Exploring the acceptability of undertaking sexual health and behaviour research in people with Severe Mental Illness: A UK perspective

Samantha Joy Gascoyne

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Abstract

Background: People with severe mental illness (SMI) experience significant inequalities in physical health and die on average 15-20 years earlier than the general population. To address this, physical health is now higher on the health policy and practice agenda. However, sexual health is significantly neglected within current UK health policy, and there is a paucity of research within the UK despite the international literature suggesting the sexual health of people with SMI is poor.

Methods: A range of methods were employed to explore the intersection of SMI and sexual health in the UK. A systematic review was undertaken to examine whether adults with SMI are more likely to engage in behaviours associated with increased risk of blood borne viruses/sexually transmitted infections compared to those with no history of SMI. A feasibility study examined recruitment processes and, explored participant feedback on the acceptability of a sexual health interview. Qualitative interviews explored mental health professional's (MHPs) views in relation to the sexual health and relationship needs of people with SMI. Lastly, secondary data analysis of survey data examined the acceptability and experiences of people with SMI in the UK who participated in the RESPECT study.

Results: Within the UK context, this thesis provides evidence that it is acceptable to speak to the SMI population about their sexual health and behaviour as well as preliminary evidence that it is feasible to recruit people with SMI to research in this area. Priorities for policy include bringing the sexual health and relationship needs to the forefront of guidance to ensure MHPs are aware of the legitimacy of supporting their service users with this aspect of their physical health.

Conclusions: The research within this thesis provides important evidence that it is acceptable to undertake sexual health and behaviour research in people with SMI in the UK.

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Authors declaration

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References. Parts of this thesis that have been accepted for publication or are under review in peer-reviewed journals include:

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Chapter One- Severe mental illness and sexual health in the UK

The overall aim of the thesis is to explore the acceptability of undertaking sexual health and sexual behaviour research in people with severe mental illness (SMI) in the UK. This chapter aims to set out the context for the thesis. This will consider the definition of SMI followed by a discussion of prevalence, economic and socioeconomic factors associated with SMI. The poor physical health of people with SMI is then discussed with a specific focus on the barriers associated with accessing good physical health care. There are a number of physical health issues that are associated with SMI such as cardiovascular disease and diabetes. However, one physical health comorbidity that has received less attention in the UK is that of sexual and reproductive health in relation to SMI. This chapter will finally discuss the sexual health and relationship needs of people with SMI in relation to previous research undertaken in this area.

1.1 Definition of severe mental illness

As there is no agreed definition of SMI, a rational definition was adopted following guidance for improving the physical health care of people with SMI, a recent epidemiological study that aimed to operationalise the term SMI, and also from reviewing how SMI has been defined in other studies (Peckham et al., 2017; Ruggeri et al., 2018; White et al., 2009). Therefore, for the purpose of this thesis, SMI is defined as a diagnosis of Schizophrenia, delusional or psychotic illness (International Classification of Disease 10 (ICD-10) F20, F21-29 or, Diagnostic and Statistical Manual of Mental Disorders (DSM-V) equivalent) or bipolar disorder (ICD F31 or DSM-equivalent) (APA, 2013; WHO, 2016). These will be described in turn below.

1.1.1 Schizophrenia and psychosis (F20)

Schizophrenia and psychosis represent a major group of mental disorders which are characterised by distortions in a person's thinking, perceptions, mood and behaviour (ICD-10, 2016). The onset of schizophrenia can begin in late adolescents to early adulthood and the course of schizophrenia can be continuous or episodic with complete or incomplete remission (Gogtay et al., 2011).

The symptoms of schizophrenia and psychosis are classified as two groups; positive symptoms and negative symptoms, in which a person will have a unique experience and combination of symptoms from both groups. Positive symptoms include any change in behaviour or thought including hallucinations and/or delusions (WHO, 2016). Hallucinations are described as distorted perceptions with no stimulus, for example, seeing, hearing, tasting, or smelling things that don't exist outside the person's mind. Despite this, these sensations are real to the person experiencing them (The National

Institute for Health and Care Excellence (NICE), 2014). Delusions are false beliefs held with conviction and are often based on unrealistic or strange views, for example, they may believe they are being followed, watched, or being plotted against (NICE, 2014). Behaviour changes commonly present as agitation and/or distress (NICE, 2014).

Negative symptoms of schizophrenia include; social withdrawal, losing interest in relationships and sex, self-neglect, lack of concentration, changes in sleeping patterns and poverty of speech (WHO, 2016; NICE, 2014). The negative symptoms of schizophrenia are referred to as the prodromal period of schizophrenia and often start gradually, getting progressively worse over a number of years before a person experiences their first acute schizophrenic episode (NICE, 2014). However, once the positive symptoms have subsided, it is common for the negative symptoms to remain, causing a significant impact on a person's ability to function (e.g. return to work).

The course of schizophrenia and psychosis varies greatly from individual to individual and is often episodic with many people experiencing relapses throughout their lifetime (NICE, 2014). Approximately 80% of individuals will recover from the initial acute episode they experience; and it is estimated that only between 14% and 20% of individuals will fully recover (Brown et al., 2010). Relapses are associated with social withdrawal, stress and not accessing services for treatment in a timely manner (Bottlender et al., 2003).

1.1.1.1 Incidence and Prevalence of Schizophrenia

Kirkbride et al. (2012) undertook a review to explore the incidence of psychosis in England between 1950 and 2009 and reported a pooled incidence of 31.7 per 100,000 person-years for psychosis and 15 per 100,000 per person-years for schizophrenia. There were variations in rates dependent on age, gender and ethnic origin. It was reported that men under the age of 45 had twice the rate of schizophrenia compared to women, however there were no gender differences in incidence beyond 45 years of age (Kirkbride et al., 2012). Significant variations in the incidence of schizophrenia and psychosis were also found between ethnic origins. In the black Caribbean population, the risk ratio (RR) of schizophrenia was reported to be 5.6 (95% confidence interval (CI), 3.4-9.2) and in the black African population a RR of 4.7 (95% CI, 3.3, 6.8) was reported compared with a Caucasian population (Kirkbride et al., 2012).

With regards to the prevalence of Schizophrenia, the Adult Psychiatric Morbidity Survey (APMS) reported that in the UK, less than one person in a hundred was diagnosed with a psychotic disorder in the year 2013 (Bebbington et al., 2014). By pooling estimates from the 2007 and 2014 APMS data in the UK, the prevalence of

psychotic disorders in the adult general population is 0.5% with no variations between age or gender being reported (Bebbington et al., 2014). However, a variation was found between male ethnic groups with the prevalence of psychotic disorder estimated at 3.2% for black men compared to 0.3% of Caucasian men and 1.3% of Asian men.

The risk of suicide is greater in people with schizophrenia, with studies reporting an approximate lifetime risk of 5% (Carlborg et al., 2008; Hor & Taylor, 2010). Risk factors associated with this increased risk of suicide were reported to be young, male, unemployed and higher levels of education (Hor & Taylor, 2010). A systematic review undertaken by Hor and Taylor (2010) also identified a number of illness related risk factors that were associated with increased rates of suicide, these included presence of auditory hallucinations, delusions, presence of insight and the presence of physical ill health.

Schizophrenia is the most common form of psychotic disorder (NICE, 2014) and, as discussed in the next section, is one that has substantial consequences for the person experiencing schizophrenia as well as the wider society.

1.1.1.2 Consequences of Schizophrenia

For some people who receive a diagnosis of schizophrenia, everyday functioning can be seriously impaired. Schizophrenia is associated with a number of social disabilities which can significantly impact on many aspects of an individual's life from work productivity, independent living, self-care, interpersonal relations and social isolation therefore limiting a person's ability to undertake socially accepted day to day tasks (NICE, 2014; Velthorst et al., 2010; Wiersma et al., 2000).

In recent years, there has been increasing awareness that as well as the impact of SMI on mental health and quality of life, there is also a significant health disparity. The average life expectancy of someone with SMI is between fifteen and twenty years less than the general population (De Hert et al., 2011; Walker et al., 2015). This has mainly been attributed to the physical comorbidities this population experience and is discussed further in section 1.2 of this chapter (Zolezzi et al., 2017; Lawrence et al., 2013). According to the Global Burden of Disease schizophrenia was ranked as the 16th leading cause of disability internationally (Murray et al., 2012). When specifically analysing data from the UK it has been reported there has been a 15% increase in years lived with disability (YLDs) and a 14% increase in disability adjusted life years from 1990 to 2010 meaning the burden of schizophrenia is growing (Murray et al., 2013).

In terms of economic cost, it is estimated that schizophrenia costs the English economy £7.9 billion per year with 30% of this being attributed to direct health care costs and the remainder being attributed to indirect costs to society (e.g. unemployment, criminal justice system, employment and support allowance, personal independence payments) (Mangalore & Knapp, 2007).

