Understanding ethnic minority differences in access to and outcomes of psychological therapies for first episode psychosis and severe mental illness

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Thesis abstract

Context: Prevalence rates of severe mental illnesses (SMI) such as psychosis differ between ethnic groups disproportionately. Disparities also exist when exploring access and outcomes to psychological therapies based on ethnicity. The literature suggests that individuals from ethnic minority groups with SMI are less likely to be offered a psychology therapy.

Methods: The broad aim of the thesis was to explore the effectiveness and accessibility of psychological therapies for ethnic minority groups who experience a SMI. A systematic review explored the effectiveness of psychological therapies for ethnic minority groups who experienced a SMI. Secondly, an empirical paper investigated whether sociodemographic factors, including ethnicity, influenced the offer and uptake of psychological therapies in a sample of service users who experienced first episode psychosis.

Results: Our systematic review included nine studies for analysis, with seven reporting significant improvements in SMI symptom severity. Seven studies made cultural adaptations which led to a reduction in SMI symptom severity compared to treatment as usual. However the quality and risk of bias varied between studies, reducing the strength of the findings.

In our empirical paper we found that service users in 'White Other' and 'Other' ethnic minority groups were less likely to be offered a psychological therapy compared to the white British reference group ('White other' OR = .48, CI . 26 - .89, p = .04, 'Other' OR = .38, CI . 17 - .87, p = .02). Presenting to Early Intervention Services increased the likelihood being offered a psychological therapy.

Conclusions: Our evidence highlights that whilst psychological therapies may be useful for ethnic minority groups with SMI, the availability is mixed depending on the

service accessed. Future research is needed to explore the frequency and use of culturally adapted therapies in clinical settings. Research is needed that allows comparisons to be made between culturally adapted and standard therapies.

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1. Introduction

1.1. What is psychosis?

Psychosis is a mental health condition where people experience the world differently to those around them in a way which causes distress (National Institute of Clinical Excellence [NICE], 2014a). It is characterised by positive and negative symptoms which can present differently between people. Symptoms of psychosis can be categorised as either positive or negative symptoms as described in the Diagnostic Statistical Manual, fifth edition (DSM-V; American Psychiatric Association [APA], 2013). Positive symptoms include delusions, hallucinations and disorganised speech or behaviour. Negative symptoms relate to a decrease in a person's normal level of functioning which may present as lack of motivation, disorganised speech, withdrawal or poverty of speech (APA, 2015). The Adult Psychiatric Morbidity Survey 2014 reported an estimate that the incidence rate of psychotic disorders was 0.7% for people aged 16 and above in England (McManus, Bebbington, Jenkins & Brugha, 2016). A systematic review of 148 studies commissioned by the Department for Health (DoH) reported that all psychotic disorders had a pooled annual incidence of 32 cases per 100,000 people (Kirkbride et al., 2012). Estimated economic burden associated with nonaffective and affective psychoses are £8.8 billion and £5.0 billion per year, factoring in service costs, informal care and lost employment. Psychosis has been classified as a 'severe mental illness' (SMI), alongside other disorders such as bipolar disorders and psychosis spectrum disorders (Wing, 2004). Future predictions made by the Kings Fund estimate that psychotic disorders will cost the United Kingdom around £14.7 billion by 2026, highlighting the impact of psychosis on a societal level (McCrone, Dhanasiri, Patel, Knapp & Lawton-Smith, 2008).

1.2. Ethnic minority group status as a risk factor for psychosis

Outcomes for people who experience psychotic symptoms vary, with research suggesting that the duration of untreated psychosis (DUP) acts a strong predictor of poorer outcomes including reduced life expectancy, symptomatic recovery and functional outcomes (Norman, Lewis & Marshall, 2005; Hjorthøj, Stürup, McGrath & Nordentoft, 2017). The need to support individuals as early as possible led to the development of the Early Intervention (EI) approach (DoH, 1999). The premise of this approach is based on being able to swiftly identify and support individuals who present to services with emerging psychosis to reduce DUP following transition to first episode psychosis (FEP; Joseph & Birchwood, 2005). The approach also aims to provide support over the 'critical period', hypothesised as the first two to three years of developing psychotic symptomatology at an accelerated rate (Crumlish et al., 2009). Research has highlighted that treating psychotic symptoms as early as possible is associated with improved quality of life, and that outcomes at two to three years strongly predict outcomes 20 years later (Harrison et al., 2001).

Research has identified that certain ethnic minority groups are at risk of developing psychosis (e.g. Davies, Thornicroft, Leese, Higgingbotham & Phelan, 1996; Van Os, Jones, Sham, Bebbington, & Murray, 1998; Fearon et al., 2006). Ethnicity as a term refers to a set of characteristics shared by collection of people (Rice & O'Donohue, 2002). Examples of these characteristics include a common language, cultural identity and geographic origin. This is different from the idea of race, which has been described as shared physical or biological characteristics (APA, 2003). An example of ethnicity could be identifying as White British or White Irish, and race would be identifying as white or black. The terms overlap at times in the literature and there is no definitive definition of both, due to the flexibility of what determines ethnicity and the lack of evidence to support racial classification systems (Bhopal, 2004).

Brugha and colleagues (2004) argued that African-Caribbean and African ethnic minority groups are at increased risk of experiencing psychosis, potentially due to social and economic disadvantage. This argument is supported by studies that have explored the relationship of migrant status on psychotic symptom presentations (e.g. Coid et al., 2008; McGrath et al, 2004). A study completed by Schofield, Kordowicz, Pennycooke & Armstrong (2019) completed focus groups with Black African and Black Caribbean service users with psychosis. The authors found that service users reported that they felt their communities had a higher risk of psychosis due to stressors related to being an ethnic minority group, lack of community support, external discrimination due to ethnicity and internal stigma about mental illness within their own communities (Schofield et al., 2019). These themes parallel research which reported that the experience of major racist discriminatory events were associated with an elevated risk in psychotic symptomatology (Oh et al., 2016; Pearce, Rafiq, Simpson & Varese, 2019).

Research into pathways to care for people who experience psychosis reported a heightened prevalence of ethnic minority groups entering services via compulsory admission (Morgan et al., 2005). Research has found that African/Caribbean ethnic minority group's engagement with services had been poor prior to admission, which could explain why compulsory sectioning may have been required, due to a longer DUP (Oluwatayo & Gater, 2004). Research has also highlighted disparities between the access to mental health interventions for psychosis based on ethnic minority group (Das-Munshi, Bhugra & Crawford, 2018). This highlights the need to further understand how ethnic minority group status impacts vulnerability towards psychosis but also what interventions could be effective at promoting engagement with services.

Estimates suggest that males are more likely to present with psychotic symptoms than females (McGrath, Saha, Welham, Saadi, & MacCauley, 2004; Leung & Chue, 2000; Ring et

al., 1991). The Race Disparity Audit reported that around 3 out of 100 Black men experienced a psychotic disorder in 2017, meaning they were ten times more likely to experience this compared to White men (Cabinet Office, 2017). Other risk factors reported include living within economically deprived areas (Richardson, Hameed, Perez, Jones & Kirkbride, 2018), and immigrant status (Cantor-Graae & Selten, 2005). Identifying risk factors has enabled clinicians and researchers to think carefully about how best to work with individuals with psychosis. For example strategies include addressing cultural or religious perspectives and how they may impact upon symptomatology (NICE, 2014b). Studies have also explored the impact of stigma within ethnic minority populations with a focus on collectivistic cultural practices (Schomerus & Angermeyer, 2008; Papadopoulos, Foster & Caldwell, 2012).

1.3. Psychological interventions for first episode psychosis

Psychological theories suggest that cognitive processes are involved in the development and maintenance of psychotic symptoms (e.g. Garety, Kuipers, Fowler, Freeman & Bebbington, 2001; Freeman, Garety, Kuipers, Fowler & Bebbington, 2002). This has informed the development of cognitive-behavioural approaches to address the psychological components of delusions and hallucinations. The NICE clinical guideline 'Psychosis and schizophrenia in adults: prevention and management' recommends that across states of psychosis, interventions should include antipsychotic medication in conjunction with psychological interventions (NICE, 2014b). The Implementing the Early Intervention in Psychosis Access and Waiting Time Standard recommends that psychological interventions such as cognitive behavioural therapy for psychosis (CBTp) or family interventions (FI) are used for people who present with psychotic symptomatology. Randomised Controlled Trials (RCTs) and meta-analyses have demonstrated that CBTp can improve symptomatology and either reduce or prevent the onset of progression to a psychotic disorder (e.g. Kuipers et al.,

1997; Mehl, Werner & Lincoln, 2015; van der Gaag, Valmaggia & Smit, 2014). CBTp has also been demonstrated to be beneficial for service users who present as 'medication resistant' (Burns, Erickson, Colleen & Brenner, 2014), supporting its use as a first line treatment in addition to medication. A meta-analysis related to the efficacy of FI and CBTp found FI provided a preventative effect on psychotic symptoms and readmission, whilst CBT was found to improve mental state and observed to have a lower dropout rate (Pilling et al., 2002). There are some criticisms of the evidence base related to the efficacy of psychological therapies. Rathod and colleagues (2005) reported that numbers of ethnic minority group research participants in CBT RCTs are low in high and middle income countries. As a result the findings from many RCTs may not provide an account of how CBT or other psychological therapies may uniquely affect outcomes for ethnic minority groups in those countries.

As a result of these considerations, a set of suggested evidenced based processes to make cultural adaptations to CBT were presented by Rathod and colleagues (2019), referred to as the 'Triple-A' principle. The triple A's referred to the 'awareness' of relevant cultural issues and using this to inform therapy, 'assessment' and engagement; and 'adjustments' in therapy (Rathod et al., 2015). The authors provided a four stage model, suggesting that initial developments should involve qualitative information gathering via exploring available literature, interviewing service users, mental health professionals and experts in the field for views and experiences. The next steps involved producing guidance based on the collected information, followed by formal adaptations to a CBT manual and translating if required. Finally a field test of the adapted CBT manual through a RCT is suggested which should help inform whether further adaptations are required (Rathod et al., 2019, Naeem et al., 2016). The authors referenced various considerations that could be made when culturally adapting CBT. Suggestions included being mindful of the setting where the intervention takes place,

modifications to therapeutic relationship in terms of limited self-disclosure to improve rapport and adaptations to therapeutic style based on cultural values. They also suggested using systemic networks to inform goals and act as protective factors, and remaining curious to the impact of spirituality and religion on the service user (Rathod et al., 2019).

1.4. Current statistics on the uptake and acceptance of psychological therapies in psychosis

Whilst psychological interventions for psychosis appear to improve symptoms and relieve distress, there have been noted difficulties regarding attrition rates, with some research indicating that less than half of potential participants engage with the treatments offered (Garety et al., 2008; Penn et al., 2009). A study exploring the offer and acceptance of a randomly selected sample of 187 service users from a mental health trust in the North West of England over a 12 month period found that only 6.9% (13) service users were offered CBT, of which 5.3% (10) received treatment, compared to three service users who were offered FI, and only two received treatment (Haddock et al., 2014). Furthermore, Colling and colleagues (2017) reported that only 34.6% of service users received at least one session of CBTp which reduced to 26.4% after two sessions. The National Clinical Audit for Psychosis (NCAP) 2018/2019 used data from 57 Early Intervention services and found that 4417 out of a total 9527 (46%) of service users attended one or more sessions of CBTp, with a range of 0-90% between NHS Trust. The audit also reported that 22% (2049) of service users received one or more (range of 1 – 60%) sessions of FI (Royal College of Psychiatrists, 2019).

The dilemma of using research to explore engagement with and outcomes from psychological interventions is that there could be selection bias within the samples, i.e. participants may be actively searching for psychological interventions. It is pertinent that data from routine clinical practice and outcome monitoring are explored in order to ascertain whether findings from RCTs are replicated in naturalistic samples. Data from the Race

Disparity Audit did not report access figures to mental health services based on ethnic minority groups but found that people from South Asian, Asian other and other ethnic minority groups were less likely to have positive outcomes compared to the White majority group who accessed mental health services (Cabinet Office, 2017). It is important to explore these differences within the context of SMI and psychosis due to the evidence related to ethnic minority group status identified as a risk factor.

1.5. Aims of portfolio

This thesis portfolio explores the effectiveness and availability of psychological interventions for ethnic minority groups who experience a severe mental illness. A systematic review was conducted in order to synthesise research related to the effectiveness of psychological interventions in ethnic minority groups who experienced a SMI. An empirical paper was completed which used anonymised service data to explore potential factors influencing the offer and acceptance of psychological therapies in an ethnically diverse area of London. The portfolio intends to develop the evidence base related to psychological interventions and their application to service users from ethnic minority groups.

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2. Systematic review

Efficacy and acceptability of psychological interventions for severe mental illness in ethnic minority populations: A systematic review

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2.1.Abstract

Aims: This systematic review aimed to synthesise research related to the efficacy of psychological interventions when applied to ethnic minority groups who experience a severe mental illness (SMI).

Methods: The databases Embase, MEDLINE, PsycINFO and Web of Science were searched from inception to January 2020. Included studies highlighted ethnic minority groups as the target population for psychological intervention, referenced ethnicity as a variable of interest and measured SMI symptom severity. Studies were excluded if they were not written in English or explored effects of psychological interventions on common mental disorders.

Narrative synthesis was used to explore the selected papers.

Results: The search identified 2328 studies, of which nine papers were included for analysis. All papers were quantitative in design, using either randomised controlled trials or secondary data. The quality ratings for the papers were generally acceptable or better. Cultural adaptations were made in seven studies which demonstrated improvements in symptom severity compared to treatment as usual. The strengths of these findings were diminished by a lack of comparable control group in seven studies. Attrition was also common across the studies.

Conclusions: Service users from ethnic minority groups with SMI can benefit from psychological interventions. Culturally informed interventions appeared to provide positive outcomes, however there was variation in the presence or form of control groups. The evidence for these findings are limited considering the range of therapies captured in the review. Future studies may benefit from comparing culturally adapted interventions to standard interventions, along with exploring factors which may affect attrition.

The prevalence of mental health problems in England has been increasing for both common and severe mental illnesses when comparing rates between 2000 to 2014 (Bebbington & McManus, 2020). The term Severe Mental Illnesses (SMI) has been defined as mental health problems that lead to a debilitating and significant impact on a person's functioning (Heller, Roccoforte, Hsieh, Cook & Pickett, 1997). Mental health problems associated with SMI include psychosis and bipolar disorder (Eack & Newhill, 2012). Public Health England (2018) reported that 0.9% of the population in England have been identified as experiencing a SMI. In addition to the psychological distress associated with SMI, studies have indicated poor outcomes such as co-morbidity with chronic physical health difficulties (De Hert et al., 2011). Earlier mortality rates as a result of experiencing a SMI have been reported on average up to 15 to 20 years earlier compared to the general population (Chesney, Goodwin & Fazel, 2014).

With these findings in mind, there has been a drive to help support people with SMI to access psychological interventions, with considerable evidence to support the use of psychological interventions with those who experience psychosis and bipolar disorder (Pilling et al., 2002; Scott, Colom & Vieta, 2007). This has been reflected in the development of Early Intervention Services and Improving Access to Psychological Therapies for SMI services (IAPT-SMI; Johns et al., 2019; Jolley et al., 2015).

2.2. Evidence base for the use of psychological interventions with SMI

Evidence suggests that receiving psychological interventions such as cognitive behavioural therapy (CBT) can help in reducing symptom severity associated with psychosis (Soneson et al., 2019; Bighelli et al., 2018), with small to medium effect sizes reported at the end of treatment and at follow up (Hazell, Hayward, Cavanagh & Strauss, 2016; Mehl, Werner & Lincoln, 2019). A systematic review and meta-analysis found that psychological interventions provided a reduction in standardised mean difference scores in negative

symptoms of psychosis compared to treatment as usual, as long as the service users remained in services (Lutgens, Gariepy & Malla, 2017). Another systematic review and meta-analysis found that family intervention (FI) improves service user functioning and reduce relapse rates (Claxon, Onwumere & Fornells-Ambrojo, 2017). A systematic review reported that individual and family based interventions were helpful to reduce symptomatology related to bipolar disorder, however there were concerns that most of the studies were of low or very low quality as assessed by the GRADE method (Oud et al., 2016). A meta-analysis competed by Ye and colleagues (2016) found that CBT reduced levels of mania assessed by the Young Mania Rating Scale, however these effects reduced over time. Despite the evidence, psychological interventions are not equally available to all, with factors such as socioeconomic deprivation acting as a risk factor for the underutilisation of psychological services (Delgadillo, Farnfield & North, 2018; Reiss et al., 2019).

This highlights a need to explore the concept of intersectionality and its impact on the access and outcomes to psychological therapies. Intersectionality is a framework to conceptualise how social identities such as gender, ethnicity, age, religion, health, location and migration history may interact to lead to discrimination (Barnard & Turner, 2011). For the purpose of this systematic review, ethnicity has been selected as the focal point in relation to outcomes of psychological therapies.

2.3. The relationship between ethnic minority status and access to psychological therapies

Ethnicity is a term that refers to a set of shared characteristics (e.g. common language, cultural identity or country of origin) held by a group of people (Rice & O'Donohue, 2002). This is distinct from race, which relates to a category assigned to people based on physical characteristics and characterisations (American Psychological Association, 2003). For example, two unrelated people may both identify as White in race, however they may assign

their ethnicities using different categories such as White British and White Irish. Data from the United Kingdom 2011 Census reported that around 19.5% of the population label themselves as being part of an ethnic minority group, however statistics suggest that black African minority groups are over-represented when exploring rates of compulsory admission under the Mental Health Act (Cheng et al., 2018; Oduola et al., 2019). Evidence also suggests that those from Asian/Asian British minority groups are 14% less likely to contact mental health services (Baker, 2020). Data from inpatient settings reported that people from black African ethnic minority groups had a higher rate of completing suicide compared to a white British reference group (Bhui, Dinos & McKenzie, 2012). Older south Asian women have been suggested to be an at-risk group for suicide in England and Wales (McKenzie, Bhui, Nanchahal & Blizard, 2008). Maura and de Mamani (2017) conducted a systematic review to explore mental health disparities, engagement and attrition in ethnic minority groups who experienced a SMI. The authors reported all ethnic minority groups were at a higher risk of disengaging from mental health services compared to White ethnic majority and experienced increased rates of schizophrenia diagnoses and poorer symptomatic and functional outcomes.

