that a recent meta-analysis that found trauma-focused psychological therapy results in a significant reduction in the severity of psychotic experiences (Brand, McEnery, Rossell, Bendall & Thomas, 2018). We would encourage clinicians working with psychosis to keep abreast of developments in the literature regarding the underlying mechanisms associated with specific relationships between forms of childhood trauma and psychotic experiences and consider the implications for clinical practice.

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Appendices

Appendix A: PROSPERO Study Protocol

Appendix B: Subsequent Changes to Protocol

Appendix C: Adapted AHRQ Study Quality Assessment Tool

Appendix D: Outcome Specific Quality Assessment Ratings

Appendix E: GRADE Assessment Criteria

Appendix F: Meta-Regression Graphs

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The evidence for relationships between specific forms of childhood trauma and paranoia in people with persecutory delusions: a meta-analytic review

David Carmichael, Karen Goodall, Sean Harper, Paul Hutton

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Review question

To what extent are specific forms of childhood trauma (sexual, physical and emotional abuse; physical and emotional neglect) related to paranoia severity in people with persecutory delusions, taking into account study and outcome quality?

Searches

Electronic databases (EMBASE, MEDLINE, PsycINFO and Web of Science) will be searched using the following terms:

Child* trauma OR child* advers* OR child* maltreat* OR physical abuse OR sexual abuse OR emotional abuse OR psychological abuse OR physical neglect OR emotional neglect

AND

Psychosis OR psychotic* OR schizo* OR delusion OR persecut* delusion OR paranoi* delusion OR paranoi*

Manual searches of reference lists in articles that meet inclusion criteria and key review articles will also be undertaken. Conference abstracts and theses identified through the searches will also be followed-up. All initial searches and screening will be undertaken by the first author (Mr David Carmichael) under the supervision of the last author (Dr Paul Hutton).

Types of study to be included

Case-control, cross-sectional correlation and prospective cohort study designs will be included. Baseline data from experimental and intervention

studies may also be included however data that has been manipulated in these types of studies, including outcome data, will be excluded.

Condition or domain being studied

The association between childhood trauma and severity of paranoia in individuals with persecutory delusions.

For the purposes of this review childhood trauma is defined as physical, sexual or emotional abuse or physical or emotional neglect (Larkin & Reid, 2008). Studies examining associations between severity of persecutory delusions/paranoia and trauma experienced in adulthood will be excluded from review.

This review will adopt a symptom specific approach (see Morrison et al, 2004) and shall only examine associations between childhood trauma and paranoia. For the purposes of this review persecutory delusions are conceptualised as existing at the most severe end of the paranoia continuum (see Freeman et al, 2004's Paranoia Hierarchy).

Participants/population

Clinical populations of participants with established diagnosis of non-affective psychosis (e.g. schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder and psychosis NOS).

Studies will be eligible for inclusion if they employ the following methodologies 1) Case-control studies, 2) Cross-sectional studies, 3) Prospective cohort studies 4) Experimental or Intervention studies (baseline data only) to investigate the association between childhood trauma (physical, sexual and emotion abuse and physical or emotional neglect) and persecutory delusions/paranoia in participant samples with non-affective psychosis (e.g. schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder and psychosis NOS).

Studies will be excluded if 1) over half of the sample have co-morbid diagnoses of an intellectual disability, bipolar disorder, a primary diagnosis of substance-induced psychosis or psychosis that is secondary to an organic pathology, 2) the study only measures the association between persecutory delusions/paranoia and an alternative form of adverse childhood experience (e.g. bullying, death of a parent, being brought up in institutional care) 3) the study only measures the association between trauma experienced in adulthood and persecutory delusions/paranoia. Data from experimental or intervention studies that has been manipulated, including outcome data, will be excluded.

Intervention(s), exposure(s)

Not applicable

Comparator(s)/control

Not applicable

Context

No limitation on settings

Main outcome(s)

The primary outcome is the magnitude of the association between each form of childhood trauma and severity of paranoia. As detailed above, in the review persecutory delusions will be conceptualised as existing at the most severe end of the paranoia continuum. A wide variety of measures exist in the literature including generic measures of positive symptoms of psychosis (e.g. PANSS, Kay et al, 1986; SAPS, Andreasen, 1984), dimensional measures of psychotic symptoms (e.g. PSYRATS, Haddock et al, 1999) and symptom specific measures of paranoia (e.g. GPTS-Part B, Green et al, 2008). The following evidence hierarchy shall be used when rating papers against quality criteria: Symptom specific measures of paranoia > dimensional measures of persecutory delusions > generic measures of persecutory delusions.

Childhood trauma has also been assessed using a wide variety of methods within the literature including case note review (e.g. Schenkel et al, 2005), structured/ unstructured clinical interview (see Arseneault et al, 2013; Janssen et al, 2004), bespoke questionnaires (see Bentall et al, 2012) and validated questionnaires (e.g. CTQ, Bernstein & Fink, 1998). The following evidence hierarchy shall be used when rating papers against quality criteria: Validated measure of childhood trauma > bespoke questionnaire/ clinical interview > case note review.

Additional outcome(s)

None

Data extraction (selection and coding)

Selection of studies for the review will be conducted by the first author (David Carmichael) against the inclusion/exclusion criteria. Decision-making will be recorded and checked with the study supervisor Dr Paul Hutton.

Extracted data will include sample characteristics (e.g. gender, age, ethnicity, clinical diagnosis, duration of difficulties, medication status, sample source and location), study design, measure/s of childhood trauma and persecutory delusions, and outcome data (e.g., means, standard deviations, proportions, correlations and regression weights where applicable).

If data is not reported in usable format, the relevant authors will be contacted initially. If they do not reply, effect sizes will be attempted to be derived from other statistics (e.g., t test values, P-values, F-values) using equations specified in the Cochrane Handbook or by Borenstein and colleagues.

Risk of bias (quality) assessment

A methodological quality assessment tool for observational research, adapted from one used by the Agency for Healthcare Research and Quality (AHRQ; Williams, Plassman, Burke, Holsinger, & Benjamin, 2010) will be used. In addition, the GRADE approach will be used to provide an assessment of quality at the outcome level. The GRADE approach will be adapted so that observational studies will not automatically be marked down for quality. This is because all studies included in the proposed review will be observational.

The reviewer carrying out the quality assessments will complete the GRADE online training (<http://cebgrade.mcmaster.ca>). Quality assessments will be presented descriptively to guide the interpretation of findings. Two raters will independently undertake the ratings of risk of bias and methodological quality, with Dr Paul Hutton acting as arbitrator. Methodological quality assessment will be reported descriptively.

Strategy for data synthesis

Random-effects meta-analyses will be used to compute the overall correlation between different types of trauma and paranoia severity. Spearman's correlations, odds ratios and other measures of the association between these variables will first be converted into approximate Pearson's correlations, following procedures outlined in the Cochrane Handbook or by Borenstein and colleagues. These and reported Pearson's correlations will be converted into Fisher's Z for meta-analyses. For regression analyses R will be converted into Fisher's Z. Meta-analyses will be performed on Fisher's Z, and then the final estimate will be converted to Pearson's r for interpretation. For all effects, 95% confidence intervals will be calculated and statistical significance will be set at $P = 0.05$.

Publication bias will be tested for using funnel plots and applying the Trim and Fill method. Heterogeneity will be assessed via the Q-statistic and quantified via the I^2 statistic.

Random-effects meta-analyses will be undertaken as some degree of heterogeneity is expected across studies. Nonetheless, when there is less than moderate heterogeneity (i.e., I^2 statistic <40%), a sensitivity analysis will be carried out to examine the difference between fixed-effects and random-effects models.

Where it is not possible to perform a meta-analyses because of limited studies, a narrative review will be undertaken of the studies identified.

The authors shall endeavour to identify a method of statistical analysis to compare non-independent samples in order to allow for discussion of the relative strength of association between each trauma type and paranoia.

Analysis of subgroups or subsets

None

Contact details for further information

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Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions

24 November 2017
19 December 2017

Appendix B. Subsequent Changes to Protocol

Changes to the original protocol included the decision to include community and first episode psychosis (FEP) samples.

The rationale for these changes was that we gave further consideration to continuum models of paranoia (see Freeman et al, 2005; Freeman & Garety, 2000; Freeman & Garety, 2014) and judged it appropriate to include community samples in addition to clinical samples as a result.

Furthermore, we did not judge that the experience of paranoia would be qualitatively different between individuals experiencing FEP and those with a more established schizophrenia spectrum diagnosis (see Freeman, 2007; Freeman & Garety, 2014)

Inclusion and exclusion criteria were updated appropriately and the final version is outlined in the method section.

Appendix C: Adapted AHRQ Study Quality Assessment Tool

Study Quality Assessment Tool

In line with previous reviews (Larkin & Hutton, 2017; Murphy *et al*, 2018) assessment of observational study quality was conducted using an adapted version of the Agency for Healthcare Research and Quality (AHRQ) assessment tool (Williams *et al*, 2010). The main methodological quality criteria were retained and adapted to reflect the specific context of this review. The only criterion not retained was 'adequate follow-up period' at this did not apply to our research question. Each study is assessment on a number of methodological quality criteria (for example, unbiased selection of groups, sample-size calculations, appropriate methods of ascertaining childhood trauma exposure and so on) and are rated on the basis of criteria being met, not met, partially met or being unclear.

We avoided scale based or aggregated study quality ratings upon consideration of the guidance of experts in the field of meta-analysis. Rather than as a means to weight or adjust aggregated effect sizes, quality assessments were presented descriptively to guide interpretation of findings. Despite this, we planned to test whether specific aspects of the methodology (sample type and study quality) were moderators of effect sizes.

The quality assessment tool utilised for this review is outlined below:

General Instructions: Grade each criteria as 'Yes', 'No', 'Partially, or 'Can't tell'. Factors to consider when making an assessment are listed under each criterion. Where appropriate, (particularly when assigning a rating other than 'Yes', please provide a brief rationale for your decision.

1. Unbiased selection of cohort?

Factors to consider:

- Inclusion/exclusion criteria clearly defined
- Recruitment strategy clearly described and relatively free from bias (e.g. selection bias might be introduced, for example, by recruitment via advertisement)
- In intervention studies, are measures of paranoia taken at baseline (e.g. pre-intervention)

2. Selection minimizes baseline differences in prognostic factors?

Factors to consider:

- Was selection of comparison group appropriate? (e.g. undergraduate students unlikely to be a suitable control as likely to differ from typical healthy population on number of demographic factors)
- Is the comparison group matched with the clinical group on key demographic variables? (age, gender, ethnicity, years of education)?

Rating Guidelines:

- Yes: a standardised mean difference (d) of <0.3 on 4 demographic variables or 3 excluding ethnicity
- Partial: d of ≥ 0.3 on 1 demographic variables
- No: d of ≥ 0.3 on at least 2 demographic variables
- Can't tell: Insufficient information provided in article to make a determination

3. Sample size calculations?

Factors to consider:

- Did the authors report conducting an a-prior power analysis or describe some other basis for determining the adequacy of study group sizes for the primary outcome of interest?
- Where a power calculation is presented, does the final sample size match this (for example within 10% of required number?)

Rating Guidelines:

- Yes: A-prior power calculation/other basis for determining sample size reported and final sample matches this within 10% of required number.
- Partial: A-prior power calculation/other basis for determining sample size reported but final sample size does not meet this target
- No: No a-prior power calculation/ other basis for determining sample size reported

4. Adequate description of the cohort?

Factors to consider:

Is the cohort well-characterised in terms of baseline:

- Age
- Gender
- Education
- Ethnicity
- Diagnosis/clinical status

Rating Guidelines:

- Yes: Reported means/SD or N/% for all 5 or 4 excluding ethnicity
- Partial: Reported means/SD for 2 to 4
- No: Reported 1 of the above or less

5. Validated method for ascertaining psychotic disorder?

Factors to consider:

- Was the method used to ascertain exposure clearly described (details should be sufficient to permit replication in new studies)
- Was a valid and reliable measure used to ascertain exposure (subjective measure based on self-report tend to have lower reliability and validity than objective measures such as clinical interview)? In addition, chart diagnosis from medical notes is likely to introduce bias due to variation in how assessment is undertaken.

Ratings Guidelines:

- Yes: Method used to ascertain exposure was clearly described and used a valid/reliable measure (SCID-I)
- Partial: Chart Diagnosis or self-report (e.g. CIDI) + consistency check with a validated measure of psychotic symptoms (e.g. chart diagnosis + meeting study threshold on validated measure of psychotic symptoms or self-report psychotic symptoms on CIDI subsequently checked against SCID-I)
- No: Chart Diagnosis/ Review of medical notes for possible psychotic symptoms

6. Validated method for ascertaining childhood trauma?

Factors to Consider:

- Was the method used to ascertain exposure clearly described (details should be sufficient to permit replication in new studies)?
- Was a valid and reliable measure used to ascertain exposure?
- Did study authors set any threshold that had to be met to meet exposure status? Do these seem reasonable/appropriate (likely to be risk of bias if thresholds appear overly conservative)?

Ratings Guidelines:

- Yes: The authors used a valid and reliable measure of childhood trauma to determine exposure status (e.g. CTQ)
- Partial: The authors developed a bespoke interview/questionnaire for determining childhood trauma exposure
- No: Case note review for evidence of childhood trauma or a simple yes/no response was used in response to the question ‘Where you sexually/physical/emotionally abuse or physically/emotionally neglected during childhood. We judged case note review as low quality given the evidence that individuals with psychosis are rarely asked about a history of childhood trauma (Lothian & Read, 2002; Read et al, 2002). Therefore, this was felt to be an unreliable method for assessing childhood trauma
- Can’t Tell: Insufficient information provided in article to make determination

7. Validated method for ascertaining paranoia/persecutory delusions?

Factors to consider:

- Was the method used to ascertain exposure clearly described (details should be sufficient to permit replication in new studies)?
- Was a valid and reliable measure used to ascertain exposure?
- Did study authors set any threshold that had to be met to meet exposure status? Do these seem reasonable/appropriate (likely to be risk of bias if thresholds appear overly conservative)?

Rating Guidelines:

- Yes: The authors used a validated and reliable symptom specific measure of paranoia/persecutory delusions to determine exposure (e.g. BSI paranoid ideation sub-scale or GPTS)
- Partial: The authors used the validated and reliable general measure of psychotic symptoms then employed an item or sum of items as measure of paranoia/persecutory delusions (e.g. PANSS suspiciousness item, PANSS delusions + suspiciousness or BPRS suspiciousness + hostility). Likewise, studies that use validated and reliable measures of delusions, which subsequently persecutory sub-type scores.

8. Does analysis control for confounding variables?

Factors to consider:

Does the analysis control for the following factors:

- Age
- Gender
- Years of Educations
- Ethnicity
- Presence of other forms of childhood trauma other than the primary outcome (e.g. does an analysis focusing on the association between childhood physical abuse and paranoia/persecutory delusions control for the presence of sexual abuse)
- Presence of other psychotic symptoms (e.g. auditory verbal hallucinations)

9. Outcome assessments blind to childhood trauma exposure?

Factors to consider:

- Were the study investigators who assessed paranoia/persecutory delusions blind to whether participants had experienced childhood trauma?
- This criterion will only apply to case control studies

Rating Guidelines:

- Yes: Raters were blind to childhood trauma exposure status
- Partial: N/A
- No: Raters were not blind to childhood trauma exposure status
- Can't tell: Insufficient information provided in article to make determination

10. Missing data low or appropriately handled?

Factors to consider:

- Are the details of any missing data clearly reported, including how missing data was handled in the analysis? If not, is there reason to suspect missing data was present (e.g. N is lower in analysis than initially reported in participants section).
- Did missing data from any group exceed 20%?
- If missing data was present and substantial, were steps taken to minimize bias (for example, sensitivity analysis or imputation)

Ratings Guidelines:

- Yes: Missing data was clearly described and appropriate method was used to deal with this for analysis (e.g. any participant missing >20% of data excluded from analysis)
- Partial: It would appear that missing data was excluded from analysis but the methods taken to manage this were not clearly/appropriately described
- No: No information given regarding missing data or how this was dealt with for analysis or strategy used to manage missing data appears inappropriate
- Can't tell: Insufficient information provided in article to make determination

Appendix D: Meta-Analytic Outcome Specific Quality Assessment Ratings

Table 10. Quality Ratings for Studies entered into Meta-Analysis for Association between CSA and Paranoia

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Clinical Psychosis Samples										
Ashcroft, 2012	Partial	No	No	Partial	Yes	Yes	Yes	No	No	Partial
Bendall, 2013	Yes	No	No	Partial	Yes	Yes	Partial	No	Unclear	Yes
Choi, 2011	Yes	-	No	Yes	No	No	Partial	No	Yes	Partial
Hardy, 2016	Partial	-	No	Yes	Partial	Yes	Yes	Yes	No	Yes
Lysaker, 2005	Partial	Unclear	No	No	Yes	Partial	Partial	No	No	Yes
Shahar, 2004	Partial	-	No	No	No	Partial	Yes	Yes	No	Partial
vanNierop, 2014	No	-	No	Yes	Yes	Partial	Partial	Yes	No	Partial
Wickham, 2016	Partial	No	No	Yes	Partial	Yes	Partial	Yes	No	Yes
Clinical Non-Psychosis Samples										
Allen, 1998	Yes	-	No	Partial	-	Yes	Yes	No	No	Yes
Read, 2003	Yes	-	No	Partial	No	No	No	No	No	Yes

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Community Samples										
Barker- Collo, 2011	Partial	-	No	Yes	-	No	Yes	No	No	Yes
Boyda, 2015	Yes	-	No	Partial	-	No	Yes	No	No	Partial
Colins, 2009	Yes	-	No	Partial	-	Yes	Yes	Partial	No	Yes
Dias, 2015	Partial	-	No	Partial	-	Yes	Yes	No	No	Yes
Freeman, 2009	Partial	-	No	Yes	-	Yes	Yes	Yes	No	No
Shevlin, 2015	Yes	-	No	Partial	-	Yes	Partial	Yes	No	Yes
Sitko, 2014	Yes	-	No	No	-	Partial	Yes	No	No	Partial

Note: ^a Relevant to Case-control studies only

Table 11. Quality Ratings for Studies entered into Meta-Analysis for the Association between CPA and Paranoia

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors?^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Clinical Psychosis Samples										
Ashcroft, 2012	Partial	No	No	Partial	Yes	Yes	Yes	No	No	Partial
Choi, 2011	Yes	-	No	Yes	No	No	Partial	No	Yes	Partial
Hardy, 2016	Partial	-	No	Yes	Partial	Yes	Yes	Yes	No	Yes
Rajkumar, 2015	Yes	-	No	Yes	No	Yes	Partial	No	No	Partial
Shahar, 2004	Partial	-	No	No	No	Partial	Yes	Yes	No	Partial
vanNierop, 2014	No	-	No	Yes	Yes	Partial	Partial	Yes	No	Partial
Wickham, 2016	Partial	No	No	Yes	Partial	Yes	Partial	Yes	No	Yes
Clinical Non-Psychosis Samples										
Allen, 1998	Yes	-	No	Partial	-	Yes	Yes	No	No	Yes
Read, 2003	Yes	-	No	Partial	No	No	No	No	No	Yes

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Community Samples										
Barker- Collo, 2011	Partial	-	No	Yes	-	No	Yes	No	No	Yes
Bentall, 2012	Yes	-	No	No	-	No	Yes	Yes	No	Partial
Colins, 2009	Yes	-	No	Partial	-	Yes	Yes	Partial	No	Yes
Dias, 2015	Partial	-	No	Partial	-	Yes	Yes	No	No	Yes
Fisher, 2012	No	-	No	Partial	-	Yes	Partial	No	No	Partial
Freeman, 2009	Partial	-	No	Yes	-	Yes	Yes	Yes	No	No
Sitko, 2014	Yes	-	No	No	-	Partial	Yes	No	No	Partial

Note: ^a Relevant to Case-control studies only

Table 12. Quality Ratings for Studies entered into Meta-Analysis for the Association between CEA and Paranoia

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Clinical Psychosis Samples										
Ashcroft, 2012	Partial	No	No	Partial	Yes	Yes	Yes	No	No	Partial
Choi, 2011	Yes	-	No	Yes	No	No	Partial	No	Yes	Partial
Hardy, 2016	Partial	-	No	Yes	Partial	Yes	Yes	Yes	No	Yes
vanNierop, 2014	No	-	No	Yes	Yes	Partial	Partial	Yes	No	Partial
Wickham, 2016	Partial	No	No	Yes	Partial	Yes	Partial	Yes	No	Yes
Clinical Non-Psychosis Samples										
Allen, 1998	Yes	-	No	Partial	-	Yes	Yes	No	No	Yes
Longden, 2016	Yes	-	No	Yes	No	No	No	No	No	Yes
Community Samples										
Colins, 2009	Yes	-	No	Partial	-	Yes	Yes	Partial	No	Yes
Dias, 2015	Partial	-	No	Partial	-	Yes	Yes	No	No	Yes
Fisher, 2012	No	-	No	Partial	-	Yes	Partial	No	No	Partial

Note: ^a Relevant to Case-control studies only

Table 13. Quality Ratings for Studies entered into Meta-Analysis for the Association between CPN and Paranoia

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Clinical Psychosis Samples										
Ashcroft, 2012	Partial	No	No	Partial	Yes	Yes	Yes	No	No	Partial
Choi, 2011	Yes	-	No	Yes	No	No	Partial	No	Yes	Partial
Wickham, 2016	Partial	No	No	Yes	Partial	Yes	Partial	Yes	No	Yes
Clinical Non-Psychosis Samples										
Allen, 1998	Yes	-	No	Partial	-	Yes	Yes	No	No	Yes
Community Samples										
Colins, 2009	Yes	-	No	Partial	-	Yes	Yes	Partial	No	Yes
Dias, 2015	Partial	-	No	Partial	-	Yes	Yes	No	No	Yes

Note: ^a Relevant to Case-control studies only

Table 14. Quality Ratings for Studies entered into Meta-Analysis for the Association between CEN and Paranoia

Study Ref (First Author, Year)	Unbiased Selection of Cohort?	Selection Minimizes Baseline Differences in Prognostic Factors? ^a	Sample Size Calculations?	Adequate Description of Cohort?	Validated Method for Ascertaining Psychotic Disorder?	Validated Method for Ascertaining Childhood Trauma?	Validated Method for Ascertaining Paranoia/ Persecutory Delusions?	Does analysis control for confounding variables?	Outcome Assessments Blind to Childhood Trauma exposure?	Missing Data Low or Adequately Handled?
Clinical Psychosis Samples										
Ashcroft, 2012	Partial	No	No	Partial	Yes	Yes	Yes	No	No	Partial
vanNierop, 2014	No	-	No	Yes	Yes	Partial	Partial	Yes	No	Partial
Wickham, 2016	Partial	No	No	Yes	Partial	Yes	Partial	Yes	No	Yes
Clinical Non-Psychosis Samples										
Allen, 1998	Yes	-	No	Partial	-	Yes	Yes	No	No	Yes
Community Samples										
Colins, 2009	Yes	-	No	Partial	-	Yes	Yes	Partial	No	Yes
Dias, 2015	Partial	-	No	Partial	-	Yes	Yes	No	No	Yes

Note: ^a Relevant to Case-control studies only

Appendix E: GRADE Assessment Criteria

Grade Assessment Criteria

All assessments were conducted by DC and checked with PH. We adapted the criteria described by Murphy et al (2018) for downgrading each outcome. These criteria are described below:

Study Limitations

Individual studies were rated for risk of bias/methodological quality using an adapted version of the Agency for Healthcare Research and Quality assessment tool (AHRQ) (Williams et al., 2010). We downgraded an outcome by 1 point if three of the parameters in our risk of bias assessment had $\geq 50\%$ studies with at least one 'no' or 'unclear' rating, and 2 points if four or more parameters had $\geq 50\%$ studies with ratings of 'no or unclear'.

We did not include the 'Selection Minimizes Baseline Differences in Prognostic Factors' criterion as this was only applicable to case-control study designs. In addition, as the 'Validated Method for Ascertain Psychotic Disorder' criterion only applied to clinical samples, we only included this as a parameter if $>50\%$ of studies with clinical populations had a 'no' or 'unclear' rating.

Imprecision

We downgraded an outcome for imprecision by 1 point if "*a recommendation or clinical course of action would differ if the upper versus the lower boundary of the CI represented the truth*" and/or the number of events and sample size meant the optimal information size was not reached (Guyatt et al., 2011).

If the only difference between the upper and low boundary of the CI simply represented a difference in the magnitude of the effect (e.g. small effect changing to a finding of a medium effect), then this was not downgraded as strength of the association would not change a recommendation.

If however, the difference between the upper and lower boundary of the CI was the difference between no effect and small, moderate, or large effect, quality was downgraded for Imprecision.

Inconsistency

We downgraded an outcome for inconsistency by 1 point if the I^2 statistic was $\geq 40\%$ in the context of an unclear direction of effect or $\geq 75\%$ in the context of a clear direction of effect. We downgraded by 2 points if the I^2 statistic was $\geq 75\%$ in the context of an unclear direction of effect.

Publication Bias

We downgraded an outcome for publication bias by 1 point when, for outcomes with at least 10 studies (Higgins & Green, 2011), the Doi plot and LFK index suggested major asymmetry (i.e., LFK index > 2) and this was not better explained by selective reporting bias or some other factor. However, if the 'trim and fill' method indicated that any publication bias was not likely to affect the overall magnitude of the effect size, we did not downgrade.

Rating Up the Quality of Evidence

In the context of a large effect size, we upgraded by 1 point where the effect size calculated was large. Using Cohen's criteria (1988), an effect size of $r \geq 0.50$ or $d \geq 0.80$ was considered large.