Unemployment rates are estimated to be between 15% and 20% for people with schizophrenia in the UK with the cost of lost productivity costing the economy £4 billion per year (Evans & Repper, 2000; Schneider et al., 2009). The main barriers to employment in this population are considered to be stigma and discrimination. According to Seebohm and Secker (2005) service users reported that the biggest barrier to employment were the attitudes of the employers. Approximately 75% of employers stated that it would be a challenge to employ someone with schizophrenia or psychotic disorder as they did not feel it was appropriate for them to be working with the public and in some cases felt they were not to be trusted (Office of the Deputy Prime Minister, 2004). They also felt it would have a negative impact on their mental health (Office of the Deputy Prime Minister, 2004). However, research suggests that employment can have a positive impact on a person's mental health as it provides them with structure, social inclusion and a role within society as well as a financial reward (Carmona et al, 2017).

1.1.2 Bipolar disorder (F31)

Bipolar affective disorder is characterised by a person experiencing two or more episodes of disturbed mood or activity levels which alternate between elation (mania or hypomania) and depression. Mania is characterised as an abnormally elevated mood, irritability and increased energy and activity levels with severe functional impairment for a period of seven days or more (WHO, 2016; NICE, 2014). Hypomania is characterised as an abnormally elated mood, increased activity levels, irritability and either an increased or decreased level of functioning for a period of four days or more (WHO, 2016; NICE 2014). The ICD-10 requires two distinct mood episodes, of which one must be hypomania or mania (WHO, 2016). However, a diagnosis of bipolar disorder would be given when a person experiences one episode of mania without experiencing depression, or one episode of hypomania with an episode of major depression if diagnosed using the DSM-V classification (APA, 2013).

The ICD-10 and DSM-V also differ as the DSM-V classifies two types of bipolar disorder, type I and type II (APA, 2013; WHO, 2016). Bipolar I disorder is classified as an individual experiencing full-scale manic episodes combined with major depressive episodes. Bipolar II disorder is classified as an individual having hypomanic symptoms

(less severe) and depressive episodes (DSM-V). This distinction is not made in the ICD-10 (WHO, 2016).

Throughout the course of bipolar disorder, symptoms of depression are more common than manic symptoms despite mania or hypomania being the defining characteristics of the illness (Judd et al., 2002a). People with bipolar disorder spend a large proportion of time with subclinical depressive symptoms (NICE, 2014). A longitudinal study found symptoms of depression were three times more commonly reported than manic or hypomanic episodes in 146 patients with bipolar disorder (Judd et al., 2002).

Major depressive episodes in bipolar disorder are similar to those experienced in unipolar major depression (NICE, 2014). Major Depressive Disorder (MDD) is characterised by an individual experiencing at least five symptoms of depression, with at least one of those being either depressed mood or loss of interest or pleasure in things for a minimum of two consecutive weeks. The additional symptoms include: changes in appetite or weight; changes in sleep pattern; psychomotor agitation or retardation; fatigue; difficulty concentrating and making decisions; feelings of worthlessness or guilt; and recurrent thoughts of death or suicidal ideation, plans or attempts (APA, 2013; WHO, 2016). The symptoms must be present almost every day, for most of the day during that consecutive two-week period and there must be a clinically significant impairment in functioning (APA 2013; WHO, 2016).

The risk of suicide is greatly elevated during depressive episodes of bipolar disorder, particularly if a person has experienced long-term subclinical depressive symptoms (NICE, 2014). Rihmer and Kiss (2002) estimate that over the course of the illness 17% of people with bipolar I disorder and 24% of people with bipolar II disorder will attempt suicide.

In terms of presentation, mania can present in numerous ways including; grandiose self-esteem, flight of ideas, pressured speech, unkempt appearance, increased activity, decreased sleep, psychomotor restlessness and increased appetite which may all lead to significantly impaired functioning (NICE, 2014). In addition, there may be an increase in impulsive behaviour during a manic episode, for example, an increased libido may lead people to engage in behaviours which place them at risk of experiencing violence, exploitation, or, contracting sexually transmitted infections (STIs) or blood borne viruses (BBVs) (NICE, 2014). In severe episodes of mania, it is also possible for people to develop psychotic symptoms (as described in section 1.1.1). During mania, full insight is lost, and the person does not consider their behaviour to be abnormal (NICE, 2014). The clinical presentation of hypomania is the same as described for mania although the symptoms are not as severe, and they do not develop psychotic symptoms (NICE, 2014).

The course of bipolar disorder varies greatly from individual to individual and there is no definition of a 'normal' cycle of mood disturbance (NICE, 2014). Some people may experience distinct episodes each year but will recover fully in-between, others may have more frequent episodes and, others may not fully recover between episodes (NICE, 2014).

In terms of the recurring nature of bipolar disorder, it is estimated that the risk of recurrence is 50% in the first year after experiencing a mood episode which increases to 75% risk of recurrence at 4 years post mood episode (NICE, 2014). Relapse is also more likely to occur when individuals experience residual symptoms of depression or mania that affect a person's ability to function (Judd et al., 2008).

1.1.2.1 Incidence and prevalence of bipolar disorder

Estimating the incidence of bipolar disorder is complex as subclinical symptoms of the disorder are often present, therefore, there can be delays in diagnosis as people often present to services with depression or ill-defined psychotic symptoms (NICE, 2014). One study undertaken in the Netherlands examined the medical records of 800,000 patients and report the overall incidence of bipolar disorder to be 0.70 per 10,000 person-years (95% CI, 0.57, 0.83) with the incidence of bipolar disorder type I reported as 0.43 per 10,000 person-years (95% CI, 0.34, 0.55), and 0.19 per 10,000 person-years (95% CI, 0.13, 0.27) for bipolar disorder type II (Kroon et al., 2013).

There are reports within the literature of variation in the incidence of bipolar disorder between ethnic groups. One study in the UK reported higher incidences of bipolar disorder among black and other minority groups compared to the Caucasian population (Lloyd et al., 2005; Van Os et al., 1996). However, the recent APMS did not report any differences in the incidence of bipolar disorder between ethnic groups in the UK (Marwaha et al., 2014).

There are varying estimates of lifetime prevalence for bipolar disorder types I and II within the literature varying from 0.1% to 2.4% (Faravelli et al., 1990; Pini et al., 2005; Regeer et al., 2004; Szadoczky et al., 1998). However, the most accepted estimates are from a large study in the USA which reports the lifetime prevalence of bipolar disorder I to be 1% (Merikangas et al., 2007). The estimates of lifetime prevalence of bipolar type II disorder vary from 0.2% and 2.0% (Faravelli et al., 1990; Szadoczky et al., 1998). However, a cross-national epidemiological study including eleven countries estimates the lifetime prevalence of bipolar type II disorder at 0.4% (Merikangas & Lamers, 2012). The APMS reports the overall rate of bipolar disorder to be between 1.6% and 2.4% in the UK adult general population (McManus et al., 2016). No

significant variations in the prevalence of bipolar disorder are reported for age and gender in the UK which is supported by the international literature (Kroon et al., 2013).

Although the lifetime prevalence of bipolar disorder is low, the condition is one that has substantial consequences for the person experiencing bipolar disorder as well as wider society as discussed in the next section.

1.1.2.2 Consequences of bipolar disorder

For an individual bipolar disorder is a serious health condition that can make day-to-day functioning extremely difficult with areas such as work, social and home life being affected (NICE, 2014). According to the Global Burden of Disease bipolar disorder was ranked as the sixth leading cause of disability internationally amongst mental and behavioural disorders and, 18th in all health conditions worldwide (Murray et al., 2012; Vos et al., 2012). When specifically analysing data from the UK it was reported there had been a 5% increase in years lived with disability (YLDs) and a 4% increase in disability adjusted life years from 1990 to 2010 meaning the burden of bipolar disorder is growing (Murray et al., 2013).

In terms of economic cost, it is estimated that bipolar disorder costs the English economy £2.055 billion per year with 10% of this being attributed to direct health care costs and the remainder being attributed to indirect costs to society (e.g. unemployment, suicide, incapacity benefits) (Young et al., 2011).