It is important for academics and clinicians to be aware of the factors that may prevent people from ethnic minority groups from accessing mental health services. Research has demonstrated poorer outcomes for individuals who wait longer to access mental health services (Marshall, Lewis & Lockwood, 2005; Addington, Van Mastrigt, Addington, 2004). A study in America found that increased levels of stigma held by family members from ethnic minority groups were correlated with a longer treatment delay (Okazaki, 2000). Cooper and colleagues (2013) analysed survey data from 23,917 participants across the 1993, 2000 and 2007 National Psychiatric Morbidity Surveys and found that people from Black and South Asian ethnic minority groups were less likely to have contacted primary care services for their mental health. A systematic review completed in the United Kingdom found that

individuals who were from Black Caribbean or African ethnic minority groups were three times more likely to enter mental health services via compulsory admission compared to the white reference group (Halvorsrud, Nazroo, Otis, Brown Hajdukova & Bhui, 2019). Asian service users were 1.5 times more likely to access services via this pathway. In the United States, after controlling for health insurance status, older adults from ethnic minority groups had poorer access to mental care services (Sorkin, Pham, & Ngo-Metzger, 2009). Similar findings were found using a sample of 134,875 adults in the general population (Harris, Edlund & Larson, 2005). When exploring psychological interventions for SMI, studies have tended to focus on ethnic minority group differences in uptake of psychological interventions compared to an ethnic majority group (Das-Munshi, Bhugra & Crawford, 2018; McKenzie et al., 2001).

In summary, there appears to be a body of research related to ethnic minority group differences in the access to mental health services. However there appears to be a paucity of research that explores the efficacy of psychological interventions specifically in those who are from ethnic minority groups and experience SMI. This review aims to answer the following questions:

- What are the outcomes for people from ethnic minority groups with SMI who receive a psychological intervention?
- From the studies identified from the review, were cultural adaptations made to the intervention?

2.4. Methods

2.4.1. Search strategy

A comprehensive literature search was carried out to locate papers related to the study research questions. The following databases were searched in January 2020: EMBASE,

MEDLINE, PsycINFO and Web of Science. Truncations were used to capture alternative endings (therap* to capture "therapy" and "therapies") whilst considerations were made to include alternative spellings of words (separate terms for "cognitive behaviour therap*" and cognitive behavior therap*). Boolean AND/OR commands were used where necessary ("psychological therap* OR cognitive behavior therap*"). A range of terms were used to identify studies where ethnic minority groups had been the population of interest or important variable ("ethnicit*, "ethnic minorit*", "migrant*"). The searches carried out explored all sections of papers (title, abstract, main text and keywords) in line with the full search criteria. Due to the hypothesised paucity of research that has focused on exploring psychological therapies with ethnic minority group with SMI the search criteria allowed scope for papers to be included that extended outside of traditional psychological interventions, including family, group, counselling, psychosocial and psychoeducational interventions. The review was registered on the PROSPERO International Prospective Register of Systematic Reviews. A link to the protocol is available via

https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019118947. A copy of the protocol and search strategy are provided in the appendices.

2.4.2. Inclusion criteria

Inclusion and exclusion criteria were determined using the PICOS (participant, intervention, comparison, outcome and study) design (Moher, Liberati, Tetzlaff & Altman, 2009).

2.4.2.1. Participants

Studies were included if participants were diagnosed with a SMI and the sample included people from ethnic minority groups. Studies were also included if they referred to ethnicity as a co-variate of interest in title or abstract. For the purposes of this study SMI included psychosis, schizophrenia spectrum disorders and bipolar related disorders, as

defined by the International Classification of Diseases (ICD-10; World Health Organisation, 1992). Studies were included if they presented a combination of these diagnoses in their samples.

2.4.2.2. Intervention

Studies were included if they referred to a psychological intervention being used with ethnic minority group participants. Psychological interventions vary in approach and modality and as such this review did not limit the model informing the intervention.

2.4.2.3. Comparison

Studies that used a control, waitlist or treatment as usual comparison group were included for review.

2.4.2.4. Outcomes

Due to the potential range of outcomes explored in studies, the study will focus on outcomes that relate to symptomatology associated with SMI.

2.4.2.5. Study design

Due to the potential paucity of studies, both RCT and non-RCT designs were included for review. Qualitative papers and mixed method studies were also permitted if they explored changes in symptom severity.

2.4.3. Exclusion criteria

Studies were excluded if they were not written in English, explored outcomes from psychological therapy in ethnic minority groups with common mental disorders or if they did not refer to ethnic minority groups as a variable of interest when exploring outcomes of psychological therapies.

2.4.4. Quality assessment

PRISMA guidelines were adhered to (Moher et al., 2009) in order to ensure that a systematic approach was taken towards searching, exploring and selecting papers for

inclusion. The Mixed Methods Appraisal Tool (MMAT; Pluye & Hong, 2014) is a quality rating tool that allows a user to appraise the quality of various types of research designs and assess for bias. The MMAT allows quantitative, qualitative and mixed methods studies to be reviewed, encompassing five categories; RCTs, non-randomised studies, quantitative descriptive, qualitative and mixed method designs (Pluye & Hong, 2014). It is two part quality rating tool, the first section contains a screening checklist to determine whether a paper is eligible for rating, followed by a quality rating assessment of the paper based on its research design. All screenings and MMAT ratings were completed by the first author (SP). Reliability of screening and MMAT ratings were completed with another member of the research team using 20% of the papers with a Cohen's kappa $\kappa = .78$ (p < .01). Rating queries or disagreements were resolved by consensus. A copy of the MMAT can be found in Appendix B.

2.4.5. Data extraction, analysis and synthesis

Data available from the selected papers were extracted for analysis. Variables extracted included country of origin, population or diagnoses of interest, study aims, study design, outcomes measured, age, gender, educational levels, and ethnic minority groups included. Two additional tables were used to extract information related to the outcomes of the study and cultural adaptations made, where applicable.

2.5. Results

The initial searches yielded 2328 articles when it was conducted in January 2020. From these articles there were nine papers which related to the aims of this review. Figure 1 provides a breakdown of how the final set of papers for inclusion were identified using the PRISMA flowchart. The MMAT provides a method to determine which studies fit into one of the five categories that are used to assess the paper quality and risk of bias (Pluye & Hong, 2014). Table 1 provides an account of MMAT ratings for each paper. Three papers (33.3%) were rated as 40% or below, indicating below poor quality and that risk of bias may be

present in the findings. Two papers (22.22%) had a quality rating of 60% which were of acceptable quality. Four papers (44.4%) had quality ratings of 80% and above, indicating very good quality and low risk of bias.

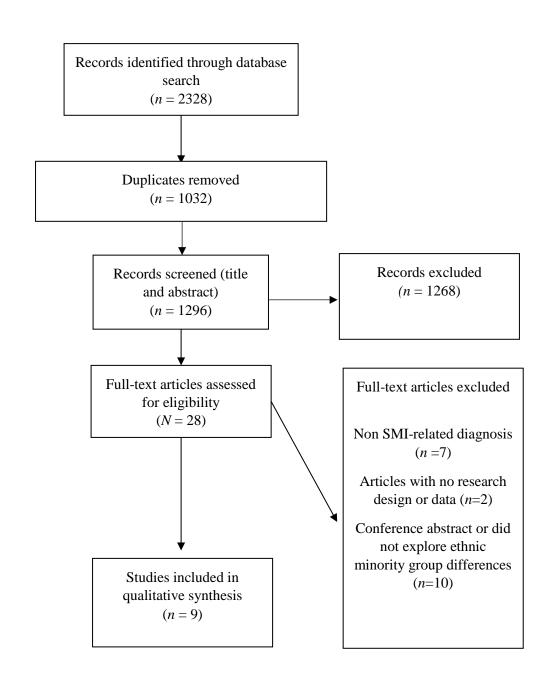


Table 1 MMAT quality ratings

Article, Year, Rating	Quantitative (Randomized)				Quantitative (non-randomized)					
	Is the randomisation appropriately performed?	Are the groups comparable at baseline?	Are there complete outcome data?	Are outcome assessors blinded to the intervention provided?	Did the participants adhere to the assigned intervention?	Did the participants adhere to the assigned intervention?	Are measurements appropriate regarding both the outcome and intervention (or exposure)?	Are there complete outcome data?	Are the confounders accounted for in the design and analysis?	During the study period, is the intervention administered (or exposure occurred) as intended?
Bae, Brekke & Bola, 2004						✓	✓	✓	×	✓
Bradley et al., 2006	×	×	√	×	✓					
Brown & de										
Mamani, 2018 de Mamani, Weintraub, Gurak & Maura,	×	✓	✓	×	✓					
2014 Fagiolini et al.,	×	✓	✓	×	✓					
2009	✓	\checkmark	\checkmark	×	✓					
Habib, Dawood, Kingdon &		,		√						
Naeem, 2015 Maura & de	×	✓	×	•	×					
Mamani, 2018 Oluwoye et al.,	*	×	✓	×	×					
2018 Rathod et al.,	×	×	✓	×	*					
2013	✓	*	✓	✓	✓					

^{*}Unused screening categories have been omitted from the table

2.5.1. Study characteristics

Six (66.7%) studies were conducted in America, with the remaining three (33.3%) conducted in the United Kingdom, Australia and Pakistan (11.1% each). Eight papers used randomized samples (88.9%) and the remaining used a cohort of secondary data to measure change in symptoms over time (11.1%).

One study specifically explored outcomes related to bipolar disorders whilst the remaining explored psychosis spectrum disorders. All of the papers explicitly referred to ethnic minority groups other than Caucasian as variables of interest. Three papers included samples that consisted solely with people from ethnic minority groups, two used a white majority reference group and the remaining four papers compared ethnic majority and minority groups across a treatment and control group. Table 2 provides a summary of each study. Supplementary data is available in Appendix C.

Table 2 Summary of study characteristics

First author, Year, Country, N	Psychological therapy and comparison (if any)	Primary/secondary aims	Primary outcome related to SMI	Study design and time frame	Population and ethnicities explored	Main results (relevant to review)	MMAT quality rating
Bae, 2004, USA, N = 226	psychosocial rehabilitation outcomes using		BPRS	Quantitative descriptive cohort design 12 months, three time points (baseline, six months, one year)	Schizophrenia and Schizoaffective disorder White = 108 (reference group, 48%) African American = 81 (36%) Latino = 37 (16%)	BPRS scores did not significantly change between baseline and follow up. No significant differences in symptom change between ethnic minority groups and White reference group.	80%
Bradley, 2006, Australia, N = 59	Multi-family group therapy (MFGT) Case management control group	To compare outcomes between multiple-family group intervention and control group.	BPRS	Randomised pre and post. 12 months, three timepoints (baseline, post treatment and 18 month follow up)	Schizophrenia, Schizoaffective disorder, or schizophreniform disorder Vietnamese 100% (English or non- English speaking)	BPRS scores were significantly lower for participants who received MFGT when comparing pre and post treatment scores.	40%

Table 2 continued

First author, Year, Country, N	Psychological therapy and comparator (if any)	Primary/secondary aims	Primary outcome related to SMI	Study design and time frame	Population and ethnicities explored	Main results (relevant to review)	MMAT quality rating
Brown and de Mamani, 2018, N = 266 participants within 155 families	Culturally informed family therapy for schizophrenia (CIT-S) Psychoeducation group (control)	To assess whether CIT-S decreased patient schizophrenia symptoms, improved caregiver wellbeing and improved family cohesion.	BPRS	RCT, three time points (baseline, mid-point and end of treatment)	Psychosis/schizophrenia Hispanic (50.75%) African American (24.5%), Caucasian (21.4%), Asian American (0.25%) Other (1.75%) (No reference group)	A time by group interaction found that CIT-S reduced symptoms from baseline to follow-up.	60%

Table 2 continued

First author, Year, Country, N	Psychological therapy and comparator (if any)	Primary/secondary aims	Outcomes measured	Study design and time frame	Population and Ethnicities explored	Main results (relevant to review)	MMAT Quality rating
de Mamani, Weintraub, 2014, N = 69 families	CIT-S Psychoeducation group (control)	To assess whether CIT-S reduced patient symptom severity. To explore if ethnicity moderated the impact of CIT-S on symptom severity.	BRPS	RCT pre-post design 12 to 15 weeks (baseline and follow up)	Schizophrenia or schizoaffective disorder Hispanic/Latino = 40 (58%), White = 14 (20.2%), Black = 11 (15.9%), Other = 4 (5.7%) (no reference group)	CIT-S group had significantly lower symptom severity compared to control group by follow up in a time by group interaction.	60%
Fagiolini, 2009, <i>N</i> = 463	Specialized Care for Bipolar Disorder (SCBD) and psychosocial treatment Enhanced Clinical Intervention (ECI) SCBD alone control	To explore if SCBD and ECI + SCBD improved outcomes and for young and elderly individuals, African Americans, and rural residents with bipolar disorder.	CGI	RCT pre and post design 18 months, two time points (baseline and 18 months)	Bipolar I and II, Bipolar NOS, Schizoaffective disorder SCBD + ECI group: Caucasian n = 189 (80%), African American = 39 (17%), other = 6 (3%)	Both SCBD+ECI and SCBD were effective at reducing symptom severity with no significant differences between the groups (pre-post change)	80%
					SCBD group: Caucasian n = 196 (86%), African American n = 29 (13%), other n = 3 (1%)	No significant differences in findings based on ethnicity.	

Table 2 continued

First author, Year, Country, N	Psychological therapy and comparator (if any)	Primary/secondary aims	Outcomes measured	Study design and time frame	Population and Ethnicities explored	Main results (relevant to review)	MMAT Quality rating
Habib, 2015, Pakistan N = 42	Culturally adapted CBT for psychosis (CaCBTp) TAU	To assess the effectiveness of CaCBTp in an inpatient setting in Pakistan.	PANSS PSYRATS Insight scale	RCT pre and post design over four to six months.	Schizophrenia Pakistani (100%)	CaCBTp group demonstrated significantly different improvements in symptomatology and insight when comparing pre-post change.	40%
Maura, 2018, USA N = 150	Culturally informed group therapy for schizophrenia (CIGT-S) No comparator	To explore if CIGT-S effects patient and family members depression, anxiety.	SCID-I/P BPRS	RCT pre and post design 15 weeks, two time points	Schizophrenia Service users: Caucasian (17.7%), African American (51.3%), Hispanic (26.5%), Other (1.8%). Missing data (2.7%). Family members: Caucasian (30%), African American (20%), Hispanic (38%), Asian American (2%), Other (6%). Missing data (4%)	Symptom severity decreased when comparing pre and post change (M = 46.59 , SE = 3.79), with a medium effect size (Cohen's $d = .66$).	20%

Table 2 continued

First author, Year, Country, N	Population and psychological therapy explored	Primary/secondary aims	Outcomes measured	Study design and time frame	Ethnicities explored	Main results (relevant to review)	MMAT Quality rating
Oluwoye, 2018, USA N = 404	NAVIGATE TAU	To examine racial and ethnic differences in psychiatric symptoms between NAVIGATE and TAU	PANSS	Secondary data from previously completed RCT. 24 months over five time points (baseline, six, 12, 18, 24 months)	Psychosis spectrum disorders Non-Hispanic White (43%, reference group) Non-Hispanic Black (34%) Asian (3%) Alaska Native/ Native American (5%) Hawaiian/Pacific Islander (<1%) Hispanic White (11%), Hispanic Black (3%). Hispanic other (4%)	Non-Hispanic Black participants in control group had significantly higher scores on PANSS positive symptoms, disorganized thoughts and the uncontrolled hostility, compared to reference group across the intervention.	80%
Rathod, 2013, UK N = 35	CaCBTp TAU	To explore the feasibility of the CaCBTp with specified ethnic minority groups. To modify CaCBTp in accordance with emerging findings	CPRS Secondary outcome measures Insight in Psychosis scale	RCT 16-20 weeks over three time points (baseline, post-treatment and six month follow up)	Schizophrenia, schizoaffective, or delusional disorders African Caribbean 9 (27%), Black African 5 (15%), mixed race 10 (30%) Pakistani 6 (18%), Bangladeshi 2 (6%), Other (Iranian) 1 (3%)	Significantly better outcomes in CaCBT group compared to TAU.	80%

MMAT = Mixed Methods Appraisal Tool, BPRS = Brief Psychotic Rating Scale, SANS = Scale for the Assessment of Negative Symptoms, RCT = Randomized Controlled Trial, PSY-ED = Psychoeducation, CGI = Clinical Global Impressions Severity Scale, GAF = Global Assessment of Functioning, NAVIGATE = psychoeducation and individual therapy using CBT, PANSS = Positive and Negative Syndrome Scale, PSYRATS = Psychotic Symptom Rating Scales, SCID-I/P = Structured Clinical Interview Patient Edition, CPRS = Comprehensive Psychopathological Rating Scale, TAU = Treatment as usual

2.5.2. Ethnic minority group outcomes of psychological therapies

The studies demonstrated a range of heterogeneity in the interventions used, ethnicities of interest, reporting of attrition rates and outcomes measured. For the purpose of this review, we focussed on outcomes related to SMI symptom change. Of the nine papers, six were rated as good or better quality using the MMAT criteria. The remaining three papers were rated as poor or worse, highlighting a risk of bias. Seven papers reported reduction in symptom severity compared to control groups. However, differences in the presence or absence of comparisons groups and attrition reduced the strength of these findings.