Appendix F: Meta-Regression Graphs



Figure 7. 1. Meta-Regression Scatterplot: Study Population in Association between CSA and Paranoia

Regression of Fisher's Z on Trauma Measure

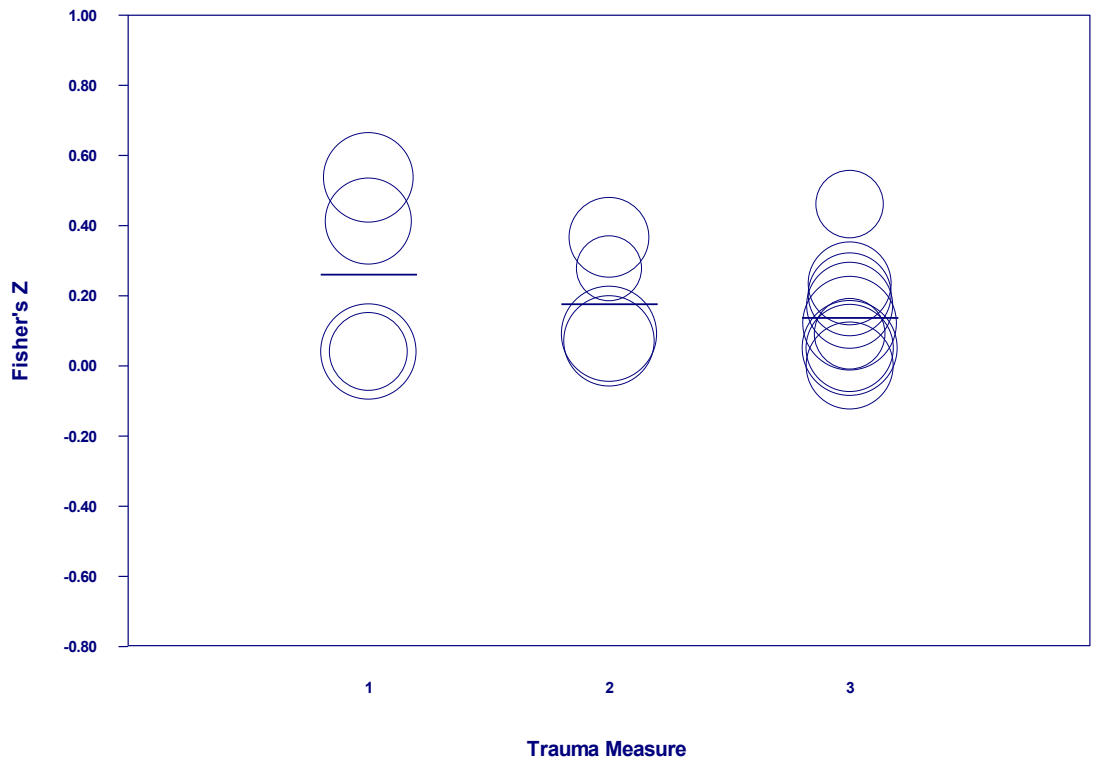


Figure 7. 2. Meta-Regression Scatterplot for Quality of Trauma Measure in Association between CSA and Paranoia

Regression of Fisher's Z on Paranoia Measure

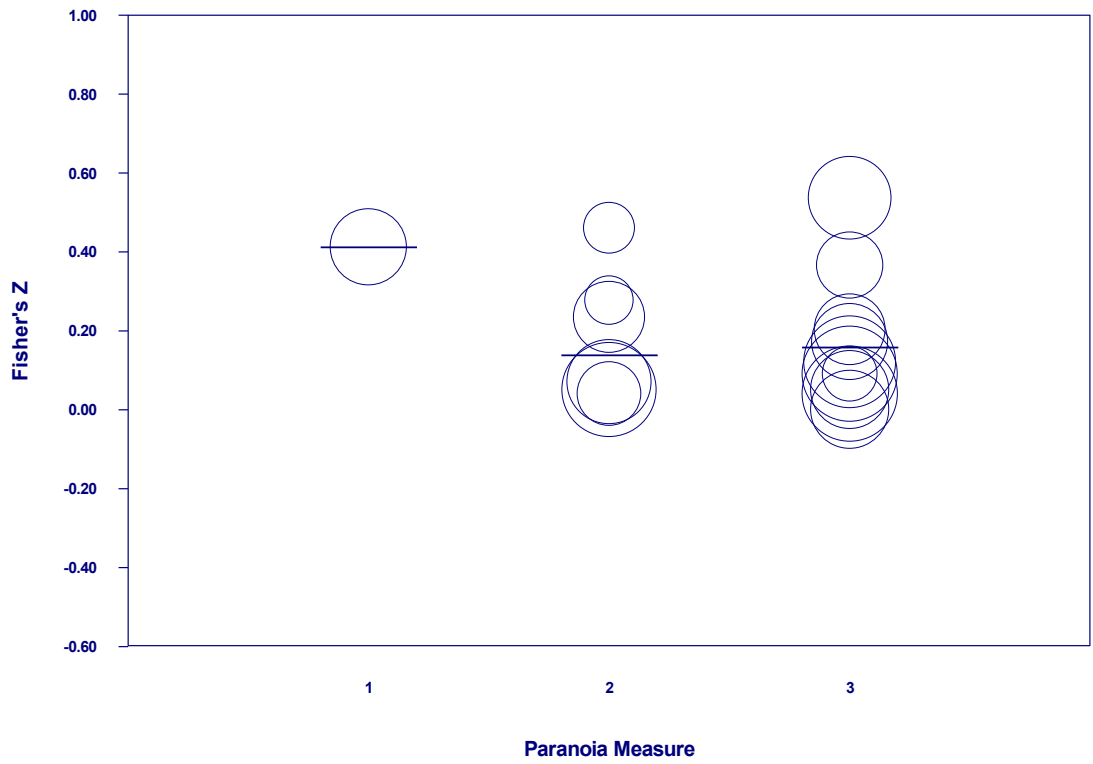


Figure 7. 3. Meta-Regression Scatterplot for Quality of Paranoia Measure in Association between CSA and Paranoia

Regression of Fisher's Z on Population

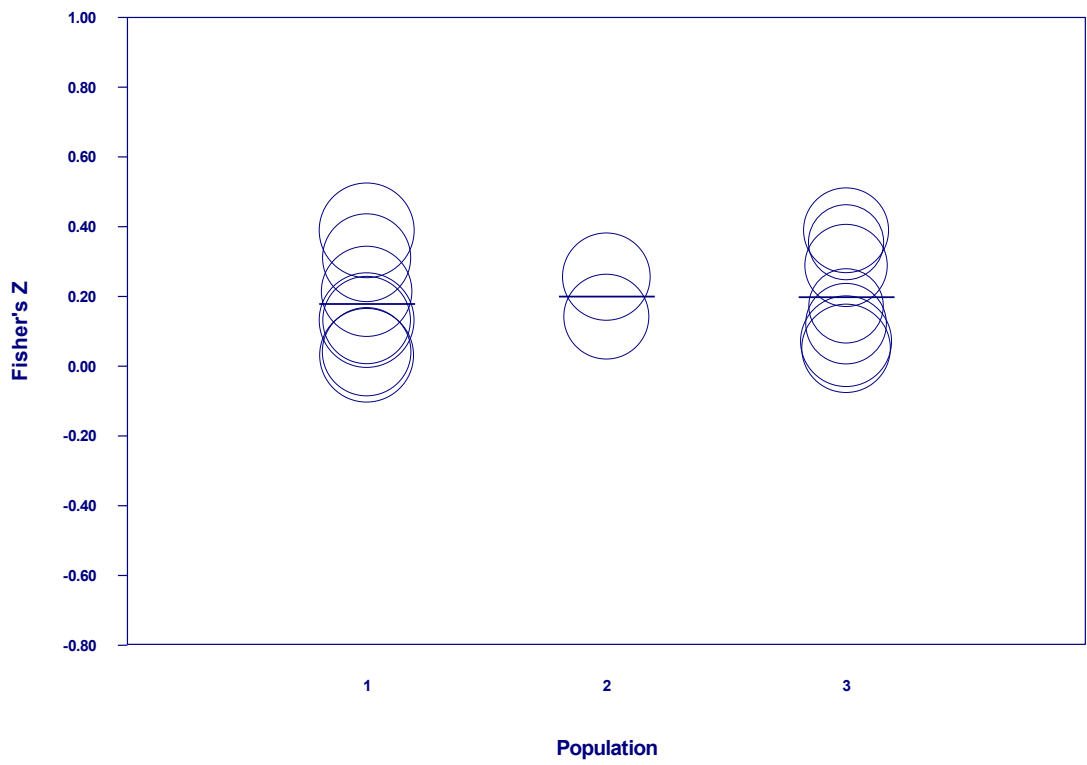


Figure 7. 4. Meta-Regression Scatterplot for Population in Association Between CPA and Paranoia

Regression of Fisher's Z on Trauma Measure

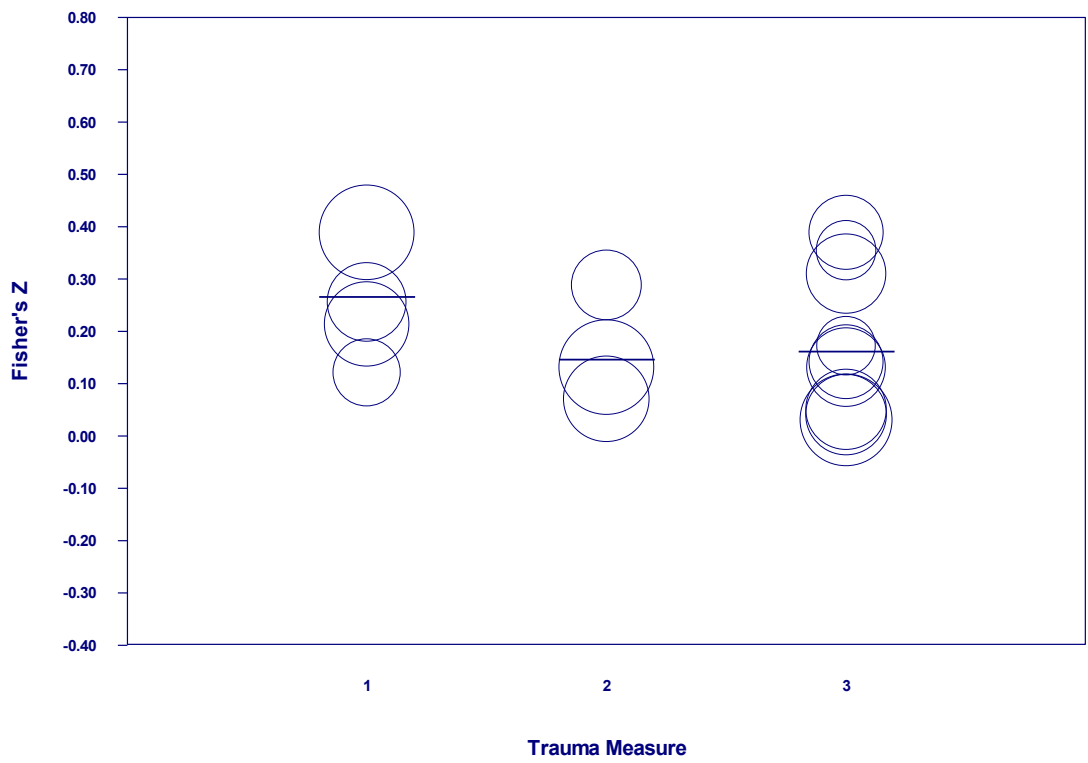


Figure 7. 5. Meta-Regression Scatterplot for Quality of Trauma Measure in Association Between CPA and Paranoia

Regression of Fisher's Z on Paranoia Measure

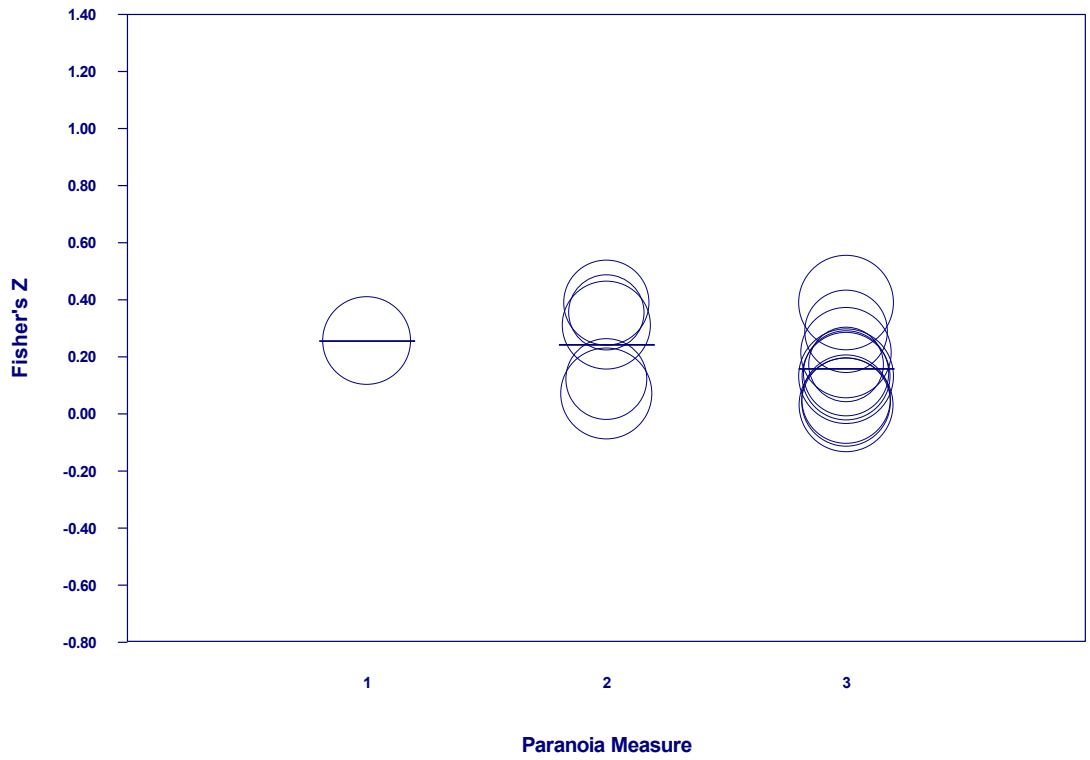


Figure 7. 6. Meta-Regression Scatterplot for Quality of Paranoia Measure in Association Between CPA and Paranoia

Regression of Fisher's Z on Population

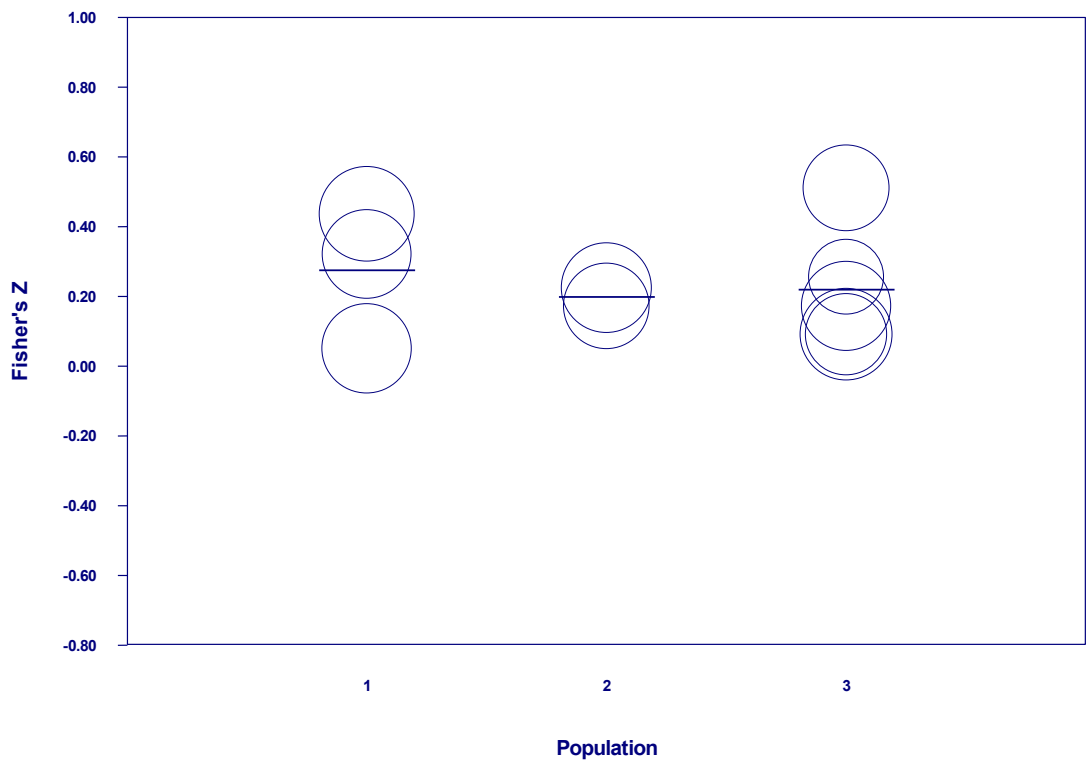


Figure 7. 7. Meta-Regression Scatterplot for Population in Association between CEA and Paranoia

Regression of Fisher's Z on Trauma Measure

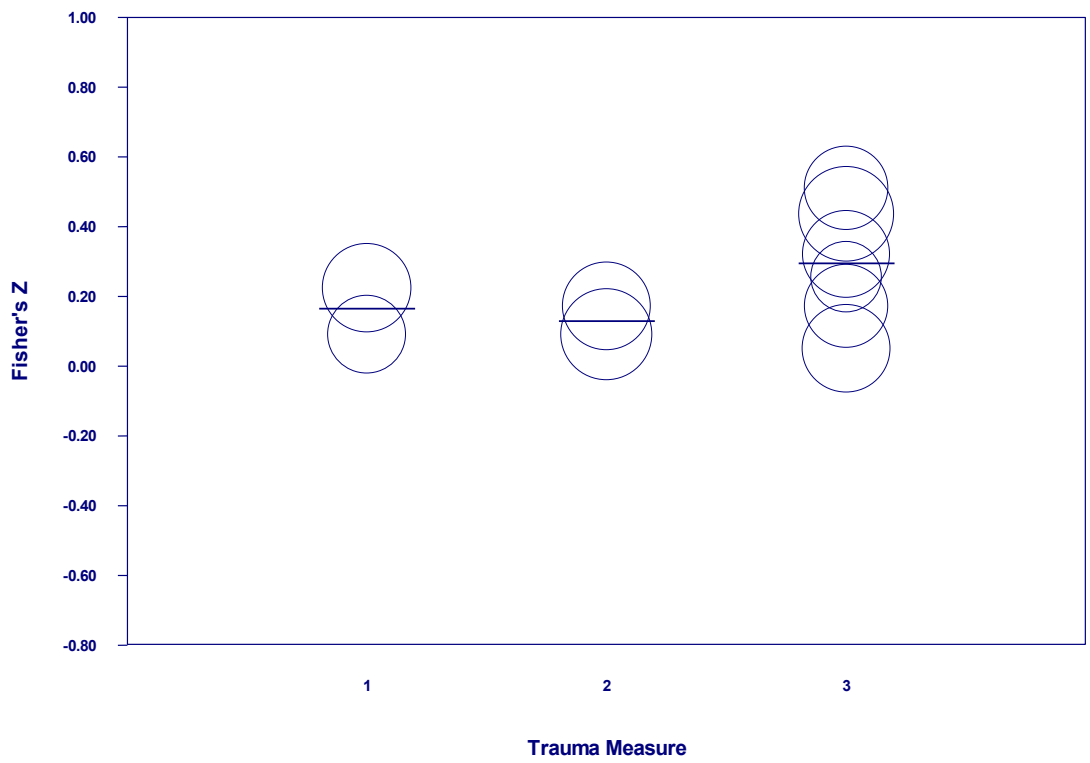


Figure 7. 8. Meta-Regression Scatterplot for Quality of Trauma Measure in Association between CEA and Paranoia

Regression of Fisher's Z on Paranoia Measure

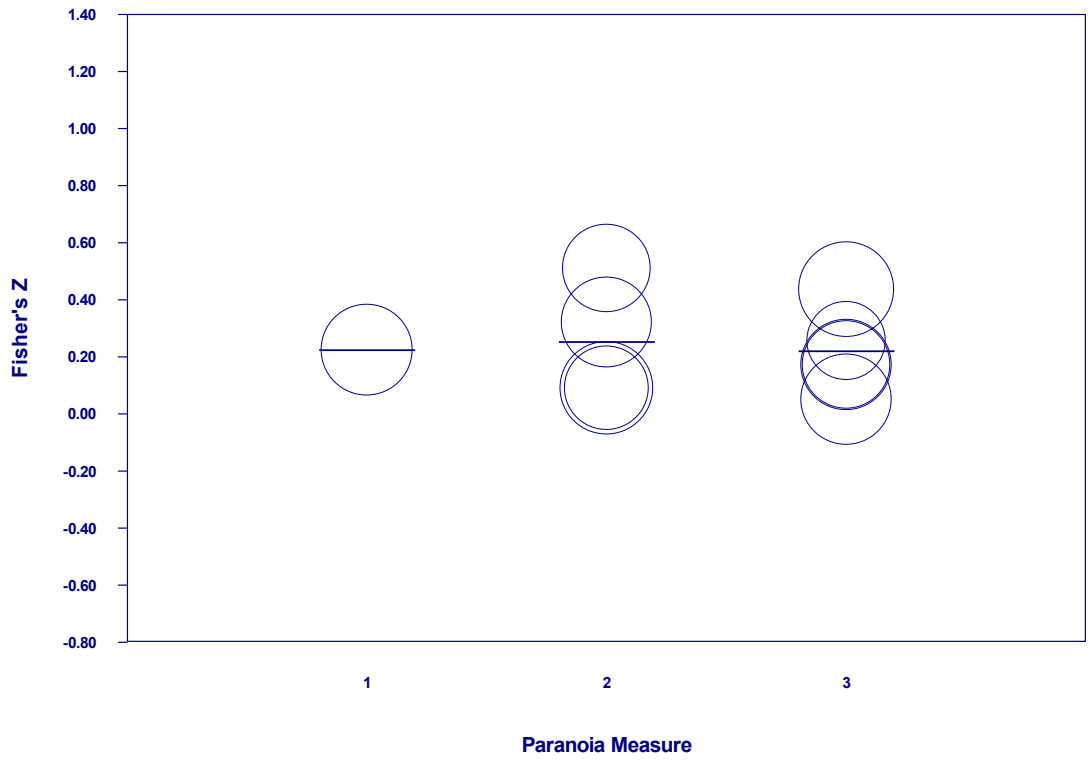


Figure 7. 9. Meta-Regression Scatterplot for Quality of Paranoia Measure in Association Between CEA and Paranoia

Appendix G: Prisma Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	9
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	10
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	11-17
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	17-18
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	18
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	19
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	18
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	18
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	19

Section/topic	#	Checklist item	Reported on page #
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	20
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	20
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	21
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	20
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	21-22
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	21
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	22
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	22-24
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	25-29
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	32-33
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	35, 38, 41, 44, 45

Section/topic	#	Checklist item	Reported on page #
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	34
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	34
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	36-45
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).	46
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	50-51
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	51-54
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	75



CLINICAL PSYCHOLOGY REVIEW

**AUTHOR
INFORMATION PACK**



CONTENTS

XXX

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Chapter 2: Empirical Journal Article

The relationship between childhood trauma, negative core schema and paranoia: A mediation analysis

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Abstract

Aims: There is now a significant evidence of a relationship between childhood trauma and psychosis. This review adopted a psychotic experience specific approach and aimed to examine whether negative-self and negative-other core schema mediate the relationship between childhood trauma and paranoia. We also piloted a new measure of negative score schema, the Schema Rating Interview (SCIRATS).

Method: Study 1 sought to test the above relationships in a cross-sectional online survey of the general population, whereas Study 2 sought to test these in a cross-sectional clinical sample of individuals with persecutory delusions. Relationships between variables were analysed using correlation and mediation analysis. We also sought to explore initial utility of the SCIRATS by repeating these analysis with this measure.

Results: A total of 460 participants participated in Study 1. Negative-self (CSE= 0.14, 95% CI= 0.08, 0.21), Negative-other (CSE= 0.08, 95% CI= 0.04, 0.15) and both Negative-self and Negative-other core schema together mediated the relationship between childhood trauma and paranoia (CSE=0.17, 95% CI= 0.11, 0.25). Repeating the analysis with the SCIRATS, negative-self (CSE= 0.13, 95% CI= 0.07, 0.18), negative-other (CSE= 0.06, 95% CI= 0.02, 0.12) and both negative-self and negative-other (CSE= 0.14, 95% CI= 0.09, 0.19) remained significant mediators of the relationship between childhood trauma and paranoia. A total of 14 participants participated in Study 2. We found a significant association between childhood trauma and negative-self core schema ($r=0.70$, $p<0.01$). This association remained when using the SCIRATS ($r=0.62$, $p<0.05$). Negative-self ($r=0.61$, $p<0.06$) and Negative-other core schema ($r=0.82$, $p<0.001$) were significantly associated with paranoia, however on the SCIRATS, only Negative-self core schema were significant associated with paranoia ($r=0.58$, $p<0.001$). We found no significant association between childhood trauma and paranoia. Positive initial feedback on the SCIRATS would suggest participants view this as an acceptable measure.

Conclusions: Our findings would appear to support a role of negative core schema in the relationship between childhood trauma and paranoia. When viewed within the context of the wider literature, our findings are consistent with cognitive models of

psychosis and contribute toward the wider evidence for a causal relationship between childhood trauma and psychosis. Associations and correlations alone however can not prove causation and we recommend that future research develop psychological interventions to target negative core schema in order to ascertain whether this reduces paranoia in people with persecutory delusions. We also suggest that future research should attempt to validate the psychometric properties of the SCIRATS.

1. Introduction

While biogenetic theories have traditionally dominated understandings of psychosis (Read, Bentall & Fosse, 2009; Read, van Os, Morrison & Ross, 2005), there is now a growing body of literature suggesting a significant association between childhood trauma and psychosis (Read et al, 2005; Varese et al., 2012). Indeed, when consistent findings regarding the strength of this association (Matheson, Shepherd, Pinchbeck, Laurens & Carr, 2013; Trotta, Murray & Fisher, 2015; van Dam et al., 2012), a dose-response relationship (Bentall, Wickham, Shevlin & Varese, 2012; Trauelsen et al, 2015; Whitfield, Dube, Felitti & Anda, 2005), the temporal relationship between experience of childhood trauma and subsequent risk of psychosis (Arseneault et al, 2011; Cutajar et al, 2010; Janssen et al, 2004), and that this relationship persists even when controlling for other recognised risk factors for psychosis (Gibson, Alloy & Ellman, 2016) are considered within the context of Bradford Hill criteria (1965), these findings have been interpreted as indicating a causal relationship (Ackner, Skeate, Patterson & Neal, 2013; Bailey et al., 2018; Bendall, Jackson, Hulbert & McGorry, 2007; Varese et al, 2012).

In light of the claims, researchers have begun to examine underlying mechanisms and develop theoretical models to explain this relationship, focusing on the common factors shared by different forms of early life trauma (Bentall et al., 2014). A wide variety of biological and psychological mechanisms have been implicated in the attempt to explain this relationship (see Bentall et al., 2014; Misiak et al., 2017 for reviews), however there is a tendency across both psychological and psychiatric research to assume that one underlying process can account for the relationship between childhood trauma and psychosis (Bentall et al., 2014). It has been argued however that this is problematic given the heterogeneous nature of psychosis (Bentall & Fernyhough, 2008). Indeed psychotic experiences have been found cluster into different domains, including positive symptoms, negative symptoms, cognitive distortion, depression and mania (Demjaha et al., 2009; Liddle, 1987; van Os & Kapur, 2009) and that any one individual may experience a unique combination of experiences across these domains (British Psychological Society (BPS), 2014; National Institute for Health and Care Excellence (NICE), 2014).

Bentall and colleagues (Bentall & Fernyhough, 2008; Bentall et al., 2014) outline findings that different forms of psychotic experience have been found to be associated with different psychological processes. The authors highlight that auditory hallucinations have been found to be associated with dissociation, where this is thought to lead to difficulties with source-monitoring and to cause individuals to interpret self-generated mental events as external to the self. Conversely, they outline that the over-anticipation of future interpersonal threat often viewed as the core-process associated with persecutory delusions, may be associated with the impact of childhood trauma on attachment relationships and the development of negative core schema regarding the self and others (see Bentall & Fernyhough, 2008; Bentall et al., 2014).