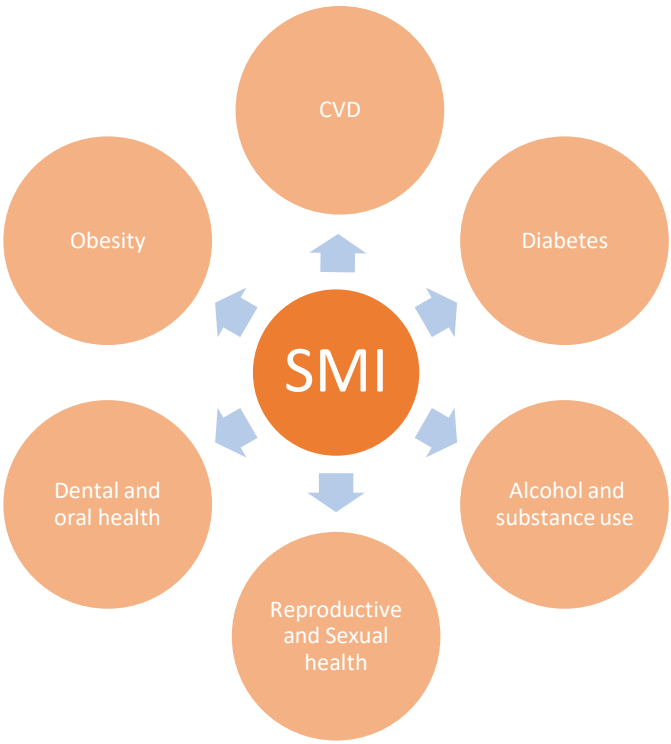
A systematic review undertaken in 2013 found that between 40% and 60% of people with bipolar disorder were in employment (McManus et al., 2016). The financial burden of unemployment and productivity losses are estimated to be £1.51 billion per year with approximately 76,000 people per year being unemployed as a result of bipolar disorder (NICE, 2014). As discussed in section 1.1.1.2 the barriers to employment for individuals with bipolar disorder are the same as those with schizophrenia; stigma and discrimination.

In addition to living with both the symptoms of the mental illness and the side effects of antipsychotic medication, the physical health of people with SMI is poor (Lawrence et al., 2013; Zolezzi et al., 2017). There are a number of physical health problems that are associated with those with SMI including, cardiovascular disease, diabetes, obesity and poor sexual health (DoH, 2016; Robson & Gray, 2007). Despite this, people with SMI face a number of barriers when accessing physical health care services (Happell et al., 2012; Robson & Gray 2007). These will be discussed in more detail in the next section of this chapter.

1.2 Severe mental illness and poor physical health

A number of studies attribute physical comorbidities among those with SMI as responsible for the lower life expectancy observed in this population (Lawrence et al., 2013; Zolezzi et al., 2017). This is generally because the severe symptomology and gaps in health care systems for people with SMI who are not routinely or consistently being offered physical health assessments or evidence-based medications for chronic physical health conditions and therefore, physical health conditions are not identified in a timely manner, nor are they managed effectively (De Hert et al., 2011; Tratnack & Kane, 2010; Zolezzi et al., 2017). It is reported that two thirds of deaths in people with SMI attributed to physical illness could be avoided (Mental Health Taskforce, 2016). The most common physical comorbidities attributed to people with SMI can be found in figure 1 below.

Figure 1 Physical health comorbidities associated with SMI



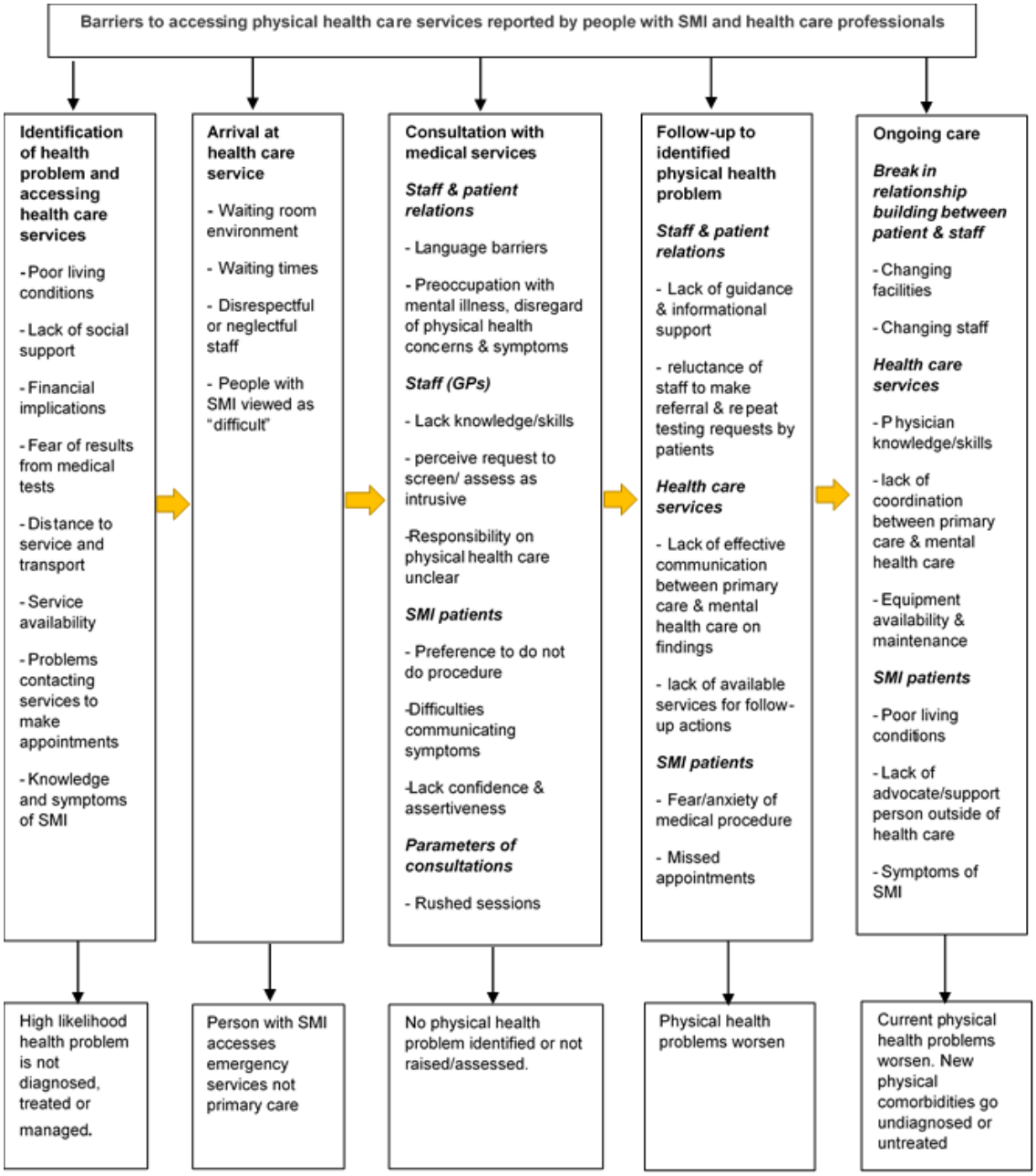
1.2.1 Barriers to good physical health in those with severe mental illness

Further to the mortality and morbidity gap, there is increasing evidence that there are inequalities in the physical health care provided to people with SMI (Zolezzi et al., 2017). There have been are a number of reasons proposed as to why the physical health of people with SMI is poor (DoH, 2016; Robson & Gray, 2007). These include health service-related factors, illness related factors, the health behaviours of people

with SMI and treatment related factors which are described below. (DoH, 2016, Happell et al., 2012; Robson & Gray 2007). It is important to note that the relationship between SMI and poor physical health is likely to be complex and multifaceted and these factors should be considered together rather than in isolation.

A narrative review was undertaken to explore the perceived barriers to good physical health for people with SMI (Happell et al., 2012). The review included 19 quantitative and qualitative studies that reported on the perceptions of both people with SMI and health care professionals in relation to barriers to care. Figure 2 below presents a summary and model of barriers in the health care process and to accessing physical health care services reported by people with SMI and health care professionals (Happell et al., 2012).

Figure 2 Model of barriers to accessing physical health care services reported by people with SMI and health care professionals (as proposed by Happell et al., 2012).



1.2.1.1 Health service-related factors for the poor physical health of people with severe mental illness

There are a number of service-related factors that are attributed to the poor physical health of people with SMI. The most commonly cited factors within the literature include the segregation of physical and mental health care services, the lack of coordination/communication between the two services, physicians lacking knowledge/skills in supporting people with SMI in primary care and, unclear roles in which health care professional should assess, manage and monitor the physical health of people with SMI (Barnes et al., 2007; Happell et al., 2012; O'Day et al., 2005; Robson & Gray, 2007). Furthermore, there is also the issue of diagnostic

overshadowing whereby clinicians attribute all symptoms of physical ill health to a person's mental disorder, thus people with SMI may receive incorrect diagnoses and/or delayed treatment (Jones et al., 2008; Shefer et al., 2014).

In addition to the organisational barriers that people with SMI face when addressing their physical health concerns there are also more practical barriers. Firstly, accessing physical health care services can be problematic with issues around making contact and telephone wait times to make an appointment (Happell et al., 2012; Schmutte et al., 2009). Transport is a further barrier to accessing physical health care services for people with SMI as many report not having access to a car nor the financial means to use public transport to attend appointments (Drapalski et al., 2008; Happell et al., 2012). In addition to these barriers people with SMI often report that when arriving at a health care setting, the environment when awaiting an appointment can be uncomfortable as they are often lengthy waits, busy and noisy causing increased levels of anxiety for people with SMI (Happell et al., 2012; O'Day et al., 2005; Miller et al., 2007). Furthermore, people with SMI have reported that staff in primary care can be disrespectful, thus encouraging people with SMI to disengage with these services (Miller et al., 2007).