Two studies (Bae, Brekker & Bola, 2004; Oluwoye et al., 2018) used an ethnic majority group to compare against ethnic minority groups for change in symptom severity scores. Of these two, Bae and colleagues (2004) reported that symptom severity measured by the BPRS lowered over time but was not statistically significant. Oluwoye and colleagues (2018) reported that participants allocated to the NAVIGATE intervention did not differ in psychiatric symptoms as measured by the PANSS over time when comparing ethnic minority groups to the white majority reference group. The authors found that non-Hispanic Black participants allocated to TAU had higher positive symptoms scores across the treatment period (b=2.15, *p*=.010), along with disorganized thoughts and uncontrolled hostility. Ethnic minority group differences in symptom severity were not found across the treatment period in the NAVIGATE group, with the authors inferring that NAVIGATE reduced ethnic minority group differences.

Of the remaining seven studies in the review, all reported an improvement in SMI symptoms in ethnic minority groups after receiving a psychological intervention. However a paper that explored SCBD+ECI for bipolar disorder found no significant differences in symptom severity mean difference scores across the treatment and TAU group (Fagiolini et

al., 2009). This meant that SCBD alone (general medication and clinical management) was effective as an additional psychosocial component to manage symptoms related to bipolar disorder. This study had a high quality rating of 80% as assessed by the MMAT, indicating low risk of bias.

The other high quality studies as rated by the MMAT were found to have a low risk of bias in their methods and analysis, however the study completed by Bae and colleagues (2004) did not use a control group and Oluwoye and colleagues (2018) did not compare symptom severity within groups to explore ethnic minority group differences. The authors also did not provide detail as what interventions the TAU control group included.

A paper exploring CaCBTp in ethnic minority groups also had a high quality rating score (80%, Rathod et al., 2013), which reported that symptom severity reduced over time across all ethnic minority groups included in their study. However the reduction in symptom severity did not reach significance when the authors adjusted for age, gender and medication dosage in participants. The sample size was also limited to 33, leaving the findings difficult to generalise. Both papers that explored the effectiveness of CaCBTp (Rathod et al., 2013; Habib et al., 2015) did not use a comparable control group (i.e. standard CBTp), which reduces the strengths of their findings.

A study conducted by Maura and de Mamani (2018) received a poor quality rating score of 20%, due to the authors proving no account of the randomisation process nor a comparison of groups at baseline. There was also no evidence that blinding was carried out and there was a high rate of dropout in the study, which could contribute towards a risk of bias in the results. This study also used a wait list as a control group to compare symptom severity, as opposed to a comparable group or family intervention. Issues related to a lack of randomisation procedure and blinding were also found in studies conducted by Brown and de

Mamani (2018) and de Mamani and colleagues (2014). These studies both had a higher quality rating of 60%, demonstrating adequate quality. Both studies explored CIT-S and reported that symptom severity reduced compared to the TAU condition for all ethnic groups in the intervention group. These studies also used comparable control groups, using a 3 week family psychoeducation control group.

With regards to the measures used to monitor SMI symptom severity, five studies used the BPRS, which has been reported to be less biased in the assessment of clinical symptoms compared to professional diagnostic decision making (Schwartz, Docherty, Najolia & Cohen, 2019). A review of the PANSS conducted by Liechti and colleagues (2017) highlighted that cultural biases may impact the delivery and rating scores by professionals when using the tool. As a result the authors argued that behaviour that could be culturally determined may be misinterpreted as a symptom related to SMI, thus biasing the scoring of the PANSS (Liechti et al., 2017). An analysis to test the measurement properties of the PANSS across different regions and cultures was completed by Khan and colleagues (2013). They used 1169 raters from six different regions including East Asia, India, the United States and Europe. The authors found that differences existed in the ratings of several items in the PANSS in both negative and positive symptoms. Cultural differences in the interpretation and understanding of service user symptoms could be present in studies where assessors were not matched to participants by ethnic minority group, thus biasing the scoring of symptom severity and findings from studies.

2.5.3. Cultural adaptations to psychological interventions

Seven out of nine papers in the review reported to make cultural adaptations to a psychological intervention One paper applied Multi Family Group Therapy (MFGT), a form of cognitive behavioural based family intervention (MacFarlane et al., 1995). Two papers focussed on Culturally Informed Therapy for Schizophrenia (CIT-S), a family based

intervention intended to reduce symptoms related to schizophrenia (de Mamani, Weintraub, Gurak & Maura, 2014). The authors reported that sessions were informed by cross cultural research and allows practitioners to access cultural beliefs and behaviours that could be used as protective factors or address potential maladaptive behaviours or beliefs. An additional study explored developing a group version of CIT-S, Culturally Informed Group Therapy for schizophrenia (CIGT-S; Maura & de Mamani, 2018).

A paper in the review (Habib et al., 2015) noted that by making appropriate cultural adaptations via specific liaison and collaborative development with ethnic minority groups led to better service user experience and outcomes compared to treatment as usual. This is in line with recommendations that integrating cultural meaningful factors such as spirituality and collectivism into psychological interventions may be appropriate and effective than not doing so (Hall, 2001). Utilising aspects of cultural practices and norms were seen in adaptations made in six of the nine studies in this review. Table 3 provides an account of the cultural adaptations made by each study.

Table 3 Cultural adaptations made to interventions

Author, year	Intervention	Details on cultural adaptations made to intervention
Bae, Brekke and Bola, 2004	Community based psychosocial rehabilitation	No cultural adaptations reported by the authors.
Bradley et al., 2009	Multi-Family Group Therapy (MFGT)	Adaptations made to MFGT included using Vietnamese speaking therapists who spoke the same language as the service users. Informal outreach sessions at service users homes were provide alongside validating cultural explanations of the SMI before presenting a biopsychosocial approach to the illness. Traditional alternative healing practices, such as herbal treatments and use of religious leaders, were acknowledged alongside Western approaches.
Brown and de Mamani, 2018; de Mamani, 2014	Culturally Informed Therapy for Schizophrenia (CIT-S)	A family based intervention intended to reduce symptoms related to schizophrenia. The authors reported that CIT-S is a fully manualised intervention that takes place over 15 weekly sessions, lasting between 60-75 minutes each. Utilised psychoeducation and communication training. Handouts provided after sessions. Incorporated components such as spirituality and family collectivism in modules delivered.
Fagiolini et al., 2009	Specialized Care for Bipolar Disorder (SCBD) Enhanced Clinical Intervention (ECI)	Referred to making specific content for African American service users but did not provide any detailed related to this.
Habib et al., 2015	CaCBTp	Developed for cultural adaptation in Pakistan. Family members were included care planning. Key carer identified and attended sessions with consent. Acknowledged bio-psycho-social-spiritual model of illness reportedly used in Pakistan.
Maura and de Mamani, 2018	CIGT-S	This intervention follows the similar cultural adaptations made with CIT-S albeit using a manualised protocol for group settings. Treatment modules included family collectivism, psychoeducation, spiritual coping, communication training, and problem solving.

Table 3 continued

Author, year	Intervention	Details on cultural adaptations made to intervention
Oluwoye et al., 2018	NAVIGATE	No cultural adaptations reported.
Rathod et al., 2013	CaCBTp	16 sessions of CaCBTp over a period of 16 to 20 weeks by trained CaCBTp therapists. Referred to Tseng and colleagues (2005) framework of cultural adaptations of psychological therapies to inform CaCBTp.

2.6. Discussion

2.6.1. Main findings

This review explored the literature relating to the efficacy of psychological interventions for people from ethnic minority groups who experience a SMI. The findings from this review suggest that symptom severity for SMI can be reduced in ethnic minority populations when using psychological interventions, however the strength of findings fluctuated due to issues related to comparison control groups and methodological considerations related to risk of bias. A paper that explored bipolar related disorders did not report any differences between the intervention and TAU group, despite making cultural adaptations (Fagiolini et al., 2009). Two papers that did not make cultural adaptations had mixed findings, with one reporting that symptom did not significantly change over time using community psychosocial rehabilitation (Bae et al., 2004), whilst the other study reported no ethnic group differences in symptom severity within the intervention group (Oluwoye et al., 2008). Five studies provided data related to attrition. The lowest rates were reported by Bradley and colleagues (2009) and Rathod and colleagues (2013). The highest was reported by Maura and de Mamani (2018), with 68% of their service users and 58% of family members dropping out. Four studies that reported attrition used an ethnic majority reference group and did not report whether drop out was a specific issue within ethnic minority groups.

2.6.2. Cultural adaptations

Seven studies explored cultural adaptations to therapies in order to meet the needs of the population in their area. Cultural adaptations have been described as a method to modify existing evidence based interventions in a way which integrate the service user's culture, meaning and values (Bernal et al., 2009). Many of the papers that explored cultural adaptations varied in their method of evaluating these interventions and four did not compare against a comparable intervention to demonstrate potential differences. Whilst the papers that

adapted interventions reported success in terms of reduction in symptom severity, drop out from therapy was still an issue despite the cultural adaptations. This needs to be explored further, as it matches research that has highlighted ethnic minority groups can be more likely to disengage with mental health services faster than a white ethnic majority (Maura & de Mamani, 2017).

2.6.3. Factors that may influence ethnic minority access to psychological therapies

To apply these findings into a wider context, a meta-analysis using 115 studies exploring CBT with a range of mental health problems found an average dropout rate of 15.9% at pre-treatment and 26.2% during treatment (Fernandez, Salem, Swift, & Ramtahal, 2015). A study by Thompson, Bazile and Akbar (2004) conducted focus groups with 201 African American service users to gain insight around psychotherapy and perceptions of therapists. The authors found that participants were concerned about the cost of therapy, which is important to keep in mind as a source of attrition in studies conducted in the countries where free healthcare is not offered. The participants also reported concerns that therapists from ethnic majority backgrounds would not understand their experiences of being an ethnic minority. One study included in this review attempted to address this by using therapists who spoke the same language as the service user or their families, however it did not mediate positive outcomes (de Mamani et al., 2014).

Factors such as stigma attending mental health services, indirect or direct financial costs associated with attending services, or pathways to care may account for some of the attrition rates seen in studies. Future studies may benefit from exploring potential reasons that contribute towards ethnic minority group attrition in trials and clinical practice to improve access to mental health services and psychotherapies. One possible reason for attrition may be due to the implementation of manualised approaches in many of the included studies.

Manualised approaches may allow a wider range of health professionals to deliver

psychologically based treatments, but at the cost of reducing the practitioner's ability to creatively work with service users to provide an intervention which uniquely meets their needs. Not all members of an ethnic minority group share the same experiences and hold the same values, practitioners should be mindful to not apply generalised interventions and hold in mind the importance of idiosyncratic formulation and interventions (Rathod, Phiri & Naeem, 2019). However there is also evidence to suggest attrition rates remain high in ethnic minority groups regardless if the intervention or service has been culturally adapted (de Haan, Boon, de Jong, & Vermeiren, 2015; Kreyenbuhl, Nossel & Dixon, 2009).

A narrative review highlighted that societal stigma can create a sense of internal anticipated stigma which would influence help-seeking behaviour, but also acknowledged that individual knowledge about SMI may be just as important (Schomerus & Angermeyer, 2008). Low perceived need and attitudes towards SMI have also been reported to be a significant factor in the process of deciding whether to initiate, continue and drop out of interventions available in America (Mojtabai et al., 2011). A study using 101 participants with SMI found that less social support was correlated with higher internalised stigma (Chronister, Chou & Liao, 2013) and increasing social support mediated the relationship between symptom distress and recovery (Chou & Chronister, 2012).

A study from Wynaden and colleagues (2005) in Australia used semi-structured interviews participants from Asian ethnic minority groups to develop themes related to factors that restrict their access to mental health care. Six themes emerged from their data; shame, stigma, causes of mental illness, family reputation, hiding up, barriers to seek help and lack of collaboration. These factors mirror other research findings (Kular et al., 2019; Ahmed, Birtel, Pyle & Morrison, 2019) and suggest that exploring these barriers in the context of accessing psychological interventions may be warranted.

2.6.4. Study limitations

This review has highlighted the range of studies being carried out to implement and at times adapt psychological interventions for ethnic minority groups. This review identified nine studies that met its inclusion criteria which was related to ensuring that the studies had a comparison group. A broader search could include studies that did not use a comparison group to determine what adaptations are being made in the wider literature. Considering the similarity in measures used to measure symptom severity in this review, a meta-analysis may be warranted in future research.

2.6.5. Conclusions

Symptom severity was seen to significantly reduce in seven studies demonstrating the positive effect receiving psychological interventions can have for ethnic minority group service users, in line with wider general findings from meta-analyses that explored the efficacy of psychological therapies for SMI (Pilling et al. 2002, Wright & Pilling, 2009). The findings from this paper highlight the need for further studies to explore attrition in psychological therapies, considering potential stigma or collaboration with cultural communities to integrate alternative conceptualisations of mental health with psychological models of distress. From this review it appears there is a paucity of research in this area. As a result it is important future studies continue to monitor ethnic minority group access to and outcomes after receiving psychological interventions, regardless if the intervention has been culturally adapted.

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2.8. Appendix A: Search terms

OVID MEDLINE/EMBASE:

- 1. Severe mental illness.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 2. Schizophrenia/
- 3. Psychotic Disorders/
- 4. Bipolar Disorder/
- 5. 1 or 2 or 3 or 4
- 6. psychological therap*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 7. psychological intervention*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 8. cognitive behavioral therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 9. cognitive behavioural therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 10. family intervention*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 11. cognitive analytic therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 12. dialectical behavioral therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 13. dialectical behavioural therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 14. mentalization based treatment.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 15. mentalization based therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 16. (acceptance and commitment therapy).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 17. ethnicit*.tw.

- 18. ethnic minorit*.tw.
- 19. racial.tw.
- 20. race.tw.
- 21. 17 or 18 or 19 or 20
- 22. psychotherap*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 23. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 22
- 24. 5 and 21 and 23
- 25. migrant*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 26. migration*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 27. 17 or 18 or 19 or 20 or 25 or 26
- 28. 5 and 23 and 27
- 29. counselling*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 30. supportive therap*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 31. therap*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 32. counseling*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
- 33. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 22 or 29 or 30 or 31 or 32
- 34. 5 and 27 and 33

PsychINFO:

Search ID#

S22	S17 OR S18 OR S19 OR S20 OR S21
S21	"ethnic minority"
S20	"ethnic minorities"
S19	racial
S18	race
S17	ethnicity
S16	S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15
S15	"mentalization based treatment"
S14	"mentalization based therapy"
S13	"dialectical behavior therapy"
S12	"acceptance and commitment therapy"
S11	"cognitive analytic therapy"
S10	"cognitive behavioural therapy"
S 9	"cognitive behavioral therapy"
S8	"family intervention"
S7	"psychological therapy"
S6	"psychological intervention"
S5	S1 OR S2 OR S3 OR S4
S4	"bipolar disorder"
S 3	"psychotic disorders"
S2	schizoprenia or schizophrenic or psychosis
S 1	"severe mental illness"

Web of Science

- # #28 AND #27 AND #20
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # #6 OR #5 OR #4 OR #3 OR #2 OR #1
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # #26 OR #25 OR #24 OR #23 OR #22 OR #21
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (migration*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # **TOPIC:** (migrant*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # TOPIC: (race)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # TOPIC: (racial)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (ethnic minorit*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # **TOPIC:** (ethnicit*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR
- 20 #9 OR #8 OR #7

- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (mentalization based therap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (mentalization based treatment*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (psychotherap*)
- 17 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # **TOPIC:** (psychodynamic psychotherap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (acceptance and commitment therap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (cognitive analytic therap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (dialectical behavioral therap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (dialectical behavioural therap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (family intervention*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- **# TOPIC:** (cognitive behavioural therap*)
- Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
- # 9 **TOPIC:** (cognitive behavioral therap*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#8 **TOPIC:** (psychological intevention*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#7 **TOPIC:** (psychological therap*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

6 **TOPIC:** (schizo*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

5 **TOPIC:** (psychosis)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#4 **TOPIC:** (bipolar disorder)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#3 **TOPIC:** (psychotic disorders)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#2 **TOPIC:** (schizophrenia)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#1 **TOPIC:** (severe mental illness)

2.9. Appendix B: Quality rating tool – The Mixed Methods Appraisal Tool (MMAT)

Category of study	N-4-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-			Responses	
designs	Methodological quality criteria	Yes	No	Can't tell	Comments
Screening questions	S1. Are there clear research questions?				
(for all types)	S2. Do the collected data allow to address the research questions?				
	Further appraisal may not be feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening	questio	ns.		
1. Qualitative	1.1. Is the qualitative approach appropriate to answer the research question?				
	1.2. Are the qualitative data collection methods adequate to address the research question?				
	1.3. Are the findings adequately derived from the data?				
	1.4. Is the interpretation of results sufficiently substantiated by data?				
	1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?				
2. Quantitative	2.1. Is randomization appropriately performed?				
randomized controlled	2.2. Are the groups comparable at baseline?				
trials	2.3. Are there complete outcome data?				
	2.4. Are outcome assessors blinded to the intervention provided?				
	2.5 Did the participants adhere to the assigned intervention?				
3. Quantitative non-	3.1. Are the participants representative of the target population?				
randomized	3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?				
	3.3. Are there complete outcome data?				
	3.4. Are the confounders accounted for in the design and analysis?				
	3.5. During the study period, is the intervention administered (or exposure occurred) as intended?				
4. Quantitative	4.1. Is the sampling strategy relevant to address the research question?				
descriptive	4.2. Is the sample representative of the target population?				
	4.3. Are the measurements appropriate?				
	4.4. Is the risk of nonresponse bias low?				
	4.5. Is the statistical analysis appropriate to answer the research question?				
Mixed methods	5.1. Is there an adequate rationale for using a mixed methods design to address the research question?				
	5.2. Are the different components of the study effectively integrated to answer the research question?				
	5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?				
	5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?				
	5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?				