Rather than a single underlying mechanism, Bentall and colleagues argue that specific forms of childhood trauma may have differential impacts underlying psychological processes and therefore may be associated with some psychotic experiences more than others (Bentall & Fernyhough, 2008; Bentall et al., 2014). They highlight the work of Bradford Hill (1965) who stated that specificity of effects is required to demonstrate causality in addition to strength of association, consistency of effects, dose-response relationships, temporality, coherence, analogy, experimental evidence and plausible theoretical mechanisms. In support of these arguments, Bentall and colleagues cite evidence of specific relationships between CSA and auditory hallucinations and victimisation experiences (e.g. bullying and CPA) and persecutory delusions (Bentall & Fernyhough, 2008; Bentall et al., 2014). Indeed, in Chapter 1, we found evidence of larger associations between CEA and CPA and paranoia than for others forms of childhood trauma, furthering the evidence for specificity between differing forms of childhood trauma and paranoia.

Bentall and colleagues argue that future research should examine the psychological mechanisms associated with these specific relationships (Bentall & Fernyhough, 2008; Bentall et al., 2014). They suggest that, if the mechanisms underlying relationships between specific forms of childhood trauma and psychotic experiences can be identified, then this would strengthen the argument for causality under Bradford Hill criteria, but may also lead to improved psychological therapies for psychosis but targeting these trauma-specific mechanisms. Bentall and colleagues

(Bentall & Fernyhough, 2008; Bentall et al., 2014) echo Bradford Hill's (1965) original caution however that specificity should not be overemphasised, highlighting that most forms of childhood trauma are likely to have a general effect on psychological processes such as emotional regulation, that childhood traumas are unlikely to have a 'pure' effect on one process but not another (e.g. CSA may impact upon attachment representations in addition to dissociation), that childhood traumas tend to co-occur and that one form of psychotic experience can often give rise to another.

In light of the above findings, this study adopted a psychotic experience specific approach focusing on paranoia. The rationale for this focus is that paranoia is thought to be one of the most common forms of psychotic experiences, occurring in 70% of first-episode and 50% of cases of psychosis thereafter (Freeman, 2007; Freeman & Garety, 2014) and given that persecutory delusions have been found to be the most likely delusions to be acted upon (Wessely et al., 1993). This study will also adhere to continuum models of paranoia (see Freeman et al., 2005; Freeman & Garety, 2000; Freeman & Garety, 2014) where paranoia is conceptualised as existing on a spectrum ranging from common social evaluative concerns or feelings or vulnerability to clinically significant persecutory delusions at the most severe range of the spectrum, where these are defined as an unfounded belief that harm is occurring, or is going to occur to them and that the perpetrator has the intention to cause that harm (see Peters et al., 2016). As a result, the term paranoia will be used throughout the review to refer to both paranoia within the general population and persecutory delusions in individuals with psychosis.

As noted above, negative core schema have been implicated as an underlying mechanism that may explain the relationship between childhood trauma and psychosis. Cognitive models of psychosis offer an insight into the nature of these relationships (Garety et al., 2001; Morrison, 2001). These models suggest that adverse early life experiences may lead to the development of negative beliefs about the self, the world and other people. These beliefs are known as negative core schema and can be defined as 'negative, rigid and deeply held beliefs about the self, the world and others that develop as a result of early life experiences' (Beck, Rush, Shaw & Emery, 1979). If, for example, an individual experiences adverse life

experiences, they may develop negative core schema such as ‘I am bad’, ‘I’m vulnerable’ or ‘Other people are dangerous’ (Morrison, Frame & Larkin, 2003; Read et al., 2005).

Subsequent adverse life experiences are thought to activate these negative core schema, resulting in emotional changes, such as anxiety or depression, and ‘unusual perceptual experiences’ (Garety et al., 2001; Morrison, 2001; Okkels, Trabjerg, Arendt & Pedersen, 2016). Individuals with psychosis are subsequently thought to attempt to make sense of or ‘appraise’ these usual perceptual experiences (Garety et al., 2001; Morrison, 2001). A number of cognitive biases are thought to influence this appraisal-formation process including jumping to conclusions (Dudley, Taylor, Wickham & Hutton, 2016; Garety et al., 2001) and attribution negative events to the actions of others (known as an external attribution style) (Garety et al., 2001; Janssen et al., 2006). Pre-existing negative core schema are also thought to shape and influence this process (Garety et al. 2001; Garety & Freeman, 2013; Morrison, 2001). Applying this model specifically to persecutory delusions, the role of anticipation or danger has been emphasised, where childhood trauma is thought to result in negative core schema regarding the self and others, and that as a result of these core schema, individuals are predisposed toward jumping to a threat-based interpretation of anomalous perceptual experiences (Freeman, Garety, Kuipers, Fowler & Bebbington, 2002).

Given that paranoia is thought to exist on a spectrum ranging from common social evaluative concerns in the general population to clinically significant persecutory delusions in people with psychosis (see Freeman et al., 2005; Freeman & Garety, 2000; Freeman & Garety, 2014), it could be argued that the relationship between childhood trauma, negative core schema and paranoia is likely to be found both within the general population and individuals with psychosis. Indeed a number of studies have examined negative-self core schema and paranoia in the general population as an analogue for clinical samples, reporting significant associations (Fowler et al., 2006; Gracie et al., 2006; Vorontsova, Garety, & Freeman, 2013). Of note, similar associations have also been found in clinical samples (Fowler et al., 2006; Fowler et al., 2011; Smith et al., 2006; Vorontsova et al., 2013). Similarly, negative-other core schema have also been found to be significantly associated with

paranoia in community (Fowler et al., 2006; Gracie et al., 2006; Vorontsova et al., 2013) and clinical samples (Fowler et al., 2006; Vorontsova et al., 2013)

While the above findings provide some degree of support the suggestion that negative core schema may be the mechanisms linking childhood trauma and paranoia, it could be argued that these findings are limited by the use of questionnaire measures to capture negative core schema. The 'paranoia as defence' model (Bentall, Corcoran, Howard, Blackwood & Kinderman, 2001) suggests that persecutory delusions might serve as a defence against feelings of inferiority becoming conscious. The assumption of this model is that individuals with persecutory delusions have typical or perhaps even elevated levels of explicit self-esteem but low levels of implicit self-esteem. Indeed a recent systematic review and meta-analysis found evidence of a 'weak' version of the paranoia as defence model, where individuals with persecutory delusions has a greater implicit-explicit self-esteem discrepancy than those with depression and severity of paranoia significantly predicted the extent of this discrepancy (Murphy, Bentall, Freeman, O'Rourke & Hutton, 2018). It could be questioned therefore if a questionnaire measure can truly capture negative core schema, as it is possible responses to questionnaire measures better reflect explicit rather than implicit self-esteem.

A further limitation of the literature is the tendency to examine either the relationship between childhood trauma and paranoia or negative core schema and paranoia. In order to test whether negative core schema are an underlying psychological mechanism linking childhood trauma to paranoia however, we need to establish to what degree negative-self and negative-other core schema mediate the relationship between childhood trauma and paranoia. To our knowledge, only two studies have attempted to do so.

Fisher, Appiah-Kusi & Grant (2012) examined to what extent anxiety, negative-self and negative-other core schema mediated the relationship between childhood trauma and paranoia in a general population sample. The authors found that only CPA and CEA were associated with paranoia, where negative-self and negative-other core schema were significant mediators of this relationship. Hardy et al. (2016) examined to what extent affect regulation, intrusive trauma memories, negative core schema

and depression mediate the relationship between childhood trauma and psychotic experiences in a clinical sample of individuals with psychosis. The authors found that while there was no significant association between CPA and paranoia, there was a significant association between CEA and paranoia, where negative-other but not negative-self core schema significantly mediate this relationship.

These findings are further limited by the fact both studies used general measures of psychotic symptoms rather than ‘symptom’ or experience specific measures of paranoia, where the measure of paranoia consisted of a limited number of items, possibly failing to capture the full continuum of paranoia beliefs. In addition, Hardy et al. (2016) measured childhood trauma history, negative core schema and paranoia at three-month follow-up post-intervention. Given this was a CBT-based intervention, it could be argued that their findings do not truly the role of negative core schema in the relationship between childhood trauma and paranoia as these negative core schema were likely to have changed to some degree following the intervention stage of the trial and therefore not adequately reflect the role of negative core schema in the development of paranoia following childhood trauma. Furthermore, studies tend to examine the frequency of childhood trauma rather than how long an individual experienced these events. This is problematic as we know from research into other mental health difficulties such as PTSD and Complex Trauma that longer trauma duration is associated with increased symptom severity (see Cloitre et al., 2009; Courtois, 2008). Finally, conflicting findings regarding whether negative-self and/or negative-other mediate of the relationship between childhood trauma and paranoia, result in a lack of clarity regarding which schema would be most beneficial to target in psychological therapies for paranoia (see Bentall et al., 2014).

In order to address some of the limitations of previous research and further test whether cognitive models of psychosis are useful in understand the link between childhood trauma and psychosis, this study sought to examine to what extent negative-self and/or negative-other negative core schema mediate the relationship between childhood trauma and paranoia in the general population (Study 1) and in a clinical sample of people with persecutory delusions. While acknowledging the important of evidence of relationships between specific forms of childhood trauma and paranoia, we were mindful of Bentall and colleagues (Bentall & Fernyhough,

2008; Bentall et al., 2014) caution that while some forms of childhood trauma are likely to impact on negative core schema to a greater extent than others, specific forms of childhood traumas are unlikely to have a ‘pure’ effect on one process but not another. We therefore elected to examine to what extent negative core schema mediated the relationship between total childhood trauma score and paranoia.

We also elected to employ a symptom specific measure of paranoia, where a recent meta-analysis (Statham, Emerson & Rowse, 2018) found the Green Paranoid Thoughts Scales (GPTS; Green et al., 2008) to be the most robust measure of paranoia across the community and clinical samples. Finally, in light of our concerns regarding the use of questionnaire measures to capture negative core schema, we adapted the Brief Core Schema Scales (BCSS; Fowler et al., 2006) and piloted a new Schema Rating Interview (SCIRATS, further details below) in order to serve as an additional check we were accurately capturing participants negative core schema (The Schema Rating Interview, further details below).

We hypothesised that:

- 1) Negative-self core schema will mediate the relationship between childhood trauma and paranoia.
- 2) Negative-other core schema will mediate the relationship between childhood trauma and paranoia.

We also aimed to examine whether the effect of either negative-self or negative-other core schema would be explained for controlling for the presence of one another and to what extent both schema together mediated the relationship between childhood trauma and paranoia. Furthermore, we viewed the SCIRATS as a more conservative measure of negative core schema and sought to compare the results of mediation analysis when measuring these through the BCSS vs when measured through the SCIRATS. Finally, in Study 2 we sought to further explore the influence of trauma duration upon negative core schema and paranoia.

2.1. Method: Study 1

2.1.1. Ethical Approval

Ethical approval for this study was granted by The University of Edinburgh's Department of Clinical and Health Psychology Research Ethics Panel (Appendix A).

2.1.2. Study Design

The study utilised a cross-sectional, quantitative, within-groups design. An online survey measured the extent to which negative core schema mediated the relationship between childhood trauma and paranoia within the general population.

2.1.3. Participants

Participants were eligible to take part in the study if they were over the age of 16 and able to read and understand written English. Participants were excluded if they had a diagnosis of an intellectual disability or dementia.

2.1.4. Measures

The online survey (Appendix B) comprised demographic questions and three standardised psychometric self-report questionnaires, including:

The Child Abuse and Trauma Scale (CAT-S; Sanders & Becker-Lausen, 1995) is a 38-item self-report questionnaire that measures the experience of sexual abuse, punishment and negative home environment/neglect during childhood and adolescence. Kent and Waller (1998) created a subscale that tapped into the constructs of 'spurning' and 'terrorizing' (Hart & Brassard, 1987; 1991). This subscale was found to have a high internal consistency, and holds items that are valid components of the construct 'emotional abuse', subsequently reflecting a relatively unitary construct. Items are rated on a 5-point Likert scale ranging from 'Never' to

‘Always’. Higher scores are thought to reflect more instances of childhood trauma. For the purposes of this study, we used the total CAT-S score as our measure of childhood trauma. The CAT-S has been found to have acceptable psychometric properties (Sanders & Becker-Lausen, 1995). Cronbach’s alpha in our study was .93

The Brief Core Schema Scales (BCSS; Fowler et al., 2006) were designed to measure beliefs about the self and others. The measure comprises four 6-item subscales including ‘negative-self’, ‘negative-other’, ‘positive-self’ and ‘positive-other’. Participants indicate whether they hold a belief and, if they do, are asked to rate the strength of this belief on a 4-point Likert scale ranging from ‘Believe it Slightly’ to ‘Believe it Totally’. Total scores on each scale range from 0-24. Higher scores indicate greater belief endorsement. The BCSS has been found to have acceptable psychometric properties (Fowler et al., 2006). For the purposes of the current study, only the negative-self (NS) and negative-other (NO) subscales were used. Cronbach’s alpha in our study was 0.77 for the NS and 0.79 for the NO subscales respectively.

The Schema Rating Scale (SCIRATS): As outlined in the introduction section, we had concerns regarding the extent to which a questionnaire measure could truly capture the negative core schema held by people experiencing paranoia. These concerns were based upon the ‘paranoia as defence’ model (Bentall et al., 2001), which posits that persecutory delusions might serve as a defence against feelings of inferiority becoming conscious. The assumption of this model is that individuals with persecutory delusions have typical or perhaps even elevated levels of explicit self-esteem but low levels of implicit self-esteem. Indeed a recent systematic review and meta-analysis found evidence of a ‘weak’ version of the paranoia as defence model, where individuals with persecutory delusions has a greater implicit-explicit self-esteem discrepancy than those with depression and severity of paranoia significantly predicted the extent of this discrepancy (Murphy et al., 2018). As a result, it could be argued that responses to questionnaire measures better reflect explicit, rather than implicit self-esteem. While it could be argued that these concerns are more relevant to the study of paranoia within clinical than community samples, we sought to adapt

the BCSS to include a more robust measure of negative core schema and to trial this in both community and clinical samples.

The SCIRATS was developed by adapting the BCSS to including questions used to measure dimensions of delusional beliefs in the Psychotic Symptoms Rating Scale (PSYRATS; Haddock, McCarron, Tarrier, Faragher, 1999). The PSYRATS is a multi-dimensional measure of auditory hallucinations and delusions. Examples of dimensions measured include amount of pre-occupation, duration of pre-occupation, conviction, amount of distress intensity of distress and disruption to life caused by distress. It was felt these dimensions could be equally applied to the schema beliefs participants endorsed through the BCSS, where criteria could subsequently be developed with respect to each of these dimensions to assess whether the belief endorsed truly reflected negative core schema. In addition, we wondered if asking participants to reflect on the schematic beliefs listed in the BCSS might make it more likely we may come closer to accessing implicit, rather than explicit self-esteem.

If participants endorsed an item on the original BCSS, the SCIRATS asks a further seven questions regarding this belief (see Appendix B for online version). These questions sought to measure dimensions such as the duration of this belief, the frequency of this belief, the duration of the belief, the conviction associated with the belief, the amount and intensity of distress associated with the belief and the disruption to wider life associated with this belief. Criteria were subsequently developed across dimensions in order for the belief to be regarded as a schema. The first (DC) and last author (PH), who have 6 and 14 years of experience of delivering Cognitive Behavioural Therapy (CBT) and working with negative core schema within this modality respectively developed these criteria. Cronbach's alpha in our study was 0.78 and .80 for BCSS NS and NO subscales after re-rating using the SCIRATS criteria.

The Paranoid Thoughts Scales- Parts A & B (GPTS; Green et al., 2008) are designed to measure paranoia across the general population to clinically significant continuum. The GPTS are comprised of two sub-scales. Part A measures ideas of social reference relevant to paranoia, whereas Part B measures ideas of persecution consistent with Freeman & Garety's (2000) criteria for persecutory delusions. Each

sub-scale includes 16-items. Responses are rated on 5-point Likert scale ranging from 'Not at all' to 'Totally'. Scores on each subscale range from 18-60, where higher scores are thought to indicate higher levels of paranoia. Both parts A and B were used to create a total score. Cronbach's alpha in our study was 0.94 for Part A, 0.96 for Part B and 0.97 for the GPTS total score.

2.1.5. Procedure

Participants were recruited via social media and emails to UK based Doctorate in Clinical Psychology training programmes. Potential participants were provided with a link for an online survey hosted by JISC Online Surveys. The link directed participants to an online information sheet and consent to participate was indicated by clicking on an 'I agree' button.

2.1.6. Statistical Analysis

All statistical analyses were conducted using the IBM Statistical Package for Social Sciences (SPSS, Version 24). Correlation analysis was used to test bivariate associations between study variables. Correlations were interpreted in line with Cohen's (1992) conventions, where correlations of 0.1, 0.3 and 0.5, were deemed as small, medium and large effects respectively. Mediation analyses, controlling for gender, age, ethnicity, years of education and psychological therapy status, were subsequently used to concurrently test the direct effect of childhood trauma on paranoia and their hypothesized indirect effects through negative-self and negative other core schema. Mediation analysis refers to the testing of to what extent the relationship between a predictor and outcome variable (the direct effect) can be accounted for by another variable (the indirect effect) (Preacher & Hayes, 2004). A wide variety of statistical techniques have been employed to test the mediation analysis, including Baron and Kenny's (1986) Causal-Steps test, the Joint Significance Test (MacKinnon, Lockwood, Hoffman, West & Sheets, 2002), Sobel's (1982) First-Order Test and Bias-Corrected Bootstrap approaches (see Preacher & Hayes, 2004). In a review of the utility of these models, Fritz & MacKinnon (2007)

recommend the use of Bias-Corrected Bootstrap approaches as this approach does not require normal distribution of the data and other methods of mediation analysis require large sample sizes to achieve 0.8 power to detect small effects. Preacher & Hayes' (2004) mediation analysis is an example of a Bias-Corrected Bootstrapping approach. Their approach is based on a logistic regression path analysis framework to detect the magnitude and significance of the direct and indirect effect and uses bootstrapping to adjust for nonparametric data and smaller sample sizes (Preacher & Hayes, 2004; 2008).

All mediation analysis were performed using the PROCESS macro for SPSS (Hayes, 2013). Model 4 was used to test whether negative-self (hypothesis 1) and negative other (hypothesis 2) core schema mediated the relationship between childhood trauma and paranoia. Model 4 with two mediators was subsequently used to explore whether negative-self and/or negative-other core schema would mediate the relationship between childhood trauma and paranoia when controlling for one another. Conceptual models for each of the above mediation analyses are outlined in Figures 1-3. In order to explore whether the potential mediating effect of negative-self or negative-other core schema would change when these were measured with the SCIRATS, we re-ran each of the above analyses, entering SCIRATS negative-self and negative-other core schema scores rather than those derived from the original BCSS. In each of our mediation models, we used 5000 bootstrap resamples.

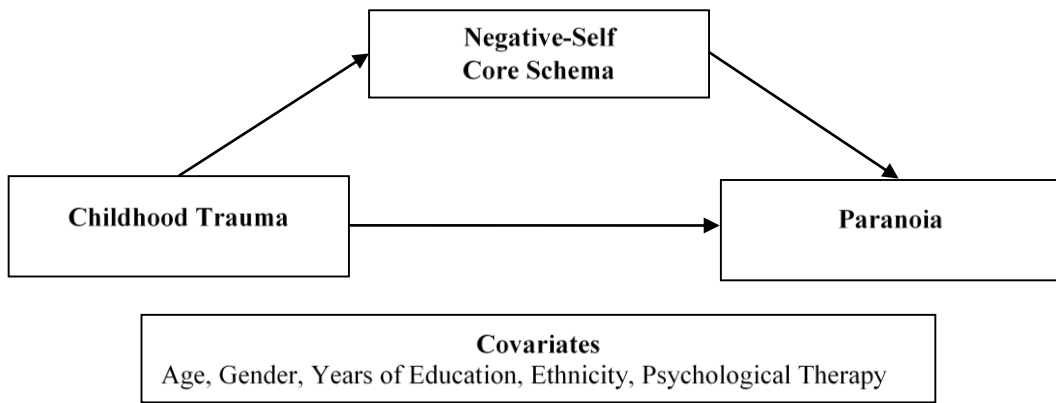


Figure 1. Conceptual Mediation Model: Hypothesis 1

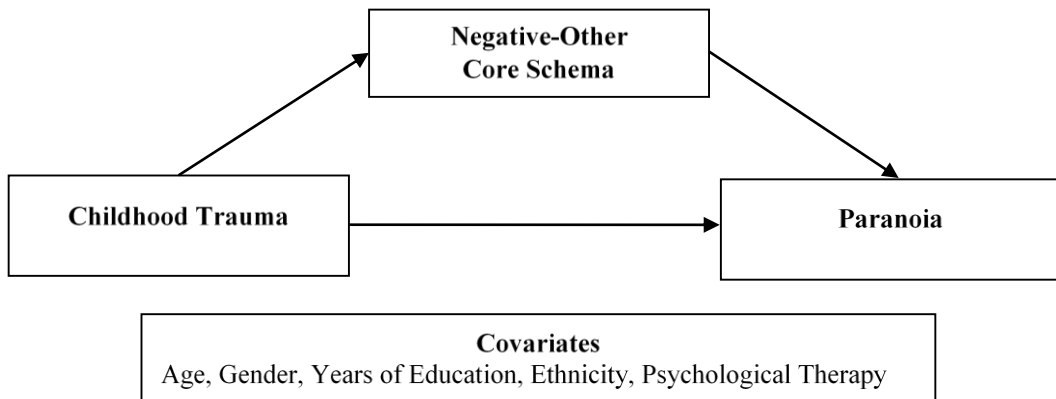


Figure 2. Conceptual Mediation Model: Hypothesis 2

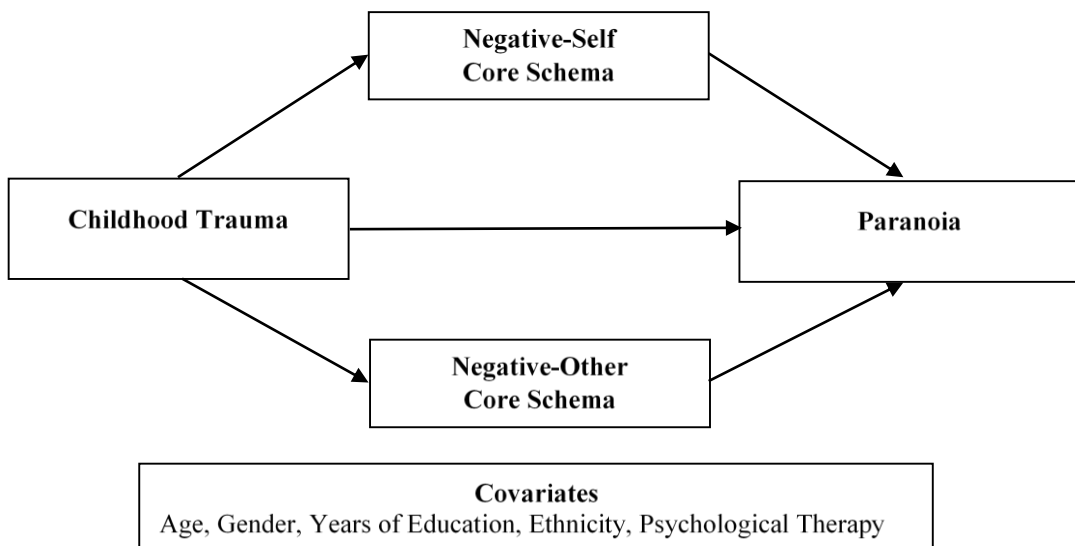


Figure 3. Conceptual Mediation Model: Hypothesis 3

In line with Hutton, Di Rienzo, Turkington, Spencer and Taylor (2018), the unstandardized direct effect (UDE) or indirect effect (UIE) and the completely standardized indirect effects (CSE) were calculated as a measure of effect size. Effect sizes extracted from mediation analysis using the original BCSS compared to the adapted BCSS were compared in order to test hypothesis 4. As outlined by Hutton et al. (2018), the UDE and UIE represent the unit change in the dependent variable per unit change in the independent variable, whether this is the direct (unmediated; UDE) or indirect (mediated; UIE) effect. The proportion of standard deviation change in the dependent variable per one SD unit change in the independent variable that occurs through the change in the mediator variable is therefore represented by the CSE. In an review of methods to report effect sizes in mediation analysis, Cheung (2009) suggest that CSEs of 0.14, 0.36 and 0.51 represent small, moderate and large mediation effects respectively.

A-priori sample size calculations for the above analysis were informed by Fritz & MacKinnon (2007), who suggest a sample size of 462 is required to achieve 0.8 power to detect an effect based on predict small effect sizes for the magnitude of the association between the predictor and the mediator variables (the a pathway) and the mediator and the outcome variables (the b pathway). In the current study, sample size calculations were based upon our primary hypothesis that negative-self core schema will mediate the relationship between childhood trauma and paranoia, where the a pathway refers to the magnitude of the association between childhood trauma and negative-self core schema and the b pathway refers to the magnitude of the association between negative-self core schema and paranoia.

Finally, we did not predict any difficulties with missing data as our online survey was designed so that participants could not complete the survey without completing all items.

2.2. Results: Study 1

A total of 460 participants completed the online survey (completion rate 76%). Participant characteristics are outlined in Table 1. The majority of our sample was female (N= 391, 85%). The mean age of participants (N= 460) was 34 (SD = 11.68) and the mean years of education was 18 (SD= 3.41). The majority identified as White British (N= 358, 78%). 208 participants (45%) were currently engaged or had previously engaged in psychological therapy.

2.2.1. Associations Between Study Variables

This was a non-clinical sample and, as expected, childhood trauma, schema and paranoia variables were not normally distributed. As a result, spearman's rho was utilised for correlation analysis. Associations between study variables are outlined in Table 2.

Significant associations were found between age and years of education ($r=.24$, $p<0.001$), negative-self core schema as measured by the BCSS ($r= -.11$, $p<0.05$), negative-other core schema as measured by the SCIRATS ($r= -.15$, $p<0.01$) and paranoia ($r= -.41$, $p<0.001$). Years of Education were found to be associated with psychological therapy status ($r= .16$, $p<0.05$), negative-other core schema as measured by the BCSS ($r= -.13$, $p<0.01$) and paranoia ($r=-.25$, $p<0.001$). A significant association was also found between ethnicity and psychological therapy status ($r=.09$, $p<0.05$). Psychological therapy status was significantly associated with childhood trauma ($r=.31$, $p<0.001$), negative-self ($r=.38$, $p<0.001$) and negative-other core schema ($r=.11$, $p<0.05$) as measured by the BCSS, negative-self core schema as measured by the SCIRATS ($r=.19$, $p<0.001$) and paranoia ($r=.15$, $p<0.01$). Moderate to large associations were found between childhood trauma, BCSS negative-self and negative-other core schema, SCIRATS negative-self core schema and paranoia ($r=.29-.49$, $p<0.001$) however the association with SCIRATS negative-other core schema was small ($r=.16$, $p<0.01$). Finally, small to moderate associations were found between BCSS negative-self core schema, BCSS negative-other core schema,

SCIRATS negative-self and negative-other core schema and paranoia ($r=.19-.40$, $p<0.001$).