1.2.1.2 Illness related factors for the poor physical health of people with severe mental illness

There are a number of illness related factors that may prevent people with SMI seeking help for their physical health. One of the key factors is that there are socio-economic consequences of suffering with an SMI, such as social isolation, unstable housing, poverty, unemployment and social stigma of which all have a negative impact on the physical health and health behaviours of people with SMI (Borba et al., 2012; Happell et al., 2012; Robson & Gray, 2007). In addition to this and in relation to a person's quality of life, living with both the symptoms of the illness and the side effects of antipsychotic medication negatively impact on a person's ability to function and therefore, even considering access to physical health care services, employment or relationships can be difficult (Happell et al., 2012; O'Day et al., 2005). It has also been suggested that individuals with SMI tend to be less willing to acknowledge the existence of physical health problems in themselves and often do not seek help for these (NICE, 2014). Due to the deficits in cognitive functioning associated with SMI, people with SMI may not be aware of any physical health problems they may be experiencing (NICE, 2014; Phelan, 2001). In addition, people with SMI experience low levels of self-esteem and are less motivated to look after their physical health (Phelan et al., 2001).

1.2.1.3 Health behaviours related to the poor physical health of people with severe mental illness

There are a number of behaviours that are commonly associated with the poor physical health of people with SMI. These include physical inactivity, use of alcohol and drugs, smoking, poor diet, and engaging in unsafe sexual practices (DoH, 2016; Gilbody et al., 2015; Gascoyne et al., 2016; Meake & Sikkema, 2005; Vancampfort et al., 2013). Within the international literature these behaviours are often referred to as 'lifestyle choices', however people with SMI may argue that these behaviours are a consequence of living with an SMI and the treatments for such (Bresee et al., 2010; De Hert et al., 2011; Robson & Gray, 2007; Zolezzi et al., 2017).

1.2.1.4 Treatment related factors for the poor physical health of people with severe mental illness

Despite antipsychotic medication helping to alleviate symptoms of schizophrenia and bi-polar disorder, aid recovery, lessen lengthy period in hospital, and reduce the risk of suicide, the side effects of such medication can have a negative impact on an individual's physical health (Correll et al., 2015; Robson & Gray 2007). Antipsychotic medication has been linked to physical health conditions such as CVD, and type 2 diabetes in the SMI population (Correll et al., 2017; Holt & Mitchell, 2015; Ward & Druss, 2015). For example, a meta-analysis was undertaken to assess the prevalence of CVD in the SMI population as CVD continues to be the largest contributor to premature death in this population (Correll et al., 2017). The meta-analysis included 92 published studies with a sample of 3,211,768 people with SMI, and 113,383,362 matched controls (Correll et al., 2017). After adjusting for confounding factors such as age, gender, diabetes and body mass index, the results of the meta-analysis found that people with SMI had 53% higher odds of CVD than the non-SMI group (odds ratio 1.53 (95% CI, 1.27, 1.83)). Furthermore, a causal link between antipsychotic medication and weight gain has been established within the SMI population (Foley & Morley, 2011; Kahn et al., 2008; Tarricone et al., 2010). Establishing this link is important as obesity is associated with physical health conditions such as diabetes and CVD which are already prominent in people with SMI (NICE, 2017).

1.3 Severe mental illness and sexual health

In the previous section of this chapter, the poor physical health of people with SMI was discussed with a specific focus on the barriers associated with accessing good physical health care. One physical health comorbidity that has received less attention in the UK is that of sexual and reproductive health in relation to SMI. This is discussed in detail throughout the rest of this chapter and will be the focus of this thesis.

1.3.1 Definition of sexual health

The World Health Organisation (WHO) (2006a) defines sexual health as “a state of physical, mental and social wellbeing in relation to sexuality. It requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free from coercion, discrimination and violence” (pg. 5). This definition is a global term which not only states that people have a right to sexual health care and to be free from sexually transmitted infections (STIs), it also incorporates people being able to express their sexuality freely, and their right to safe and satisfying relationships (WHO, 2006a). In addition to this, people have a human right to choose whether or not they are sexually active and engage in sexually intimate relationships (WHO, 2006a; Berer, 2004; Perlin, 2008; Dixon-Mueller et al., 2009; McCann & Shareck, 2013; McCann & Sharek 2016).

With regards to blood-borne viruses (BBVs), they are viruses caused by human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV). In relation to transmission, BBVs can be transmitted by blood or other body fluid that may contain blood (Pfaender et al., 2016). The most common form of transmission occurs when blood, semen or vaginal fluids pass from an infected person to another person by the virus entering the bloodstream of another person via a break in the skin or mucous membrane (i.e. sexual intercourse, sharing intravenous needles) (Pfaender et al., 2016). BBVs are considered to be a public health concern given their international prevalence and are responsible for millions of deaths each year (Pfaender et al., 2016).

According to the WHO (2016) each country should define the specific populations that are most like to be affected by BBV and STI epidemics. These are likely to include populations whom are likely to have a high number of sexual partners, such as sex workers and those paying for sex. The WHO suggest a number of other populations who may be at increased risk of BBVs and STIs including; men who have sex with men, transgender people, adolescents, prisoners, those living on the streets and people who use drugs (2016). One population that is not considered to be vulnerable or to be at a high risk of contracting a BBV or STI are people with SMI. However, the evidence base for this will be explored throughout the remainder of this chapter.

1.3.2 Sexual health and people with severe mental illness

A number of physical health conditions are associated with SMI and are well documented within the international literature, however, there is a limited evidence base for SMI and sexual health where there are often unmet needs. The barriers to

overall good physical health were discussed in section 1.2 of this chapter, this section will now consider the specific barriers to good sexual health within the SMI population.

Over the last four years, sexual health services in England have seen an increase in attendance of 13% from 2.9 million in 2013 to 3.3 million in 2017 (Health and Social Care Committee, 2019). This is despite the geographical variation in being able to access sexual health services in addition to the substantial public health budget cuts and the disintegration of services (Health and Social Care Committee, 2019). The difficulty in accessing sexual health services is then further compounded for those with SMI as they may not have access to a car nor the financial means to use public transport to attend appointments if services aren't local (Drapalski et al., 2008; Happell et al., 2012). In addition to this, the appointments in sexual health clinics are often on a 'drop-in' basis, this means that people with SMI can often feel uncomfortable due to lengthy waiting times and busy and noisy environments which may cause increased levels of anxiety, and therefore decrease the likelihood of them engaging with sexual health services (Happell et al., 2012; O'Day et al., 2005; Miller et al., 2007).

Although the data suggests that there is an increase in people attending sexual health services in England, there isn't any data for those with diagnoses such as schizophrenia or bipolar disorder, therefore, it is not possible to infer whether there are certain demographics (age, gender, socio-economic or marital status) within this population that influence their sexual health, or that make them more or less likely to engage with sexual health services. However, a cross sectional study within a cohort study of 'young people' exploring the association between psychiatric disorder and STIs found that people diagnosed with a mental illness were more likely to have an STI than those without a mental illness, however, when adjusted for gender and socio-economic status, there were no differences found between groups (Ramrakha et al., 2000).

In addition to person related factors, there are also a number of illness specific factors that need to be considered when discussing the impact of SMI on a person's sexual health. According to Waldinger (2015) both the positive and negative symptoms of schizophrenia may negatively impact on sexual relationships. Of particular interest is the negative symptom anhedonia (inability to experience pleasure) in which hypo-sexuality is associated. Hypo-sexuality manifests itself as a lack of sexual desire and lack of sexual interest (Raja & Azzoni, 2003). Although many of the sexual difficulties experienced by people with SMI are said to be common across all diagnostic groups, one aspect of sexual health that is unique to bipolar disorder is hyper-sexuality (Kopeykina et al., 2016). Hyper-sexuality occurs in the manic or hypomanic phase of

bipolar disorder, and is often characterised by a significantly increased libido, impulsive and disinhibited sexual behaviour which can lead to people engaging in risky sexually practices and can result in unplanned pregnancies or contracting BBVs/STIs (Kopeykina et al., 2016). However, once this acute phase of illness has passed, service users can often experience significant issues with their self-esteem due to their impulsive sexual behaviour, which in turn can influence how they view future sexual relationships in the post-manic period (Kopeykina et al., 2016; McCandless & Sladen, 2003).

As discussed above, there are a number of specific illness related factors that may have an impact on a person's sexual health. In addition to this, and to further complicate the sexual health of those with SMI, the adverse events of antipsychotic medication can have a significant impact on a person's sexual health (Robson & Gray, 2007). Both antipsychotic and antidepressant medication are known to cause sexual dysfunction in both men and women (Robson & Gray, 2007). The effects of these medications can result in increased levels of the hormone prolactin which can cause decreased levels of testosterone in men and decreased levels of oestrogen in women resulting in sexual dysfunction (Robson & Gray, 2007). The clinical effects of sexual dysfunction include reduced libido, difficulties with sexual arousal, disturbances in ejaculation/orgasm, loss of sensation in the genitals, painful and swollen breasts, and for women disturbed menstrual cycle and in some cases amenorrhea (Balon & Clayton, 2014; Higgins et al., 2010; Ma et al., 2018; Waldinger, 2015).