2.10. Appendix C: Table C1 Supplementary information of studies included for review

First author (Year)	Mean age (sd)	Gender	Educational levels	Dropout or attrition
Bae, (2004)	White = 36.0(9.4) African American - 37.8(9.3): Latino = 31.0(6.9)	White male 71 (65.7%) White female 37 (34.3%). African American Male = 65 (80.2%) AA Female 16 (19.8%). Latino male = 26 (70.3%) Latina female = 11 (29.7%)	Years of education mean (<i>sd</i>) - White 12.2 (2.0), African American = 12.0 (1.6), Latino = 11.4 (1.9)	Not reported.
Bradley, (2006)	Mean age treatment group = 33.6 (6.68), control group mean age = 34 (9.60)	Treatment group: female = 18 (72%) male 7 (28%); control group: female 17(68%), male 8 (32%)	Not reported	Nine pairs dropped out after treatment or follow up (15%). Four pairs assigned to MFGT declined to join the family group (7%) One participant died and one relocated (3%). Two in the control group declined to complete follow-up (3%).

Table C1 continued

First author	Mean age (sd)	Gender	Educational	Dropout or attrition
First author (Year) Brown, (2018)	Mean age (sd) CIT-S group: 37.24 (13.4), Family members 49.19 (16.4) Control group: 38.72 (11.69, Family members 49.64 (15.39),	Gender CIT-S Group patient gender 36.5% women, Family Member gender 54.1% women Control group: Service user gender 43.6 women, Family member control gender 58.4% women)	Educational levels CIT-S: College or higher 17.6%, Some college 27.5%, High school or lower 47.9% CIT-S Family Members: College or higher 38.8%, Some college 15.3%, High school or lower 45.9% Control: College or higher 10.5%, Some college 34.2%, High school or lower 55.9% Control Family members: College or	Data was not provided but the authors reported dropout was high. In CIT-S group higher education was associated with more sessions completed. Black ethnic minority families were more likely to attend less sessions.
			higher 39.1%, Some college 20.3%, High school or lower 51.4%	
Table C1 contin	nued		31.470	
First author (Year)	Mean age (sd)	Gender	Educational levels	Dropout or attrition

de Mamani, (2014)	CIT-S mean age 42.73(14.31), PSY-ED Mean age 42.42(12.7)	CIT-S gender 39% female). PSY-ED 41.9% female	Not reported	Around a third (33%) of patients did not complete therapy. Attrition rates did not significantly differ between conditions.
Fagiolini, (2009),	SCBD + ECI group: Mean age =	SCBD + ECI group: Women n = 149 (63%)	n (%) - SCBD + ECI group: <high school="</td"><td>Total completed = 317 (68%) Attrition after 1 year = 106 (33%)</td></high>	Total completed = 317 (68%) Attrition after 1 year = 106 (33%)
	41.7(17.5). SCBD only	SCBD only group: Women	43 (18), High school or GED	Year $2 = 40$ from $211 (19\%)$
	group: Mean age =	n = 132 (58%)	= 41 (18), Some College = 70	African American completion = 40 (60%)
	39.7(17.8)		(30), College	After one year = $17 (42.5\%)$
	` '		degrees = 43 (18) Graduate =	Year $2 = 10$ out of $23 (43\%)$
			37 (16)	Overall 50% drop out in total sample over 24 month period.
			SCBD: <high school = 43 (19), High school or GED = 38 (17), Some College = 75 (32) College degrees = 49 (22), Graduate = 21 (9)</high 	

Table C1 continued

First author (Year)	Mean age (sd)	Gender	Educational levels	Dropout or attrition
Habib, (2015)	CBTp group = 33.5(10.5) Control group = 30.2(6.7),	CBTp gender males = 11 (44%) female 10 (58.8%) Control group Male = 14 (56%), female = 7 (41.2%)	CBTp group up to 9 years = 7 (46.7%), 10 or more years = 14 (51.9%) Control group up to 9 years = 8 (53.3%), 10 or more years = 13 (48.1%)	Not reported
Maura, (2018)	mean age (sd) = 43.5(10.02)	Patients were primarily male (75.2% male, 24.8% female)	Not reported	65% of patients and 58% of family members dropped out. No significant difference between groups on attrition between patients and family members.
Oluwoye, (2018)	23.61 (5.06)	Total sample Male = 293 (72%) Female = 111	Not reported	Not reported.
Rathod, (2013)	Total sample = 33.5 (11.60) CaCBT = 31.37 (12.43, TAU = 35.58 (10.72)	(28%) Total sample male = 20 (61%), female = 13 (39%), CaCBT male = 10 (63%), female = 6 (37%), TAU male = 10 (59%), female = 7 (41%)	Not reported	65% of patients and 58%. A of family members dropped out. No significant difference between groups on attrition between patients and family members. Six withdrew or missed post-treatment timepoint in both TAU and CaCBTp (18%). Two lost at follow up (6%). One participant died (3%).

3. Bridging Chapter

This chapter provides a summary of the systematic review and rationale for the empirical paper.

The systematic review explored the available literature related to the effectiveness of psychological interventions for people from ethnic minority groups who experience a severe mental illness (SMI). This indicated that culturally adapted interventions were the preferred choice of intervention when supporting people from ethnic minority backgrounds which led to improvements in symptom severity. The strength of these findings were reduced by a lack of a comparable control group intervention or control group in general. Attrition was also prevalent across the studies that reported this, however it was difficult to ascertain if this was a problem associated with ethnic minority group status or in general due to how the papers reported their data. There was also a lack of consistency related to how each paper reported attrition.

The systematic review explored one aim of the thesis portfolio; to explore the effectiveness of psychological interventions for ethnic minority groups who experience a severe mental illness. The other aim of this portfolio is to explore the accessibility of psychological interventions in this population. Previous research has reported on data related to ethnic minority group differences in the offer and uptake of psychological interventions (e.g. McKenzie et al., 2001; Oluwoye et al., 2018). The empirical paper aims to build on the previous literature by exploring whether ethnicity and sociodemographic factors influence the offer and uptake of psychological therapies using a large, ethnically diverse sample of service users who experienced first episode psychosis.

4. Empirical paper

Offer and uptake of psychological therapies in different ethnic groups: A report from the CRIS-FEP study.

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Keywords: first episode psychosis, psychological interventions, psychological therapies, ethnicity, offer, uptake,

4.1. Abstract

Aims: Ethnic minority groups are over-represented when viewing prevalence of first episode psychosis (FEP) and have poorer outcomes when referred to mental health services. This study explored whether ethnicity, sociodemographic and clinical characteristics influenced the offer and uptake of psychological therapies (PT) in sample of service users (SUs) who experienced FEP.

Methods: Data were collected from the Clinical Record Interactive Search-First Episode Psychosis (CRIS-FEP) study. Descriptive statistical tests were used to determine associations between sociodemographic, clinical and PT offer/uptake. Multivariable logistic regressions were used to estimate odds of PT offer by ethnic minority group, adjusting for confounders.

Results: Of a total 558 SUs, 193 (34.59%) were offered a PT; 182 (93.33%) accepted the offer. SUs were offered cognitive behavioural therapy (CBT; 84.10%) or group therapy (13.33%). No SUs were offered a family intervention. SUs from 'White Other' and 'Other' groups were less likely to be offered a PT compared to the White British reference group ('White other' OR = .48, CI .26 – .89, p = .04, 'Other' OR = .38, CI .17- .87, p = .02). SUs who accessed mental health services via early intervention (EI) services were more likely to be offered a PT compared to other pathways to care (x^2 (1, N = 556) = 16.06, p < .05).

Conclusions: Accessing EI services increased the likelihood of being offered a PT, whilst 'White Other' and 'Other' groups were less likely to be offered a PT. This is discussed in light of current interventions, strategies and directions of mental health services.

4.2. Current interventions for psychosis

Psychosis is a mental health condition where people experience the world differently to those around them in a way which causes distress, characterised by positive and negative symptoms (National Institute of clinical excellence [NICE], 2018). Early intervention services (EIS) were introduced in England to provide timely and evidenced based interventions to people who experience psychotic symptoms, reduce duration of untreated psychosis and prevent relapse (Neale & Kinnair, 2017; NICE, 2015). NICE guidelines suggest that psychological therapies such as cognitive behavioural therapy (CBT) and family interventions (FI) should be accessible for service users who present with psychotic symptomatology. Existing research has developed a wide evidence base to support the use of CBT for psychosis (CBTp; Lutgens, Gariepy & Malla, 2017; Wykes, Steel, Everitt & Tarrier, 2008; Heavens, Odgers & Hodgekins, 2019). A systematic review and meta-analysis conducted by Claxton, Onwumere and Fornells-Ambrojo (2017) found that from the 17 studies included for analysis, FI for psychosis improved service user function and reduced the likelihood of relapse by the end of treatment. Research has highlighted that such approaches may be cost effective (Aceituno, Vera, Prina, & McCrone, 2019).

4.3. Cultural adaptations

The Early Intervention in Psychosis Access and Waiting Time Standard suggested that specific considerations are made related to working in culturally sensitive methods to engage those who appear at higher risk of developing psychosis. A review using 55 studies by Radua and colleagues (2018) aimed to explore the strength of various risk factors associated with psychotic symptomatology. The strongest factors associated with psychotic disorder were presence of ultra-high risk symptomatology and Black Caribbean ethnicity in England, followed by ethnic minority groups living in low ethnically diverse areas, immigrant status and urbanicity. These findings support previous research that social

disadvantage increases the risk of psychosis (Stilo et al., 2017), along with immigrant status (Tarricone et al; 2017). The development of culturally adapted CBTp (Ca-CBTp) ties in with these findings, with studies demonstrating significantly improved outcomes compared to treatments as usual (Habib, Dawood, Kingdon & Naeem, 2015; Rathod et al., 2013). A systematic review conducted by Pathan, Teague, Oduola and Hodgekins (in prep) identified seven studies that implemented cultural adaptations towards a mixture of psychological interventions for severe mental illnesses. They found symptom severity reduced as a result of the interventions, however the quality of each study varied, with some studies lacking a control group to compare effects. Attrition was a problem across many studies, reflecting evidence to suggest ethnic minority groups are at risk of dropping out of mental health treatments (Maura & de Mamani, 2017; de Haan, Boon, de Jong & Vermeiren, 2018).

4.4. Uptake of psychological therapies by ethnicity

Statistics have demonstrated that the uptake of these interventions are lower in people from ethnic minority groups (Department of Health, 2005; 2007; MIND, 2013). The evidence suggests men of all ethnic minority groups were more reluctant to seek help for psychological distress compared to women (Liddon, Kingerlee & Barry, 2018). This is important as data from the Race Disparity Audit reported Black women were the most likely to have experienced a common mental disorder such as anxiety or depression in the last week, and Black men were the most likely to have experienced a psychotic disorder in the past year (McManus, Bebbington, Jenins & Brugha, 2016; Cabinet Office, 2017). However, White British adults were more likely to be receiving treatment for a psychological problem than adults in ethnic minority groups. Of those receiving psychological therapies, White adults reported better outcomes based on NHS and Public Health Outcome Frameworks than those in ethnic minority groups. Black adults were more likely than adults in other ethnic minority

groups to have been sectioned under the Mental Health Act (Oduola et al., 2019; Cabinet Office, 2017).

Das-Munshi and colleagues (2018) reported that each ethnic minority group in their sample were less likely to be offered CBTp compared to the White British reference group. However a study from Jolley and colleagues (2015) reported outcomes for service users who specifically received CBTp in a pilot Improving Access to Psychological Therapies Severe Mental Illness (IAPT-SMI) service and found that completion and dropout rates did not differ by ethnic minority status, along with no significant differences in outcome change by ethnic minority group. In a study conducted in the United States, Oluwoye and colleagues (2018) found that Black ethnic minority group service users with FEP were significantly less likely to receive individual therapy within the treatment as usual group. In the intervention group, service users in the Black ethnic minority group were less likely to receive family psychoeducation and more likely to receive medication management (OR = 2.93 CI 1.72 – 5.01). A further study found that of those diagnosed with schizophrenia in community services, there were significantly less Black/Black British and 'Other' ethnic minority groups accessing psychological therapies (Mercer, Evans, Turton & Beck, 2019). These studies demonstrate that there are differences in the offer and uptake of psychological therapies based on ethnicity, service setting and location. However there is a lack of further investigation regarding what factors may contribute to these differences.

Ethnicity appears to be a factor when considering access to psychological therapies in both common and severe mental disorders (e.g. Loewenthal, Mohamed, Mukhopadhyay, Ganesh & Thomas, 2012). Other factors associated with poorer engagement with mental health services include socio-economic and employment status (Batic-Mujanovic et al., 2017). With regards to psychosis, statistics have highlighted that in western countries ethnic minority groups appear to have a heightened likelihood of experiencing a combination of

these risk factors at once (Kirkbride, Jones, Ullrich & Coid, 2012). These demographic variables have also been reported as factors that may affect engagement with mental health services and engagement with psychotherapy (Memon et al., 2016; Wierzbicki & Pekarik, 1993; de Haan, Boon, Vermeiren, Hoeve & de Jong, 2015).

This study aims to build on existing studies by using data from the Clinical Record Interactive Search – First Episode Psychosis dataset (CRIS-FEP; Oduola & Craig, 2017; Oduola et al., 2019). This dataset contained clinical service data of individuals who presented to mental health services with FEP between 2010-2014. The following research questions were posed:

4.5.Primary research questions

- How many service users from ethnic minority groups were offered and accepted psychological therapies?
- What demographic factors, including ethnic minority group, affected the likelihood of being offered a psychological therapy?

4.6.Secondary research questions

- What types of psychological therapies were offered to ethnic minority groups?
- How many sessions of psychological therapy did service users attend?

4.7. Methods

4.7.1. Design

This study used the CRIS-FEP dataset at the South London and Maudsley NHS Foundation Trust (SLaM). The methods and sampling procedures have been published in an earlier study (Oduola et al., 2019). The sample in the dataset were followed up two years after their initial access to SLaM services between 2010 to 2012. Therefore the dataset contains data relating to service users who accessed community and inpatient SLaM mental

health services between 2010 and 2014. A retrospective incidence design was used to conduct this study. We used pre-existing data to determine if exposure factors such as ethnicity and other sociodemographic characteristics influenced the incidence of a condition, i.e. the offer and uptake of a psychological therapy.

4.7.2. Participants

Five hundred and fifty eight service users' case records were explored, in line with the original data present in the CRIS-FEP study (Oduola et al., 2019). Services users were screened by Oduola and colleagues (2019) for psychotic symptoms using the Screening Schedule for Psychosis (Jablensky et al., 1992) and assessed using the Operational Criteria Checklist for Psychotic Illness (McGuffin et al., 1991). Sociodemographic data were coded using the Medical Research Council Socio-demographic Schedule (MRC-SDS; Mallet, 1997).

Participants were included if they resided within the London boroughs of Lambeth or Southwark, aged 18-65 and presented to mental health services for psychosis for the first time. Service user data was excluded if there was evidence of an organic cause of psychosis, drug induced psychotic symptoms or if services users had previous support for psychotic symptoms. As the retrospective data were non-identifiable, anonymised and collected as part of routine clinical care, service users were not required to provide consent for their data to be explored for research purposes.

4.7.3 *Ethics*

Ethical approval for the CRIS case register to be used for secondary research analysis was approved by the Oxfordshire Research Ethics Committee (reference 08/H0606/71).

Permission was sought from the CRIS Oversight committee to collect additional data on the approved CRIS-FEP study (reference: 09-041).

4.7.4 Procedure and variables

4.7.4.1 Sociodemographic data

Within the CRIS-FEP study, data relating to participants' age, gender, ethnicity, living arrangements, relationship status, employment status, and pathway into care (either Early Intervention Service or other) were extracted using the Medical Research Council Socio-demographic Schedule (MRC-SDS; Mallet, 1997). Ethnic groups were categorised using the UK Office of National Statistics (ONS) 2011 Census ethnic categories (ONS, 2011). If ethnicity was not stated in clinical records, Oduola and colleagues (2019) explored CRIS free-text clinical records to explore country of origin, nationality, language spoken at home, parents country of birth and religious group to determine ethnicity, following guidelines from the ONS (ONS, 2011).

4.7.4.2. Psychological therapies data

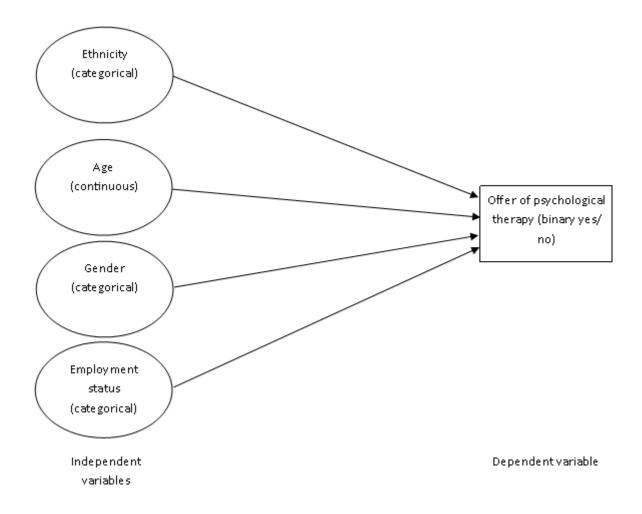
For this purpose of this paper, data on the offer and uptake of a psychological therapy were extracted from both the structured and free-text fields of the electronic health records, using an adapted version of the Life Chart Schedule for case notes (Harrison et al., 2001). Manual data extraction was required to explore the free-text data within each service user's case notes to determine whether the service users were offered and accepted a psychological therapy. Psychological therapy was defined using the event intervention identification category extracted from the CRIS-FEP dataset (e.g. 'formal psychotherapy') and additional clinical identification label ('CBT', 'group therapy'). Furthermore, case notes may have been written to record that a service user had declined the offer, or that appointments were cancelled or rearranged by staff or service users. Exploring the free text case notes allowed the research team to determine what type of psychological therapy was offered, whether the offer was accepted and how many appointments were attended.