Table 1. Participant Characteristics

Variable	N (%)	Mean (SD)	Median	Range
Gender				
<i>Male</i>	68 (14.8)			
<i>Female</i>	391 (85)			
<i>Other</i>	1 (0.2)			
Age				
		34.54 (11.68)	31.00	18-79
Relationship Status				
<i>Single</i>	104 (22.6)			
<i>Married</i>	185 (40.2)			
<i>In a relationship</i>	153 (33.3)			
<i>Divorced</i>	11 (2.4)			
<i>Widowed</i>	3 (0.7)			
<i>Other</i>	4 (0.9)			
Years of Education				
		17.96 (3.41)	18.00	2-28
Employment Status				
<i>Employed</i>	323 (70.2)			
<i>Unemployed</i>	10 (2.2)			
<i>Student</i>	104 (22.6)			
<i>Retired</i>	12 (2.6)			
<i>Unable to work</i>	3 (0.7)			
<i>Other</i>	8 (1.7)			
Ethnic Background				
<i>Asian British</i>	17 (3.7)			
<i>Asian Other</i>	14 (3.0)			
<i>Black British</i>	3 (0.7)			
<i>Black Other</i>	1 (0.2)			
<i>White British</i>	358 (77.8)			
<i>White Other</i>	61 (13.3)			
<i>Other</i>	6 (1.3)			
Psychological Therapy Status				
<i>Current Therapy</i>	44 (9.6)			
<i>Previous Therapy</i>	164 (35.7)			
<i>No current/previous therapy</i>	252 (54.8)			
Childhood Trauma Total				
		41.59 (20.61)	37.00	8-115
BCSS Negative-Self Core Schema Total				
		2.57 (3.82)	1.00	0-20
BCSS Negative-Other Core Schema Total				
		2.17 (3.60)	2.17	0-24
SCIRATS Negative-Self Core Schema Total				
		0.43 (2.02)	0.00	0-20
SCIRATS Negative-Other Core Schema Total				
		0.15 (1.24)	0.00	0-20
GPTS Part A Total				
		28.30 (12.82)	24.00	16-80
GPTS Part B Total				
		22.09 (11.16)	17.00	16-80
GPTS Total Score				
		50.39 (22.43)	42.00	32-160

List of abbreviations: BCSS: Brief Core Schema Scales, GPTS: Green Paranoid Thoughts Scale, SCIRATS: The Schema Rating Scale.

Table 2. Correlation Matrix Between Covariates, Mediators and Outcome Variables

	1	2	3	4	5	6	7	8	9	10	11
1. Gender	1	-.08	-.04	-.00	.06	.03	-.02	-.03	.09	.02	.01
2. Age		1	.24***	.06	.01	-.06	-.11*	-.01	-.15**	-.05	-.41***
3. Years of Education			1	.63	.16*	.09	-.01	-.13**	-.06	-.08	-.25***
4. Ethnicity				1	.09*	0.6	.05	-.05	.05	.04	-.01
5. Psychological Therapy					1	.31***	.38***	.11*	.19***	.06	.15**
6. Childhood Trauma						1	.49***	.30***	.29***	.16**	.34***
7. BCSS Negative-Self							1	.34***	.40***	.19***	.40***
8. BCSS Negative-Other								1	.19***	.26***	.39***
9. SCIRATS Negative-Self									1	.30***	.29***
10. SCIRATS Negative-Other										1	.21***
11. GPTS Total Score											1

List of abbreviations: BCSS: Brief Core Schema Scales, GPTS: Green Paranoid Thoughts Scale, SCIRATS: The Schema Rating Scale

*Correlation is significant at the $p = <0.05$ level (2-tailed)

**Correlation is significant at the $p = <0.01$ level (2-tailed)

***Correlation is significant at the $p = <0.001$ level (2-tailed)

2.2.2 Childhood trauma, negative-self core schema and paranoia.

In our first hypothesis, we sought to test whether negative-self core schema mediated the relationship between childhood trauma and paranoia (see Figure 1) Mediation analysis results are outlined in Table 3. In line with our hypothesis, childhood trauma was related to paranoia through negative-self core schema (CSE= 0.14, 95% CI= 0.08, 0.21). As a result, for every 1 SD change in childhood trauma, there was a 0.14 SD change in paranoia through negative-self core schema.

We subsequently repeated the above analysis for negative-self core schema as measured by the SCIRATS. As outlined in Table 4, childhood trauma was related to paranoia through SCIRATS negative-self core schema (CSE= 0.13, 95% CI= 0.07, 0.18). These results indicate that for every 1 SD change in childhood trauma, there is a 0.13 SD change in paranoia through SCIRATS negative-self core schema.

Table 3. Results of Mediation Analysis: Childhood Trauma, Negative-Self Core Schema and Paranoia

Predictor		Unstandardized coefficients (SE)	Completely standardized coefficients (SE) (95% CI)
Control Variables (Direct effects on paranoia)	Gender (<i>Male/Female/Other</i>)	-4.324 (2.449)	-
	Age (<i>Years</i>)	-.485 (.076)***	-
	Years of Education (<i>Years</i>)	-1.303 (.260)***	-
	Ethnic Background (<i>Asian British, Asian Other, Black British, Black Other, White British, White Other, Other</i>)	.093 (.855)	-
	Psychological Therapy (<i>Yes/No</i>)	.376 (1.897)	-
Independent Variables (Direct effects on paranoia)	Childhood Trauma	.143 (.0491)*	-
	R ²	.316***	
Bootstrap Indirect Effects of	Childhood Trauma > BCSS	.154 (.036)	.141 (.033)
	Negative-Self Core Schema (Total indirect effect)	95% CI (.089, .232)	95% CI (.082, .213)

List of abbreviations: BCSS: Brief Core Schema Scales

Table 4. Results of Mediation Analysis: Childhood Trauma, SCIRATS Negative-Self Core Schema and Paranoia

Predictor		Unstandardized coefficients (SE)	Completely standardized coefficients (SE) (95% CI)
Control Variables (Direct effects on paranoia)	Gender (<i>Male/Female/Other</i>)	-.5.736 (2.465)	-
	Age (<i>Years</i>)	-.487 (0.770)***	-
	Years of Education (<i>Years</i>)	-1.357 (.261)***	-
	Ethnic Background (<i>Asian British, Asian Other, Black British, Black Other, White British, White Other, Other</i>)	-.114 (.860)	-
	Psychological Therapy (<i>Yes/No</i>)	1.906 (1.871)	-
	Independent Variables (Direct effects on paranoia)	Childhood Trauma R ²	.157 (.047)** .310***
Bootstrap Indirect Effects of	Childhood Trauma > SCIRATS	.140 (.033)	.128 (.027)
	Negative-Self Core Schema (Total indirect effect)	95% CI (.077, .208)	95% CI (.074, .183)

List of abbreviations: SCIRATS: The Schema Rating Scale.

2.2.3. Childhood trauma, negative-other core schema and paranoia

In our second hypothesis, we should to test whether negative-other core schema mediated the relationship between childhood trauma and paranoia (see Figure 2). As outlined in Table 5, childhood trauma was related to paranoia through negative-other core schema (CSE= 0.08, 95% CI= 0.04, 0.15). These results indicated that for every 1 SD change in childhood trauma, there as a 0.08 SD change in paranoia through negative-other core schema.

Table 5. Results of Mediation Analysis: Childhood Trauma, Negative-Other Core Schema and Paranoia

Predictor		Unstandardized coefficients (SE)	Completely standardized coefficients (SE) (95% CI)
Control Variables (Direct effects on paranoia)	Gender (<i>Male/Female/Other</i>)	-.2.778 (.2.381)	-
	Age (<i>Years</i>)	-.575 (.074)***	-
	Years of Education (<i>Years</i>)	-1.095 (.253)***	-
	Ethnic Background (<i>Asian British, Asian Other, Black British, Black Other, White British, White Other, Other</i>)	.082 (.829)	-
	Psychological Therapy (<i>Yes/No</i>)	2.952 (1.794)	-
	Independent Variables (Direct effects on paranoia)	Childhood Trauma R ²	.206 (.044)*** .357***
Bootstrap Indirect Effects of	Childhood Trauma > BCSS	.091 (.035)	.083 (.030)
	Negative-Other Core Schema (Total indirect effect)	95% CI (.037, .170)	95% CI (.036, .150)

List of abbreviations: BCSS: Brief Core Schema Scales

Again, we repeated the above analysis negative-other core schema as measured by the SCIRATS. As outlined in Table 6, childhood trauma was related to paranoia through SCIRATS negative-other core schema (CSE= 0.06, 95% CI= 0.02, 0.12). These results indicated that for every 1 SD change in childhood trauma, there was a 0.06 SD change in paranoia through SCIRATS negative-other core schema.

2.2.4. Childhood trauma, negative-self and negative-other core schema and paranoia

In order to explore whether the mediation effect of negative-self and/or negative-other core schema would be influenced by controlling for each of these variables, we conducted parallel mediation analysis (see Figure 3). As outlined in Table 7, childhood trauma was related to paranoia through both negative-self and negative-other core schema (CSE=0.18, 95% CI= 0.11, 0.25). These results indicated that for every 1 SD change in childhood trauma, there was a 0.18 SD change in paranoia through both negative-self and negative-other core schema. The mediation effect of both schema remained after controlling for the presence of the other schema in our model.

Table 6. Results of Mediation Analysis: Childhood Trauma, SCIRATS Negative-Other Core Schema and Paranoia

Predictor		Unstandardized coefficients (SE)	Completely standardized coefficients (SE) (95% CI)
Control Variables (Direct effects on paranoia)	Gender (<i>Male/Female/Other</i>)	-3.766 (2.340)	-
	Age (<i>Years</i>)	-.515 (.075)***	-
	Years of Education (<i>Years</i>)	-1.193 (.255)***	-
	Ethnic Background (<i>Asian British, Asian Other, Black British, Black Other, White British, White Other, Other</i>)	-.208 (.839)	-
	Psychological Therapy (<i>Yes/No</i>)	2.666 (1.815)	-
Independent Variables (Direct effects on paranoia)	Childhood Trauma	.230 (.044)***	-
	R ²	.344***	
Bootstrap Indirect Effects of	Childhood Trauma > SCIRATS	.067 (.030)	.062 (.026)
	Negative-Other Core Schema (Total indirect effect)	95% CI (.020, .133)	95% CI (.019, .117)

List of abbreviations: SCIRATS: The Schema Rating Scale.

Table 7. Results of Mediation Analysis: Childhood Trauma, Negative-Self and Negative-Other Core Schema and Paranoia

Predictor		Unstandardized coefficients (SE)	Completely standardized coefficients (SE) (95% CI)
Control Variables (Direct effects on paranoia)	Gender (<i>Male/Female/Other</i>)	-2.902 (2.302)	-
	Age (<i>Years</i>)	-.518 (.072)***	-
	Years of Education (<i>Years</i>)	-1.081 (.245)***	-
	Ethnic Background (<i>Asian British, Asian Other, Black British, Black Other, White British, White Other, Other</i>)	.026 (.802)	-
	Psychological Therapy (<i>Yes/No</i>)	.713 (1.778)	-
	Independent Variables (Direct effects on paranoia)	Childhood Trauma	.105 (.046)*
	BCSS Negative-Self Core Schema	1.491 (.260)***	-
	BCSS Negative-Other Core Schema	1.947 (.244)***	-
	R ²	.401***	-
Bootstrap Indirect Effects of	Childhood Trauma > BCSS Negative-Self Core Schema	.115 (.029) 95% CI (.062, .175)	.105 (.025) 95% CI (.058, .156)
	Childhood Trauma > BCSS Negative-Other Core Schema	.077 (.030) 95% CI (.030, .144)	.071 (.026) 95% CI (.029, .127)
	Total indirect effect	.192 (.043) 95% CI (.114, .284)	.176 (.035) 95% CI (.111, .249)

List of abbreviations: BCSS: Brief Core Schema Scales

As previously, we repeated the above analysis for SCIRATS negative-self and negative-other core schema. As outlined in Table 8, childhood trauma was related to paranoia through both SCIRATS negative-self and negative-other core schema (CSE= 0.14, 95% CI= .09, .19). As a result, for every 1 SD change in childhood trauma, there was a 0.14 SD change in paranoia through both SCIRATS negative-self and negative-other core schema.

Table 8. Results of Mediation Analysis: Childhood Trauma, SCIRATS Negative-Self and Negative-Other Core Schema and Paranoia

Predictor		Unstandardized coefficients (SE)	Completely standardized coefficients (SE) (95% CI)
Control Variables (Direct effects on paranoia)	Gender (<i>Male/Female/Other</i>)	-4.723 (2.356)	-
	Age (<i>Years</i>)	-4.723 (2.356)***	-
	Years of Education (<i>Years</i>)	-1.214 (.250)***	-
	Ethnic Background (<i>Asian British, Asian Other, Black British, Black Other, White British, White Other, Other</i>)	-.332 (.821)	-
	Psychological Therapy (<i>Yes/No</i>)	1.777 (1.785)	-
Independent Variables (Direct effects on paranoia)	Childhood Trauma	.150 (.047)**	-
	SCIRATS Negative-Self Core Schema	1.597 (.345)***	-
	SCIRATS Negative-Other Core Schema	3.005 (.445)***	-
	R ²	.374***	
Bootstrap Indirect Effects of	Childhood Trauma > SCIRATS Negative-Self Core Schema	.092 (.027) 95% CI (.044, .152)	.085 (.024) 95% CI (.041, .136)
	Childhood Trauma > SCIRATS Negative-Other Core Schema	.054 (.026) 95% CI (.013, .113)	.050 (.022) 95% CI (.013, .100)
	Total indirect effect	.147 (.032) 95% CI (.088, .215)	.135 (.026) 95% CI (.085, .187)

List of abbreviations: SCIRATS: The Schema Rating Scale.

3.1. Method: Study 2

3.1.1. Ethical Approval

Ethical approval for this study was granted by the The University of Edinburgh's Department of Clinical and Health Psychology Research Ethics Panel, The West of Scotland 3 Research Ethics Committee (Reference: 17/WS/0090), and by Research and Development (R&D) Departments in NHS Forth Valley (R&D Ref: FV1051), NHS Greater Glasgow and Clyde (R&D Ref: GN17MH497), NHS Lanarkshire (R&D Ref: L17084) and NHS Lothian (R&D Ref: 2017/0233). Ethical approval documentation and approval of amendments is included in Appendix D. The Study Protocol is included in Appendix E.

3.1.2. Study Design

The study utilised a cross-sectional, quantitative, within-groups design to examine the relationship between childhood trauma, duration of childhood trauma, negative-self and negative-other core schema and paranoia in a clinical sample of participants with persecutory delusions.

3.1.3 Changes to protocol

We had initially planned to conduct a series of correlation and mediation analysis to test whether 1) negative-core schema mediate the relationship between childhood trauma and paranoia, 2) negative-other core schema mediate the relationship between childhood trauma and paranoia, 3) negative-self and negative-other core schema mediate the relationship between childhood trauma and paranoia, 4) to explore whether there were any differences in the mediation effect when measuring negative core schema through the clinician administered version of The Schema Rating Interview (SCIRATS) and 5) to test whether trauma duration was related to increased negative schema severity and whether this relationship mediated the relationship between childhood trauma and paranoia.

With reference to Fritz & MacKinnon (2007), we aimed to recruit a sample of 34 participants in order to achieve 0.8 power to detect large mediation effects on both the ‘a’ (i.e. the indirect effect of childhood trauma on negative-self core schema) and ‘b’ (i.e. the indirect effect of negative-self core schema on paranoia) mediation pathways). Due to a lower than anticipate recruit rate, we did not achieve the required sample to conduct mediation analysis. For the same reason, we did not report Cronbach’s alpha for Study 2 measures (see Bonnett, 2002). As a result, we elected to examine bivariate associations between study variables. Cohen’s (1992) conventions were used to interpret findings, where correlations of 0.1, 0.3 and 0.5, are thought to indicate small, medium and large effects respectively. Further changes to the Study Protocol are outlined in Appendix F.

3.1.4. Participants

Participants were eligible to take part in the study if they were 1) adults over the age of 16, 2) with a diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder or ‘non-affective psychosis’ determined through the chart diagnosis offered to by the treating psychiatrist, 3) Who were currently in contact with community mental health services in NHS Forth Valley, NHS Greater Glasgow and Clyde, NHS Lanarkshire or either inpatient or community mental health services in NHS Lothian, 4) Were currently experiencing persecutory delusions that had persisted for the last 3 months and 5) Scored above 3 on the PSYRATS (Haddock et al., 1999) delusions subscale conviction item (i.e. at least 50% conviction in the delusional belief).

Persecutory delusions were defined in the current study as an unfounded belief that harm is occurring, or is going to occur to the individual and the perpetrator has the intent to cause harm (Freeman & Garety, 2000). Our decision to use a PSYRATS (Haddock et al., 1999) delusions subscale conviction item score of at least 3 in order to meet the criteria for persecutory delusions was in line with previous research by Freeman et al. (2015) and Startup et al. (2016).

Participants were not eligible to take part if 1) They scored less than 3 on the conviction items of the PSYRATS delusions subscale (Haddock et al., 1999), 2) They were not currently in contact with NHS Mental Health Services or were currently without a Keyworker/Care coordinator, 3) They did not provide consent for the researcher to liaise with their Keyworker/Care coordinator and Consultant Psychiatrist, 4) Individuals with a primary diagnosis of psychosis due to an organic cause, substance induced psychosis, bipolar disorder or psychotic depression, 5) Individuals with a diagnosed intellectual disability or neurodevelopmental disorder such as ASD, 6) Individuals who currently lacked the capacity to consent to research, 7) Individuals who were currently experiencing a psychiatric crisis and/or severe suicidal ideation or intent, 8) Individuals who presented a significant risk of harm to the researcher.

3.1.5. Measures

The measures employed in our second study were broadly similar to those utilized in study one, however these were all completed face to face with the interviewer rather than online. We made the following further additions and/or adaptations to study measures with our clinical sample.

The Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein & Opfer, 1987): The Positive and Negative Syndrome Scale is a 30-item interviewer-rated questionnaire that assesses the severity of psychotic symptoms in the previous 72 hours. Responses are rated on a 7-point Likert scale where symptom severity is rated from 'absent' to 'extreme'. Higher scores represent increased symptom severity. The measure has acceptable psychometric properties (Kay et al., 1987; Kay, Opler & Lindenmayer, 1988). In the current study, the PANSS will be used to provide detailed descriptive statistics regarding the nature of psychotic symptoms experienced by the sample. A modified interview schedule developed by experienced clinical psychology researchers at the Psychosis Research Unit (PRU) of the Greater Manchester West Mental Health foundation NHS Trust (GMW) and used in

numerous NREC-approved clinical trials will be used to guide the interview process and maximise acceptability to participants. Full training and supervision on the administration and scoring of the PANSS was provided to the first author (DC) by the last author (PH).

The Psychotic Symptoms Rating Scale (PSYRATS; Haddock et al., 1999): The PSYRATS is a 17-item multi-dimensional measure of auditory hallucinations (11-items) and delusions (6-items) over the previous week. Examples of dimensions measured include frequency, duration and loudness of voices, amount of and duration of preoccupation with delusions, conviction in delusions and amount of and intensity of distress in response to voices or delusions. Items are rated on a 4-point likert scale, where higher scores reflect greater symptom severity. The measure has acceptable psychometric properties (Haddock et al., 1999; Kay, Opler, & Fiszbein, 1986; Steel et al., 2007). The PSYRATS was used in the current study to further describe and characterise the sample, but also as a check of our inclusion criteria as outlined above.

The Childhood Trauma Questionnaire (CTQ; Bernstein & Fink, 1998): The Childhood Trauma Questionnaire is a 28-item self-report questionnaire that assesses five different forms of childhood trauma: physical, sexual and emotional abuse, and physical and emotional neglect. Responses are rated on a 5-point likert scale ranging from 'Never True' to 'Very Often True'. Higher scores are thought to reflect more instances of trauma. The measure has acceptable psychometric properties (Bernstein et al., 1994). This measure was used as an alternative to the CAT-S as it assesses a broad range of different forms of childhood trauma and as often considered the 'gold-standard' measure of childhood trauma (Bendall et al., 2013). Due to the licensing fee associated with questionnaire, we were able to utilise this measure in our clinical yet not general population sample study.

Trauma Duration: The CTQ was adapted in our second study to include a measure of trauma duration. The purpose of this adaptation as to allow for the testing of our fifth hypothesis, that trauma duration will be related to increased negative schema

severity and this relationship will mediate the relationship between childhood trauma and paranoia in people with persecutory delusions. Participants were asked to indicate their age (in months) when trauma began and ended for each trauma domain measured by the CTQ (i.e. physical abuse, sexual abuse, emotional abuse, physical neglect and emotional neglect). The researcher assisted participants in converting their age in years to months where required. Where participants experienced a single incident of trauma within each domain, this was scored as one month in duration. Where participants experienced multiple episodes of trauma within a domain, the duration of each traumatic event was coded in number of months and the duration of each episode was summed to create a 'duration of trauma score' within each domain. Scores across each trauma domain were then summed to create a 'total duration of childhood trauma score'. We felt that this approach was the most pragmatic method to measure multiple traumatic experiences and/or concurrent traumas.

The Brief Core Schema Scales (BCSS; Fowler et al., 2006): The BCSS were administered face-to-face with participants rather than online as in Study 1.

The Schema Rating Scale (SCIRATS): The SCIRATS was administered face-to-face with participants rather than online as in Study 1. For each schematic belief endorsed by participants on the BCSS, the SCIRATS asked participants seven questions regarding this belief. The BCSS was subsequently re-scored based upon whether participant's ratings across the additional seven dimensions measured by the SCIRATS met our criteria for a schematic belief. A copy of the paper version of the SCIRATS is included in Appendix G.

The Paranoid Thoughts Scales- Part B (GPTS; Green et al., 2008): The GPTS was administered as in Study 1, however in Study 2 this measured was administered face-to-face. Furthermore, as we were only interested in the severity of clinically significant persecutory beliefs in Study 2, we only administered Part B of the GPTS in Study 2.

3.1.6. Procedure

There were two recruitment pathways in the current study. In the first pathway, posters advertising the study (see Appendix H) were displayed in Community Mental Health Team (CMHT) bases across NHS Forth Valley, NHS Greater Glasgow and Clyde, NHS Lanarkshire and NHS Lothian. Potential participants were asked to contact the researcher via email or telephone if they were potentially interested in participating. During the initial contact, participants were given further information regarding the study, subsequently sent a copy of the participant information sheet (PIS) and were asked for their verbal consent to contact their Consultant Psychiatrist and Keyworker/Care coordinator regarding their eligibility to participate in the current study. In the event consent was granted, the Consultant Psychiatrists and Keyworker/Care coordinators were contacted regarding the potential participants eligibility to take part in the current study. Where potential participants met inclusion criteria, they were subsequently contacted to arrange a date to meet with the first author (DC) to complete study measures.

In the second pathway, clinicians working in the CMHTs outlined above and in acute inpatient wards in NHS Lothian were asked to identify and approach potential participants currently on their caseload who may have been willing to participate in the above study. Clinicians requested potential participants' verbal consent to discuss their eligibility to participate with the first author (DC) and for the first author to contact them with further information regarding the study. During the first contact, potential participants were given further information regarding the study and sent a copy of the PIS if they had not already received this from their clinician. In both recruitment pathways potential participants were given at least 48 hours to consider the participant information sheet before being asked if they wished to participate and being given an appointment to meet with the first author (DC) to complete study measures. In both pathways, meetings between the researcher and the potential participants always took place on the premises of their CMHT base. Participants were given the option to complete study measure either one or two sessions and to take breaks were necessary.

3.2. Results: Study 2

A total of 16 participants were recruited into our study. Of these, two did not meet the PSYRATS delusions subscale conviction criterion for inclusion in the study and were excluded from final analysis. Clinical team identified a significantly greater number of potential participants, however as these potential participants did not subsequently consent to participate in our study, no data regarding numbers of potential participants was recorded. This resulted in a final sample size of 14.

Participant characteristics are outlined in Table 9. There were an equal proportion of males and females in our sample (N=7, 50%). The mean age of our sample was 45 (SD= 9.83). The majority of participants were single (N= 11, 79%) and unable to work (N=7, 50%) and the mean years of education in our sample was 14 (SD= 3.53). All of our participants identified as White British. Diagnoses included Schizophrenia (N=7, 50%), Schizoaffective Disorder (N=4, 29%), Delusional Disorder (N=1, 7%) and Psychosis NOS (N=2, 14%). The mean years since diagnosis was 9.5 (SD= 9.56), the majority of participants were prescribed a combination of antipsychotic medications (N=6, 43%) and the majority of participants were currently or had previously received a psychological therapy (N=8, 57%). 13 participants (93%) were recruited from CMHTs, whereas one participant was recruited from an acute inpatient ward.

3.2.1. Associations Between Study Variables

As a number of our study variables were not normally distributed (gender, relationship status, employment status, diagnosis, medication status, PANSS negative symptoms and negative-self and negative-other core schema as measured by the SCIRATS), spearman's rho was utilised for correlation analysis. Associations between study variables are outlined in Table 10.