The reporting of sexual dysfunction within the literature varies considerably (25%-90%), therefore it is difficult to provide accurate estimates for incidence and prevalence (Higgins et al., 2010; Ma et al., 2018; Waldinger 2015). The impact of antipsychotic and antidepressant medication on sexual function and sexual satisfaction is one of importance for people with SMI, as this can lead to poor levels of medication adherence, which in turn can result in increased chances of relapse and poor long-term outcomes (Ma et al., 2018). Although it is clear that the adverse effects of medication can have a negative impact on a person's sexual function and quality of life, there are also a number of physical comorbidities and health behaviours associated with SMI that should also be considered within the context of sexual health and sexual dysfunction.

As discussed in section 1.2.1.3, there are a number of behaviours/lifestyle choices (poor diet, smoking, low levels of physical activity) that are associated with physical illnesses such as diabetes, obesity and CVD. The relationship between these physical health conditions, lifestyle choices and SMI are likely to be complex and multifaceted.

In addition to this, each of these are also considered to have an impact on a person's sexual health, function and satisfaction (Brown et al., 1999; Holt & Mitchell, 2015; Lambert et al., 2003; Maiorino et al., 2014; Robson & Gray, 2007; Ward & Druss, 2015). For example, diabetes is 2-3 times more prevalent in people with SMI compared to the general population and is associated with sexual dysfunction in both males and females (Enzlin et al., 2009; Holt & Mitchell, 2015; Feldman et al., 1994, Lu et al., 2009). Diabetes is a recognised risk factor for erectile dysfunction with studies reporting three times the risk of erectile dysfunction in the male diabetic population compared to the nondiabetic male population (Feldman et al., 1994; Giugliano et al, 2010). One explanation for this is the decreased flow of blood to the penis as a result of damaged blood vessels due to microvascular complications (Chew et al., 2013; Maiorino et al., 2014). The association between sexual function and women with diabetes is not as convincing, although most studies do report higher levels of dysfunction when compared to nondiabetic women (Maiorino et al., 2014). However, people with diabetes also often present clinically with obesity, sedentary lifestyles, hypertension, and as smokers with each of these factors alone being associated with sexual dysfunction and poorer sexual outcomes and satisfaction (Bajo et al., 2010; Maiorino et al., 2014; Mitchell & Holt, 2015; Robson & Gray, 2007). Sexual dysfunction is also associated the physical health conditions CVD and obesity, and as with diabetes the relationship is likely to be complex and inter-related (Foley & Morley, 2011; Jackson, 2009; Kahn et al., 2008; Roushias & Ossei-Gerning, 2018; Tarricone et al., 2010).

Aside from sexual dysfunction there are also factors such as poor diet, physical inactivity, self-esteem and body image that may impact on a person't sexual health as a result of obesity (Bajos et al., 2010; Esfahani & Pal., 2018; Newell & Gournay, 2009). Antipsychotic medications are associated with increased appetite, therefore people with SMI often consume foods that contain large amounts of fat and sugar in order to satisfy the hunger and also because they are a cheap option for those with a limited income (Newell & Gournay, 2009). In addition, people with SMI have been shown to be less physically active than the general population which further compounds the increased levels of obesity in the SMI population (Brown et al., 1999; Homel et al., 2002; McCreadie, 2003; Vancampfort et al., 2013). Bajos et al., (2010) reported that obsese men and women were more likely to report negative sexual outcomes compared to those who were not obese. However, this was particularly true for women who were less likely to view sex as an important part of life and whom were less likely to report having had a sexual partner in the previous 12 months (Bajos et al., 2010).

In addition to the factors discussed above, it is also important to consider the role of the mental health workforce and the wider general health workforce as there is some pessimism about whether it is possible to improve the physical health outcomes of people with SMI (Hyland et al., 2003). Despite this, research suggests that the attitudes of mental health professionals are generally positive, and they believe that it is part of their role to undertake physical health checks such as checking blood pressure and weight as well as providing dietary and exercise advice (Howard & Gamble 2011; Nash, 2005; Robson et al., 2013). However, lower levels of confidence were reported when mental health professionals were asked about supporting people with SMI with issues such as smoking cessation and sexual health (Hughes & Gray 2009; Hughes et al., 2017; Quinn et al., 2011; Robson et al., 2013). With regards to sexual health, mental health professionals and nurses in primary care report that they avoid this subject with their service users for a number of reasons; they do not feel comfortable broaching the subject; lack of knowledge/confidence in supporting service users with their sexual health; they don't feel the sexual health of service users is a priority and there is also concern over blurring professional boundaries (Hughes & Gray 2009; Hughes et al., 2017; Norman & Mitchell, 2016; Quinn et al., 2011; Robson et al., 2013).

Despite there being a number of barriers to good sexual health for people with SMI, sexual health and sexual satisfaction are still vital to relationship satisfaction, medication adherence, and overall quality of life (Byers, 2005, Sprecher and Cate, 2004, Yeh et al., 2006, Zemishlany and Weizman, 2008).

Whilst this body of literature is important, the specific focus of this thesis is the sexual health and behaviour of people with SMI and therefore will be the focus for the remainder of the thesis.

1.3.3 Previous research into the sexual health and relationship needs of people with severe mental illness

As discussed in previous sections of this chapter, mental health conditions such as schizophrenia and bipolar disorder can have a significant impact on an individual's life from employment, self-care, and also intimate relationships (NICE, 2014; Velthorst et al., 2010). The symptoms associated with schizophrenia (e.g. hallucinations, delusions) can be problematic for people when forming and maintaining relationships (Gray et al., 2002). In addition to this, elevated rates of depression have been reported in this population which is associated with a reduced libido (Gotesman & Groome 1997). Despite this, people with SMI still desire sexual contact (McEvoy et al., 1983). In contrast to historical beliefs that people with SMI are asexual, people with SMI are sexually active (Meade & Sikkema, 2005; Cournos et al., 1994). A systematic review

including 52 studies reported that 44% of people with SMI had reported being sexually active within the previous 12 months (Meade & Sikkema, 2005). The frequency of sexual contact was compared in a case-control study by McDermot et al. (1994), who found no difference in levels of sexual activity between those with SMI and those without SMI. Both groups reported an average of 11 sexual contacts in a month (McDermot et al., 1994). However, it is not possible to estimate the levels of sexual activity in the UK SMI population as there has been no data collected on this.

In the past, people with mental illness would spend their lives incarcerated in psychiatric hospitals 'asylums', a practice that continued into the 20th century (Gascoyne et al., 2016). The human rights of people with mental illness were disregarded, and in relation to their sexuality, the majority of people considered them to be asexual (Dobal & Torkelson, 2004). As asylums closed down and people with mental illness have been integrated into communities, this has afforded them more freedom in their adult relationships (Gascoyne et al., 2016). However, this also means that they are exposed to risks such as drugs, alcohol, domestic violence and sexual exploitation within those relationships, and it is unclear whether mental health services focused on life skills during these transitions in care (Ford et al., 2003; Elkington et al., 2010; Elliot et al., 2004; McCann, 2010a; Oram et al., 2014). The recovery movement promotes the concept of quality of life and living a life beyond that of managing a mental illness (Boardman & Friedli, 2012; Shepard et al., 2008). However, a criticism of the recovery movement is that it has failed to incorporate sexuality and intimate relationships which are an important aspect of an individual's wellbeing (Gascoyne et al., 2016).

Although the human rights of people with SMI are receiving increased attention, they continue to face stigmatisation and discrimination (Gerlinger et al., 2013, Link et al., 1997). Stigma is defined as: "The phenomenon whereby an individual with an attribute which is deeply discredited by his/her society is rejected as a result of the attribute. Stigma is a process by which the reaction of others spoils normal identity" (Goffman, 1963, pg. 3). Stigma was identified as the biggest obstacle to the progress of mental health care by the WHO (WHO, 2001). The negative effects of labelling someone with SMI are widely documented within the literature, and is associated with people facing discrimination in employment, education and health care (NICE, 2014; Link et al., 1997; Ben-Zeev et al., 2010; Corrigan, 2002).

However, until recently there has been little consideration about how stigma impacts on the sexuality and sexual behaviours of people with SMI despite it being acknowledged

that they contribute to a person's potential recovery (Wainberg et al., 2016, Kelly & Deane, 2011, Maj, 2011).