Individual case notes were read to determine whether psychological therapy was offered or accepted, coded into a binary response in separate variables. If the offer was accepted, the amount of sessions was determined by exploring case records individually and then entered as a number in a separate variable. Inter-rater reliability was completed with another rater from the research team (SO) with ten percent of the data to oversee the quality of coding completed. The intraclass correlation coefficient related to number of sessions attended was .973 (95% CI = .828 - .982) p < .001, indicating a high level of reliability. There was a moderate agreement with coding the type of psychological therapies using two raters, with k = .613, p < .001. Discrepant or ambiguous cases were resolved by consensus with members of the research team.

4.7.5. Statistical Analysis

Data were analysed used STATA 15.1. Descriptive statistics were used to explore sample sociodemographic data and frequencies related to the offer and uptake of psychological therapies. Chi square tests were used to determine significant statistical differences in the offer of psychological therapies using the categorical demographic data as variables of interest. T-tests were used to explore whether there was a difference between those who were and were not offered psychological therapy by age. Unadjusted logistic regressions were used to assess associations between ethnicity and the offer of psychological therapies using the full dataset. Adjusted logistic regressions were used to determine if any the variables affected the odds of being offered a psychological therapy, controlling for confounders of age, gender, and employment status. Figure 1 provides a visual representation of the final regression model used.

Figure 1: Final regression model diagram



4.8. Results

4.8.1 Sample characteristics

In total, 558 first episode psychosis patients were identified. The mean age of the sample was 33.26 (SD = 10.68, range = 46) and 52% of the sample were male (n = 292). To improve sample size of smaller ethnic groups, White Irish service users were added to the 'White Other' group due to the small sample size (n = 6), whilst 'Arab' (n = 20) service users were combined into the 'Other' group. The sample demographic data is presented in table 1.

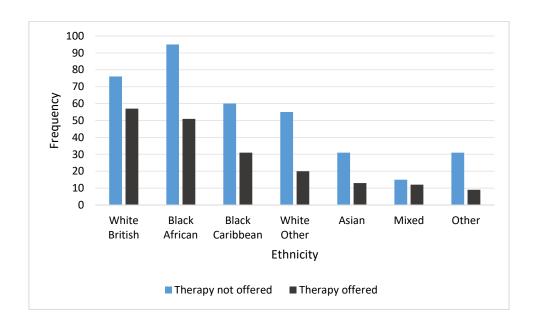
Table 1: Sample characteristics

	N	% of sample
Gender		1
Male	292	52.33
Female	266	47.67
Ethnicity		
White British	133	23.84
Black African	147	26.34
Black Caribbean	91	16.31
White other	75	13.44
Asian	44	7.89
Mixed	27	4.84
Other	41	7.35
Living arrangements (n=541)		
Alone, alone with children	262	48.43
With a partner, spouse, family or friends	279	51.57
Relationship status (<i>n</i> =532)		
Single, divorced, separated, widowed	405	76.13
Married, living with a partner, in a	127	23.87
steady relationship		
Employment status (<i>n</i> =505)		
Unemployed	315	62.38
Economically inactive/disabled	31	6.14
Student	60	11.88
Part-time employed	18	3.56
Full-time employed	65	12.87
Self-employed	16	3.17
Pathway to care (n=556)		
Other service	334	60.07
Early Intervention Service	222	39.93
Offered psychological therapy (n =		
558)		
No	363	65.05
Yes	193	34.59
Not recorded	2	.36
Type of therapy offered $(n = 195)$		
CBT	164	84.10
Group intervention	26	13.33
Not recorded	5	2.56
Accepted offer (n=195)		
Yes	183	93.33
No	3	1.54
Outcome not recorded	10	5.13

4.8.2. Number of service users offered and accepted a psychological therapy One hundred and ninety-three participants were offered a psychological therapy. A t-test found that there was no difference in age between those offered or not offered a psychological therapy (t = 1.39, df = 554, p = .16). The frequencies of who was offered and

accepted psychological therapy based by ethnicity within the sample is presented in Figure 2.

Figure 2: Frequency of sample offered a psychological therapy



4.8.3. Associations between sociodemographic factors and the offer of psychological therapies

There were significant differences in the offer of psychological therapies based on employment status (x^2 (5, N = 505) = 11.42, p < .05) and type of mental health service accessed (x^2 (1, N = 556) = 16.06, p < .05). Sixty four percent of patients who were not offered a psychological therapy were unemployed compared to 59% who were offered. Posthoc tests determined that there were significant differences in patients who were not offered a therapy and accessed a service other than an EIS (66.20%) compared to those who accessed an EIS (33.80%; z = 5.86, adjusted p < .001). There were also significant differences related to those who were not offered a psychological therapy based on the service accessed. More

service users were not offered a psychological therapy when they attended services other than an EIS (71.77%) compared to those who attended an EIS (28.23%; z = 7.27, adjusted p < .05). Tables 2 and 3 provide an account of the chi square tests.

Table 2: Associations between sociodemographic, clinical characteristics and offer of psychological therapies

Variable	Therapy not	Therapy offered	$x^2(df)$	p
	offered (%)	(%)		
Gender $(n = 558)$			0.51(1)	.47
Male	194 (53)	97 (50)		
Female	169 (47)	96 (50)		
Ethnicity $(n = 558)$			10.33(6)	.11
White British	76 (21)	57 (30)		
Black African	95 (26)	51 (26)		
Black Caribbean	60 (16)	31 (16)		
White Other	55 (15)	20 (10)		
Asian	31 (9)	13 (7)		
Mixed	15 (4)	12 (6)		
Other	31 (9)	9 (5)		
Living arrangement $(n = 539)$			0.04(1)	.85
Alone, alone with children	172 (49)	89 (48)		
Partner, spouse, family	181 (51)	97 (52)		
Relationship Status ($n = 530$)			0.18(1)	.67
Single, divorced, separated	261 (80)	143 (77)		
Married, living with	84 (20)	42 (23)		
Employment status (<i>n</i> =505)			11.42(5)	0.04*
Unemployed	212 (64)	103 (59)		
Economically inactive/disabled	17 (5)	12 (7)		
Student	34 (10)	26 (15)		
Part-time employed	14 (4)	4(2)		
Full-time employed	38 (12)	27 (16)		
Self-employed	15 (5)	1 (1)		
Pathway $(n=554)$		• •	16.06(1)	.000**
Other service	239 (66)	94 (49)	` '	
Via EIS	122 (34)	99 (51)		

^{* = &}lt; .05 significance level, ** < .005 significance level

4.8.4. Type of psychological therapies offered

Service users were offered either cognitive behavioural therapy (CBT) or family intervention (FI). A chi-square test indicated that the type of therapy offered to service users varied by the type of service accessed. Service users who were seen by services other than EIS were significantly more likely to be offered a group therapy (N = 190, x^2 (1) = 7.33, p= <.01).

4.8.5. Number of sessions of psychological therapy

Exploring median values of attendance based on the type of therapy offered found that service users attended more sessions of CBT (median= 4, range = 48) than a group therapy (median = 1.5, range = 9).

4.8.6. Factors that affect the likelihood of being offered a psychological therapy

Logistic regressions were modelled with the offer of psychological therapies set as the outcome variable and sociodemographic data set as factor variables. Three models were created to explore the sample data in various combinations to account for incomplete data and to compare adjusted vs unadjusted odds ratios when controlling for factor variables. Due to the evidence presented earlier related to the uptake of therapy based on demographic factors such as gender, age and ethnicity these were initially included in the preliminary analyses. This was possible as there was complete data on these factors for the entire sample. Following this, the other variables were added into the model at the cost of reducing the sample size to 505. All models used the binary outcome related to whether a service user was offered a psychological therapy. Table 5 provides an account of the models. The first model contained the full sample size and estimated the odds ratios of associations between ethnicity and offer of psychological therapy. The results showed service users from the 'White Other' ethnic minority group (OR = .52 CI .28 - .95, p = .04) were less likely to not be offered a psychological therapy compared with White British ethnic majority group.

When adjusted for age and gender, the 'White other' and 'Other' service users were less likely to be offered a psychological therapy compared with White British service users ('White other' group OR = .44, CI . 23 - .84, p = .01, 'Other' group OR = .41, CI . 17- .99, p = .04). The final model was adjusted for age, gender and employment status. The final model showed similar findings to the previous models, with 'White other' and 'Other' service users

less likely to receive a psychological therapy compared to white British service users ('White other' group OR = .45, CI.23 - .86, p = .02, 'Other' group OR = .39, CI.16 - .96, p = .04).

Table 3: Unadjusted and adjusted odds ratios of associations between ethnicity and offer of psychological therapy

Variable	Model 1 (n =	Model 2 (n =	Model 3 (n =
	505)	505)	505)
Ethnicity			•
Black African	.72 (.43-1.20)	.71 (.43-1.14)	.71 (.42-1.20)
Black Caribbean	.64 (.37-1.15)	.63 (.35-1.13)	.63 (.35-1.14)
White other	.43 (.2382)*	.44 (.2384)*	.45 (.2386)*
Asian	.51 (.23-1.12)	.50 (.23-1.10)	.52 (.241.17)
Mixed	1.04 (.45-2.11)	1.01(.43-2.34)	1.00 (.43-2.37)
Other	.40 (.1796)	.41 (.1799)*	.39 (.1696)*
Age		.99 (.971.01)	.99 (.97-1.01)
Gender (female)		1.1 (.80-1.72)	1.11 (.75-1.64)
Employment status			
Economically Inactive			1.76 (.81-3.81)
Student			1.37 (.81-3.81)
Part-time employed			.51 (.16-1.61)
Full-time employed			1.40 (.80-2.45)
Self-employed			.15 (02-1.15)

^{* = &}lt; .05 significance level

CI confidence interval

Model 1 unadjusted

Model 2 adjusted for age and gender

Model 3 adjusted for age, gender and employment status

4.9. Discussion

4.9.1. Main findings

This study found that 35% of the sample were offered a psychological therapy, and psychological therapies were significantly more likely to be offered if a patient accessed Early Intervention Services (EIS). We also found that 'White Other' and 'Other' ethnic minority group service users in this sample were significantly less likely to be offered a psychological therapy when adjusting for age, gender, ethnicity and employment. The main therapy on offer was CBT, with small percentage being offered a group psychological

intervention. Other types of psychological therapies were not identified in the CRIS-FEP dataset. Age was not identified as significant predictor of being offered a psychological therapy across the whole sample. This finding matches NICE guidelines which recommend that CBT or family intervention (FI) should be offered to people who experience FEP. However this also causes concerns related to those who have accessed services outside of EIS', as NICE guidelines and the literature suggests that psychological interventions for psychosis can be efficacious in other service settings (Bach, Guadino, Hayes & Herbert 2013; Jolley et al., 2015). The lower rates of psychological therapies being offered outside of EIS may be due to service settings. For example if a person experiencing FEP is sectioned under the Mental Health Act in an inpatient setting, it may be deemed inappropriate to offer a talking therapy in the short term.

Curiously, the CRIS-FEP dataset identified that no service users were offered a FI, despite NICE guidelines and research demonstrating the benefits of FI in FEP populations (Claxton et al., 2017). The National Clinical Audit for Psychosis 2018/2019 reported that across 57 service providers in England, 22% (2049 out of 9527 service users) received one or more sessions of FI, with a range of 1 – 60% in NHS Trusts (Royal College of Psychiatrists [RCP], 2019). The findings in this study could have been confounded by the methods used to extract data from CRIS. Other mental health professionals besides Clinical Psychologists or CBT therapists may have delivered the FI. Therefore, case records relating to this may be under different categories or care events in the CRIS-FEP system. It is important that an accurate representation of the work mental health professionals are conducting in service are correctly recorded to be recognised and to determine the access to psychological therapies for service users. Improved details related to this would also inform analyses related to the cost-effectiveness of psychological therapies. This study identified records of psychological groups being facilitated to service users, reflecting evidence that these interventions can be

successful with people who experience FEP and that group interventions may be better received for male service users (Liddon et al., 2018).

4.9.2. Comparison of findings with previous studies

This study identified that the 'White Other' and 'Other' ethnic minority groups were less likely to be offered a psychological therapy compared to the White British reference group, which differ from earlier research (Das-Munshi et al. 2018; McKenzie et al., 2001). This may be due to differences in sample characteristics, in terms of the origin of where the samples were selected and how researchers categorised ethnic groups. For example, the present study separated between 'White British' from 'White Other' and 'Black African' and 'Black Caribbean', which allowed differences between these ethnic groups to be explored. This study did not find that individuals with Black African and Caribbean ethnic minority groups were less likely to be offered a psychological therapy, which contrasts previous findings (Oluwoye et al., 2018; Mercer et al., 2019). We focussed on the offer and uptake for service users with FEP, whereas Mercer and colleagues (2019) explored a range of schizophrenia diagnoses and did not include IAPT-SMI or inpatient service data. However we also found that service users from the 'White Other' and 'Other' ethnic minority groups were less likely to be offered a psychological therapy, matching findings from Mercer and colleagues (2019). A potential explanation for this finding could relate to the demographics of the sample location. Ethnic minority groups such as Black African or Black Caribbean are identified as ethnic minorities nationally, but were an ethnic majority group within the SLaM locality (ONS, 2011). These findings may represent the progress to improve access to psychological therapies for nationally identified ethnic minority groups, but may come at the cost of potentially missing the needs of smaller minority groups in this specific locality.

4.9.3. Methodological considerations – strengths and limitations

A weakness of the CRIS-FEP dataset is that no reasons are provided as to why a psychological therapy was not offered to the 362 service users identified as not offered a therapy. Future research could investigate this further, in terms of exploring professionals' understanding of the psychological interventions available for service users who experience FEP. Future clinical practice may benefit from explicitly recording why a psychological therapy was not offered if a clinical decision was made on the service user's behalf, or alternatively to record that a therapy was offered and declined by the service user. There is a possibility that this information was recorded in a manner which made it difficult to extract from CRIS. For example, if the case note was not recorded under an event or category label that is associated with psychological interventions (e.g. psychiatry, mental health nursing categories, general uncategorised case note). Indeed there were instances of general case notes documenting cancellations of appointments and email correspondences under 'formal psychotherapy' or 'CBT' categories. This justified the need for manual interpretation of each case note to determine the offer and uptake of therapies, along with number of sessions attended.

A strength of this study relates to the diversity of its sample and its sample size. The London boroughs served by the SLaM NHS Trust contains 45% of people who identify as an ethnic minority as reported by the 2011 Census, (ONS, 2011). The sample in this study had a similar amount of ethnic minorities included. This strengthens the study's findings, however they are limited to the SLaM catchment area.

4.9.4. Implications of findings

Thirty nine percent of service users who experienced FEP attended an EIS and 44.80% within this group were offered a psychological therapy. Only three service users were recorded to decline the offer. This demonstrated the service user's willingness to accept the

offer. The median and range values related to attendance indicated that whilst suggested length of therapy was lower than NICE guidance, service users were able to receive an intervention that has robust evidence for reducing symptom severity (Lutgens et al., 2017; Heavens et al., 2019). Future studies could explore the relationship between attendance rates of psychological therapy appointments and the sociodemographic data collected in the CRIS-FEP dataset to explore potential factors towards therapy attrition.

Dropout from psychological therapies and mental health service engagement is a concern (Maura & de Mamani, 2017). Evidence suggests that people from ethnic minority groups who experience psychosis may respond better to culturally adapted psychological therapies (Rathod et al., 2013; Habib et al., 2015). Considering the diverse ethnic groups within the SLaM service area, future research could explore the application and availability of these interventions in this and other ethnically diverse regions. Future studies may also benefit from exploring the differences and factors associated with attendance with CaCBTp compared to traditional CBT.

Another consideration relates to the timeframe of the dataset used. Post 2014 saw the implementation of the Early Intervention in Psychosis Access and Waiting Time Standards (NICE, 2016) and Standards for Early Intervention in Psychosis Services (RCP, 2018). This made clear criteria stating that psychological therapies should be offered to people who have FEP in EI teams. However, these guidelines specifically relate to EIS's and as a result may not be followed as stringently in other settings. The Access and Waiting Time Standards has also widened access to EIS's by extending inclusion criteria to people aged 14-65, and allowances may be made to accept people outside of this age range based on clinical judgement (NHS England, 2016). Therefore the demographics and statistics related to the availability, offer and uptake of psychological therapies may have changed over time. Recent data from the National Clinical Audit of Psychosis reported that from their sample of 9527

service users, 4416 (46%) accepted the offer of a psychological therapy and received one or more sessions of CBTp (RCP, 2019). The present study identified that 93% of the CRIS-FEP cohort accepted the offer of either a group intervention or CBTp. However these findings should be treated with caution, as low attendance may not equate to receiving a full dose of the intervention.

Future research may benefit from exploring what factors differentiate the 'White Other' from 'White British' majority. The 'White Other' the category was devised as a means to include people who did not fit the 'White British' group, such as people from Europe (ONS, 2011) This study included White Irish participants into the White Other group, however their sample size was small but may have impacted the findings. This suggests that risk factors known for other ethnic minority groups may be evident in these groups. Future research may benefit from exploring what factors within these specific ethnic minority groups effect their access to psychological therapies.