Table 9. Participant Characteristics

Variable	N (%)	Mean (SD)	Median	Range
Gender				
<i>Male</i>	7 (50%)			
<i>Female</i>	7 (50%)			
Age		45.79 (9.83)	49.00	28-62
Relationship Status				
<i>Single</i>	11 (78.6)			
<i>Married</i>	1 (7.1)			
<i>In a relationship</i>	1 (7.1)			
<i>Divorced</i>	1 (7.1)			
Years of Education		14.21 (3.53)	13.00	11-24
Employment Status				
<i>Employed</i>	1 (7.1)			
<i>Unemployed</i>	5 (35.7)			
<i>Student</i>	1 (7.1)			
<i>Unable to work</i>	7 (50)			
Ethnic Background				
<i>White British</i>	14 (100)			
Diagnosis				
<i>Schizophrenia</i>	7 (50)			
<i>Schizoaffective Disorder</i>	4 (28.6)			
<i>Delusional Disorder</i>	1 (7.1)			
<i>Psychosis NOS</i>	2 (14.3)			
Years since diagnosis		9.50 (9.56)	7.00	1-30
Medication Status				
<i>None</i>	2 (14.3)			
<i>Aripiprazole</i>	1 (7.1)			
<i>Clozapine</i>	2 (14.3)			
<i>Combination Therapy</i>	6 (42.9)			
<i>Olanzapine</i>	3 (21.4)			

Variable	N (%)	Mean (SD)	Median	Range
Psychological Therapy Status				
<i>Current Therapy</i>	4 (28.6)			
<i>Previous Therapy</i>	4 (28.6)			
<i>No current/previous therapy</i>	6 (42.9)			
PANSS Positive Symptoms		22.36 (4.67)	22.00	15-29
PANSS Negative Symptoms		11.29 (4.62)	10.50	7-22
PANSS General Psychopathology		35.57 (5.59)	35.00	27-48
PSYRATS Auditory Hallucinations Total		18.57 (13.08)	22.00	0-34
<i>Frequency</i>		1.50 (1.40)	1.50	0-4
<i>Duration</i>		1.57 (1.28)	2.00	0-4
<i>Location</i>		1.86 (1.56)	2.00	0-4
<i>Loudness</i>		1.50 (1.35)	1.00	0-4
<i>Beliefs re-origin of voices</i>		2.29 (1.73)	3.00	0-4
<i>Amount of negative content of voices</i>		1.93 (1.69)	2.50	0-4
<i>Degree of negative content</i>		1.64 (1.50)	1.50	0-4
<i>Amount of Distress</i>		1.71 (1.86)	1.00	0-4
<i>Intensity of Distress</i>		1.43 (1.60)	1.00	0-4
<i>Disruption to life caused by voices</i>		1.36 (1.22)	2.00	0-4
<i>Controllability of voices</i>		1.79 (1.67)	2.00	0-4
PSYRATS Delusions Total		16.43 (3.21)	16.00	9-22
<i>Amount of preoccupation with delusions</i>		2.43 (0.94)	2.00	1-4
<i>Duration of preoccupation with delusions</i>		2.86 (0.86)	3.00	1-4
<i>Conviction</i>		3.29 (0.47)	3.00	3-4
<i>Amount of distress</i>		3.14 (1.23)	3.50	0-4
<i>Intensity of distress</i>		2.86 (1.03)	3.00	0-4
<i>Disruption to life causes by beliefs</i>		1.86 (0.36)	2.00	1-2
Childhood Trauma Total		54.64 (21.66)	48.50	25-104
<i>Childhood emotional abuse</i>		13.29 (7.05)	11.50	5-25
<i>Childhood physical abuse</i>		8.21 (3.68)	7.00	5-16
<i>Childhood sexual abuse</i>		9.71 (6.67)	6.00	5-25
<i>Childhood emotional neglect</i>		12.29 (6.70)	9.50	5-25
<i>Childhood physical neglect</i>		10.14 (3.66)	10.00	5-18

Variable	N (%)	Mean (SD)	Median	Range
Duration of childhood trauma (months)		278.64 (231.22)	276.00	0-773
BCSS Negative-Self Core Schema Total		10.07 (6.43)	10.00	1-24
BCSS Negative-Other Core Schema Total		14.57 (6.00)	14.00	5-24
SCIRATS Negative-Self Core Schema Total		7.71 (8.98)	3.00	0-24
SCIRATS Negative-Other Core Schema Total		9.57 (8.47)	10.50	0-21
GPTS Part B Total		47.21 (21.61)	50.00	16-79

List of abbreviations: BCSS: Brief Core Schema Scales, GPTS: Green Paranoid Thoughts Scale, PANSS: The Positive and Negative Syndrome Scale, PSYRATS: The Psychotic Symptoms Rating Scale, SCIRATS: The Schema Rating Scale.

Table 10. Association Between Study Variables

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1. Gender	1	.05	.16	.28	.21	.18	.41	.29	.09	-.27	.50	.00	-.05	.51	.87***	.52	-.11	.44	.22	-.07
2. Age		1	-.06	.00	.10	.10	-.51	.36	-.45	.09	.20	-.24	.15	-.26	-.14	-.07	.08	.22	.17	.24
3. Education Yrs			1	.35	-.26	.26	.31	.31	-.04	-.26	-.34	.30	-.63**	.00	-.04	-.03	-.23	.05	-.13	-.33
4. Ethnicity				1	.26	-.10	-.11	-.24	.10	.28	.00	-.35	-.45	-.03	.31	-.31	-.41	-.40	-.35	-.38
5. Diagnosis					1	-.43	-.66**	.12	-.23	-.20	-.01	-.53*	-.08	-.37	.03	-.40	-.15	-.28	-.19	-.23
6. Years Dx						1	.56*	.37	-.19	.30	.21	.60*	.26	.34	.01	.28	-.01	.35	.25	.13
7. Medication							1	.06	.66	.54	.18	.51	.21	.51	.41	.61*	.00	.38	.18	.05
8. Psych Therapy								1	-.47	-.31	.00	.13	.18	.11	.22	.20	.13	.50	.53*	-.04
9. PANSS P									1	-.24	.33	.14	-.34	.31	.07	-.01	.08	-.09	-.31	.26
10. PANSS N										1	-.03	-.27	.29	-.08	-.20	.01	.03	-.04	.05	.13
11. PANSS GP											1	-.00	.22	.47	.49	.56*	.57*	.60*	.44	.71**
12. PSYRATS A												1	.18	-.00	-.18	.04	-.25	-.01	-.19	-.04
13. PSYRATS B													1	.02	.03	.39	.22	.28	.33	.37
14. CT														1	.67**	.70**	.26	.62*	.48	.25
15. Duration of CT															1	.66*	.06	.50	.38	.03
16. BCSS NS																1	.52	.52	.82***	.61*
17. BCSS NO																	1	.62*	.66**	.82***
18. SCIRATS NS																		1	.87***	.58***
19. SCIRATS NO																			1	.41
20. GPTS Part B																				1

List of abbreviations: BCSS: Brief Core Schema Scales, CT: Childhood Trauma, Dx: Diagnosis, Education Yrs: Years of Education, GPTS: Green Paranoid Thoughts Scale, PANSS: The Positive and Negative Syndrome Scale, PANSS P: PANSS Positive Symptoms, PANSS N: PANSS Negative Symptoms, PANSS GP: PANSS General Psychopathology, Psych Therapy: Psychological Therapy, PSYRATS: The Psychotic Symptoms Rating Scale, PSYRATS A: PSYRATS Auditory Hallucinations, PSYRATS B: PSYRATS Delusions, SCIRATS: The Schema Rating Scale.

Gender was significantly associated with duration of childhood trauma ($r=.87$, $p<0.001$). Years of education was significantly associated with PSYRATS delusions ($r=-.63$, $p<0.001$). Medication status was found to be significantly associated with diagnosis ($r=-.66$, $p<0.01$), years since diagnosis ($r=.56$, $p<0.05$) and BCSS negative-self core schema ($r=.61$, $p<0.05$). Diagnosis ($r= -.53$, $p<0.05$) and years since diagnosis ($r=.60$, $p<0.05$) were also significant associated with PSYRATS auditory hallucinations. Psychological therapy was only significantly associated with SCIRATS negative-other core schema ($r=.53$, $p<0.05$). Large significant associations were found between PANSS general psychopathology and BCSS negative-self and negative-other core schema, SCIRATS negative-self core schema and paranoia ($r=.65-.71$). Duration of childhood trauma was found to be significantly associated with BCSS negative-self core schema ($r=.66$, $p<0.05$). Finally, large associations were typically found between BCSS negative core schema, SCIRATS negative core schema and paranoia ($r=.58-.87$). Of note however, there was no significant association between BCSS negative-self core schema and BCSS negative-other core or SCIRATS negative-self core schema. There was also no significant association between SCIRATS negative-other core schema and paranoia.

3.2.2. Initial Acceptability

We were curious to explore participant's views regarding the SCIRATS during the study, and sought feedback after participants had completed this interview. Initial feedback was positive, where a selection of quote from participants are outlined below:

*'I think maybe it's easier to measure it in percentages...think about it a bit more...
it's easier to express how you feel in percentages'*

*'Makes you think about it a wee bit more when it's percentages...easier to judge the
strength of belief'*

'When you read it out to me it feels different to when I read it myself... think about it more'

'To me this is general (the questionnaire)... when asked questions I can elaborate...you get a clearer picture'

'It's more accurate when you have the questionnaire and additional questions...checks for consistency'

'Follow-up questions easier because you think about it more'

'I think the follow-up questions are good as they cover all the negative aspects...covers a lot of what one goes through'

4. Discussion

4.1. Summary of Findings

A total of 460 participants from the general population participated in Study 1. We found significant associations between childhood trauma and negative-self core schema (BCSS and SCIRATS), childhood trauma and negative-other (BCSS and SCIRATS) and childhood trauma and paranoia. In addition, we found significant associations negative-self and negative-other core schema, whether measured by the BCSS or SCIRATS and paranoia.

In line with our hypotheses, negative-self and negative-other core schema mediated the relationship between childhood trauma and paranoia. This mediation effect persisted in our parallel mediation model when controlling for the effect of one form of negative core schema upon the other. When we repeated our analysis using the SCIRATS the above mediation models all remained significant.

In Study 2 we found significant associations between childhood trauma and duration of childhood trauma, and negative-self core schema (whether measured by the BCSS or SCIRATS). There was no significant association between childhood trauma and negative-other core schema (whether measured by the BCSS or SCIRATS) and no significant association between childhood trauma and paranoia. Negative-self core schema were significant associated with paranoia (again, whether measured by the BCSS or SCIRATS), however only negative-other measured by the BCSS were significantly associated with paranoia. We received positive preliminary feedback on the SCIRATS, suggesting that participants found this to be an acceptable measure of negative core schema.

4.2. Discussion of Findings and Theoretical Implications

In Study 1 we found that childhood trauma was associated with both negative-self and negative-other core schema and paranoia. There was also a significant association between both negative-self and negative-other core schema and paranoia significant association between both of these forms of schema and paranoia. We noted a large effect between childhood trauma and negative-self core schema ($r=0.49$, $p<0.001$) and that moderate magnitude of effects between childhood trauma and paranoia and both negative-self and negative-other core schema and paranoia ($r=0.34-0.40$). In Study 2, we noted that childhood trauma was not significantly associated with paranoia or negative-other core schema but that both negative-self and negative-other core schema were associated with paranoia ($r=0.61-0.82$). We wondered if our small sample size might have resulted in being underpowered to detect an effect between childhood trauma and paranoia.

The SCIRATS could be considered a more conservative measure of schema due to the criteria participants must meet to score on this measure. We considered that the fact negative-self, negative-other and both negative-self and negative-other core schema remained significant mediators of the relationship between childhood trauma and paranoia as strengthening our findings.

The above results are consistent with cognitive models of psychosis and strengthen the suggestion that both negative-self and negative-other core may be important in understanding the relationship between childhood trauma and paranoia (Bentall et al, 2014). We note that significant associations and mediation models can not demonstrate causality; however when we consider that Bradford Hill (1965) highlights plausible theoretical mechanisms as one of many criteria for causality, our findings could be seen as contributing to the wider evidence for a causal relationship.

4.3. Strengths and Limitations

There are a number of strengths associated with this study. In Study 1 we recruited a sample of 460 participants from the general population. Fritz and MacKinnon (2007) recommend a sample of 462 participants in order to detect small effects on both the 'a' and 'b' mediation pathways in a bias-corrected bootstrap mediation analysis such as Preacher and Hayes' (2004) approach. Previous mediation analyses (Fisher et al., 2012; Hardy et al., 2016) included sample sizes of 212 and 228 respectively and are therefore likely to be underpowered to detect small mediation effects. A further strength associated with our large sample size was achieving greater precision of estimates, where the margin between our upper and lower 95% CI margins was narrow. Furthermore, we suggest that our use of a validated measure of childhood trauma and a validated symptom specific measure of the paranoia continuum (see Statham, Emerson & Rowse, 2018) are significant strengths associated with our study.

Strengths associated with Study 2 included adopting a psychotic experience specific approach (i.e. examining the relationship between childhood trauma and paranoia) with a clearly defined clinical sample. Again we argue that the use of validated measures of childhood trauma and paranoia are a significant strength of this study. We also view the fact we made a distinction between trauma frequency (as measured by the CTQ) and trauma duration and attempted to measure both constructs as a significant strength.

Finally, we argue that the development and use of the SCIRATS across both studies is a strength, as this to further scrutinise our hypothesis and study aims by employing a more conservative measure of negative core schema. Furthermore, the initial feedback received from participants in Study 2 appears to suggest that participants found this measure acceptable.

Despite significant strengths associated with our studies, we must also highlight a number of limitations. White British, female, employed and highly educated participants were over-represented in Study 1 and this may limit the generalisability of our findings to other groups. Furthermore, our small sample size in Study 2 results in being underpowered to detect medium or small effects and our findings must therefore be interpreted with caution.

4.4 Recommendations for Future Research

We make a number of recommendations for future research. We recommend that future research could further expand on our community sample study by examining the influence of trauma duration as well as trauma frequency on negative core schema and paranoia. We also suggest that future research should attempt to replicate our clinical sample study and achieve a sample size suitable to conduct mediation analysis. We recognise however that even if this were to be achieved, it could not be considered a complete test of cognitive models of psychosis (Garety et al., 2001; Morrison, 2001) as did not account for the influence of trauma in adulthood or the metacognitive biases associated with paranoia and persecutory delusions (see Moritz, Vitzthum, Randjbar, Veckenstedt & Woodward, 2010). Future research could expand on our design by including the above constructs in their model.

We also recommend that future research attempt to validate the psychometric properties of the SCIRATS. Our findings suggest that participants found this measure acceptable and we suggest that a more conservative measure of negative core schema may be of benefit in future research. We wonder if the SCIRATS might also be beneficial for intervention trials or clinical practice have benefits may have

benefits for intervention trials or clinical practice. While schema change techniques typically focus on reductions in conviction (see Morrison, Renton, Dunn, Williams and Bentall, 2004), in the development of the PSYRATS, Haddock et al. (1999) argue that measuring dimensions of hallucinations or delusions could be benefit in the assessment, formulation and treatment of psychosis. We argue that the same could be true for negative core schema, where reductions in preoccupation with schematic beliefs, amount of distress and intensity of distress could also be clinically meaningful.

4.5. Implications for Clinical Practice

While our findings perhaps have greater implications for theory, we make some tentative suggestions for clinical practice. Our findings are consistent with cognitive models of psychosis and support claims that negative core schema may be important underlying processes in the relationship between childhood trauma and paranoia. We suggest that fruitful avenue for potential research would be to design intervention trails including trauma-informed formulation and targeting negative core schema in the hope this may reduce paranoia in people with persecutory delusions. This would have the potential two-fold benefit of translating theoretical results into psychological therapies for psychosis, however we note Bradford Hill (1965) included experimental evidence in criteria for causality. As a result, if a psychological therapy were to be developed that targeted negative core schema and was subsequently found to reduce paranoia, this could be viewed as further evidence for a causal relationship between childhood trauma and paranoia.

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Appendices

- Appendix A: Study 1 University Ethical Approval
- Appendix B: SCIRATS- Online Version
- Appendix C: SCIRATS Scoring Criteria
- Appendix D: Study 2 Ethical Approvals
- Appendix E: Study 2: Study Protocol
- Appendix F: Changes to Protocol
- Appendix G: SCIRATS- Paper Version
- Appendix H: Study 2 Posters
- Appendix I: Psychosis: Psychological, Social and Integrative Approaches
Authorship Guidelines

Appendix A: Study 1 University Ethical Approval



SCHOOL of HEALTH IN SOCIAL SCIENCE
CLINICAL AND HEALTH PSYCHOLOGY

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969

Fax 0131 650 3891

Email submit@ethics@med.ed.ac.uk

David Carmichael
Trainee Clinical Psychologist
School of Health in Social Science
University of Edinburgh

28 January 2019

Dear David,

Application for Level 1 Ethical Approval

Reference: CLIN538

Project Title: The relationship between childhood trauma, negative core schema and
paranoid: A mediation analysis

Academic Supervisor: Karen Goodall

Thank you for submitting the above research project for review by the Department of
Clinical and Health Psychology Ethics Research Panel. I can confirm that the submission has
been independently reviewed and was approved on the 28th August 2018.

Should there be any change to the research protocol it is important that you alert us to this
as this may necessitate further review.

Yours sincerely,

Kirsty Gardner
Administrative Secretary, Clinical Psychology

Appendix B: SCIRATS- Online Version

Beliefs about self and others

This questionnaire lists beliefs that people can hold about themselves and other people.

Please indicate whether you hold each belief (YES or NO). Try to judge beliefs on how you have generally, over time, viewed yourself and others. Do not spend too long on each belief. There are no right or wrong answers and the first response to each belief is often the most accurate.

Depending on your responses, you may be asked some additional questions regarding each belief.

I am unloved * *Required*

Yes No

How strongly do you hold this belief?

- 1. Believe it slightly
- 2. Believe it moderately
- 3. Believe it very much
- 4. Believe it totally

How long have you had this belief?

- 0. Since age 25+
- 1. Since ages 20-25
- 2. Since ages 15-19
- 3. Since ages 10-14
- 4. Before the age of 10

How often do you view yourself in this way?

- 0. Less than once a week
- 1. At least once a week
- 2. At least once a day
- 3. More than once a day
- 4. Thinks about the belief continuously or almost continuously

When you think about this belief, how long does it stay on your mind?

- 0. Does not think about this belief
- 1. Thoughts about belief last for a few seconds
- 2. Thoughts about belief last for several minutes
- 3. Thoughts about belief last for at least 1 hour
- 4. Thoughts about belief usually last for hours at a time

How strongly do you believe this belief is true on a scale of 0-100% (0 = not at all, 100 = totally true)?

- 0. 0% Do not believe it at all
- 1. Believe it less than 10%
- 2. Believe it somewhat. Between 10-49%
- 3. Believe it strongly. Between 50-99%
- 4. Totally believe it 100%

When you think about this belief, how often does it upset you?

- 0. Belief never causes distress
- 1. Belief causes distress on the minority of occasions
- 2. Belief causes distress on less than 50% of occasions
- 3. Belief causes distress on the majority of occasions they occur. Between 50-99% of the time
- 4. Beliefs always cause distress when they occur

How distressing do you find this belief?

- 0. No distress
- 1. Belief causes slight distress
- 2. Belief causes moderate distress
- 3. Belief causes marked distress
- 4. Belief causes extreme distress, could not be worse

To what extent does this belief get in the way of day to day life?

- 0. No disruption to life. No impact on daily living skills, social or family relationships
- 1. Belief causes minimal amount of disruption to life e.g. interferes with concentration although able to maintain daytime activity, social and family relationships and able to maintain independent living without support
- 2. Belief causes moderate amount of disruption to life, causing some disturbance to daytime activity and/or family and social activities. May require some assistance with daily living skills.
- 3. Belief causes severe disruption to life in terms of activities, daily living skills and/or relationships
- 4. Belief causes complete disruption of daily life. Unable to maintain any daily living activities and social relationships. Self-care is severely disrupted

I am worthless * Required

- Yes
- No

How strongly do you hold this belief?

- 1. Believe it slightly
- 2. Believe it moderately
- 3. Believe it very much

Appendix C: SCIRATS Scoring Procedure and Criteria

In the current study if participants endorsed an item on the BCSS, they were asked a further seven questions regarding this belief. These questions sought to measure dimensions such as the duration of this belief, the frequency of this belief, the duration of the belief, the conviction associated with the belief, the amount and intensity of distress associated with the belief and the disruption to wider life associated with this belief.

Criteria were subsequently developed across dimensions in order for the belief to be regarded as a schema. The first (DC) and last author (PH), who have six and 14 years of experience of delivering Cognitive Behavioural Therapy (CBT) and working with negative core schema within this modality respectively developed these criteria. These criteria included:

- 1) A score of 2 or more on Question 1 (the belief must have been present before the age of 20)
- 2) A score of 1 or more on Question 2 (the belief must be present at least once per week)
- 3) A score of 2 or more on Question 3 (thoughts about the belief last for several minutes)
- 4) A score of 1 or more on Question 4 (believe it less than 10%)
- 5) A score of 2 or more on Question 5 (Belief causes distress on less than 50% of occasions).
- 6) A score of 2 or more on Question 6 (Beliefs cause moderate distress)
- 7) A score of 2 or more on Question 7 (Moderate amount of disruption to life, causing some disturbance to daytime activity and/or family and social events)

For each belief endorsed by participants on the original BCSS, we applied the above criteria. If these criteria were met, we scored the belief as 'YES'. The decision to score each belief as 'believe slightly', 'believe it moderately', 'believe it very much' or 'believe it totally' will be based on participants responses to question 5, 'How much do you believe this is true?' The following scoring rules will be applied:

- 1) Very little conviction in belief <10% = Believe it slightly
- 2) Some doubts relation to belief, between 10-49% = Believe it moderately
- 3) Belief is very strong, between 50-99% = Believe it very much
- 4) 100% conviction in belief = Believe it totally

For the purposes of analysis, the re-scored BCSS was referred to as the ABCSS. Raw data for each of schema item on the BCSS and additional questions was entered into an excel spreadsheet and formula were developed to score the ABCSS given the above criteria. The first author (DC) can be contacted for these formula.

Appendix D.1: Study 2 University Ethical Approval



SCHOOL of HEALTH IN SOCIAL SCIENCE
CLINICAL AND HEALTH PSYCHOLOGY

The University of Edinburgh
Medical School
Doonkey 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891
Email g.gardner@ed.ac.uk

David Carmichael
Trainee Clinical Psychologist
Department of Clinical and Health Psychology
School of Health in Social Science
University of Edinburgh

18 August 2017

Dear David,

Application for Level 1 Ethical Approval

Reference: CLIN405

Project Title: The relationship between childhood trauma, negative core schema and
paranoia in people with persecutory delusions: A mediation analysis

Academic Supervisor: Karen Goodall

Thank you for submitting the above research project for review by the Department of
Clinical and Health Psychology Ethics Research Panel. I can confirm that the submission has
been independently reviewed and was approved on the 12th August 2017.

Should there be any change to the research protocol it is important that you alert us to this
as this may necessitate further review.

Yours sincerely,

Kirsty Gardner
Administrative Secretary, Clinical Psychology

Appendix D.2: NHS Research Ethics Committee Favourable Opinion

WoSRES
West of Scotland Research Ethics Service



Mr David Carmichael
Psychology Department, 2nd Floor,
MacKinnon House
Royal Edinburgh Hospital, Morningside
Terrace
Edinburgh
EH10 5HF

West of Scotland REC 3
West Ambulatory Care Hospital
Dalnair Street
Yorkhill
Glasgow
www.nhsqgc.org.uk

Date 17 July 2017
Direct line 0141-232-1806
e-mail Wosrec3@ggc.scot.nhs.uk

Dear Mr Carmichael

Study title: The relationship between childhood trauma, negative core schema and paranoia in people with persecutory delusions: A mediation analysis
REC reference: 17/WS/0090
IRAS project ID: 214964

Thank you for your letter of 05 July 2017, 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. 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 opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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

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

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

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions from host organisations

Registration of Clinical Trials

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

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. 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).

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 [A3 Poster- David Carmichael- Version 2 05072017]	2	05 July 2017
Copies of advertisement materials for research participants [A4 Poster- David Carmichael- Version 2 05072017]	2	05 July 2017
Covering letter on headed paper [Cover Letter- Amendments following Provisional Opinion- David Carmichael 05072017]	1	05 July 2017
GP/consultant information sheets or letters [Clinician Information Sheet- David Carmichael]	1	31 March 2017
Interview schedules or topic guides for participants [The Schema Rating Interview]	1	31 March 2017
Other [Care Protocol- David Carmichael]	1	31 March 2017
Participant consent form [Consent Form- David Carmichael- Version 2 05072017]	2	05 July 2017
Participant information sheet (PIS) [Participant Information Sheet- David Carmichael- Version 2 05072017]	2	05 July 2017
REC Application Form [REC_Form_06042017]		06 April 2017
Research protocol or project proposal [Study Protocol- David Carmichael]	2	05 July 2017
Summary CV for Chief Investigator (CI) [CV- David Carmichael- March 2017]	1	31 March 2017
Summary CV for supervisor (student research) [CV-Karen Goodall- March 2017]	1	31 March 2017
Validated questionnaire [PANSS/PSYRATS Modified Interview Schedule]	1	31 March 2017
Validated questionnaire [The Childhood Trauma Questionnaire]	1	31 March 2017
Validated questionnaire [The Brief Core Schema Scales]	1	31 March 2017
Validated questionnaire [The Paranoid Thoughts Scale]	1	31 March 2017

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/>

17/WS/0090	Please quote this number on all correspondence
------------	--

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

Yours sincerely

On behalf of
Dr Adam Burnel
Chair

*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: Ms Charlotte Smith
NHS Lothian Research & Development Office*

West of Scotland REC 3

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Adam Bumel	Consultant Psychiatrist - Chair	Yes	
Mrs Rosie Rutherford	Volunteer - Lay Plus Member and Vice Chair	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Sophie Bagnall	Assistant Co-ordinator

Appendix D.3: Non-Substantial Amendment 1

10/26/2017

Mail - s1580014@sms.ed.ac.uk

Non-substantial amendment 31 August 2017

SMITH Charlotte

Tue 31/08/2017 16:44

To: CARMICHAEL David <s1580014@sms.ed.ac.uk>

Sponsor Amendment Classification

Title:	The relationship between childhood trauma, negative core schema and paranoia in people with persecutory delusions: A mediation analysis
REC Reference	17/WS/0090
Sponsor Reference:	Non-substantial amendment 31 August 2017
Chief Investigator:	David Carmichael

Dear David,

I have reviewed your proposed changes as outlined in our previous correspondence. I can confirm that in the opinion of the Sponsor's representative the following changes:

- *Cover GP letter, demographic information sheet and patient contact details form (detailed in IRAS form missed off from checklist in error but not requested at REC meeting) to be added to study documentation (non-patient study documentation)*

Comprise a **non-substantial amendment**.

What to do next...

REC	You should now email all missing documentation to the relevant Research Ethics Committee. You should contact REC via the email address listed on your original Favourable Opinion letter. Please copy me into this correspondence.
------------	---

NHS R&D	You are obliged to inform the relevant NHS R&D group of your proposed changes. You should provide the same details as you provided to me, plus any amended supporting documentation. For multi-site studies, please contact NRS: nhsq.NRSPCC@nhs.net . Please copy me into this correspondence.
--------------------	---

Sites	Please ensure that any revised documentation is circulated to all participating sites in a timely manner (and also sent to myself as Sponsor representative) and that no sites use outdated/superseded documentation after this amendment has been implemented.
--------------	---

**** Note that you cannot implement the amendment until such time as approval has been given by REC and R&D. ****

Please copy me into, or forward on all correspondence with REC and R&D.

<https://outlook.office365.com/owa/?realid=ed.ac.uk&path=/mail/inbox>

1/2

Appendix D.4: Non-Substantial Amendment 2

10/26/2017

Mail - s1580014@sms.ed.ac.uk

Non-substantial amendment 24 October 2017

SMITH Charlotte

Tue 24/10/2017 15:18

To: CARMICHAEL David <s1580014@sms.ed.ac.uk>

Sponsor Amendment Classification

Title:	The relationship between childhood trauma, negative core schema and paranoia in people with persecutory delusions: A mediation analysis
REC Reference	17/WSi0090
Sponsor Reference:	Non-substantial amendment 24 October 2017
Chief Investigator:	David Carmichael

Dear David,

I have reviewed your proposed changes as outlined in our previous correspondence. I can confirm that in the opinion of the Sponsor's representative the following changes:

- *Minor changes to study documentation (CI contact details updated on participant information, no change to CI)*

Comprise a **non-substantial amendment**.

What to do next...	
REC	There is no requirement to inform the REC of this amendment.
NHS R&D	You are obliged to inform the relevant NHS R&D group of your proposed changes. You should provide the same details as you provided to me, plus any amended supporting documentation. For multi-site studies, please contact NRS: nhsq.NRSPCC@nhs.net . Please copy me into this correspondence.
Sites	Please ensure that any revised documentation is circulated to all participating sites in a timely manner (and also sent to myself as Sponsor representative) and that no sites use outdated/superseded documentation after this amendment has been implemented.