Although mental illness stigma is associated with social and sexual isolation, recent evidence suggests that it may also be linked to individuals engaging in behaviours associated with increased risk of BBV/STI infection (Wright et al., 2007; Elkington et al., 2010; Elkington et al., 2013). A study undertaken in New York City explored the views of 92 women in relation to stigma, discrimination and their sexual health and behaviour (Collins et al., 2008). The study found an association between women that had experienced discrimination due to ethnicity, gender, drug use, mental health diagnosis and having casual sexual partners (Collins et al., 2008). The women stated that having a mental illness limited their opportunities for intimate relationships which led them to engage in sexual behaviours associated with increased risk of BBV/STI infection (Collins et al., 2008). Similarly, in a sample of 98 people with SMI in Brazil it was found that those who had experienced greater sexual stigma reported that they were more likely to have condom less sex (Guimarães et al., 2010). Furthermore, a qualitative study undertaken in Brazil found that sexual stigma was associated with an inability to choose their sexual partners and negotiate safe sex (Wainberg et al., 2007). These studies provide evidence that people with SMI experience sexual stigma and this is associated with them engaging in high risk sexual practices. As a result of this people with SMI are at an increased risk of contracting BBVs and STIs (Hughes et al., 2015).

A systematic review exploring the prevalence of BBVs in people with SMI found elevated rates of Human Immunodeficiency Virus (HIV), hepatitis B and hepatitis C (Hughes et al., 2015). The pooled prevalence of HIV from 44 studies, including a total of 21,071 individuals was found to be the highest in Africa at 19% (Hughes et al., 2015). For Europe and America, the pooled prevalence rates for HIV were reported to be 2% (95% CI, 0.8, 4.4) and 6% (95% CI, 4.3, 8.3) respectively which suggests significantly elevated rates of infection in the SMI population as the prevalence of HIV in the American general population is reported to be 0.6% (Hughes et al., 2015). There was no prevalence data for the UK.

In relation to hepatitis B, the pooled prevalence from nineteen studies and a total of 8163 individuals with the highest pooled prevalence rate of 9.7% (6.0 to 15.3) being reported in Asia (Hughes et al., 2015). The pooled prevalence rate for hepatitis C was from 28 studies with a total of 14,888 individuals and were found to be the highest in America at 17% (95% CI, 13.2, 22.6) (Hughes et al., 2015). Again, this suggests significantly elevated rates of hepatitis C in the SMI population as the prevalence of

hepatitis C in the American general population was reported to be 1% (Centre for Disease Control and Prevention, 2015).

A number of explanations for the elevated rates of BBVs have been proposed within the research literature such as sexual stigma as discussed above, acute exacerbation of symptoms, comorbid drug and alcohol use, and engaging in sexual behaviours associated with the increased risk of BBV/STI infection (Elkington et al., 2013; Hughes et al., 2015; McKinnon et al., 2003; Meade & Sikkema, 2005; Wainberg et al., 2016).

1.4 Summary

This chapter has set out the context for the thesis by highlighting that the physical health of people with SMI is poor, and in particular the sexual health and relationship needs of those with SMI has received less attention in the UK. This will be the focus for the remainder of this thesis.

The next chapter presents the rationale, motivation, and overarching aims of this thesis as well as a brief discussion for the need for pragmatism in health services research (HSR). The thesis structure is also described.

Chapter 2- Rationale and aims of the thesis

This chapter will provide a brief summary of the background to this subject area as discussed in chapter 1, presenting the rationale and motivation for this thesis. The overarching aims of this thesis are then presented, followed by a brief discussion around the need for pragmatism in health services research (HSR). Finally, the structure of the thesis is described.

2.1 Rationale

People with severe mental illness (SMI) experience significant inequalities in physical health and die on average between 15 and 20 years earlier than the general population (Zolezzi et al., 2017; Lawrence et al., 2013). The lower life expectancy observed in people with SMI has been attributed to the physical comorbidities that are commonly associated with this population including cardiovascular disease (CVD), diabetes, substance use, obesity, dental and oral health and reproductive and sexual health (DoH, 2016; Lawrence et al., 2013; Zolezzi et al., 2017). To address this, physical health is now higher on the health policy and practice agenda (DoH, 2016). Despite this, sexual health is significantly neglected within current UK health policy, and research suggests that the sexual health of people with SMI is poor (Gascoyne et al., 2016; Hughes et al., 2015; Lagios & Deane 2007; Wainberg et al., 2016).

One area of concern is that people with SMI are at an increased risk of contracting Blood Borne Viruses (BBVs) and other Sexually Transmitted Infections (STIs). A recent meta-analysis found a pooled prevalence rate of HIV in the USA to be 6% in people with SMI compared to 0.6% of HIV infection in the USA general population (Hughes et al., 2015). One suggestion for the increased risk of contracting BBVs/STIs in this population is that people with SMI are more likely to engage in sexual behaviours that are associated with the increased likelihood of BBV/STI infection such as, unprotected sex, sex trading and paid sex work as well as the risks associated with substance use itself (intoxication, impairing decision-making or leading to being exploited whilst under the influence) (Elkington et al., 2010; McKinnon et al., 2001; Meade et al., 2009).

There is a need to be able to reliably assess those deemed to be at risk of contracting BBVs and other STIs in this ‘at risk’ population to inform the development of interventions to promote positive sexual health and relationships. Much of the research in this field has be undertaken in the USA and Brazil (Cournos et al., 1994; Guimarães et al., 2014; McKinnon et al., 1993; Wainberg et al., 2008) and has demonstrated feasibility and acceptability with populations of people with SMI in those countries.

However, these countries have a very different set of cultural, organisational and socio-economic factors compared to the UK.

The motivation for this thesis and research originates from the researcher working in both NHS and private psychiatric hospitals as a support worker. Observations from this experience suggest that despite staff not wanting to engage in conversations around sexual relationships, patients openly wanted to discuss their relationships and sexual experiences as part of their recovery. There is limited information on this subject area from a UK perspective, and there is a need to undertake research that begins to explore whether it is feasible and acceptable to talk to the SMI population about their sexual health and behaviour. Further research in the UK is also needed to provide data that would guide the future direction of health care services in terms of being able to identify the people most at risk of contracting STIs and BBVs and inform government policy on improving the overall sexual health of those with severe mental ill health in the UK.

2.2 Thesis aims

As part of the Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC YH) there was a programme of research led by Professor Liz Hughes on improving the sexual health of people with SMI. As part of this programme of research, this PhD thesis will explore the intersection between SMI, sexual health and behaviours associated with an increased risk of BBV/STI infection, with a specific focus on the acceptability of undertaking sexual health and behaviour research in people with SMI in the UK. This will be addressed through a systematic review; an acceptability and feasibility study; a qualitative study and the analysis of an acceptability survey collected as part of the Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment study (RESPECT study). The aims of the thesis are outlined below:

- To explore sexual behaviours associated with the increased risk of BBV/STI infection in people with SMI.
- To explore whether it is feasible to undertake sexual health and behaviour research in the UK in a population of people with SMI.
- To explore whether it is acceptable to undertake sexual health and behaviour research in the UK in a population of people with SMI.
- To explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI in the UK.

2.3 The pragmatic nature of health services research

The focus of this thesis is not to reflect the interests of academics alone, it also constitutes Health Services Research (HSR) as it aims to provide feedback to Community Mental Health Teams (CMHTs) with the view that this information will facilitate conversations amongst their peers about addressing the sexual health and relationship needs of their service users with SMI (Stryer et al., 2000). In addition to this, it is anticipated that the findings of this thesis will be disseminated widely. Summaries of the findings will be disseminated to the service user participants, and also to the NHS trusts that were involved in this research as they may not be aware of, be readers of, or have access to academic publications. Furthermore, this information will highlight areas which need addressing within UK policy and health agenda surrounding the physical health care needs of people with SMI and more specifically their sexual health needs.

The philosophical position of both the author and that of the thesis, is underpinned by pragmatism. The pragmatic paradigm promotes a mixed methods approach to understanding human behaviour as it argues that phenomena cannot be solely answered using one scientific method as would be suggested by positivists (quantitative methods) and interpretivists (qualitative methods) (Kivunja & Kuyini, 2017; Seale, 1999). Therefore, the research methods within this thesis were selected based upon whether they were the most appropriate to answer the research questions presented in section 2.2 of this chapter. Silverman (1993) suggested that there is a need for a healthy relationship between philosophy and pragmatism. More recently it has been suggested that a mixed methods approach allows researchers to gain a more holistic understanding of human behaviour as it advocates the understanding of actual human behaviour as well as the beliefs surrounding those behaviours (Alise & Teddlie, 2010; Kivunja & Kuyini, 2017).

Despite this thesis using predominantly quantitative research methods (chapters 3, 4 and 6), where appropriate has also used qualitative research methods to gain a deeper understanding of the research question (chapter 5). The different methods and justifications for their use are described within the chapters to which they apply throughout this thesis.

2.4 Thesis structure

This thesis consists of five chapters which aims to address the research aims described above in section 2.2:

Chapter 3 presents a systematic review and meta-analyses which explored whether people with SMI are more likely to engage in sexual behaviours that are associated with the increased risk of contracting BBVs/STIs compared to those with no history of mental illness. The methodology for the systematic review is described in that chapter including; information sources, search terms, eligibility criteria, study selection, data extraction, quality assessment and data synthesis. The results and discussion are also presented.