4.10. Conclusions

Previous studies have reported the offer and uptake of psychological therapies to individuals who experience FEP (e.g. Das-Munshi et al., 2018; Jolley et al. 2015). This paper attempted build on previous research by investigating potential factors that influenced the offer and uptake using sociodemographic data in an ethnically diverse sample. Future research may benefit from exploring this question in other diverse populations to determine if the findings are consistent. Considering the impact of psychosis on individuals and society, there is a further need to explore outcomes of psychological therapies, but also to monitor its availability. If people who are suitable for psychological therapies are not being offered these potentially beneficial interventions, it places additional burden on NHS services and may prevent a service user from an intervention which may decrease symptom severity, hospital admissions and relapse (Bird et al., 2010). Whilst access to EI teams appear to show

increased offer of psychological therapies compared to other services, the number of people being offered could be higher, in line with NICE guidelines and national standards.

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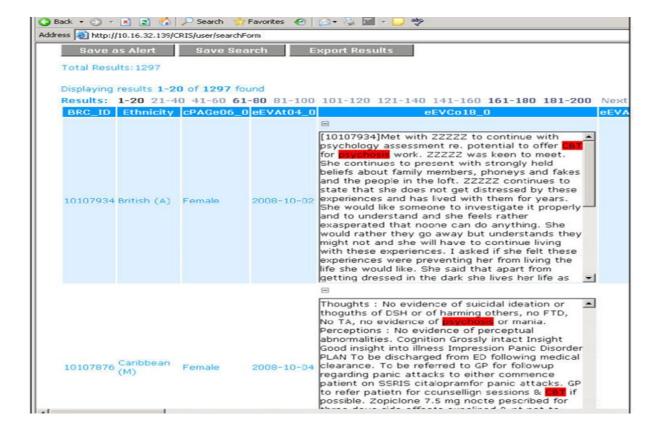
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5. Additional Methodology

5.1. Utilising the Clinical Record Interactive Search (CRIS) database

In order to achieve a large sample size to conduct meaningful statistical analysis, anonymised clinical records were accessed using the Case Record Interactive Search (CRIS) system, developed by the South London and Maudsley Biomedical Research Council (SLaM BRC). Previous studies have adopted a similar methodology (e.g. Patel et al., 2017; Odula & Craig., 2017; Oduola et al., 2019). The CRIS system extracted information from service users' case records who received support from SLaM, a specialist mental health trust in London which covers in four London Boroughs. It estimated that 20,000 new cases are added each year (Stewart et al., 2009; Perera et al., 2016). CRIS allows service user notes from SLaM care records to be viewed in an anonymised and ethical manner. The development of the CRIS case register has allowed researchers to explore routine clinical case notes in order to provide epidemiological research on mental health problems. Previous research has utilised CRIS to identify cases of first episode psychosis (FEP) successfully using machine learning programming to explore free-text anonymised clinical case notes (Gorrell et al., 2016; Jackson et al., 2017). A screenshot of the CRIS system is provided in figure 1.

Figure 1: Screenshot of CRIS system



It was possible to explore the CRIS dataset manually, using the search function developed by Gorrell and colleagues (2016) using key terms such as "CBT", "CBTp", "cognitive behavioural therapy" "psychology", "therapy", "family intervention", "family work", "offered", "accepted", "declined". The breadth of terms is required due to the non-standardised form of recording used in routine clinical practice by healthcare professionals; this method is designed to reduce the likelihood of relevant cases being missed. Oduola and colleagues (2019) used this searching method to identify 558 service users who experienced FEP between the dates of May 2010 and April 2012. This sample, named the 'CRIS-FEP' dataset was used in the empirical paper to answer our research questions. Service users' data were included in the CRIS-FEP dataset if they lived in the London boroughs of Southwark or Lambeth, aged between 19-64 years old and experienced psychotic symptoms as determined by free text case notes. Oduola and colleagues (2019) screened and assessed for psychotic symptoms and FEP using the Screening Schedule for Psychosis (SSP; Jablensky et al., 1992a) and Operational Criteria Checklist for Psychotic Illness (OPCRIT; McGuffin et al.,

1991). The SSP is a checklist that includes items related to demographics, service user history, symptoms and behaviours which served as a method for professionals to assess eligibility for further assessment (Jablenski et al., 1991). The OPCRIT is a checklist of symptoms that health professionals can use to determine a diagnosis of psychosis and associated disorders from clinical records. Reliability of the checklist was reported with Cohen's k ranging from .57 to .87 between comparisons using three raters, indicating fair or better agreement (McGuffin et al., 1991). Cases were excluded from the CRIS-FEP dataset if the psychotic symptomology reported were organic in origin, induced by drugs or if the service user had previous contact with mental health services for similar symptoms. When present, ethnicity was obtained from self-report data that had been stored in CRIS. When this was not available Oduola and colleagues (2019) explored free text data to determine service user ethnicity searching for information such as country of birth, nationality, language spoke at home and parents country of birth. Reliability of coding ethnicity demonstrated substantial agreement (Cohens k = .87, p < .001; Oduola et al., 2019).

In the empirical paper conducted, individual case notes were read from the CRIS-FEP dataset to determine whether psychological therapy was offered or accepted, coded into a binary 'yes' or 'no' response in separate variables. If service users in the sample accepted the offer of therapy, the amount of sessions they attended were also recorded by exploring case records and then entered as a number in a separate variable. A list of variables collected from the CRIS-FEP data are presented in table 1.

Table 1 Variables collected from CRIS-FEP dataset

Variable name	Level of measurement	Coding via free text case	
		notes required?	
Age	Continuous	No	

Gender	Categorical	No
Ethnicity	Categorical	No
Living arrangements	Categorical	No
Relationship status	Categorical	No
Employment status	Categorical	No
Pathway (EIS or other)	Categorical	No
Psychological therapy	Binary	Yes
offered		
Was the offer accepted?	Binary	Yes
Type of psychological	Categorical	Yes
therapy offered		
Number of psychological	Continuous	Yes
therapy sessions attended		

5.2. Coding CRIS-FEP data

An adapted version of the life chart schedule (LCS; World Health Organisation, 1992) was used to code the free text notes. The LCS was constructed to assess the long term course of psychosis and a study assessing its reliability found favourable results, with an intraclass correlation and kappa ratings ranging from fair to excellent (Susser et al., 2000). The LCS was adapted in this study to determine whether psychological therapy was offered, accepted and how many sessions were attended. Binary coding was used for the first two questions ('0' = no, '1' = yes, '-77' = not recorded) and the number of sessions attended was given a numerical value. Coding was explored into a STATA file which also contained the extracted CRIS-FEP demographic data to be used for analysis.

5.3. Ethics

Data from the CRIS-FEP study was extracted from routine electronic clinical records from the SLaM NHS mental health services and automatically anonymised with no patient identifiable information. The data was collected with approval from the CRIS Oversight Committee and adheres to the Code of Human Research Ethics set out by the British Psychological Society (BPS; BPS 2014). The CRIS Oversight Committee is chaired by a service user and designed to review all research applications to determine if they meet legal and ethical standards. Service users are informed of the CRIS database and are allowed to opt-out to avoid potential distress and deception, thus reducing the risk of harm and allowing a right to withdraw. The development of the CRIS dataset prevents disruption to clinical services through its ability to extract information automatically and reduces the need for researchers to recruit participants individually. The anonymous CRIS-FEP dataset was accessed remotely within the SLaM firewall, using a secure virtual private network. No data are permitted to be exported outside the SLaM virtual desktop, and data use is tracked by the CRIS Oversight Committee.

5.4.References

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6. Extended Results

6.1. Additional exploration of study variables and ethnicity

Chi square tests were conducted to explore differences in sociodemographic variables and ethnicities. There were significant differences between patient ethnicity and gender, with the proportions between male and females in Black Caribbean and Asian ethnic minority groups contributing the most towards the chi square distribution frequencies. There were differences between the type of therapy offered and ethnicity. Service users from Black African minority groups were more likely to be offered a group intervention compared to the other ethnic groups. Table 1 provides an account of the chi square tests carried out.

Additional exploration of variables that influenced whether a service user was seen by EIS or other services were conducted, as reported in table 2. These analyses showed that there were significant differences in presenting to EIS or other services based on ethnicity, gender, living arrangements and employment status.

Table 1: Associations between ethnicity and study variables

Variable	Frequency (%)								
	White British	Black African	Black Caribbean	White Other	Asian	Mixed	Other	$x^2(df)$	p
Gender (<i>n</i> =558)								14.13(6)	.03*
Male	68 (23)	79 (27)	39 (13)	41 (14)	19 (7)	15 (5)	31 (11)		
Female	65 (24)	68 (26)	52 (20)	34 (13)	25 (9)	12 (5)	10(3)		
Living arrangements								1.41(6)	.10
Alone, alone with children	59 (23)	73 (28)	45 (17)	36 (14)	19 (7)	12 (5)	18 (7)		
Partner, spouse, family	69 (25)	71 (25)	43 (15)	37 (13)	25 (9)	14 (5)	20 (8)		
Relationship status								3.70(6)	.72
Single, divorced, separated	95 (25)	109(27)	67(17)	54 (13)	28 (7)	22 (5)	30 (7)		
Married, living with	32 (25)	32 (25)	19 (15)	20 (16)	13 (10)	4(3)	7 (6)		
spouse, partner									
Employment status								35.91(30)	.21
Unemployed	72 (23)	75 (24)	62 (20)	43 (14)	24 (8)	15 (5)	24 (8)		
Economically	6 (19)	9 (29)	4 (13)	4 (13)	0 (0)	3 (10)	5 (16)		
inactive/disabled									
Student	15 (25)	19 (32)	8 (13)	5 (8)	8 (13)	3 (5)	2 (3)		
Part-time employed	5 (28)	7 (39)	2 (11)	3 (17)	0 (0)	1 (6)	0(0)		
Full-time employed	21 (32)	15 (23)	6 (9)	13 (20)	4 (6)	4 (6)	2 (3)		
Self-employed	3 (19)	4 (25)	0 (0)	4 (25)	3 (19)	1 (6)	1 (6)		
Pathway								8.89(6)	0.18*
Not EIS	78 (23)	77 (23)	55 (16)	51 (15)	29 (9)	15 (4)	28 (9)		
EIS	55 (25)	70 (32)	35 (16)	24 (11)	14 (6)	12 (5)	12 (5)		
Therapy offered								9.65(6)	.14
No	76 (21)	95 (26)	60 (17)	54 (15)	31 (9)	15 (4)	31 (9)		
Yes	57 (29)	51 (26)	31 (16)	21 (11)	13 (7)	12 (6)	9 (5)		
Type Offered	, ,	,	. ,	. ,	• •	` '	` '	13.56(6)	.04*
CBT	54 (33)	36 (22)	26 (16)	19 (12)	10 (6)	12 (7)	8 (5)	. ,	
Group Therapy	3 (12)	13 (50)	4 (15)	2(8)	3 (12)	0 (0)	1 (4)		

^{* = &}lt;.05 significance level.

Table 2: Differences in characteristics of accessing early intervention or other services

Variable	Accessed other mental health	Accessed	$x^2(df)$	p	
	service (%)	EIS (%)			
Gender (n= 556)			13.52(1)	.00**	
Male	153 (53)	137 (47)			
Female	181 (68)	85 (32)			
Ethnicity (n=554)			8.89(6)	.018*	
White British	78 (59)	55 (41)			
Black African	77 (53)	70 (48)			
Black Caribbean	55 (61)	35 (39)			
White Other	51 (68)	24 (32)			
Asian	29 (67)	14 (33)			
Mixed	15 (56)	12 (44)			
Other	28 (71)	12 (29)			
Living arrangements			23.07(1)	.00**	
(n=538)					
Alone, alone with	183 (70)	78 (30)			
children					
Partner, spouse, family	139 (50)	140 (50)			
Relationship Status (n			1.31(1)	.25	
= 528)					
Single, divorced,	234 (58)	169 (42)			
separated					
Married, living with	81 (64)	46 (36)			
Employment status (n=			44.30(5)	.00**	
502)					
Unemployed	199 (63)	115 (37)			
Economically	25 (81)	5 (19)			
inactive/disabled					
Student	15 (25)	45 (75)			
Part-time employed	9 (50)	9 (50)			
Full-time employed	36 (55)	29 (45)			
Self-employed	14 (88)	2 (12)			

^{* = &}lt; .05 significance level, ** < .005 significance level

7. General discussion and critical review

This chapter reflects on the findings from both the systematic review and empirical paper. It will consider how they both contribute to research exploring disparities in the access, offer and uptake of psychological therapies for ethnic minority groups who experience a severe mental illnesses (SMI). This chapter will consider how these papers may influence clinical practice and research. Strengths and weaknesses of the studies are discussed with reflections on the overall research process.

7.1. Summary

This portfolio aimed to explore access, uptake and outcomes for people in ethnic minority groups who experience a severe mental illness (SMI). To this end, we conducted a systematic review that explored the effectiveness of psychological interventions when delivered to ethnic minority groups who experience a SMI. The empirical paper used clinical service data to explore whether sociodemographic factors impacted the offer and uptake of psychological therapies in large, ethnically diverse sample.

The systematic review identified nine papers that met the eligibility criteria. Of these nine papers, seven reported a statistically significant reduction in symptom severity as a result of receiving a psychological intervention. One paper found that both the treatment and control group were effective at reducing symptom severity with no significant differences (Fagiolini et al., 2009), and another reported that whilst symptom severity lowered over time, it was not statistically significant (Bae, Brekke & Bola, 2004). Despite the majority of papers receiving acceptable or better quality ratings, there were issues related to an absence of a control group or a lack of comparable control group, diminishing the strength of reported findings. The review also found that seven of the nine papers made cultural adaptations to psychological interventions, with improvements in symptom severity reported. However four

of these studies did not use a comparable control group intervention to compare differences in effectiveness. Attrition was reported in six out of nine studies and ranged in rates.

The empirical paper used anonymised clinical records from a south London National Health Service (NHS) Foundation Trust to explore whether sociodemographic factors influenced the offer and uptake of psychological therapies in a diverse cohort of 558 service uses who experienced First Episode Psychosis (FEP). The results indicated that 193 (34.59%) were recorded as being offered a therapy and 182 (93.33%) accepted the offer. Logistic regressions found that service users from 'White Other' and 'Other' ethnic minority groups were less likely than the White British reference group to be offered a psychological therapy ('White other' OR = .48, CI . 26 - .89, p = .04, 'Other' OR = .38, CI . 17 - .87, p = .02).

7.2. Systematic Review Critical Review

7.2.1. Considerations related to attrition in research

A lack of consistency related to reporting attrition was found in our systematic review that impacted our ability to detect differences in attrition by ethnic groups. Five papers reported attrition data, however only one paper explored whether ethnic minority group status impacted the number of sessions attended (Brown & de Mamani, 2018). This raises the question of whether ethnicity is a factor in attrition in clinical trials and practice. A study exploring drop out in a service for paediatric bipolar disorder reported that ethnicity did not predict attrition in service use (Isaia, Weinstein, Shankman & West, 2018). A systematic review identified that service user-therapist ethnic match was not a significant predictor of reducing drop out from psychological therapy (Maramba & Nagayama Hall, 2002). Research has highlighted potential factors that influence disengagement from psychological therapies such as negative beliefs (Holding, Gregg & Haddock, 2016) and stigma associated with

engaging in psychological therapy (Holding, Haddock & Gregg, 2019). A study completed by Richardson and colleagues (2019) reported that in their sample of service users who accessed CBTp, factors such as young age, low mood, and alcohol or substance misuse were significantly associated with drop out. It would be important to monitor external factors that may impact a person's ability to engage with psychological therapies.

With regards to how studies report attrition, a systematic review which explored disengagement with FEP service users reported that of the 18 studies included in the review, only four used a measure to predict disengagement (Reynolds, Kim, Brown, Tindall, & O'Donoghue, 2019). As a result the authors argued that a comparable outcome measure and definition of dropout is required in order to better understand what factors contribute towards this phenomenon. This was also observed in our systematic review, which highlights the need for consensus related on how best to report attrition.

7.2.2. A focus on ethnic minority group status or cultural factors?

A reflection on completing the systematic review relates to the application and focus of ethnic minority groups in the literature. Bhopal (1998) proposed that there was a lack of agreement within the international research community related to defining ethnic groups, which was apparent in the ethnic categories used across studies in the systematic review. Across various studies there appeared to be no consensus on how best to identify service users based on ethnic group. For example studies in America used the terms 'African American' (e.g. Maura & de Mamani, 2018) or 'non-Hispanic black' (Oluwoye et al., 2018) based on the author. Conflation between race and ethnicity was observed in some studies (e.g. Maura & de Mamani, Bae, Brekke & Bola, 2004). This makes comparison between studies problematic when comparing findings between ethnic minority groups. Separating

service users or participants using race has been discouraged due to lack of evidence supporting racial categorisation (Wagner et al., 2017) and prejudiced associations made using these categories in the past (Hardeman, Medina & Kozhimannil, 2016). Indeed current research has reported that biases exist in the diagnosis of psychosis spectrum disorders based on ethnic minority group (Schwartz & Blankenship, 2014; Schwartz, Docherty, Najolia & Cohen, 2019). Nazroo, Bhui and Rhodes (2019) acknowledge that whilst the literature highlights that people from Black African and Black Caribbean ethnic minority groups appeared to show an increased risk of psychosis, they argue that this stems from social and economic inequalities.

Considering the fluidity and changeable nature of ethnic groupings (Bhopal, 2004), the focus on cultural interventions found in seven out of the nine papers in the systematic review appear to offer a better direction on how best to engage, retain and change outcomes for ethnic minority groups who experience a SMI. Focussing on a person's unique background, circumstances and experiences have been recommended as a pathway to develop individually tailored formulations and interventions for people from ethnic minority groups (Rathod et al., 2015).

Future studies may benefit from following the 'Triple A' framework and developed by Rathod and colleagues (2019). Whilst these are not compulsory to adhere to, the guidelines provide a detailed framework regarding how to develop culturally adapted CBT and would allow comparisons between study findings based on a similar framework utilised. Additional research is required to explore the efficacy of the framework itself and to explore the impact the adaptations have on outcomes and engagements with ethnic minority groups.