**** Note that you cannot implement the amendment until such time as approval has been given by R&D. ****

Please copy me into, or forward on all correspondence with R&D.

Best wishes,

Charlotte

Charlotte Smith
Research Governance Coordinator
College of Arts, Humanities & Social Sciences

The University of Edinburgh
Room B.04, 55 George Square
Edinburgh, EH8 8JU

<https://outlook.office365.com/owa/?realm=ed.ac.uk&path=/mail/inbox>

1/2

Appendix D.5: Substantial Amendment: Sponsor Classification

27/02/2019

Mail – s1580014@sms.ed.ac.uk

Substantial amendment 1 - 2 March 2018

SMITH Charlotte

Tue 06/03/2018 10:55

To: CARMICHAEL David <s1580014@sms.ed.ac.uk>;

Sponsor Amendment Classification

Title:	The relationship between childhood trauma, negative core schema and paranoia in people with persecutory delusions: A mediation analysis
REC Reference	17/WS/0090
Sponsor Reference:	Substantial amendment 1 – 02 March 2018
Chief Investigator:	David Carmichael

Dear David,

I have reviewed your proposed changes as outlined in our previous correspondence. . .
I can confirm that in the opinion of the Sponsor's representative the following changes:

- *Addition to demographic information collected (completed by participant) – whether therapy received currently/previously and if yes, the form of therapy this was*
- *Extension of study to 30th October 2018 (no change to study numbers or PI)*

Comprise a substantial amendment.

What to do next...

REC

You should now email the IRAS Notification (signed by me), and all updated documentation (with changes highlighted) to the relevant Research Ethics Committee.

You should contact REC via the email address listed on your original Favourable Opinion letter.

Please copy me into this correspondence.

NHS R&D

You are obliged to inform the relevant NHS R&D group of your proposed changes. You should provide the same details as you provided to me, plus any amended supporting documentation.

The IRAS Notice of Substantial Amendment form should also be included

For multi-site studies, please contact NRS: nhsq.NRSPCC@nhs.net.

Please copy me into this correspondence.

Sites

Please ensure that any revised documentation is circulated to all participating sites in a timely manner (and also sent to myself as Sponsor representative) and that no sites use outdated/superseded documentation after this amendment has been implemented.

**** Note that you cannot implement the amendment until such time as approval has been given by REC and R&D. ****

Please copy me into, or forward on all correspondence with REC and R&D.

Best wishes,

Charlotte

<https://outlook.office365.com/owa/?realm=ed.ac.uk&path=/mail/search>

1/2

Appendix D.6: Substantial Amendment: REC Approval

WoSRES
West of Scotland Research Ethics Service

Mr David Carmichael
Psychology Department, 2nd Floor, MacKinnon
House
Royal Edinburgh Hospital, Morningside Terrace
Edinburgh
EH10 5HF



West of Scotland REC 3
Research Ethics
Clinical Research and Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ
(Formerly Yorkhill Childrens Hospital)

Date 19 March 2018
Direct line 0141 232 1807
E-mail WoSREC3@ggc.scot.nhs.uk

Dear Mr Carmichael

Study title: The relationship between childhood trauma, negative core schema and paranoia in people with persecutory delusions: A mediation analysis
REC reference: 17/WS/0090
Amendment number: Amendment 1 02032018 (REC Ref AM02)
Amendment date: 06 March 2018
IRAS project ID: 214964

The above amendment was reviewed by the Sub-Committee in correspondence. The purpose of this amendment is to request permission to collect information regarding whether participants are currently or have previously received psychological therapy and the type of therapy if this is known. It also involves an extension of the study end date to 30 October 2018.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	Amendment 1 02032018 (REC Ref AM02)	06 March 2018
Other [Demographic Information Sheet]	2	02 March 2018
Other [E-mail confirming no other study documents require any changes]		08 March 2018

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/WS/0090:	Please quote this number on all correspondence
--------------------	---

Yours sincerely

On behalf of
Mrs Rosie Rutherford
Chair

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *NHS Lothian Research & Development Office*

West of Scotland REC 3

Attendance at Sub-Committee of the REC meeting in March 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr John Cassels	Environment Protection Officer	Yes	
Dr Anne-Louise Cunnington	Consultant Geriatrician and Vice Chair	Yes	Chair of Meeting
Mr Ben Parkinson	Lecturer in Nursing	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Abibat Adewumi-Ogunjobi	REC Manager

Appendix E: Study 2: Study Protocol



THE UNIVERSITY
of EDINBURGH



Study Protocol: Childhood Trauma, Negative Core Schema and Paranoia in People with Persecutory Delusions: A Mediation Analysis

Protocol Author: David Carmichael

List of Abbreviations

APA	American Psychiatric Association
BCSS	The Brief Core Schema Scales
BPS	British Psychological Society
CBT	Cognitive Behavioural Therapy
CMHT	Community Mental Health Team
CTQ	The Childhood Trauma Questionnaire
EMDR	Eye Movement Desensitization and Reprocessing
GMW Trust	Greater Manchester West Mental Health foundation NHS
MSc	Master of Science University Qualification
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PANSS	The Positive and Negative Syndrome Scale
PRU	Psychosis Research Unit
PSYRATS	Psychotic Symptoms Rating Scale
PTSD	Post Traumatic Stress Disorder
REC	Research Ethics Committee
SCIRATS	The Schema Rating Scale
GPTS-Part B	The Green Paranoid Thoughts Scale-Part B

Background

Overview of Psychosis

Psychosis refers to a state in which an individual's perceptions, thoughts, mood and behaviour are significantly altered (National Institute for Health and Care Excellence (NICE), 2014). Experiences thought to characterise psychosis include hallucinations, delusions, thought disorder and negative symptoms including poor self-care, reduced emotional expression, withdrawal, listlessness, apathy or the inability to enjoy

previously pleasurable or valued activities (American Psychiatric Association (APA), 2013; British Psychological Society (BPS), 2014). Psychosis is associated with significant impairments in personal, social and occupational functioning, where mortality rates are approximately 50% higher than the general population (NICE, 2014; Singleton *et al*, 2003). Biological theories have typically dominated understandings of psychosis (Reid *et al*, 2005), however in recent years there has been increased recognition that psychosis is likely to develop from a number of interacting factors (Freeman & Fowler, 2009; Garety *et al*, 2001; Garety *et al*, 2007). One psychological factor that has recently gained prominence within the research literature is the influence of childhood trauma (Freeman & Fowler, 2009),

Childhood Trauma

Childhood trauma refers to a range of negative life experiences including physical, sexual and emotional abuse as well as physical and emotional neglect (Larkin & Reid, 2008). There is now a significant body of research investigating the relationship between traumatic events in childhood and psychosis (Arseneault *et al*, 2013; DeRosse *et al*, 2014; Reid *et al*, 2005), where a recent study analyzing the current body of research found evidence of causal relationship (Varese *et al*, 2012). In light of these findings, it has been claimed that childhood trauma gives approximately the same risk of developing psychosis as smoking does for lung cancer (Bentall *et al*, 2012).

Consistent with a causal relationship, a number of studies have reported a ‘dose-response’ effect of trauma on psychotic symptoms, where the number of traumatic childhood events experienced predicts the subsequent risk and severity of symptoms of psychosis (Bentall *et al*, 2012; Trauelsen *et al*, 2015; Whitfield *et al*, 2005). Furthermore, severity and frequency of childhood trauma has been found to be associated with the severity of symptoms of psychosis (Schenkel *et al*, 2005).

Cognitive Models of Psychosis

Cognitive models of psychosis offer an insight into the relationship between childhood trauma and positive symptoms of psychosis (Garety *et al* 2001; Garety *et al*, 2007; Morrison *et al*, 2001). These models suggest that adverse early life experiences may lead to the development of negative beliefs about the self, the world and other people. These beliefs are known as negative core schema and can be defined as ‘negative, rigid and deeply held beliefs about the self, the world and others that develop as a result of early life experiences’ (Beck *et al*, 1979). If, for example, an individual experiences adverse life experiences, they may develop negative core schema such as ‘I am bad’, ‘I’m vulnerable’ or ‘Other people are dangerous’ (Morrison *et al*, 2003; Reid *et al*, 2005).

Subsequent adverse life experiences are thought to activate these negative core schema, resulting in emotional changes, such as anxiety or depression, and ‘unusual perceptual experiences’ (Garety *et al*, 2001; Morrison *et al*, 2001; Okkles *et al*, 2016). Unusual perceptual experiences refer to experiences such as ‘heightened perceptions, actions being experienced as unintended, racing thoughts, thoughts

appearing to be broadcasted, thoughts being experienced as voices or two unconnected events appearing to be linked' (Garety *et al*, 2001; Freeman & Garety, 2014). Individuals with psychosis are subsequently thought to attempt to make sense of or 'appraise' these usual perceptual experiences (Garety *et al*, 2001; Morrison *et al*, 2001). A number of cognitive biases are thought to influence this appraisal-formation process including jumping to conclusions (Dudley *et al*, 2016; Garety *et al*, 2001) and attribution negative events to the actions of others (known as an external attribution style) (Garety *et al*, 2001; Janssen *et al*, 2006). Pre-existing negative core schema are also thought to shape and influence this process (Garety *et al* 2001; Garety & Freeman, 2013; Morrison *et al*, 2001). If for example an individual has negative core schema such as 'I am bad' and 'Other people are dangerous' and they have a tendency to form conclusions quickly, then the cognitive model predicts that, if faced with an ambiguous behaviour by another person (e.g., someone unknown glances at them), they will be more likely to quickly form a negative opinion about the motives of that individual, which will be likely to assume malicious intent.

Childhood Trauma and Paranoia

This study will adopt the symptom specific approach (Morrison *et al*, 2004) as it is possible that the influence of negative core schema may vary across different experiences of psychosis (see Freeman & Fowler, 2009; Gracie *et al*, 2007). Paranoia is thought to be one of the most common symptoms of psychosis, occurring in 70% of first-episode, 50% of cases thereafter (Freeman, 2007; Freeman & Garety, 2014) and has been found to be the most likely delusions to be acted upon (Wessely *et al*, 1993). Paranoia is thought to exist on a continuum in the population (Freeman & Garety, 2014). While most individuals may experience paranoia in the form of fears or rejection, feelings of vulnerability or worry that others are talking about them, Freeman & Garety (2000) suggest that clinically significant levels of paranoia can be distinguished by the presence of persecutory delusions, where these are defined as a belief that harm is occurring, or is going to occur to them and that the perpetrator has the intention to cause that harm (see Peters *et al*, 2016). In line with the wider literature examining the relationship between childhood trauma and symptoms of psychosis, severity of childhood has been found to predict severity of paranoia in the community (Freeman & Fowler, 2009; Gracie *et al*, 2007), amongst prison populations (Shevlin *et al*, 2015) and in individuals current accessing mental health services (Carvalho *et al*, 2016). Furthermore, a study that interviewed people with persecutory delusions found that they had all experienced difficulties in their early life relationships with caregivers and linked these to their subsequent difficulties in adulthood (Dickson *et al*, 2016)

Negative Core Schema and Paranoia

Studies with the community have found that negative beliefs about the self and negative beliefs about others significantly predict the severity of paranoia (Fowler *et al*, 2006; Gracie *et al*, 2007). While findings in the community do not necessarily mean the same is true for individuals accessing mental health services, negative beliefs about the self have been found to significantly predict severity of persecutory

delusions in adults with psychosis (Fowler *et al*, 2012; Smith *et al*, 2006; Vorontsova *et al*, 2013). Few studies however have examined the influence of negative beliefs about others in individuals with persecutory delusions. Finally, a recent study interviewing individuals with persecutory delusions reported that their experience of difficulties within their early relationships with caregivers resulted in beliefs that they are unloved, bad, worthless or vulnerable, others are powerful, dangerous, threatening, not to be trusted and that the world is unfair (Dickson *et al*, 2016). When considered in relation to the evidence regarding the causal influence of childhood trauma, the above findings provide some degree of support for cognitive models of psychosis. Despite this, a number of limitations limit the conclusions that can be drawn from the current literature.

Limitations of Previous Research & Rational for Current Study

Research in this area tends to examine all symptoms of psychosis as a whole when studying the relationship between childhood trauma and psychosis. This prevents researchers from establishing whether the effect of childhood trauma and negative core schema might vary across different experiences of psychosis. In addition, studies tend to examine the frequency of childhood trauma rather than how long an individual experienced these events. This is problematic as we know from research into other mental health difficulties such as PTSD and Complex Trauma that longer trauma duration is associated with increased symptom severity. Furthermore, research in this area tends to focus on negative beliefs about the self however; there is some evidence to suggest that negative beliefs about others may also be important in the development of paranoia and persecutory delusions.

Finally, the most significant limitation associated with previous research is the tendency for studies to either examine the relationship between childhood trauma and paranoia or the relationship between negative core schema and paranoia. In order to test whether cognitive models of psychosis are useful in explaining the relationship between childhood trauma and paranoia, what we need to ask is how much of the relationship between childhood trauma and paranoia is explained by negative core schema.

To the researcher's knowledge, only two studies have attempted to address this question Anilmis *et al* (2015) found that severity of bullying significantly predicted severity of unusual experiences in a clinical sample of 8-14 year olds and that negative beliefs about the self and negative beliefs about others did explain some degree of the relationship between bully and unusual distressing experiences. While this study provides further evidence for cognitive models of psychosis, it is limited as the authors only examine one form of traumatic childhood experience and results in relation to unusual distressing experiences in children cannot be applied to adult clinical samples.

Hardy *et al* (2016) examined a number of mechanisms thought to explain the relationship between childhood trauma and different experiences of psychosis in a clinical sample of individuals with psychosis who had recently relapsed. The authors found no relationship between childhood physical abuse and persecutory delusions

but found a significant relationship between childhood emotional abuse and persecutory delusions. This relationship was explained in part by negative beliefs about others but not negative beliefs about the self.

Despite these findings, a number of weaknesses limit the conclusions that can be drawn from their findings. While there is some evidence to suggest that specific forms of trauma predict specific experiences of psychosis (see Bentall *et al*, 2014), Trauelsen *et al* (2015) argues that the risk of psychosis increases for each additional trauma experienced and as a result, research should study all possible forms of childhood trauma that an individual might experience rather than focusing of specific types of traumatic event.. As a result, it could be argued that is premature to only examine the relationships between childhood physical and emotional abuse and persecutory delusions. This is a particular limitation of Hardy *et al* (2016) when one also considers that they only asked 3 questions about physical abuse, 3 questions about sexual abuse, 1 question about emotional abuse and did not examine the impact of neglect. The authors also discounted experiences of abuse if it was felt these were related to delusional or hallucinatory experiences. Given that their decision making process in this regard was not specified and that reports of childhood trauma in individuals with psychosis have been found to be as reliable as the general population (Reid *et al*, 2005), it could be argued this approach could possibly unduly influencing their results.

Furthermore, the study was part of a larger research study examining the effectiveness of different psychological therapies in preventing relapse and reducing symptoms of psychosis. Participants were asked about negative beliefs about themselves and other people after they had completed treatment for psychosis. As a result, it could be argued that their results do not truly reflect the factors involved in the development of psychosis as treatment specifically focused on reducing negative beliefs about the self and others in the home this would lead to a reduction in the individual's symptoms of psychosis.

In order to address some of the limitations of previous research and further test whether cognitive models of psychosis are useful in understanding the link between childhood trauma and paranoia in the form of persecutory delusions, this study focuses solely on paranoia and persecutory delusions in people currently accessing mental health services. In addition, the current study will examine negative beliefs about others as well as negative beliefs about the self and will examine the influence of trauma duration as well as trauma severity.

Study Aims

The current study will aim to expand our understanding of the relationship between childhood trauma and paranoia in people with persecutory delusions. The following hypotheses will be tested:

- 1) Negative-self core schema will mediate the relationship between childhood trauma and paranoia in people with persecutory delusions.

- 2) Negative-other core schema will mediate the relationship between childhood trauma and paranoia in people with persecutory delusions.
- 3) Negative-other core schema will be stronger mediators of the relationship between childhood trauma and paranoia in people with persecutory delusions.
- 4) Trauma duration will be related to increased negative schema severity and this relationship will mediate the relationship between childhood trauma and paranoia in people with persecutory delusions.

Principle Research Question

Do negative-self core schema mediate the relationship between childhood trauma and paranoia in people with persecutory delusions?

Secondary Research Questions

Do negative-other core schema mediate the relationship between childhood trauma and paranoia in people with persecutory delusions?

Are negative-other core schema stronger mediators of the relationship between childhood trauma and paranoia in people with persecutory delusions than negative-self core schema?

Is trauma duration related to increased negative schema severity and does this relationship in turn mediate the relationship between childhood trauma and paranoia in people with persecutory delusions?

Methodology

Design

The study will use a cross-sectional, quantitative, within-groups design. It will recruit a clinical sample of adults with psychosis and current persecutory delusions as defined by Freeman & Garety (2000) currently in contact with NHS Mental Health Services. It will use statistical analysis to compare participants within this group in order to test the study's hypotheses. Participants will be invited to complete one semi-structured interview measuring severity of psychotic symptoms. This interview will determine whether participants meet inclusion criteria for the current study. Should participants meet inclusion criteria, they will be asked to complete a further three questionnaires and one further semi-structured interview measuring severity/duration of childhood trauma, negative core schematic beliefs and paranoia. In the event participants do not meet inclusion criteria, they will be thanked for their participation, told that the current study is looking to recruit individuals with a specific set of experience and no further measures will be administered. A series of mediation analyses will be utilised in order to answer the research questions associated with the current study.

Participants

Adults over the age of 16 with a diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder or 'non-affective psychosis' determined through the chart diagnosis offered by the treating psychiatrist, and who are currently in contact with NHS Mental Health Services will be able to participate if they have current persecutory delusions, as defined by Freeman and Garety (2000). These authors define persecutory delusions as unfounded beliefs that harm is occurring, or is going to occur to the individual and that the perpetrator has the intention to cause that harm.

In line with previous research (e.g. Freeman *et al*, 2015; Startup *et al*, 2016), a score of 3 or more on the conviction item of the PSYRATS delusions subscale (Haddock *et al*, 1999) will be used in order to confirm participants have delusions that meet this criterion. The Positive and Negative Syndrome Scale (PANSS; Kay *et al*, 1986) and full Psychotic Symptom Rating Scale (PSYRATS; Haddock *et al*, 1999) will also be used to describe and characterise the various domains of psychotic symptoms that participants hold, with specific reference to persecutory delusions, thus allowing reporting in accordance with the recommendations of Freeman & Garety (2000).

It is not possible to determine whether participants will meet inclusion criteria 3) a score of 3 or more on the conviction item of the PSYRATS delusion subscale (i.e. at least 50% conviction in the delusions) (Haddock *et al*, 1999) through initial screening telephone calls with potential participants as this must be determined through the completion of the PSYRATS with participants. Participants will be made aware that they will be asked to complete a 45 minute-1 hour interview and then may be invited to complete further measures based on their responses during this interview on information sheets and consent forms prior to taking part in the study.

Recruitment will take place across Community Mental Health Teams (CMHTS) in NHS Lothian, NHS Greater Glasgow and Clyde, NHS Forth Valley and NHS Lanarkshire. Recruitment will also take place in inpatient acute wards in NHS Lothian and NHS Forth Valley.

Procedure

There will be two recruitment pathways into the current study. In the first pathway, posters advertising the study will be displayed in NHS Lothian, NHS Greater Glasgow and Clyde, NHS Forth Valley and NHS Lanarkshire Community Mental Health Teams (CMHTS). Posters shall also be displayed in inpatient wards in NHS Lothian and NHS Forth Valley. Potential participants will be asked to contact the researcher via email or telephone if they would like to participate. Having made contact, the researcher will complete a potential participant contact details form and will ascertain whether the individual meets inclusion criteria for the study during an initial telephone contact. Potential participants will then be asked for their verbal consent for the researcher to contact their keyworker/ care coordinator in order to assure that participants meet inclusion criteria and to assess whether participation

would be likely to result in any risks to the participant or the researcher. If potential participants do not consent to the researcher contacting their keyworker/ care coordinator they will be excluded from the current study.

Potential participants will be sent a participant information sheet following this initial contact. Potential participants will be asked for their verbal consent for the researcher to contact them no less than 48 hours after receiving the participant information sheet to ascertain whether they remain interested in taking part in the current study. If participants do not provide their consent, the researcher shall wait for them to make further contact. Should potential participants continue to express an interest in the study during further contact and meet inclusion criteria, an appointment will be made for participants to complete study measures. The researcher shall send appointment letters to potential participants if they wish this as a reminder of the appointment.

In the event participants do not meet inclusion criteria for the current study, they shall be thanked for their interest during further contact, advised that they do not meet inclusion criteria for the study and the potential participant contact details form shall be destroyed.

In the second recruitment pathway, clinicians will be asked to identify individuals on their current caseload that may meet inclusion criteria. Clinicians will be provided with clinician and participant information sheets and asked to discuss these with any potential participants. Clinicians will acquire verbal consent from potential participants to be contacted by the researcher and for the researcher to discuss whether they meet inclusion criteria for the project with their keyworker/ care coordinator. If verbal consent is granted, clinicians will be asked to either contact the researcher with the potential participant's details or to complete a potential participant contact details form. The potential participant contact details form shall ask clinicians to provide details regarding the potential participant's name, contact number, address, and email address (optional), name of mental health team, name of NHS Health Board and name of keyworker / care coordinator. Clinicians will then forward these forms to the researcher.

For potential participants entering the study through this method, discussions with the individual's keyworker/ care coordinator will take place prior to contacting the potential participant. In the event potential participants meet inclusion criteria for the study and no significant concerns regarding risks to the patient or researcher are evident, participants will be contacted via telephone by the researcher. Again, potential participants will always have at least 48 hours to consider the participant information sheet, before being contacted by the researcher. As in recruitment pathway one, in the event participants do not meet inclusion criteria for the current study, they shall be thanked for their interest in the current study, advised that they do not meet inclusion criteria and the potential participant contact details form shall be destroyed. If potential participants remain interested in participating in the study when contacted by the researcher, an appointment will be made for participants to

complete study measures. The researcher shall send appointment letters to participants if they wish this as a reminder.

Upon meeting potential participants, the researcher will check that they have read and understood the participant information sheet. Potential participants will be encouraged to ask the researcher questions before deciding to take part. They will also be provided with the contact details for the researchers academic and clinical supervisors on the information sheet. Prior to completing consent forms, participants will be read the following statement regarding confidentiality:

‘Any information you provide me with today will be confidential, however there is some information I am not able to keep confidential. Should during the course of the assessment, I become concerned that there is a risk of harm to either yourself or others, I have an obligation to share this information to keep you/others safe. If this is the case, I will explain to you why I need to share this information and tell you with whom I plan to share this information. In most cases, this would be your keyworker/ care co-ordinator. Do you have any questions?’

For those potential participants who continue to express an interest in the study, written consent will be obtained prior to proceeding with the study measures. Participants will be made aware of their right to withdraw from the study at any time, without having to give a reason, an assured that using their right to withdraw will have no impact upon the care they current receive from their mental health team.

Inclusion Criteria

- 1) Adults over the age of 16 with a diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder or non-affective psychosis, determined through the chart diagnosis offered by the treating psychiatrist and currently in contact with NHS Mental Health Services.
- 2) Individuals with current persecutory delusions that have persisted for at least 3 months. In the current study, persecutory delusions are defined as the belief that harm is occurring, or is going to occur to the individual and that the perpetrator has the intent to cause harm (Freeman & Garety, 2000).
- 3) In line with previous research (Freeman *et al*, 2015; Startup *et al*, 2016), a score of 3 or more on the conviction item of the PSYRATS delusion subscale (i.e. at least 50% conviction in the delusions) (Haddock *et al*, 1999).

Exclusion Criteria

- 1) Individual scoring less than 3 on the conviction item of PSYRATS delusion subscale (i.e. at least 50% conviction in the delusions).
- 2) Individuals not currently in contact with NHS Mental Health Services or without a keyworker/ care coordinator.

- 3) Individuals who do not provide consent for the research to contact their keyworker/care coordinator.
- 4) Individuals with psychosis due to an organic cause e.g. brain injury or dementia.
- 5) Individuals with a primary diagnosis of substance-induced psychosis.
- 6) Individuals with a diagnosis of bipolar disorder.
- 7) Individuals with a diagnosed intellectual disability or developmental disorder such as ASD.
- 8) Individuals who currently lack capacity to consent to research.
- 9) Individuals currently experiencing a psychiatric crisis and/or severe suicidal ideation or intent.
- 10) Individuals who present a significant risk of harm to the researcher.
- 11) Individuals who have a level of English ability that prevents completion of semi-structured interviews or questionnaires.

Data Collection

Where possible, data collection will take place in the base of whichever mental health service the participant has been recruited from. Participants will be advised that appointments will last approximately between 60-90 minutes. They will be advised they have to option to complete the study over one or two sessions.

Participants will also be asked to provide basic demographic information regarding age, gender, relationship status, years of education, ethnicity, diagnosis, duration of illness and medication status. They will also be asked for an email address in the event they wished to be contacted with the results of the study once available. In the event participants are unaware of their specific diagnosis, this information will be sourced from the individual's keyworker/ care coordinator.

Participants will then be asked to complete a modified interview schedule consisting of the Positive and Negative Syndrome (PANSS; Kay *et al*, 1986) and the Psychotic Symptoms Rating Scales (PSYRATS; Haddock *et al*, 1999). This section of the study shall be audio recorded with the participants consent. Throughout the process, the researcher will check the level of distress the participant is experiencing, and they will be reminded at all times that they can discontinue if they find they are becoming uncomfortable or upset by the questions. If participants choose to complete the study in one session, following the completion of this interview, participants will be given a short 5 minute break and informed that this is to allow the researcher to score their responses to the interview. Participants will be reminded at this stage that the study may be complete following this break or asked to complete three further questionnaires and one further short interview approximately 30 minutes in duration.

Participants who score less than 3 on the conviction item of the PSYRATS (Haddock *et al*, 1999) will be informed of the full aims of the study and thanked for their participation. Participants who score 3 or more on the conviction item of the PSYRATS (Haddock *et al*, 1999) will be invited to complete a further three questionnaire measures and one short interview. These include three self-report questionnaires, the Childhood Trauma Questionnaire (CTQ; Bernstein & Fink, 1998), the negative-self and negative-other subscales of the Brief Core Schema Scales (BCSS; Fowler *et al*, 2006) and Part B of the Green Paranoid Thoughts Scales (GPTS; Green *et al*, 2008). After completing the BCSS, participants will be asked to complete a novel short interview designed for the current study (The Schema Rating Interview; SCIRATS) regarding their responses to the BCSS prior to completing Part B of the GPTS. The SCIRATS will be audio recorded with the participants consent. The full aims of the study will then be explained to participants, who will also be thanked for their participation. Throughout the process, the researcher will check the level of distress the participant is experiencing, and they will be reminded at all times that they can discontinue if they find they are becoming uncomfortable or upset by the questions.