To address gaps identified in the literature, an acceptability and feasibility study was undertaken in chapter 4 which sought to explore the acceptability and feasibility of conducting sexual health research, specifically in relation to sexual behaviours associated with the increased risk of BBV/STI infection, in a population of people with SMI in the UK. The feasibility of undertaking research in this area was explored by a quantitative assessment of numbers eligible, numbers consenting to participate and numbers of completed questionnaire/interviews. To explore whether it is acceptable to discuss sexual and health behaviour with people with SMI in the UK, questionnaires/interviews were undertaken with service users to gain feedback on the data collection measures used and the method of data collection. The methods of this primary research, followed by the results and discussion are presented within that chapter.

In order to gain a deeper understanding and build on the findings of the acceptability and feasibility study, a qualitative study was undertaken and reported in Chapter 5. This study used semi-structured interviews with mental health professionals to explore their views on the sexual health and relationship needs of people with SMI in the UK. Chapter 5 presents the methods used, the results as guided by thematic analysis and the discussion.

Chapter 6 builds on the preliminary findings of the acceptability and feasibility study presented in Chapter four. It aimed to explore the acceptability and experiences of people with SMI in the UK who took part in the RESPECT study using acceptability data from the baseline and exit feedback questionnaires. This chapter provides some context to the RESPECT study and its relevance to this thesis followed by the study's methods. In addition, the results and discussion are then presented.

The findings for the thesis are synthesised in chapter 7 which considers the key findings in relation to the overall aims of the thesis before discussing the suggestions for future research, recommendations for policy and practice, and the strengths and limitations of the thesis as a whole. Some of these issues are also identified and

discussed separately within each of the thesis' empirical chapters (Chapters 3, 4, 5 and 6).

Chapter 3 - Are adults with severe mental illness more likely to engage in sexual behaviours that are associated with increased risk of blood borne viruses/sexually transmitted infections compared to adults without no history of mental illness? A systematic review.

The aims and methodology for a systematic review of observational studies exploring whether people with severe mental illness (SMI) are more likely to engage in sexual behaviours that are associated with increased risk of contracting blood borne viruses (BBV) or sexually transmitted infections (STIs) compared to adults with no history of mental illness will be outlined in this chapter. Following an introduction to the systematic review methodology, the rationale and aims of this study will be described. The chapter then presents a description of the study's methodology including; information sources, search terms, eligibility criteria, study selection, data extraction, quality assessment and data synthesis. Finally, the results and discussion are presented.

3.1 Introduction

Systematic reviews are becoming more extensively used by researchers, clinicians and policy-makers to inform practice and decision making related to health care (Centre for Reviews and Dissemination (CRD), 2009). Due to the large volume of research being conducted in health care, it can be difficult to keep abreast of the latest research and therefore best practices (CRD, 2009). In addition, individual studies may have methodological weaknesses and be open to bias, which in turn can lead to misleading results and inconsistent conclusions. Hence it can make it difficult to know which the most reliable results are, and what evidence should guide clinical practice and policy (Wilson et al., 2008). Systematic reviews allow researchers to apply strict scientific and reproducible methodology based on pre-defined criteria to identify and explore all relevant studies in order to summarise all of the available evidence in relation to a specific topic area, meaning that it is more accessible to those making decisions about policy, commissioning and healthcare practice (Chalmers et al., 2002; Wilson & Petticrew, 2008). Some systematic reviews also, where appropriate, include quantitative syntheses or meta-analyses which use specific statistical methods for pooling data from separate datasets (Biondi-Zoccai et al., 2011). If studies are homogenous enough then combining the results of several studies in a meta-analysis can produce more accurate and reliable estimates than one study alone (Oxman, 1993).

Despite the strengths of undertaking a systematic review and meta-analyses, it is also important to consider the limitations. One limitation is that many systematic reviews will only include studies in English whereby positive results are more likely to be published, therefore, likely to be missing important international research and thus increasing the likelihood of bias at an early stage of the review process (Biondi-Zoccai et al., 2011). A further limitation to consider is that some systematic reviews may only include a small number of studies in relation to a specific topic area, or some studies may be assessed as being methodologically flawed (or of low quality) whereby combining them in a systematic review or meta-analysis would lead to misleading results and conclusions (Higgins et al., 2011).

The methodology underpinning systematic reviews of randomised controlled trials (RCTs) has been extended to systematic reviews of observational studies (Reeves et al., 2008). There are instances whereby research questions cannot be answered by an RCT, for example, rare health conditions, or when it would it be unethical to expose participants to potentially harmful situations, therefore observational studies may be a more appropriate method of gathering data (Stroup et al., 2000).

3.2 Rationale and aims

3.2.1 Severe mental illness and behaviours associated with the increased risk of BBV/STI infection

The evidence from chapter 1 suggests that people with SMI are a high-risk group for contracting BBVs and/or other STIs. One explanation for this within the international literature is that people with SMI engage in behaviours that are associated with an increased risk of contracting BBVs and/or STIs, this will be explored further in this section.

Sexual risk behaviour in the context of BBVs and STIs refers to condom less anal, vaginal and oral sexual behaviour. There are a number of sexual behaviours identified within the international literature that are linked to the increased risk of a person contracting BBVs/STIs. To provide some context for this chapter and the remainder of this thesis these are defined below.

Sexual trading is defined within the literature as having sexual intercourse in exchange for drugs, alcohol, accommodation, favours or other things (Brown et al., 2010; Coverdale et al., 1997; Coverdale et al., 2000). Sex with a person who uses drugs is defined within the literature as having sexual intercourse with an intravenous drug user (Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007). Pressured into unwanted sex is referred to within the literature as a person being coerced into

engaging in sexual acts rather a person being sexually assaulted (Coverdale et al., 1997; Coverdale et al., 2000; Koen et al., 2007; Miller & Finnerty, 1996). More than one sexual partner in 12 months (multiple sexual partners) is considered to be a sexual risk behaviour as research suggests that between 30% and 50% of people who report more than one sexual partner use condoms inconsistently, and therefore increase their risk of BBV/STI infection (Bailey et al., 2008; Gibbs, 2013). Paid sex work is defined within the international literature as receiving money to engage in sexual acts (Grassi et al., 1999; Mc Grath-Lone et al., 2014; Miller & Finnerty, 1996). STIs and BBVs are considered to be more prevalent in people who engage in paid sex work (Mc Grath-Lone et al., 2014; Mc Grath-Lone et al., 2014). Having sex with someone known for less than 24 hours is defined within the literature as engaging in casual sex (Coverdale et al., 2000; Koen et al., 2007; Lyons, 2017). Casual sex is associated with inconsistent condom use, and therefore increases the risk of contracting a STI or BBV (Lyons 2017).

Factors such as consuming alcohol/drugs prior to sexual intercourse are reported within the literature as sexual risk behaviours (Brown et al., 2011; Grassi et al., 1999; Koen et al., 2007). However, they should be considered mediating factors as they are likely to increase the likelihood of condom less oral, vaginal and anal sexual intercourse (Kalichman et al., 2004; Meade & Sikemma, 2005). This is typically due to loss of inhibition leading to poor judgement and not using condoms however, it could also be due to someone being drunk and incapacitated and another person exploiting the situation (Dutra et al., 2014; Khalifeh et al., 2016; Meade & Sikemma, 2007).

3.2.2 Previous research on the sexual risk behaviour of people with severe mental illness

A search on the international prospective register of systematic reviews (PROSPERO) found that there have been no systematic reviews undertaken to explore whether people with SMI are more likely to engage in sexual behaviours that are associated with increased risk of BBV/STI infection compared adults with no history of mental illness. There are however, a number of scoping reviews which have explored the relationship between SMI and the acquisition of BBVs (Cournos & McKinnon, 1997; Lagios and Deane, 2007; McCann, 2003). The literature review undertaken by Cournos and McKinnon (1997) explored the first decade of research in this area in the USA and found that only 11 peer reviewed studies had been undertaken. Of those studies all were based in New York, which was considered to be an epicentre of the Acquired Immune Deficiency Syndrome (AIDS) epidemic worldwide. They found the seroprevalence of HIV amongst the SMI population varied from 4% to 22.9% and that

the rate of infection was as equally likely between men and women (Cournos & McKinnon, 1997). The review also reported that rates of HIV infection were linked to risky sexual behaviours with the highest rates of seroprevalence being associated with people reporting a history of being paid for sex, or paying for sex, 37.9%; or sex with a person who injected drugs, 37.5% (Cournos & McKinnon, 1997). The sample sizes of the individual studies however were small (n=29 and n=24) and the results should be considered with caution. A further review was undertaken in 2007 by Lagios and Deane which aimed to explore whether SMI was a risk marker for contracting BBVs or other sexually transmitted infections (STIs). The review found 51 studies which were mainly conducted in the USA reporting on rates of sexual risk behaviour. The findings of the scoping review support those suggested by the earlier scoping review (Cournos & McKinnon 1997). In the later scoping review they found that sexual risk behaviour, rates of BBVs and other STIs were more prevalent in those with SMI compared to the general population with prevalence rates of HIV ranging from 0% to 23.8% in the SMI population compared to 0% to 17.4% in the general population (Lagios & Deane, 2007). The review also found that there were few countries that had data relating to the prevalence of BBVs or other STIs in people with SMI and therefore these estimates may be inflated (Lagios & Deane, 2007).