7.3. Empirical paper critical review

Whilst previous research has reported the odds of being offered a psychological therapy compared to an ethnic majority group (e.g. Mckenzie et al. 2001), this paper attempted to develop the evidence by exploring whether certain sociodemographic variables influenced the offer and uptake of psychological therapies. We found that 'White Other' and 'Other' ethnic minority groups were less likely to be offered a psychological therapy compared to the 'White British' reference group. This contrasts the findings of previous research where most findings reported differences between a White majority reference group and ethnic Black groups (Das-Munshi et al., 2018, McKenzie et al., 2001). The differences found in the empirical paper may relate to the large number of ethnic minority groups in the CRIS-FEP sample, or improved efforts by services and clinicians to reduce these disparities previously reported. These findings also suggest that the definition of ethnic minority groups may vary between regions based on the population in that area.

The findings from the empirical paper diverge from previous research, in relation to which ethnic minority groups were less likely to be offered a psychological therapy. A possible factor for this finding relates to the locality where the data was collected. As highlighted in the empirical paper, 45% of people who live within the SLaM catchment identify as an ethnic minority group according to the 2011 Census. As a result, this raises the notion that within certain localities, traditionally labelled ethnic minority groups may in fact be an ethnic majority. This may also effect the service delivery of mental health services. According to the SLaM 2020 Equality and Diversity report, 44.5% of their staff identified as an ethnic group other than White British. The match between service user and provider ethnicity may help to reduce disparities for ethnic minority groups accessing mental health care for severe mental illnesses. The findings may provide strength for arguments calling for diverse staffing arrangements based on locality demographics.

The empirical paper found that the number of service users who were offered a psychological therapy were low, at around 35%. However to put this into context, the 2018/2019 National Clinical Audit of Psychosis (NCAP) reported that in 2017, 37% of people seen in early intervention (EI) services received one or more sessions of CBTp, with the figure rising to 46% in the 2018/2019 audit (Royal College of Psychiatrists, 2019). With the addition of the new Access and Waiting Times standards (NICE, 2016), there is a need to continue to monitor the offer and uptake of psychological therapies in mental health services, along with service user experience and outcomes as EI services continue to increase in terms of who is eligible to access these services. The NCAP reported that a limitation of its own audit was that it excluded people who experienced FEP who were being seen from other services. As a result there is still a need to monitor the offer of psychological therapies outside of EI services, as previous research has highlighted that barriers such as lack of integration of services, unclear referral pathways and knowledge of CBTp may influence how widely the intervention may be offered (Switzer, Harper, Peck, 2019).

The empirical study identified that no service users were offered a family intervention, an intervention recommended for the treatment of psychotic symptoms (NICE, 2014b). Concerns related to the implementation of family intervention have been reported in other western countries (Bucci, Berry, Barrowclough & Haddock, 2016). The NCAP reported that 22% of patients received one or more sessions of family intervention in EI services (Royal College of Psychiatrists, 2019). Eassom, Giacco Dirik and Priebe (2014) conducted a systematic review related to problems, barriers and facilitating factors that contribute towards family involvement of service users with psychosis. From exploring 42 studies, they found that barriers to working with families may come in the form of organisational (e.g. workload, lack of out of hours work allowances), personal (lack of training or specific supervision) and

systemic factors (workplace beliefs around family work, lack of shared team commitment). Research has highlighted the benefits of using family interventions with service users who experience psychosis and their families (Claxton, Onwumere & Fornells-Ambrojo, 2017). As a result it is crucial for services to monitor the offer of this intervention, considering its ability to incorporate and value cultural specific elements within the intervention which may improve quality of life and outcomes for patients and their families (Edge & Grey, 2018).

7.3.1. Considerations for supporting ethnic minority groups to access psychological interventions

Findings from the empirical paper indicate that service users from some ethnic minority groups were less likely to be offered a psychological therapy compared to a White British ethnic majority group. Help-seeking behaviours have been researched within the context of receiving mental health support, and studies have noted that stigma may affect a person's ability to seek and maintain engagement with interventions (Thornicroft, 2008). Stigma has been investigated as a potential factor that may affect help seeking behaviour when an individual experiences and SMI. Link and Phelan (2001) provide a socio-cultural perspective of stigma, describing it as a process where difference from others is acknowledged to be important. For example, the label of mental illness could act as a means to identify someone as being different. The identification of difference is then used to group people based on undesirable characteristics, leading to negative stereotypes or beliefs about the group, which are then used to emphasise the difference between this group from the majority, leading to an 'us and them' boundary. This leads to a devaluation of stigmatised groups, where they are disadvantaged in many areas of their life, such as income, housing, healthcare access; effecting them on an individual or structural level (Link & Phelan, 2001). This definition provides a critical perspective on stigma, suggesting that stigma is attributed

by those in groups of social and economic power upon individuals who have been positioned into a label of 'the other' by the majority. This highlights the impact contextual external factors can have on an individual's sense of self-perception of discrimination from others (Thornicroft, 2008). This also mirrors research that has highlighted that ethnic minority groups are at risk of developing psychosis experience a combination of social adversities (Kirkbride, Jones, Ullrich & Coid, 2012).

A narrative review highlighted that societal stigma can create a sense of internal anticipated stigma which would influence help seeking behaviour, but also acknowledged that individual knowledge about SMI may be just as important (Schomerus & Angermeyer, 2008). Low perceived need and attitudes towards SMI have been reported to be a significant factor in the process of deciding whether to initiate, continue and drop out of interventions available in the United States (Mojtabai et al., 2011).

Intersectionality and its effect on stigma is not well researched yet however researchers are attempting to understand this relationship further. Intersectionality refers to the complex interaction between a person's different identities (e.g. race, gender, physical ability, socio-economic status) which impacts upon one's experience of life. Cole (2009) argued that an intersectional approach can be adopted when conducting psychological research in order to gain a better understanding of marginalised people's experiences which can shape psychological theory and practice. Research has supported this idea, suggesting that this interaction impacts the perception of mental health problems (DuPont-Reyes, Villatoro, Phelan, Painter & Link, 2019). A study by Haarmans, Vass and Bentall (2016) reported that the content of voices heard by people who experience psychotic symptoms may reflect social and structural inequalities in society. The authors suggest that these inequalities could be addressed in therapies such as CBTp to improve outcomes with ethnic minority service users. Evidence has highlighted the connection between self-stigma and its impact on

self-schemas (Shimotsu & Horikawa, 2016). Interventions that have focussed on reducing internalised stigma using cognitive therapy reported that this led to reduced internalised shame, hopelessness and self-rated recovery, with good recruitment and retention rates compared to a TAU control group (Morrison et al., 2016).

With these findings in mind, there may be great value in understanding ethnic minority group experiences of mental health services and psychological interventions. Enabling conversations with service users communities may allow researchers and clinicians to identify potential factors for poor engagement and attrition. The relationship between pathways to care and ethnic minority differences have been reported in research (Oduola et al., 2019; Cheng et al., 2018). However there appears to be a paucity of research related to the relationship between intersectionality and accessing psychological therapies. Researchers have attempted to explore this looking at certain 'pieces' of the intersectionality puzzle. For example this thesis explored the impact of ethnicity on access and outcomes to psychological therapy, whereas other studies have explored socio-economic status (Delgadillo, Farnfield & North, 2018; Reiss et al., 2019), gender (Brabban, Tai & Turkington, 2009), and religion and class (Ciftci, Jones & Corrigan, 2013). Issues such as stigma and intersectionality considerations may contribute towards the findings of the empirical paper, however we were only able to highlight that differences between the offer of therapy based on ethnic minority groups were present. Future research is needed to explore the impact of stigma and intersectionality in relation to the offer of psychological therapies for ethnic minority groups who experience SMI. Approaches such as the Power Threat Meaning Framework (PTMF; Johnstone & Boyle, 2018) have provided an alternative framework to medical diagnoses in order to formulate a person's distress whilst acknowledging the impact of intersectionality factors. The authors argued that using medical diagnoses are intertwined with certain assumptions that may provide a limited understanding of a person's mental health problem or

distress. The medical model attempts to explains a person's mental distress by asserting that the phenomenon is an 'illness' and that symptoms can be categorised into clusters that are labelled as specific diagnoses (Johnston & Boyle, 2018). This may shift the focus of a person's mental distress into an internalised experience, often understood as what is 'wrong with a person' and may ignore systemic, structural and environmental factors that have contributed to an individual's current state. The PTMF argues that an alternative way of understanding a person's problem relates to finding out what has happened to a person, how it affected them and what they did in order to survive (Harper & Cromby, 2020). As a result this approach can include a focus on inequalities a person has experienced and how they have contributed towards the development and presentation of their distress.

7.4. Strengths of the portfolio

The systematic review provided a structured exploration of the effectiveness of psychological interventions for ethnic minority groups who experience a SMI. The review highlighted a paucity of research that used a comparable control group to compare differences in the intervention of focus. The review demonstrated a trend in the development of culturally adapted therapies that showed improvements in symptom severity. It highlighted that further studies are needed to develop our understanding of what interventions are helpful for ethnic minority groups who experience a SMI.

The empirical paper was able to explore questions related to the offer and uptake of psychological therapies in an ethnically diverse sample of service users who experienced FEP using clinical data. Previous studies have explored offer and uptake of psychological therapies using service data (Johns et al., 2019; Das-Munshi, Brugha & Crawford, 2018).

This study built on existing research by attempting to explore factors that influenced these

disparities using sociodemographic data. The findings of the empirical paper provided novel outcomes compared to previous studies that have typically highlighted that people from Black African or Black Caribbean groups were less likely to be offered psychological interventions (Das-Munshi et al., 2018, McKenzie et al., 2001). The nature of the sample provided ecological validity to the study and its findings. The large sample size is also a strength considering that this was completed during clinical training.

7.5. Limitations of studies

Whilst the studies in this portfolio have added novel information to the evidence base, there are some limitations that restrict the applicability and generalisability of the findings. First, within the systematic review, the studies varied in their country of origin, ethnic minority groups' explored, psychological therapy of focus, and presence of a suitable control condition. The lack of control or comparison group meant that some studies were at risk of bias whilst the quality of the studies varied with a range of quality ratings between 20-80%. As a result it problematic to generalise the results from the review. Whilst some studies provided clear details on the adaptations made and process used to guide their process, a majority provided a short summary of the changes made, making this difficult to replicate in future research.

In the empirical paper, issues related to how information was recorded may have impacted our ability to determine who had been offered a family intervention, as other professionals aside from psychologically trained staff may have delivered this. A further limitation in the study is that it was not possible to identify why the majority of service users were not offered a psychological therapy. This is important as it would contribute to studies exploring the barriers that service users face when accessing mental health services. Another limitation with this study was that it was not possible to determine if cultural adaptations had taken place via exploration of the case notes. This would be important for future research to

explore, following the findings from the systematic review which suggested that cultural adaptations may lead to a reduction in symptom severity and improved functioning.

7.6. Conclusions and clinical implications

Despite these limitations, this thesis identified that psychological therapies can reduce symptom severity associated with SMI yet disparities exist in terms of who is offered a psychological therapy in this cohort based on ethnic minority group. In the empirical paper the amount of people being offered a psychological therapy was at a comparable level to statistics provided by the NCAP report (RCP, 2019) and a high amount of service users accepted the offer. The empirical paper highlighted that certain ethnic minority groups are still less likely to be offered a therapy compared to an ethnic majority reference group, however this may have changed over time due to changes in national guidelines and frameworks.

Psychosis is a complex mental health problem with a range of potential causes and risk factors. As our understanding of this experience changes over time, so will psychological interventions which aim to reduce symptom severity. Further research is needed to unpick the findings found in this body of work to determine why access to and engagement with psychological therapies varies between ethnic minority groups. The use of term 'ethnic minority' can be problematic and could be argued as reductionist (Grey, Sewell, Shapiro & Ashraf, 2013). Each ethnic minority consist of a range of cultures, histories, values and experiences that shape their beliefs around mental health and interactions with mental health services. As such the answer to these concerns may not be provided quickly or readily available in a manualised manner or by focussing on ethnicity. A possible alternative solution could focus on exploring cultural differences and how institutional and structural power inequalities have contributed towards a person's mental health problem. Careful

considerations to each service user and their own experiences are required to shape idiosyncratic formulations and interventions to provide effective psychological support.

7.8.References

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Appendix A: Journal Submission Guidelines for Authors – Social Psychiatry and Social Epidemiology

Submission guidelines

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Instructions for Authors

Types of Papers

Original research, literature reviews, consensus and policy papers, case studies, conference abstracts

It is strongly recommended that submitted articles not exceed 7000 words, excluding abstracts and references.

Perspectives are written only at the invitation of the Editor-in-Chief and Editorial Board.

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Inquiries

Inquiries regarding journal policy and other general topics should be sent to the Deputy Editor, Wai Hong (Kevin) Lo, Ph.D., wlo@uchc.edu.

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Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) for both the print and online format and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Online Submission

Please follow the hyperlink "Submit online" on the right and upload all of your manuscript files following the instructions given on the screen.

Please ensure you provide all relevant editable source files. Failing to submit these source files might cause unnecessary delays in the review and production process.

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Title page

Title Page

Please use this **template title page** for providing the following information.

The title page should include:

- The name(s) of the author(s)
- A concise and informative title
- The affiliation(s) of the author(s), i.e. institution, (department), city, (state), country
- A clear indication and an active e-mail address of the corresponding author
- If available, the 16-digit ORCID of the author(s)

If address information is provided with the affiliation(s) it will also be published.

For authors that are (temporarily) unaffiliated we will only capture their city and country of residence, not their e-mail address unless specifically requested.

Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

For life science journals only (when applicable)

Trial registration number and date of registration

Trial registration number, date of registration followed by "retrospectively registered"

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations'.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

To be used for non-life science journals

Funding (information that explains whether and by whom the research was supported)

Conflicts of interest/Competing interests (include appropriate disclosures)

Availability of data and material (data transparency)

Code availability (software application or custom code)

Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)

To be used for life science journals + articles with biological applications

Funding (information that explains whether and by whom the research was supported)

Conflicts of interest/Competing interests (include appropriate disclosures)

Ethics approval (include appropriate approvals or waivers)

Consent to participate (include appropriate statements)

Consent for publication (include appropriate statements)

Availability of data and material (data transparency)

Code availability (software application or custom code)

Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)

Please see the relevant sections in the submission guidelines for further information as well as various examples of wording. Please revise/customize the sample statements according to your own needs.

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Classification code

MSC

An appropriate number of MSC codes should be provided. The Mathematics Subject Classification (MSC) is used to categorize items covered by the two reviewing databases, Mathematical Reviews and Zentralblatt MATH, see

www.ams.org/msc

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Text

Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Manuscripts with mathematical content can also be submitted in LaTeX.

LaTeX macro package (Download zip, 188 kB)

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

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Scientific style

- Please always use internationally accepted signs and symbols for units (SI units).
- Nomenclature: Insofar as possible, authors should use systematic names similar to those used by Chemical Abstract Service or IUPAC.
- Genus and species names should be in italics.
- Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.
- Please use the standard mathematical notation for formulae, symbols, etc.:Italic for single letters that denote mathematical constants, variables, and unknown quantities Roman/upright for numerals, operators, and punctuation, and commonly defined functions or abbreviations, e.g., cos, det, e or exp, lim, log, max, min, sin, tan, d (for derivative) Bold for vectors, tensors, and matrices.

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References

Citation

Reference citations in the text should be identified by numbers in square brackets. Some examples:

- 1. Negotiation research spans many disciplines [3].
- 2. This result was later contradicted by Becker and Seligman [5].
- 3. This effect has been widely studied [1-3, 7].

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

The entries in the list should be numbered consecutively.

Journal article

Smith JJ. The world of science. Am J Sci. 1999;36:234–5.

• Article by DOI

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. J Mol Med. 2000; https://doi.org/10.1007/s001090000086

Book

Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.

Book chapter

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. pp. 251–306.

Online document

Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.

Always use the standard abbreviation of a journal's name according to the ISSN List of Title Word Abbreviations, see

ISSN.org LTWA

If you are unsure, please use the full journal title.

For authors using EndNote, Springer provides an output style that supports the formatting of in-text citations and reference list.

EndNote style (Download zip, 4 kB)

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Tables

• All tables are to be numbered using Arabic numerals.

- Tables should always be cited in text in consecutive numerical order.
- For each table, please supply a table caption (title) explaining the components of the table
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

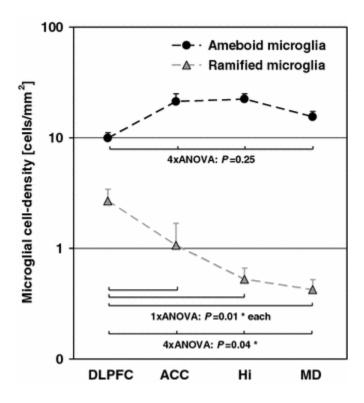
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Artwork and Illustrations Guidelines

Electronic Figure Submission

- Supply all figures electronically.
- Indicate what graphics program was used to create the artwork.
- For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
- Vector graphics containing fonts must have the fonts embedded in the files.
- Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

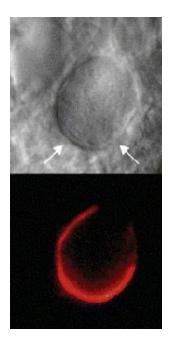
Line Art



- Definition: Black and white graphic with no shading.
- Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.
- All lines should be at least 0.1 mm (0.3 pt) wide.
- Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.

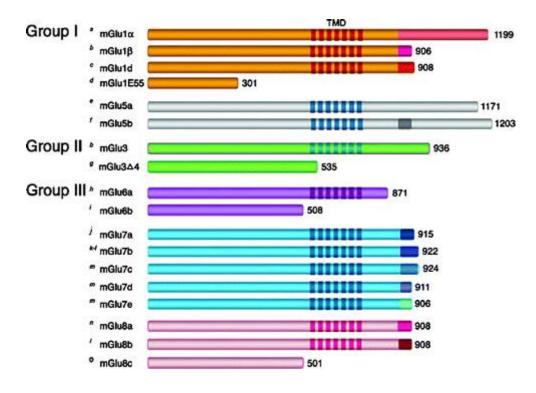
• Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art



- Definition: Photographs, drawings, or paintings with fine shading, etc.
- If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.
- Halftones should have a minimum resolution of 300 dpi.