Should participants choose to complete the study over two sessions, the first session will last 45 minutes to 1 hour and consist of the PANSS/PSYRATS (Haddock *et al*, 1999; Kay *et al*, 1986). If they score 3 or more on the conviction item of the PSYRATS (Haddock *et al*, 1999), they will be invited to schedule another appointment with the researcher to complete the CTQ (Bernstein & Fink, 1998), BCSS (Fowler *et al*, 2006), SCIRATS and GPTS (Green *et al*, 2008). In the event participants score less than 3 on the conviction item of the PSYRATS and have chosen to participate over two sessions, they will be informed they do not meet criteria for the second part of the study, advised of the full aims of the study and thanked for their participation.

Study Measures:

The Positive and Negative Syndrome Scale (PANSS)- (Kay *et al*, 1986):

The Positive and Negative Syndrome Scale is a 30-item interviewer-rated questionnaire that assesses the severity of psychotic symptoms in the previous 72 hours. Responses are rated on a 7-point Likert scale where symptom severity is rated from 'absent' to 'extreme'. Higher scores represent increased symptom severity. The measure has acceptable psychometric properties, where internal consistence, test-retest reliability and inter-rated have been found to be above 0.8 (Kay *et al*, 1987; Kay *et al*, 1988). Furthermore convergent validity of above 0.7 has been reported with the Scale for Assessment of Positive Symptoms (SAPS; Andreasen, 1987).

In the current study, the PANSS will be used to provide detailed descriptive statistics regarding the nature of psychotic symptoms experienced by the sample. The developers suggest that the PANSS takes approximately 40 minutes to complete, where 10-15 minutes are spent developing rapport and a further 30 minutes are spent rating each item. A modified interview schedule developed by experienced clinical

psychology researchers at the Psychosis Research Unit (PRU) of the Greater Manchester West Mental Health foundation NHS Trust (GMW) and used in numerous NREC-approved clinical trials will be used to guide the interview process and maximise acceptability to participants. Full training on administration of the PANSS was provided by Dr Paul Hutton, who has used the PANSS extensively in the context of clinical trials. Access to training tapes and expert PANSS ratings will be available for the trainee to use to calibrate their ratings.

The Psychotic Symptoms Rating Scale (PSYRATS): (Haddock *et al*,1999):

The PSYRATS is a 17-item multi-dimensional measure of auditory hallucinations (11-items) and delusions (6-items) over the previous week. Examples of dimensions measured include frequency, duration and loudness of voices, amount of and duration of preoccupation with delusions, conviction in delusions and amount of and intensity of distress in response to voices or delusions. Items are rated on a 4-point likert scale, where higher scores reflect greater symptom severity. The measure has acceptable psychometric properties, where inter-rater reliability has been found to be above 0.8 (Haddock *et al*, 1999) and acceptable convergent validity (Steel *et al*, 2007) has been demonstrated with the PANSS (Kay *et al*, 1986) and the SAPS (Andreasen, 1987).

Freeman & Garety (2000) suggest that detailed information be gathered regarding the nature of persecutory delusions be gathered during research. Administering the delusions subscale of the PSYRATs will allow nature of persecutory delusions with the sample to be described through the reporting of mean scores on items measuring the preoccupation, distress, duration, conviction, intensity of distress and disruption association with persecutory delusions within the sample. In line with previous research, a PSYRATS conviction item score of 3 or more on the PSYRATS delusions subscale will be required to meet criteria for persecutory delusions as defined by Freeman & Garety and for inclusion in the current study. The modified interview schedule developed by the Psychosis Research Unit (PRU) of the Greater Manchester West Mental Health foundation NHS Trust (GMW) also allows for the administration and scoring of the PSYRATS in addition to the PANSS. The developers suggest that administering the modified interview schedule to include the PANSS and PSYRATS takes between 45minutes- 1 hour.

The Childhood Trauma Questionnaire (CTQ; Bernstein & Fink, 1998):

The Childhood Trauma Questionnaire is a 28-item self-report questionnaire that assesses five different forms of childhood trauma: physical, sexual and emotional abuse, and physical and emotional neglect. Responses are rated on a 5-point likert scale ranging from 'Never True' to 'Very Often True'. Higher scores are thought to reflect more instances of trauma. The measure has acceptable psychometric properties, where internal consistency, test-retest reliability and convergent validity with the Childhood Trauma Interview have all been found to be above 0.8 (Bernstein *et al*, 1994). This measure was selected as it focuses specifically on traumatic events during childhood, assesses a broad range of different forms of trauma and has been widely used in the previous literature examining the association between childhood

trauma and psychosis. According to the copyright holders, Pearson Clinical, it takes participants 5 minutes to complete on average (www.pearsonclinical.co.uk).

The Childhood Trauma Questionnaire will be adapted in the current study to include a measure of the duration of each traumatic event. The rationale for this adaptation is it will allow for the testing of secondary hypotheses relating to the duration of trauma. Individuals will be asked to indicate their age (in months) when trauma began and ended for each trauma domain measured by the CTQ (i.e. physical abuse, sexual abuse, emotional abuse, physical neglect and emotional neglect). The researcher will assist participants in converting their age in years to months if required. Should individuals have experienced multiple episodes of trauma within a domain, the duration of each traumatic event will be coded in number of months and the duration of each episode will be added to create a 'duration of trauma score' within each domain. Scores across each trauma domain will then be added to create a 'duration of trauma' score. It was felt summing the duration of trauma episodes within each domain and then creating a 'total duration of trauma' score encompassing all domains was the most pragmatic way to measure multiple traumatic experiences and/or concurrent traumas. It is difficult to estimate the required to administer further questions regarding the duration of trauma however given that the CTQ itself is through to take 5 minutes to complete, it is envisioned that a further 5 minutes will allow participants time to answer items regarding the total duration of trauma.

While there is no evidence to suggest that asking individuals with psychosis about childhood trauma results in serious or long term psychological harm (Reid *et al*, 2007), it is possible that some individuals may find completing the CTQ distressing. Furthermore it is possible that the researcher may be the first person to whom participants disclose a previous history of childhood trauma or that information provided by a participant may suggest that a child is currently at risk of harm. A Care Protocol has been developed to manage potential distress, disclosures of childhood trauma and the possibility of risk of harm to children should this occur. This protocol is based upon that developed by the The Psychosis Research Unit (PRU) of Greater Manchester West Mental Health Foundation NHS Trust (GMW) and which has been approved for use in a number of NREC-approved studies. A copy of the Care Protocol developed for the current study is included in Appendix 1.

The Brief Core Schema Scales (BCSS; Fowler *et al*, 2006):

The Brief Core Schema Scales are designed to measure beliefs about the self and others. The measure is comprised of four 6-item subscales including 'negative-self', 'negative-other', 'positive-self' and 'positive-other'. Participants first indicate whether they hold a belief and if they do, are asked to rate the strength of this belief on a 4-point Likert scale ranging from 'Believe it Slightly' to 'Believe it Totally'. Total scores on each scale range from 0-24. Higher scores indicate greater belief endorsement.

The measure has acceptable psychometric properties (Fowler *et al*, 2006). Internal consistency for all four sub-scales is above 0.8, construct validity has been

demonstrated through principle component analysis yielding a four factor solution and convergent validity has been demonstrated through moderate associations with the Rosenberg Self-Esteem Scale (Rosenberg, 1965) and with the Young Schema Questionnaire (Young, 1998) defectiveness/shame, mistrust/abuse and social isolation sub-scales.

This measure was selected as traditional measures of self-esteem have been criticised for failing to adequately measure the construct of schema as outlined in cognitive models of psychosis (Fowler *et al*, 2006). Given that the BCSS allows for a distinction to be made between different forms of core schema and that BCSS was specifically designed and validated for use among clinical populations of psychosis, it was felt this was the most appropriate measure for the current study. Descriptive statistics will be reported on all sub-scales however given that the previous literature has found negative-self and negative-other beliefs significantly predict the severity of paranoia, only these sub-scales will entered into the analysis in the current study. According to the scale developers, the BCSS takes participants approximately 1-2 minutes to complete (Fowler *et al*, 2006).

The Schema Rating Scale (SCIRATS):

The Schema Rating Scale is a novel semi-structured interview measure designed for the current study. This section of the study shall be audio recorded with the participant's consent.

There are a number of purposes for including this measure in the current study. The first purpose is to describe and characterise the negative core schema experienced by participants by information regarding the percentage of the sample that experience these beliefs and average scores for the duration of these beliefs, the amount these beliefs are on an individual's mind (known as amount and duration of preoccupation), how strongly participants believe these beliefs to be true (known as degree of conviction), how often participants experience distress in relation to these beliefs (amount of distress), how intense they find this distress (intensity of distress) and the degree to which they interfere with participants day to day functioning (disruption to life).

The second purpose of including this measure in the current study is to provide an additional check that what is being measured by the BCSS truly represents an individual's core schema. One theoretical model of persecutory delusions (the Paranoia as Defence Hypothesis; Bentall *et al*, 1994) suggests that persecutory delusions might serve as a defence against feelings of inferiority becoming conscious. The assumption of this model is that individuals with persecutory delusions have typical or perhaps even elevated levels of explicit self-esteem but low levels of implicit self-esteem (Bentall, 1994; Kinderman, 1994). This raises questions as to whether a questionnaire can truly measure an individual's negative core schema. It was felt that a semi-structured interview exploring an individual's negative beliefs about themselves and others would serve an additional check that is being measured in the current study truly does represent an individual's negative core schema; that is their deepest beliefs about themselves and other people.

The final purpose of including this measure is that it could be argued that there is a significant overlap between negative beliefs about other people and paranoia. The current study argues that these constructs are highly related yet distinct as negative core schema refer to negative, rigid, deeply held beliefs about the self, the world and others that develop as a result of early life experiences (Beck *et al*, 1979), whereas paranoia refers to beliefs in the here and now regarding the intentions of others that are likely to fluctuate on a day to day basis.

In order to provide an additional check that what is being measured by the BCSS truly represents negative core schema, rather than paranoia, the current study ask 8 additional questions for each negative core schema endorsed on the BCSS. Should participants endorse the majority of items on the BCSS, the researcher shall ask these 8 questions in relation to all negative core schema endorsed but check with the participant whether there are any core schema to which their response doesn't apply or to which their response may be different.

A number of criteria have been developed in relation to participants responses as to whether the belief constitutes a negative core schema. These criteria were developed by two clinicians (one of which is the principle investigator) trained to MSc level in Cognitive Behavioural Therapy (CBT) who currently have four years of experience delivering CBT based interventions and working with negative core schema within this therapeutic modality. The criteria were subsequently reviewed by qualified Clinical Psychologist with twelve years of experience delivering CBT based interventions.

These include:

- 1) A score of 2 or more on Question 1 (the belief must have been present before the age of 20)
- 2) A score of 1 or more on Question 3 (the belief must be present at least once per week)
- 3) A score of 2 or more on Question 4 (thoughts about the belief last for several minutes)
- 4) A score of 1 or more on Question 5 (how strongly do you believe this belief is true on a scale of 0-100%)
- 5) A score of 3 or more on Question 6 (Belief causes distress on the majority of occasions when they occur between 50-99% of the time)
- 6) A score of 3 or more on Question 7 (Beliefs cause marked distress)
- 7) A score of 2 or more on Question 8 (Moderate amount of disruption to life, causing some disturbance to daytime activity and/or family and social events)

The BCSS will be re-administered as a clinician rated measure and will be coded as BCSS+ SCIRATS for the purposes of analysis. This coding shall occur after the participant has completed the study and will be based on audio recordings of the SCIRATS. For each belief endorsed by participants on the original BCSS, the researcher will apply the above criteria. Should the criteria be met, the clinician will score the belief as YES. The decision to score each belief as 'believe slightly',

'believe it moderately', 'believe it very much' or 'believe it totally' will be based on participants responses to question 5 on the SCIRATS, 'How much do you believe this is true?' The following scoring rules will be applied:

- 1) Very little conviction in belief <10% = Believe it slightly
- 2) Some doubts relation to belief, between 10-49% = Believe it moderately
- 3) Belief is very strong, between 50-99% = Believe it very much
- 4) 100% conviction in belief = Believe it totally

The Paranoid Thoughts Scale - Part B (GPTS- Part B; Green *et al*, 2008):

The GPTS was designed to measure paranoia and persecutory beliefs across the general population- psychopathology continuum (Green *et al*, 2008). It has been suggested that a 'hierarchy' of paranoia exists in the general population, ranging from mild social evaluative concerns, through to ideas of social reference, to persecutory beliefs concerning mild, moderate and severe threat (Freeman *et al*, 2005). The GPTS is comprised of two sub-scales. Part A measures ideas of social reference relevant to paranoia, whereas Part B measures persecutory beliefs. Each sub-scale includes 16-items. Responses are rated on a 5-point Likert scale ranging from 'Not at all' to 'Totally'. Scores range from 18-60, where higher scores are thought to indicate higher levels of paranoia.

Both sub-scales have acceptable psychometric properties (Green *et al*, 2008), where internal reliability in clinical samples and test-retest reliability have been found to be greater than 0.8 and convergent validity have been demonstrated through large and statistically significant relationships with the Paranoia Scale (PS; Fenigstein & Vanable, 1992) and comparable dimensions of the Psychotic Symptoms Rating Scales (PSYRATS; Haddock *et al*, 1999).

While individuals in the general population may experience paranoia in the form of mild social evaluative concerns and ideas of social reference, Freeman & Garety (2000) suggest that clinically significant levels of paranoia can be distinguished by the presence of persecutory beliefs, where individuals believe that harm is occurring, or is going to occur to them and that the perpetrator has the intention to cause that harm. Ideas of social reference are not included in this definition as they do not contain the element of intention to harm. Given that the current study is concerned with measuring clinically significant levels of paranoia, and in line with previous research (see Freeman & Fowler, 2009), this study will only utilise Part B of The Green Paranoid Thoughts Scales. The GPTS-Part B is likely to take participants less than 5 minutes to complete.

Total Time to Complete Measures: Approximately 90 minutes
PANSS + PSYRATS modified interview schedule: 45minutes- 1 hour
CTQ (+ trauma duration items): 5 minutes (+5minutes)
BCSS: 1 minute
SCIRATS: 10-15minutes
GPTS-Part B: 5 minutes

Sample Size

Sample size calculations were based upon the primary research question, ‘Do negative-self core schemas mediate the relationship between childhood trauma and persecutory beliefs?’ Fritz and MacKinnon (2007) provide the sample sizes required to achieve 0.8 power to detect small, medium and large effects in simple mediation models. In order to calculate sample size, the authors recommend that the estimated effect sizes for the ‘a’ and ‘b’ pathways are informed by previous research. In the current study, the ‘a’ pathway in the simple mediation analysis is the relationship between childhood trauma and negative-self core schemas, whereas the ‘b’ pathway is the relationship between negative-self core schemas and persecutory beliefs. Anilmis *et al* (2015) evaluated the relationship between childhood traumatic experiences and negative core schema, and reported large effects, and Gracie *et al* (2007) also reported large effects for the relationship between negative-self schematic beliefs and predisposition to paranoia. Based upon the above findings, Fritz & MacKinnon (2007) suggest a sample size of 34 is required. In order to allow for the detection of moderate effects for the ‘a’ pathway and large effects for the ‘b’ pathway however, this study shall aim to recruit a sample of 53.

Two of the secondary questions will be examined using parallel and serial mediation analyses. Following guidelines published by Thoemmes *et al* (2010), Monte-Carlo simulations were performed using Mplus software, and this confirmed that this sample size would not provide sufficient power to determine whether the observed relationships were statistically significant. Unfortunately it is not feasible to increase the sample size; therefore the focus of these analyses will be on quantifying the magnitude of any relationships and their 95% confidence intervals. These analyses should be regarded as exploratory rather than hypothesis-testing, and capable of only providing preliminary data to inform planning of future studies. This caveat applies regardless of whether the results are statistically significant, and the findings should only be used to inform the planning of larger-scale definitive research.

The researcher’s academic and clinical supervisors have previous experience in supervising studies within the field of psychosis and have stated that it should be feasible to recruit this sample size across NHS Lothian, NHS Greater Glasgow and Clyde, NHS Forth Valley and NHS Lanarkshire.

Analysis

The primary research question will be addressed using mediation analysis (Preacher & Hayes, 2004). Hayes PROCESS macro Model 4 (Hayes, 2013) for SPSS will be used to test whether negative-self core schema mediate the relationship between childhood trauma and persecutory beliefs. Overall, indirect and direct effects will be computed, and reported with 95% confidence intervals and p-values. Effects will be deemed to be statistically significant if $p < .05$. Preacher and Kelley (2011) provide guidelines for the reporting of effect sizes in mediation analysis. Previous authors (MacKinnon *et al*, 2007; MacKinnon, 2008) have recommended that standardised regression coefficients can be used as an effect size measure for the ‘a’ coefficient,

whereas partial correlations can be used as an effect size measure for the *b* coefficient. In the case of standardised regression coefficients, values of $B=0.14$, 0.36 and 0.54 represent small, medium and large effects, whereas for partial correlations values of $r=0.1$, 0.3 and 0.5 represent small medium and large effects (Cohen, 1988).

Preacher and Kelley (2011) state however that these measures are not entirely satisfactory as ‘*a*’ and ‘*b*’ alone do not convey the full meaning of an indirect effect. As a result, the authors recommend that effect sizes in mediation analysis are best expressed as the magnitude of the indirect effect relative to the maximum possible indirect effect. Expressed as k^2 , values of 0.1 , 0.9 and 0.25 represent small, medium and large effects respectively. The current study will report effect sizes as recommended by Preacher and Kelly (2011) yet will also report standardised regression coefficients and partial correlations to allow for comparisons with previous studies. Preacher and Kelly (2011) state there is no reason effect size cannot be expressed in multiple forms within the same study.

The secondary research questions will also be examined using PROCESS (Hayes, 2013). Whether negative-other core schema mediates the relationship between childhood trauma and persecutory beliefs will be examined as per the primary research question. A parallel mediation model (PROCESS macro Model 4- 2 mediators; Hayes, 2013) will be used to investigate whether negative-other core schemas are a stronger mediator of the relationship between childhood trauma and persecutory beliefs in comparison to negative-self core beliefs. Finally serial mediation analysis (PROCESS macro Model 6; Hayes, 2013) will be utilised to order to examine research question 4.

The third research question, ‘Are negative-other core schemas a stronger mediator of the relationship between childhood trauma and persecutory beliefs than negative-self core schemas’ would potentially be more appropriate as the primary research question. However Monte Carlo simulations indicated that 90 participants would be required to achieve 0.8 power to detect large relationships in this model. It was agreed a sample of this size would not be feasible to recruit in the timeframes, even if multiple sites were recruited. As a result, analyses of research questions 3 and 4 will be exploratory in nature only. These analyses will seek to quantify the magnitude of any relationships and their 95% confidence intervals. They should be regarded as exploratory rather than hypothesis-testing, and capable of only providing preliminary data to inform planning of future studies. This caveat applies regardless of whether the results are statistically significant, and the findings should only be used to inform the planning of larger-scale definitive research.

Concurrent validity between the BCSS and BCSS+ SCIRATS will be tested through the Pearson’s correlation analysis in SPSS. The criteria required to demonstrate concurrent validity between the BCSS and BCSS+SCIRATS will be $r = >0.7$, $p = <0.05$.

All analysis related to primary and secondary research hypotheses will be repeated twice. In the first set of analysis BCSS scores for negative-self and/or negative-other

core schema will be entered into mediation analysis and results shall be reported. In the second set of analysis BCSS+SCIRATS scores for negative-self and/ or negative-other core schema will be entered into mediation analysis. Results shall be reported and any difference in findings shall be reported and discussed in the write up of the study.

Project Management Timetable

Thesis Proposal Submitted	July 2016
Feedback on Proposal Received	August 2016
Refine study following feedback	August-December2016
PANSS/PSYRATS Training	November 2016
Prepare ethics application	January- March 2017
Submit ethics application	April 2017
Recruitment in NHS Lothian	May- July 2017
Recruitment in NHS Forth Valley	July- September 2017
Recruitment in NHS GG&C	October- December 2017
Recruitment in NHS Lanarkshire	October- December 2017
Systematic Review	June 2017- November 2017
Data Analysis	December 2017
Final Draft to Supervisor	January 2018
Final Corrections	February 2018
Thesis Submission	March 2018
Viva	April 2018
Corrections and Preparation for Publication	April 2018

Management of Risks to the Project

1. Failure to Receive Ethical Approval

As with all research studies in a vulnerable population, it is anticipated that NHS Research Ethics Committees (RECs) may raise concerns regarding possible adverse outcomes to participants, the management of risk to participants and the management of risks to others. This may result in the study failing to receive ethical approval. Details of possible concerns and the actions taken to mitigate these risks are detailed below.

1.1. Concerns regarding adverse outcomes as a result of participation

Research into the link between childhood trauma and psychosis is a relatively recently phenomenon (Reid *et al*, 2005). It has been suggested that this may be the result of a concern that asking individuals with psychosis about childhood trauma may result in adverse outcomes, in the form of a deterioration in the individual's mental health (Frueh *et al*, 2006; Reid *et al*, 2007). Given that this concern is widely acknowledged in the literature regarding childhood trauma and psychosis, it is anticipated NHS RECs may raise similar concerns and fail to grant ethical approval as a result.

In order to mitigate this risk, the researcher reviewed the literature regarding asking with individuals with psychosis about childhood trauma. Reid *et al* (2007) states that there is no evidence to suggest that asking about childhood trauma results in serious or long term psychological harm. Furthermore, there is evidence to suggest that while the majority of individuals who have experienced abuse believe there is a connection between their experiences of abuse and mental health difficulties, most individuals are not asked about abuse during assessment. Individuals who had experienced abuse, yet were not asked about this during assessment were more likely to express dissatisfaction with their treatment and less likely to believe their diagnosis was an accurate description of their problems (Lothian & Reid, 2002).

Finally, a number of studies evaluating psychological therapy, in the form of prolonged exposure or EMDR, for trauma in individuals with psychosis have reported no adverse outcomes (Frueh *et al*, 2009; Mueser *et al*, 2008; van der Berg & van der Gaag, 2012). The above findings will be detailed in NHS ethics applications and as a result the risk that ethical approval may not be granted due to concerns that asking individuals with psychosis about childhood trauma may result in adverse outcomes is felt to be low. Finally, a Care Protocol (Appendix 1) has been developed for the current study outlining the steps that will be taken to manage any possible distress participants may experience as a result of being asked about childhood trauma.

1.2. Ethical approval may be refused because management of risks to participants is deemed insufficient.

In order to improve and develop psychological treatments, it is vital that research is carried out into the effects of childhood trauma. However this must be balanced with the management of potential risks and burden to the participant or others.

The Psychosis Research Unit (PRU) of Greater Manchester West Mental Health Foundation NHS Trust (GMW) has developed a protocol for the management of potential risks that arise as a result of completing the Childhood Trauma Questionnaire (Appendix 2). This protocol has been approved for use in several NREC-approved studies, and will therefore be adapted to guide decision-making in this study.

1.3. Ethical approval may be refused because management of risks to others is deemed insufficient

Possible risks to the researcher will be addressed by conducting a full risk assessment prior to meeting any participants, excluding individuals who present a risk of harm to the researcher and meeting participants on NHS premises only.

The Psychosis Research Unit (PRU) of Greater Manchester West Mental Health Foundation NHS Trust (GMW) has developed a protocol for the management of potential risks that arise as a result of completing the Childhood Trauma Questionnaire (Appendix 1). This protocol has been approved for use in several

NREC-approved studies, and will therefore be adapted to guide decision-making in this study.

1.4. Ethical approval may be refused because arrangements regarding the assessment of capacity to consent to research are deemed insufficient.

The following protocol has been developed regarding the assessment of capacity to consent to research:

- The researcher conducting the interviews will receive full training in assessing capacity to consent to research from Dr Paul Hutton, Academic Supervisor. Dr Hutton is Honorary Consultant Clinical Psychologist in NHS Lothian and Associate Professor of Therapeutic Interventions at Edinburgh Napier University. He is a member of the Expert Steering Group for the Centre for Mental Health and Incapacity at Edinburgh Napier, and an Expert Member of the National Institute for Clinical Excellence Committee developing a ‘Decision making and mental capacity’ guideline. He has extensive experience assessing capacity in psychosis, has a number of active REC-approved research projects in this area, and has provided training on capacity to consent to research assistants in a number of REC-approved projects, including a large HTA-funded trial of cognitive therapy for clozapine-resistant psychosis.
- For every participant, the researcher will consult closely with their psychiatrist and clinical team (or GP if not available) regarding their capacity to consent to research, their diagnosis, and their level of risk to self and others. He will also liaise closely with his Academic and Clinical Supervisors throughout this process.
- Although the researcher holds responsibility under the Adults with Incapacity (Scotland) Act (2000) for ensuring participants have capacity to consent to research if any of the clinical team or medical staff involved in a participant’s care believe that individual does not have capacity to consent to research, the researcher will respect that view and will not proceed with the research.
- The researcher recognises that capacity assessment and consent is not a ‘one-off’ process, and will therefore monitor these issues carefully throughout the participants’ involvement.
- The researcher will refer to the principles of the Adults with Incapacity (Scotland) Act (2000) throughout participant’s involvement in the study. Should, at any point, the researcher suspect that a participant lacks the capacity to consent to research, the participant’s involvement in the study will halt immediately. The researcher will then immediately seek advice from his academic supervisors and a member of the participants NHS Mental Health team.

2. Failure to Recruit Required Sample Size

As will all research in psychosis, the main risk to the study is the failure to recruit the required sample. Allowing 8 months for recruitment, an average monthly recruitment rate of 7 participants is required to meet the required sample of 53. The researchers academic and clinical supervisors have extensive experience of conducting research in the field of psychosis and have stated it should be feasible to recruit this sample size by 8 months for recruitment and conducting a multi-site study across 4 NHS Health Boards.

3. Reliance on Others

The study includes some degree of reliance on clinicians to approach potential participants on their caseload regarding the study. This present's potential risk to the project as reliance on others can often be unpredictable, possibly resulting in the failure to recruit the required sample. In order to reduce the risk of reliance on others, the burden on clinicians has been designed to be low and participants will also have the option of self-referring into the study.

Knowledge Exchange

Once ethical approval has been obtained, the researcher will upload the empirical research project protocol to the Open Science Framework (<https://osf.io/>) in the interest of academic transparency. Once results are available, the researcher will also attempt to identify academic conferences where it would be appropriate to present their finding of the study.

The results of the study will be written up in portfolio thesis format including a systematic review and empirical research project and submitted to the Doctorate in Clinical Psychology course at the University of Edinburgh. The researcher's thesis will be uploaded to the Department of Clinical Psychology Thesis Database in order to ensure open access to the results of the study. The systematic review and empirical research project will subsequently be prepared for submission to an academic journal. The researcher will endeavour to publish in a journal that allows open access so that results are available to the widest possible audience.

The researcher will also prepare a powerpoint presentation detailing the findings of their study following submission. The trainee will offer to present findings to all the NHS Mental Health Teams from which participants were recruited. Finally, the full results of the thesis project and an overview of findings will be prepared and made available to participants following submission, together with an easy-read summary.