Combination Art



- Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.
- Combination artwork should have a minimum resolution of 600 dpi.

Color Art

- Color art is free of charge for online publication.
- If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.
- If the figures will be printed in black and white, do not refer to color in the captions.
- Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

- To add lettering, it is best to use Helvetica or Arial (sans serif fonts).
- Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).
- Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.
- Avoid effects such as shading, outline letters, etc.
- Do not include titles or captions within your illustrations.

Figure Numbering

- All figures are to be numbered using Arabic numerals.
- Figures should always be cited in text in consecutive numerical order.
- Figure parts should be denoted by lowercase letters (a, b, c, etc.).
- If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures,"A1, A2, A3, etc." Figures in online appendices (Electronic Supplementary Material) should, however, be numbered separately.

Figure Captions

- Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.
- Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.
- No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.
- Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.
- Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

- Figures should be submitted separately from the text, if possible.
- When preparing your figures, size figures to fit in the column width.
- For large-sized journals the figures should be 84 mm (for double-column text areas), or 174 mm (for single-column text areas) wide and not higher than 234 mm.
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In order to give people of all abilities and disabilities access to the content of your figures, please make sure that

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- Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)
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- To accommodate user downloads, please keep in mind that larger-sized files may require very long download times and that some users may experience other problems during downloading.

Audio, Video, and Animations

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- Minimum video duration: 1 sec
- Supported file formats: avi, wmv, mp4, mov, m2p, mp2, mpg, mpeg, flv, mxf, mts, m4v, 3gp

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- Submit your material in PDF format; .doc or .ppt files are not suitable for long-term viability.
- A collection of figures may also be combined in a PDF file.

Spreadsheets

• Spreadsheets should be submitted as .csv or .xlsx files (MS Excel).

Specialized Formats

• Specialized format such as .pdb (chemical), .wrl (VRML), .nb (Mathematica notebook), and .tex can also be supplied.

Collecting Multiple Files

• It is possible to collect multiple files in a .zip or .gz file.

Numbering

- If supplying any supplementary material, the text must make specific mention of the material as a citation, similar to that of figures and tables.
- Refer to the supplementary files as "Online Resource", e.g., "... as shown in the animation (Online Resource 3)", "... additional data are given in Online Resource 4".
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Captions

• For each supplementary material, please supply a concise caption describing the content of the file.

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Authorship principles

These guidelines describe authorship principles and good authorship practices to which prospective authors should adhere to.

Authorship clarified

The Journal and Publisher assume all authors agreed with the content and that all gave explicit consent to submit and that they obtained consent from the responsible authorities at the institute/organization where the work has been carried out, **before** the work is submitted.

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ICMJE, Defining the Role of Authors and Contributors,

Transparency in authors' contributions and responsibilities to promote integrity in scientific publication, McNutt at all, PNAS February 27, 2018

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All authors are requested to include information regarding sources of funding, financial or non-financial interests, study-specific approval by the appropriate ethics committee for research involving humans and/or animals, informed consent if the research involved human participants, and a statement on welfare of animals if the research involved animals (as appropriate).

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- providing transparency on re-use of material and mention any unpublished material (for example manuscripts in press) included in the manuscript in a cover letter to the Editor;
- making sure disclosures, declarations and transparency on data statements from all authors are included in the manuscript as appropriate (see above).

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Examples of such statement(s) are shown below:

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All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [full name], [full name] and [full name]. The first draft of the manuscript was written by [full name] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Example: CRediT taxonomy:

• Conceptualization: [full name], ...; Methodology: [full name], ...; Formal analysis and investigation: [full name], ...; Writing - original draft preparation: [full name, ...]; Writing - review and editing: [full name], ...; Funding acquisition: [full name], ...; Resources: [full name], ...; Supervision: [full name],

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A Graduate Student's Guide to Determining Authorship Credit and Authorship Order, APA Science Student Council 2006

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Compliance with Ethical Standards

To ensure objectivity and transparency in research and to ensure that accepted principles of ethical and professional conduct have been followed, authors should include information regarding sources of funding, potential conflicts of interest (financial or non-financial), informed consent if the research involved human participants, and a statement on welfare of animals if the research involved animals.

Authors should include the following statements (if applicable) in a separate section entitled "Compliance with Ethical Standards" when submitting a paper:

- Disclosure of potential conflicts of interest
- Research involving Human Participants and/or Animals
- Informed consent

Please note that standards could vary slightly per journal dependent on their peer review policies (i.e. single or double blind peer review) as well as per journal subject discipline. Before submitting your article check the instructions following this section carefully.

The corresponding author should be prepared to collect documentation of compliance with ethical standards and send if requested during peer review or after publication.

The Editors reserve the right to reject manuscripts that do not comply with the abovementioned guidelines. The author will be held responsible for false statements or failure to fulfill the above-mentioned guidelines.

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Disclosure of potential conflicts of interest

Authors must disclose all relationships or interests that could have direct or potential influence or impart bias on the work. Although an author may not feel there is any conflict, disclosure of relationships and interests provides a more complete and transparent process, leading to an accurate and objective assessment of the work. Awareness of a real or perceived conflicts of interest is a perspective to which the readers are entitled. This is not meant to imply that a financial relationship with an organization that sponsored the research or compensation received for consultancy work is inappropriate. Examples of potential conflicts of interests **that are directly or indirectly related to the research** may include but are not limited to the following:

- Research grants from funding agencies (please give the research funder and the grant number)
- Honoraria for speaking at symposia
- Financial support for attending symposia
- Financial support for educational programs
- Employment or consultation
- Support from a project sponsor
- Position on advisory board or board of directors or other type of management relationships
- Multiple affiliations
- Financial relationships, for example equity ownership or investment interest
- Intellectual property rights (e.g. patents, copyrights and royalties from such rights)
- Holdings of spouse and/or children that may have financial interest in the work

In addition, interests that go beyond financial interests and compensation (non-financial interests) that may be important to readers should be disclosed. These may include but are not limited to personal relationships or competing interests directly or indirectly tied to this research, or professional interests or personal beliefs that may influence your research.

The corresponding author collects the conflict of interest disclosure forms from all authors. In author collaborations where formal agreements for representation allow it, it is sufficient for the corresponding author to sign the disclosure form on behalf of all authors. Examples of forms can be found

here:

The corresponding author will include a summary statement in the text of the manuscript in a separate section before the reference list, that reflects what is recorded in the potential conflict of interest disclosure form(s).

See below examples of disclosures:

Funding: This study was funded by X (grant number X).

Conflict of Interest: Author A has received research grants from Company A. Author B has received a speaker honorarium from Company X and owns stock in Company Y. Author C is a member of committee Z.

If no conflict exists, the authors should state:

Conflict of Interest: The authors declare that they have no conflict of interest.

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Research involving human participants, their data or biological material

Ethics approval

When reporting a study that involved human participants, their data or biological material, authors should include a statement that confirms that the study was approved (or granted exemption) by the appropriate institutional and/or national research ethics committee (including the name of the ethics committee) and certify that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. If doubt exists whether the research was conducted in accordance with the 1964 Helsinki Declaration or comparable standards, the authors must explain the reasons for their approach, and demonstrate that an independent ethics committee or institutional review board explicitly approved the doubtful aspects of the study. If a study was granted exemption from requiring ethics approval, this should also be detailed in the manuscript (including the reasons for the exemption).

Retrospective ethics approval

If a study has not been granted ethics committee approval prior to commencing, retrospective ethics approval usually cannot be obtained and it may not be possible to consider the manuscript for peer review. The decision on whether to proceed to peer review in such cases is at the Editor's discretion.

Ethics approval for retrospective studies

Although retrospective studies are conducted on already available data or biological material (for which formal consent may not be needed or is difficult to obtain) ethics approval may be required dependent on the law and the national ethical guidelines of a country. Authors should check with their institution to make sure they are complying with the specific requirements of their country.

Ethics approval for case studies

Case reports require ethics approval. Most institutions will have specific policies on this subject. Authors should check with their institution to make sure they are complying with the specific requirements of their institution and seek ethics approval where needed. Authors should be aware to secure informed consent from the individual (or parent or guardian if the participant is a minor or incapable) See also section on **Informed Consent**.

Cell lines

If human cells are used, authors must declare in the manuscript: what cell lines were used by describing the source of the cell line, including when and from where it was obtained, whether the cell line has recently been authenticated and by what method. If cells were bought from a life science company the following need to be given in the manuscript: name of company (that provided the cells), cell type, number of cell line, and batch of cells.

It is recommended that authors check the <u>NCBI database</u> for misidentification and contamination of human cell lines. This step will alert authors to possible problems with the cell line and may save considerable time and effort.

Further information is available from the <u>International Cell Line Authentication Committee</u> (ICLAC).

Authors should include a statement that confirms that an institutional or independent ethics committee (including the name of the ethics committee) approved the study and that informed consent was obtained from the donor or next of kin.

Research Resource Identifiers (RRID)

Research Resource Identifiers (RRID) are persistent unique identifiers (effectively similar to a DOI) for research resources. This journal encourages authors to adopt RRIDs when reporting key biological resources (antibodies, cell lines, model organisms and tools) in their manuscripts.

Examples:

Organism: Filip 1^{tm1a(KOMP)Wtsi} RRID:MMRRC 055641-UCD

Cell Line: RST307 cell line RRID:CVCL_C321

Antibody: Luciferase antibody DSHB Cat# LUC-3, RRID:AB_2722109

Plasmid: mRuby3 plasmid RRID:Addgene_104005

Software: ImageJ Version 1.2.4 RRID:SCR_003070

RRIDs are provided by the <u>Resource Identification Portal</u>. Many commonly used research resources already have designated RRIDs. The portal also provides authors links so that they can quickly <u>register a new resource</u> and obtain an RRID.

Clinical Trial Registration

The World Health Organization (WHO) definition of a clinical trial is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". The WHO defines health interventions as "A health intervention is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health,

functioning or health conditions" and a health-related outcome is generally defined as a change in the health of a person or population as a result of an intervention.

To ensure the integrity of the reporting of patient-centered trials, authors must register prospective clinical trials (phase II to IV trials) in suitable publicly available repositories. For example www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries that participate in the who-understanding-www.clinicaltrials.gov or any of the primary registries of the support o

The trial registration number (TRN) and date of registration should be included as the last line of the manuscript abstract.

For clinical trials that have not been registered prospectively, authors are encouraged to register retrospectively to ensure the complete publication of all results. The trial registration number (TRN), date of registration and the words 'retrospectively registered' should be included as the last line of the manuscript abstract.

Purely observational trials will not require registration.

Standards of reporting

Springer Nature advocates complete and transparent reporting of biomedical and biological research and research with biological applications. Authors are recommended to adhere to the minimum reporting guidelines hosted by the <u>EQUATOR Network</u> when preparing their manuscript.

Exact requirements may vary depending on the journal; please refer to the journal's Instructions for Authors.

Checklists are available for a number of study designs, including:

Randomised trials (CONSORT) and Study protocols (SPIRIT)

Observational studies (STROBE)

Systematic reviews and meta-analyses (PRISMA) and protocols (Prisma-P)

Diagnostic/prognostic studies (STARD) and (TRIPOD)

Case reports (CARE)

Clinical practice guidelines (AGREE) and (RIGHT)

Qualitative research (SRQR) and (COREQ)

Animal pre-clinical studies (ARRIVE)

Quality improvement studies (SQUIRE)

Economic evaluations (CHEERS)

Summary of requirements

The above should be summarized in a statement and included on a title page that is separate from the manuscript with a section entitled "Declarations" when submitting a paper. Having all statements in one place allows for a consistent and unified review of the information by the Editor-in-Chief and/or peer reviewers and may speed up the handling of the paper. Declarations include Funding, Conflicts of interest/competing interests, Ethics approval, Consent, Data and/or Code availability and Authors' contribution statements. Please use the following template title page for providing the statements.

Once and if the paper is accepted for publication, the production department will put the respective statements in a distinctly identified section clearly visible for readers.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

• Provide "Ethics approval" as a heading (see template)

Examples of ethics approval obtained:

- All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Bioethics Committee of the Medical University of A (No. ...).
- This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University B (Date.../No. ...).
- Approval was obtained from the ethics committee of University C. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.
- The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of C (Ethics approval number: ...).

Examples of a retrospective study:

- Ethical approval was waived by the local Ethics Committee of University A in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.
- This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of XYZ who determined that our study did not need ethical approval. An IRB official waiver of ethical approval was granted from the IRB of XYZ.
- This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of University B approved this study.

Examples no ethical approval required/exemption granted:

- This is an observational study. The XYZ Research Ethics Committee has confirmed that no ethical approval is required.
- The data reproduced from Article X utilized human tissue that was procured via our Biobank AB, which provides de-identified samples. This study was reviewed and deemed exempt by our XYZ Institutional Review Board. The BioBank protocols are in accordance with the ethical standards of our institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

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Informed consent

All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said during a study or an interview, as well as to any photograph that was taken. This is especially true concerning images of vulnerable people (e.g. minors, patients, refugees, etc) or the use of images in sensitive contexts. In many instances authors will need to secure written consent before including images.

Identifying details (names, dates of birth, identity numbers, biometrical characteristics (such as facial features, fingerprint, writing style, voice pattern, DNA or other distinguishing characteristic) and other information) of the participants that were studied should not be published in written descriptions, photographs, and genetic profiles unless the information is essential for scholarly purposes and the participant (or parent or guardian if the participant is incapable) gave written informed consent for publication. Complete anonymity is difficult to achieve in some cases. Detailed descriptions of individual participants, whether of their whole bodies or of body sections, may lead to disclosure of their identity. Under certain circumstances consent is not required as long as information is anonymized and the submission does not include images that may identify the person.

Informed consent for publication should be obtained if there is any doubt. For example, masking the eye region in photographs of participants is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic profiles, authors should provide assurance that alterations do not distort scientific meaning.

Exceptions where it is not necessary to obtain consent:

• Images such as x rays, laparoscopic images, ultrasound images, brain scans, pathology slides unless there is a concern about identifying information in which case, authors should ensure that consent is obtained.

• Reuse of images: If images are being reused from prior publications, the Publisher will assume that the prior publication obtained the relevant information regarding consent. Authors should provide the appropriate attribution for republished images.

Consent and already available data and/or biologic material

Regardless of whether material is collected from living or dead patients, they (family or guardian if the deceased has not made a pre-mortem decision) must have given prior written consent. The aspect of confidentiality as well as any wishes from the deceased should be respected.

Data protection, confidentiality and privacy

When biological material is donated for or data is generated as part of a research project authors should ensure, as part of the informed consent procedure, that the participants are made what kind of (personal) data will be processed, how it will be used and for what purpose. In case of data acquired via a biobank/biorepository, it is possible they apply a broad consent which allows research participants to consent to a broad range of uses of their data and samples which is regarded by research ethics committees as specific enough to be considered "informed". However, authors should always check the specific biobank/biorepository policies or any other type of data provider policies (in case of non-bio research) to be sure that this is the case.

Consent to Participate

For all research involving human subjects, freely-given, informed consent to participate in the study must be obtained from participants (or their parent or legal guardian in the case of children under 16) and a statement to this effect should appear in the manuscript. In the case of articles describing human transplantation studies, authors must include a statement declaring that no organs/tissues were obtained from prisoners and must also name the institution(s)/clinic(s)/department(s) via which organs/tissues were obtained. For manuscripts reporting studies involving vulnerable groups where there is the potential for coercion or where consent may not have been fully informed, extra care will be taken by the editor and may be referred to the Springer Nature Research Integrity Group.

Consent to Publish

Individuals may consent to participate in a study, but object to having their data published in a journal article. Authors should make sure to also seek consent from individuals to publish their data prior to submitting their paper to a journal. This is in particular applicable to case studies. A consent to publish form can be found

here. (Download docx, 36 kB)

Summary of requirements

The above should be summarized in a statement and included on a title page that is separate from the manuscript with a section entitled "Declarations" when submitting a paper. Having all statements in one place allows for a consistent and unified review of the information by the Editor-in-Chief and/or peer reviewers and may speed up the handling of

the paper. Declarations include Funding, Conflicts of interest/competing interests, Ethics approval, Consent, Data and/or Code availability and Authors' contribution statements. **Please use the template Title Page for providing the statements**.

Once and if the paper is accepted for publication, the production department will put the respective statements in a distinctly identified section clearly visible for readers.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

Provide "Consent to participate" as a heading

Sample statements consent to participate:

Informed consent was obtained from all individual participants included in the study.

Informed consent was obtained from legal guardians.

Written informed consent was obtained from the parents.

Verbal informed consent was obtained prior tothe interview.

The patient has consented to the submission of the case report for submission to the journal.

Provide "Consent to publish" as a heading

The authors affirm that human research participants provided informed consent for publication of the images in Figure(s) 1a, 1b and 1c.

The participant has consented to the submission of the case report to the journal.

Patients signed informed consent regarding publishing their data and photographs.

Sample statements if identifying information about participants is available in the article:

Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

Images will be removed from publication if authors have not obtained informed consent or the paper may be removed and replaced with a notice explaining the reason for removal.

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List of Repositories

Research Data Policy

General repositories - for all types of research data - such as figshare and Dryad may also be used.

Datasets that are assigned digital object identifiers (DOIs) by a data repository may be cited in the reference list. Data citations should include the minimum information recommended by DataCite: authors, title, publisher (repository name), identifier.

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Springer Nature provides a research data policy support service for authors and editors, which can be contacted at **researchdata@springernature.com**.

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