Costs

The main costs for this study will be the printing/photocopy required in order to produce posters advertising the study, participant and clinician information sheets, consent forms, demographic information sheets, potential participant contact details forms, care protocols and debriefing forms. Other cost likely to be incurred will be

travel across NHS Health Boards in order to meet participants. NHS Lothian shall meet these costs.

The majority of study semi-structured interviews and questionnaires are in the public domain and are free to use however The Department of Clinical Psychology within the University of Edinburgh has agreed to meet the cost of the Childhood Trauma Questionnaire (CTQ).

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***The Relationship between Childhood Trauma,
Negative Core Schema and Paranoia in People with
Persecutory Delusions: A Mediation Analysis***

Care Protocol

Chief Investigator: David Carmichael, Trainee Clinical Psychologist, NHS Lothian & University of Edinburgh

Clinical Supervisor: Dr Sean Harper, NHS Lothian

Academic Supervisor 1: Dr Karen Goodall, University of Edinburgh

Academic Supervisor 2: Dr Paul Hutton, Edinburgh Napier University

In order to improve and develop psychological treatments, it is vital that research is carried out into the effects of childhood trauma. However this must be balanced with the management of potential risks and burden to the participant or others.

The Psychosis Research Unit (PRU) of Greater Manchester West Mental Health Foundation NHS Trust (GMW) has developed a protocol for the management of potential risks that arise as a result of completing the Childhood Trauma Questionnaire (Appendix 1). This protocol has been approved for use in several NREC-approved studies, and will therefore also be used to guide decision-making in this study.

The care protocol detailed below outlines possible concerns that may be raised in relation to asking individuals with psychosis about childhood trauma and the processes in place in order to manage any potential risks to participants.

Asking Individuals with Psychosis about Childhood Trauma

Research into the link between childhood trauma and psychosis is a relatively recently phenomenon (Reid *et al*, 2005). It has been suggested that this may be the result of a concern that asking individuals with psychosis about childhood trauma may result in adverse outcomes, in the form of a deterioration in the individual's mental health (Frueh *et al*, 2006; Reid *et al*, 2007). Given that this concern is widely acknowledged in the literature regarding childhood trauma and psychosis, it is anticipated NHS Research Ethics Committees, clinicians and/ or participants may raise similar concerns.

In order to address these concerns, the researcher reviewed the literature regarding asking with individuals with psychosis about childhood trauma. Reid *et al* (2007) states that there is no evidence to suggest that asking about childhood trauma results in serious or long term psychological harm. Furthermore, there is evidence to suggest that while the majority of individuals who have experienced abuse believe there is a connection between their experiences of abuse and mental health difficulties, most individuals are not asked about abuse during assessment. Individuals who had experienced abuse, yet were not asked about this during assessment were more likely to express dissatisfaction with their treatment and less likely to believe their diagnosis was an accurate description of their problems (Lothian & Reid, 2002).

Finally, a number of studies evaluating psychological therapy, in the form of prolonged exposure or EMDR, for trauma in individuals with psychosis have reported no adverse outcomes (Frueh *et al*, 2009; Mueser *et al*, 2008; van der Berg & van der Gaag, 2012).

While it is not thought that participating in this study will result in any long term disadvantages to participants, it is possible that some participants may find interviews or questionnaires distressing. The following measures are in place in order to address and manage any distress expressed by participants:

- The researcher will be a 2nd year or 3rd year Trainee Clinical Psychologist throughout the duration of the study and will have the clinical ability to manage distress and risk assess if required.
- While it is thought that 90 minutes will be required to complete the study, the researcher shall allocate a two hour window for each participant in order to have additional time to address and manage any possible distress.
- Participants will be seen for recruitment at their usual clinic in order to allow the researcher access to their care team/duty worker if required.
- Throughout the process, the researcher will check the level of distress the participant is experiencing, and they will be reminded at all times that they can discontinue if they find they are becoming uncomfortable or upset by the questions.

- Given that completion of questionnaires may result in some degree of distress, the researcher shall use their clinical judgement to ascertain whether it is appropriate to check how the participant is feeling following completion of questionnaires using the following script:

‘Some people later in the day or week may have some feelings about this how do you think you would cope, have you done anything before that has helped? If that doesn’t help, here are some numbers others have found helpful’.

The researcher shall issue the participant with the numbers for The Samaritans, Breathing Space and ensure they have the contact details for the duty worker at their local CMHT.

In the event participants experience significant distress, the researcher shall conduct a routine risk assessment in relation to suicidal ideation or intent. Any information regarding suicide risk will be shared with the participant’s keyworker/care coordinator straight away.

- Clinical supervision during recruitment will be provided by Dr Sean Harper, Consultant Clinical Psychologist and Lead Psychologist for Psychosis and Complex Mental Health, NHS Lothian

Managing Disclosures of Childhood Trauma

Prior to completing consent forms, participants will be read the following statement regarding confidentiality:

‘Any information you provide me with today will be confidential, however there is some information I am not able to keep confidential. Should during the course of the assessment, I become concerned that there is a risk of harm to either yourself or others, I have an obligation to share this information to keep you/others safe. If this is the case, I will explain to you why I need to share this information and tell you with whom I plan to share this information. In most cases this would be your keyworker/ care co-ordinator. Do you have any questions?’

Should participants disclose a history of childhood trauma, the researcher shall enquire as to whether their keyworker/ care-coordinator are aware of this experience. If the participant’s care team are unaware of this experience, the researcher shall discuss the potential benefits of sharing this information with their care team.

Should participants wish this information to be passed on to their keyworker/ care-coordinator, the researcher shall seek their written consent to do so. Information regarding previous experience of childhood trauma will then be fed back to the individual’s keyworker/ care-coordinator following local procedures.

Managing Possible Risk to Others

Prior to completing consent forms, participants will be read the following statement regarding confidentiality:

‘Any information you provide me with today will be confidential, however there is some information I am not able to keep confidential. Should during the course of the assessment, I become concerned that there is a risk of harm to either yourself or others, I have an obligation to share this information to keep you/others safe. If this is the case, I will explain to you why I need to share this information and tell you with whom I plan to share this information. In most cases this would be your keyworker/ care co-ordinator. Do you have any questions?’

In the event participants disclose a history of childhood abuse, this protocol suggests the following response:

‘I need to ask you because of statutory obligations whether you currently know if there are any children at risk however I need to remind you that if you tell me there is the I need to pass that on to my supervisor and to your care coordinator and beyond that I can't really tell you what would happen with that information’.

In the event that a participant discloses information that suggests to the researcher that a child is currently at risk, the researcher will liaise with their clinical research supervisor immediately or at the earliest opportunity. If it is agreed that a disclosure is warranted, the researcher pass this information to the participant's keyworker/ care-coordinator on an urgent basis. At all times the researcher will liaise with their clinical research supervisor and the keyworker to ensure any resulting distress for the participant is fully assessed, managed and contained.

The above protocol for managing disclosures of childhood trauma complies with recent guidelines issued by the British Psychological Society regarding the management of disclosures of non-recent (historic) child sexual abuse (BPS, 2016).

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Appendix 2: Protocol for Administering the CTQ

Protocol for administering the CTQ

V5 22.11.2013

Developed by Melissa Pyle in consultation with Professor John Read

FOCUS

Focusing on Clozapine Unresponsive Symptoms (FOCUS): a randomised controlled trial

Procedures for administering the Childhood Trauma Questionnaire and for supporting participants who report experiences of abuse

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Rationale for administering the CTQ

Research indicates that experiences of childhood abuse are common in people who have experience of psychosis. In a review of 46 studies of female patients 48% reported childhood sexual abuse and 48% reported childhood physical abuse (Read et al, 2005). Childhood sexual abuse was found to have occurred for 28% of men and physical childhood abuse in 50% (Read et al, 2005). There is good evidence that people with histories of trauma want to be asked about this within clinical services. People who have experienced abuse are more likely to tell mental health professionals than anyone else (Read, Hammersley & Rudegear, 2007). There is evidence that people view questionnaires as an acceptable way of assessing this (disclosure rates are often higher than face-to-face interviews). Although this guidance has been developed in relation to the CTQ, much of the information provided will be helpful if a participant verbally reports abuse during the assessment.

2. Consent and confidentiality

NHS Trusts will have a safeguarding children and young people policy and when carrying out research there is a statutory obligation to work in line with the trust policy. Therefore, **it is very important that you are familiar with the NHS Trust policies for the trusts you are working within.** At Greater Manchester West Mental Health NHS Foundation Trust (sponsor of FOCUS), we have been advised by the safeguarding team that written disclosures of childhood abuse should be followed up with a question to check whether any children are currently at risk as would verbal disclosures. When doing this it is important not to assume that the participant has remembered the confidentiality information given at the start of the assessment. Therefore, if you are required by your trust to follow up information with a question about current risk to children, the following script should be used to remind participants about confidentiality:

I need to ask you because of statutory obligations whether you currently know if there are any children at risk however I need to remind you that if you tell me there is the I need to pass that on to my supervisor and to your care coordinator and beyond that I can't really tell you what would happen with that information.

If you are unsure of your obligations please speak to your supervisor in the first instance. Please note, as research assistants are not a clinically qualified clinician you are not expected to gather any further details in addition to the question about current risk to children. This information should be followed up by the participants clinician i.e. care co-ordinator. Therefore, it is your responsibility to pass this information to their clinician.

3 Introducing & administering the CTQ

3.1 Introducing the CTQ

When discussing the CTQ, it is important to make sure that the person is aware what the questionnaire focuses on before they complete it and that completion of the measure is optional. An example of a script to introduce the CTQ is as follows:

*'We now have a questionnaire which should be completed by you, rather than us doing it together. This looks at factors such as traumatic experiences you may have had in childhood. If you are interested in completing this, then we would appreciate that. However, **it is entirely up to you and you can decline doing so without it affecting any treatment, support or anything else.** If you do decide to complete the questionnaire and feel you wish to not answer certain questions that is also fine. **If you wish to stop or take a break please do let me know as this is also fine**'.*

3.2 Administering the CTQ

The CTQ should be completed as self-report unless the participant specifically expressed a wish to complete it with you because they are unable to complete questionnaires on their own.

4. End of assessment procedure

4.1 Checking out how the participant is feeling after completing the CTQ

All participants should be thanked for completing the measure and you should inform them that the information they provided was all you needed for the purpose of the research. Participants should also be asked how they are feeling now.

People with lived experience of abuse report that their preference is not for a big emotional response from the person they have disclosed the information to. However, responding in a human, empathic manner is appropriate. If the person is distressed the focus should be on how they are feeling **now in the assessment**. Therefore, any follow-up questions should not be about the details of the abuse but should focus on how they participant feels now in the assessment. However, it would be appropriate to ask if they have told anyone before.

If a participant discloses abuse in the general discourse of the assessment, you can respond in a normalising and supportive manner by asking the following:

- Thank you for sharing that with me, some people say that is upsetting for them and I wondered how are you feeling now?

If the person reports they do feel distressed in relation to the experiences they disclosed, communicate that you are aware the person is distressed, sit with the distress for a little while and you can move this on by asking what usually helps when they feel upset. You can also make an offer of support in a non-prescriptive way by saying:

- “Here are some examples of things other people have found helpful [here you could suggest the book detailed above, helpline numbers or services detailed below]

4.2 Following up on how the person feels at the end of the assessment

If a participant has disclosed abuse on the CTQ during the course of the assessment it may in some cases be appropriate to return to asking how they feel now, at the end of the assessment. This should be left as a judgement call; if they have been very distressed and you have had to move them on to cover other questionnaires it may then be appropriate to go back. However, be mindful of the potential for this to require more time. It may also be appropriate to carry out some preventative work that can empower the participant by saying:

“Some people later in the day or week may have some feelings about this how do you think you would cope, have you done anything before that has helped? If that doesn’t help, here are some numbers others have found helpful [provide helpline numbers detailed below]”

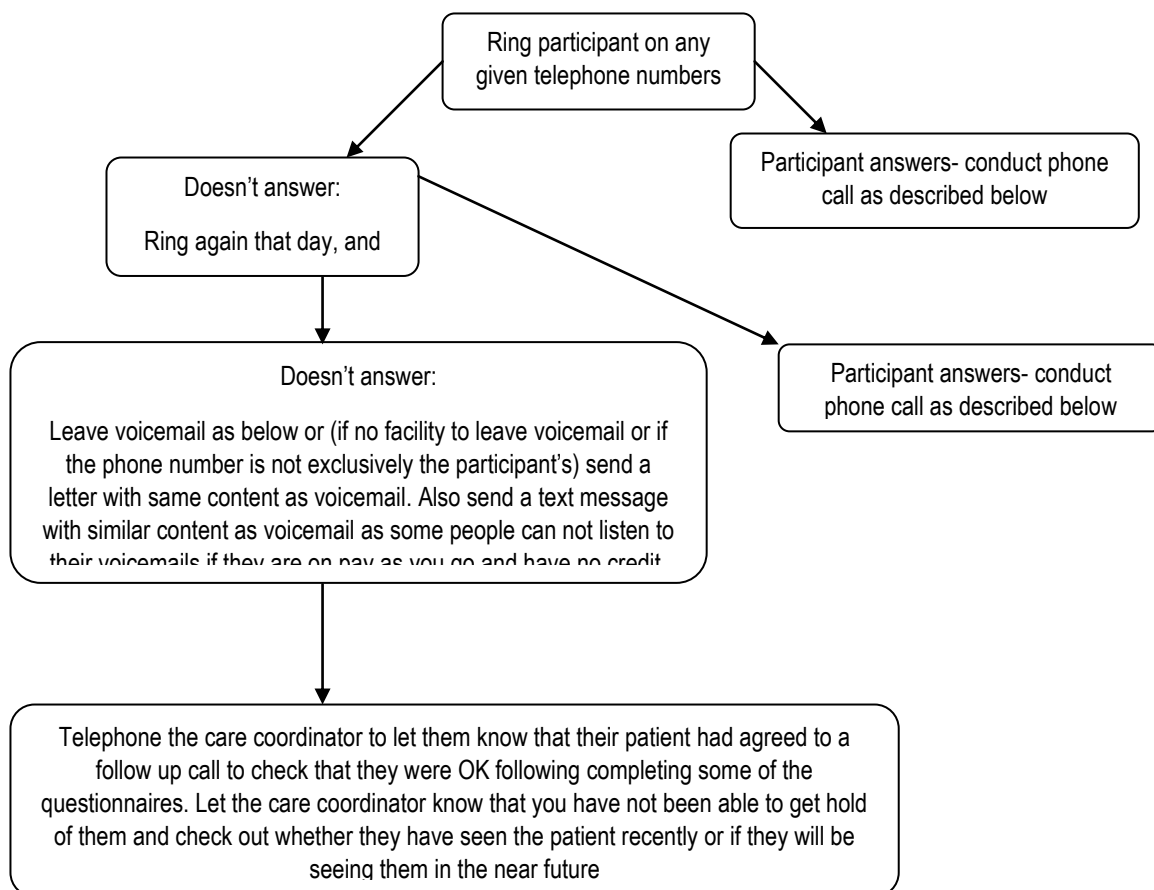
If you are concerned about a participants mood following a disclosure, or have observed that the participant is distressed or stuck following the disclosure then it may be appropriate to check out with the participant whether they have any thoughts of suicide. This can be done using the following script:

“Given what we have talked about today I wanted to check with you now whether you have any thoughts of suicide”

Remember all participants should be given a crisis card at the end of each assessment.

4.3 Follow-up support after the assessment

All participants should be offered they option of a follow up phone call the next day to check if they are ok. For those who accept a telephone call, follow the steps below.



4.3.1 Script for follow up call

'Hello its NAME OF RESEARCHER from the FOCUS Trial. We met up the other day and you did some questionnaires and interviews with me. Some of the questions that were asked you were quite sensitive so I am just ringing as agreed to check how they are doing. Have you experienced any distress as a result of what was discussed in the visit'?

If have to leave voicemail:

'Hello its NAME OF RESEARCHER from the FOCUS Trial. We met up the other day and you did some questionnaires and interviews with me. Some of the questions that were asked you were quite sensitive so I am just ringing as agreed to check how they are doing. If something has come up as a result of the visit and you would like to discuss it with me, give me a ring [input number here]. If you are distressed or need to speak to someone urgently, ring your care coordinator'.

4.3.2 Acting on information provided:

If participant says they have not experienced distress/ they are 'fine':
Thank participant for their time and end phone call

If participant describes displeasure at the procedure: What aspect is this? Could it be changed for next time? E.g. reiterate that the participant can skip certain questions if they wish/have a break.

If participant describes low mood/ distress: clarify the severity of this, ask if it was during the visit or if it has persisted. Ask if the participant would be ok speaking to their care coordinator about this or if they would like us to pass the information on. Ask if they would like guidance around sources of support and help. If so provide them with the national numbers, site specific numbers and crisis cards.

If participant expresses severe distress/ suicidal thoughts or plans or other extreme negative affect: tell the participant's care coordinator (or other appropriate health care professional), and convey the necessity of this to the participant during the call (where appropriate). If the participant expresses imminent or current suicidal intent/ plan, phone an ambulance to go to the participant's address. Ask if they would like guidance around sources of support and help. If so provide them with the national numbers, site specific numbers and crisis cards.

5. Self-help books and helpline numbers

5.1 Self-help books

If participants report they would like some information of self-help books. We recommend the following:

Ainscough, C and Toon, K ***"Breaking Free Workbook: Practical help for survivors of child sexual abuse"***.

Kennerley, H, ***"Overcoming Childhood Trauma"***.

5.2 Helpline numbers

This list is not exhaustive, there may be other specific support centres in your local area that you know about, please feel free to add any. It may be helpful to ask the trial therapist if they are aware of any other abuse survivors support numbers or services as they may be able to give you recommendations.

5.2.1 National numbers

National Association for People Abused in Childhood (NAPAC)

This service supports both men and women who have experienced any form of abuse in childhood.

Telephone: 0800 085 3330 (Monday, Tuesday and Thursday 10.00am – 9.00 pm; Wednesday 10.00am -8.00 pm and Friday 10.00 am – 6.00 pm)

If calling from a mobile you can call the NAPAC free from Orange and Virgin mobiles on 0800 085 3330 or from O2, Vodafone and T-Mobile on 0808 801 0331.

Website: <http://www.napac.org.uk>

Rape and sexual abuse support centre (RASASC)

This has a national helpline that survivors of sexual abuse can contact.

Telephone: 0808 802 9999 Open everyday 12.00 am – 2.30 pm and 7.00 pm – 9.30 pm

Website: <http://rasasc.bizview.co.uk/>

CARELINE

Providing support to all survivors of childhood sexual abuse.

Telephone: 0181 514 1177 (Monday to Friday 10.00 am – 4.00 pm and 7.00 pm – 10.00 pm)

Survivors UK

Provide advice and support to men who have experienced rape and sexual abuse.

Telephone: 0845 122 1201 (Monday and Tuesday 7.00 pm – 9.30 pm or Thursday 12 pm – 2.30 pm)

Website: <http://www.survivorsuk.org/>

5.2.2 Regional support

Appendix F: Changes to Study 2 Protocol

Change 1: We modified the hypothesis outlined in our original Study Protocol. Hypotheses 1 and 2 were retained, however we changed Hypothesis 3 to an exploratory aim to examine whether negative-self and negative-other core schema mediated the relationship between childhood trauma and paranoia when controlling for one another. Hypothesis 4 was also changed to an exploratory aim to examine the impact of entering negative core schema as measured by the SCIRATS into our mediation models.

Change 1: In our original protocol, we specified the follow criteria for schema on SCIRATS

- 1) A score of 2 or more on Question 1 (the belief must have been present before the age of 20)
- 2) A score of 1 or more on Question 2 (the belief must be present at least once per week)
- 3) A score of 2 or more on Question 3 (thoughts about the belief last for several minutes)
- 4) A score of 1 or more on Question 4 (how strongly do you believe this belief is true on a scale of 0-100%)
- 5) A score of 3 or more on Question 5 (Belief causes distress on the majority of occasions when they occur between 50-99% of the time)
- 6) A score of 3 or more on Question 6 (Beliefs cause marked distress)
- 7) A score of 2 or more on Question 7 (Moderate amount of disruption to life, causing some disturbance to daytime activity and/or family and social events)

While scoring the data from our general population study, we became aware that these criteria might be too conservative. We found for example that while 64 participants had endorsed the 'I am unloved' schema on the BCSS, only two participants would meet the above criteria for a schema for our adapted BCSS.

As a result, we elected to downgrade criteria 5 and 6 by one point, resulting in the following criteria being required for an item to be positive rated as a schema on the SCIRATS:

- 1) A score of 2 or more on Question 1 (the belief must have been present before the age of 20)
- 2) A score of 1 or more on Question 2 (the belief must be present at least once per week)
- 3) A score of 2 or more on Question 3 (thoughts about the belief last for several minutes)
- 4) A score of 1 or more on Question 4 (how strongly do you believe this belief is true on a scale of 0-100%)
- 5) A score of 2 or more on Question 5 (Belief causes distress on the majority of occasions when they occur between 50-99% of the time)
- 6) A score of 2 or more on Question 6 (Beliefs cause marked distress)

- 7) A score of 2 or more on Question 7 (Moderate amount of disruption to life, causing some disturbance to daytime activity and/or family and social events)

Change 2: Upon further consideration, we made a further change regarding the reporting of effect sizes in mediation analysis. We elected to change the method outlined in our study protocol to that employed by Hutton et al. (2018).



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The Schema Rating Scale

Childhood experiences, beliefs about self and others and paranoia

Thank you for completing the Brief Core Schema Scales. I would like to ask you some further questions about these beliefs.

Note: Questions will be repeated for each belief endorsed by participants. Should participants endorse the majority of beliefs, the following questions shall be asked with regarding to all beliefs. Participants will be asked however if there are any beliefs to which their response does not apply and how their response might be different for the belief in question

For each belief endorsed:

1. How long have you had this belief?

0. Since age 25+
1. Since ages 20-25
2. Since ages 15-20
3. Since ages 10-15
4. Before the age of 10

2. How often do you view yourself/others this way?

0. Less than once a week
1. At least once a week
2. At least once a day
3. More than once a day
4. Thinks about beliefs continuously or almost continuously

3. When you think about this belief, how long does it stay on your mind?

0. Does not think about this belief
1. Thoughts about belief last for a few seconds
2. Thoughts about belief last for several minutes
3. Thoughts about belief last for at least 1 hour
4. Thoughts about belief usually last for hours at a time

- 4. How strongly do you believe this belief is true on a scale of 0-100%?**
0. No conviction at all
 1. Very little conviction in belief <10%
 2. Some doubts relation to belief, between 10-49%
 3. Belief is very strong, between 50-99%
 4. 100% conviction in belief
- 5. When you think about this belief, how often does it upset you?**
0. Belief never causes distress
 1. Belief causes distress on the minority of occasions
 2. Belief causes distress on <50% of occasions
 3. Belief causes distress on the majority of occasions when they occur between 50-99% of the time
 4. Beliefs always cause distress when they occur
- 6. How distressing do you find this belief?**
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
- 7. To what extent does this belief get in the way of day to day life?**
0. No disruption to life. No impact upon daily living skills, social or family relationships
 1. Belief causes minimal amount of disruption to life e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and able to maintain independent living without support.
 2. Belief causes moderate amount of disruption to life, causing some disturbance to daytime activity and/ or family and social activities. May require some assistance with daily living skills.
 3. Belief causes severe disruption to life in terms of activities, daily living skills and/ or relationships.
 4. Belief causes complete disruption of daily life. Unable to maintain any daily living activities and social relationships. Self-care is severely disrupted.

Scoring:

	Score for Schema Rating Interview Questions							Meets Criteria for Schema (Y/N)
Schema	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	
I am unloved								
I am worthless								
I am weak								
I am vulnerable								
I am bad								
I am a failure								
Other people are hostile								
Other people are harsh								
Other people are unforgiving								
Other people are bad								
Other people are devious								
Other people are nasty								

Criteria for Schema:

- 1) A score of 2 or more on Question 1 (the belief must have been present before the age of 20)
- 2) A score of 1 or more on Question 2 (the belief must be present at least once per week)
- 3) A score of 2 or more on Question 3 (thoughts about the belief last for several minutes)
- 4) A score of 1 or more on Question 4 (how strongly do you believe this belief is true on a scale of 0-100%)
- 5) A score of 2 or more on Question 5 (Belief causes distress on the majority of occasions when they occur between 50-99% of the time)
- 6) A score of 2 or more on Question 6 (Beliefs cause marked distress)
- 7) A score of 2 or more on Question 7 (Moderate amount of disruption to life, causing some disturbance to daytime activity and/or family and social events)

For each belief endorsed by participants on the original BCSS, we applied the above criteria. If these criteria were met, we scored the belief as 'YES'. The decision to score each belief as 'believe slightly', 'believe it moderately', 'believe it very much' or 'believe it totally' will be based on participants responses to question 5, 'How much do you believe this is true?' The following scoring rules will be applied:

- 1) Very little conviction in belief <10% = Believe it slightly
- 2) Some doubts relation to belief, between 10-49% = Believe it moderately
- 3) Belief is very strong, between 50-99% = Believe it very much
- 4) 100% conviction in belief = Believe it totally

Appendix H: Study 2 Posters



Childhood experiences, beliefs about self and others and paranoia- A3 Poster

Non-CTIMP/CE Device, Version 2, Date: 05/07/17



THE UNIVERSITY
of EDINBURGH



Childhood Experiences, Beliefs about Self and Others and Paranoia

Are you currently receiving care from an NHS Mental Health Team?

Do you currently experience paranoia or believe that other people intend to cause you harm?

Research has found that there may be a link between childhood experiences and paranoia; however the factors that might explain this relationship are still poorly understood.

We would like to invite you to take part in a research study exploring experiences during childhood, experience of paranoia and the psychological factors that might explain this relationship. This will take between 1 hour and 1.5 hours. You can split this into two meetings if you would prefer.

If you would like further information about this study, please speak to a member of your NHS Mental Health Team or contact:

David Carmichael

Trainee Clinical Psychologist

Telephone: 0131 537 6905

Email: [\[redacted\]](#)



Childhood experiences, beliefs about self and others and paranoia- A4 Poster

Non-CTIMP/CE Device, Version 2, Date: 05/07/17



THE UNIVERSITY
of EDINBURGH



Childhood Experiences, Beliefs about Self and Others and Paranoia

Are you currently receiving care from an NHS Mental Health Team?

Do you currently experience paranoia or believe that other people intend to cause you harm?

Research has found that there may be a link between childhood experiences and paranoia however; the factors that might explain this relationship are still poorly understood.

We would like to invite you to take part in a research study exploring experiences during childhood, experience of paranoia and the psychological factors that might explain this relationship. This will take between 1 hour and 1.5 hours. You can split this into two meetings if you would prefer.

If you would like further information about this study, please speak to a member of your NHS Mental Health Team or contact the researcher through the details below.

David Carmichael 0131 537 6995 david.carmichael@nhs.uk	David Carmichael 0131 537 6995 david.carmichael@nhs.uk	David Carmichael 0131 537 6995 david.carmichael@nhs.uk	David Carmichael 0131 537 6995 david.carmichael@nhs.uk	David Carmichael 0131 537 6995 david.carmichael@nhs.uk
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