3.2.2.1 Assessing the methodological quality of systematic reviews 2- Appraisal of Meade and Sikkema systematic review (2005)

One systematic review conducted by Meade and Sikkema (2005) was found when scoping the literature entitled “HIV risk behaviour among adults with severe mental illness: A systematic review”. One reason to conduct a further review is the age of that review: it was published 13 years ago. It is possible that subsequent studies have altered the conclusions of Meade and Sikkema (2005). An additional reason to conduct a further review is if there are methodological limitations of an earlier review. To assess this, the review by Meade and Sikkema (2005) was examined using the Assessing the Methodological quality of Systematic Reviews 2 (AMSTAR 2) 16 item checklist developed by Shea et al. (2017), which is a tool specifically designed to assess the quality of systematic reviews that include RCTs, observational studies or both. A copy of the AMSTAR 2 checklist can be found in Appendix 2.

Item one on the AMSTAR 2 checklist asks whether the research question and inclusion criteria covered aspects of the population, intervention, comparator group and outcomes. The Meade and Sikkema review (2005) did report on population, intervention and outcomes, however, only cross-sectional studies were included in the review and therefore a description of comparator groups would not have been applicable.

Item two on the AMSTAR 2 checklist asks whether an *a priori* design was provided. Meade and Sikkema (2005) did not meet this criterion; they did not report whether or not there was a review protocol that outlined *a priori* study methods and therefore it is unclear whether the review method was established before commencing the review. It is important to have a review protocol because it limits bias in post hoc decisions in methodology and selective reporting (Liberati *et al.,* 2009).

The third item questions whether review authors justified their selection of study designs included in their review. This criterion was not met as Meade and Sikkema (2005) did not provide a description or justification for the study design included in their review.

The fourth item on the AMSTAR 2 checklist item refers to a comprehensive literature search being performed. The authors reported searching electronic databases MEDLINE and PsychINFO from the year 1981, when the AIDS epidemic began but did not report the end date of the search. Although this would meet part of the AMSTAR 2 criterion, which requires a search of at least two electronic databases, there is evidence which suggests that this is not adequate (McDonald *et al.,* 1999; Sampson *et al.,* 2006). McDonald *et al.* (1999) found that whilst there is an overlap in health care databases, there are studies that are in one but are not indexed in others; therefore, to ensure a comprehensive search is undertaken more than two electronic databases should be searched to ensure maximum coverage of the literature (McDonald *et al.,* 1999). The keywords used during the search were reported but no search strategy was provided. The search strategy is a complex but integral part of a systematic review; it allows readers to determine the scope of the search and to replicate it if necessary (Liberati *et al.,* 2009). It is recommended by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement, the internationally accepted standard for reporting systematic reviews, that authors should report a complete search strategy for at least one electronic database (Liberati *et al.,* 2009).

Meade and Sikkema (2005) documented that reference lists of published studies were checked, and additional studies were found using this method. There was however, no mention by the authors of hand searching or that grey literature sources were searched. In addition to this, the authors reported that the search was limited to studies published in English only with no justification for this. The absence of a comprehensive grey literature search and restricting the search to studies only published in English may have subjected the review to publication bias. Publication bias refers to when studies that report positive results usually get published in English, more frequently and in higher impact journals than studies that report negative or neutral results or studies

not reported in other languages (Shea *et al.,* 2017). When systematic reviews do not search grey literature, thus only including published results, it is possible that the results may show inflated outcomes and therefore conclusions drawn should be interpreted with caution (Liberati *et al.,* 2009; Shea *et al.,* 2017). In light of this, Meade and Sikkema (2005) did not meet the criteria for this item on the AMSTAR 2 checklist.

The authors did not describe their procedures for study selection against the inclusion criteria, methods for data extraction or report the way in which disagreements were resolved, and thus the review may be subject to reviewer bias. Edwards *et al.* (2002) found that approximately 8% of eligible studies would be missed if a single researcher undertook the selection process compared to all eligible studies being selected when more than one researcher is involved in the process. The data extraction process should be undertaken by a minimum of two independent researchers in order to minimise bias (CRD, 2009). Therefore, Meade and Sikkema (2005) did not meet criterions five or six (duplicate study selection and data extraction).

Meade and Sikkema (2005) did not describe the number of studies that did not meet the inclusion criteria for the review, nor did they provide a list of excluded studies, therefore, the authors did not meet criterion seven on the AMSTAR 2 checklist.

Item eight on the AMSTAR 2 checklists asks whether the review authors describe the populations, interventions, comparators, outcomes and research designs of the included studies in adequate detail, Meade and Sikkema (2005), met this criterion.

The quality of the included studies was not formally assessed, and it is therefore difficult to establish whether the conclusions and recommendations suggested by Meade and Sikkema (2005) are appropriate. It is important to assess the quality of the included primary studies as bias in the primary studies may lead to increases in the effects reported in a meta-analysis (Higgins *et al.,* 2011). The outcomes of quality assessing the included studies are also used to guide the interpretation of the results and when this is not completed, conclusions should be considered with caution (Higgins *et al.,* 2011). Meade and Sikkema (2005), therefore, did not meet the AMSTAR 2 criteria for items nine or 13 (scientific quality of included studies assessed and documented, and risk of bias accounted for when interpreting the findings of the review).

Meade and Sikkema (2005) did not report on the sources of funding for the studies included in the review, or whether they looked for this information and therefore don't meet the criteria for item ten on the AMSTAR 2 checklist.

Items 11, 12 and 15 on the AMSTAR 2 checklist refer to the appropriateness of, and method of meta-analysis if a meta-analysis was undertaken as part of the systematic review. A meta-analysis was not conducted in the Meade and Sikkema review (2005), therefore, these items of the AMSTAR 2 checklist are not applicable. The authors did report that a meta-analysis was considered but because of the heterogeneity of data collection tools and outcomes this was not conducted. In relation to this, item 14 on the AMSTAR 2 checklist asks whether authors provide an explanation of, or discuss the impact of heterogeneity on the results of the review. As noted above heterogeneity in data collection tools and outcomes was the justification for not undertaking a meta-analysis, however, the impact of this on the results and conclusions of the review were not discussed. Therefore, Meade and Sikkema (2005) did not meet the criteria for item 15 on the AMSTAR 2 checklist.

Finally, item 16 on the checklist asks whether the review authors reported on any potential conflicts of interest or funding they received to undertake the review. Meade and Sikkema (2005) did not report whether there were any potential conflicts of interest but did report the funding came from a National Institute of Mental Health grant. However, both of these aspects need to be reported in order to meet the criteria on the AMSTAR 2 checklist, therefore the review undertaken by Meade and Sikkema (2005) did not meet this criterion.

To conclude, the quality assessment using the AMSTAR 2 checklist indicates there are a number of methodological limitations with the Meade and Sikkema (2005) review of HIV risk behaviour in people with severe mental illness. Therefore, in line with the AMSTAR 2 checklist, the overall rating for the confidence in the results of the review would be critically low as there was more than one critical methodological weakness, suggesting that the results of the review should not be relied upon.

3.2.3 Aims of the review

The research literature presented in chapter 1 (section 1.3.2) and the scoping reviews discussed above in section (3.2.2) suggest that people with SMI appear to engage in sexual behaviours that are associated with an increased risk of contracting BBVs and/or other STIs, however, the magnitude of this relationship remains unclear. As discussed in the previous section there has been one systematic review undertaken in this area, however, this was conducted 13 years ago and there were a number of methodological flaws identified. Therefore, to further explore the intersection between SMI and sexual behaviour, and to address some of the methodological flaws of the earlier review, a systematic review has been undertaken with the aim of exploring whether adults with SMI are more likely to engage in sexual behaviours that are

associated with the increased risk of contracting BBVs/STIs compared to those with no history of SMI.

3.3 Methodology

This systematic review was undertaken following the Centre for Reviews and Dissemination (CRD) guidelines for undertaking systematic reviews in healthcare to ensure rigor and transparency (CRD, 2009). These have been recommended by the National Institute for Health and Care Excellence (NICE) as a source of good practice (CRD, 2009). The core stages of a systematic review include: ensuring objectives are stated clearly with pre-defined inclusion and exclusion criteria for studies; a transparent and reproducible methodology; a rigorous and systematic search in order to try and capture all studies that would meet the eligibility criteria; assessing the methodological quality of included studies and a narrative synthesis of the results of included studies, along with a meta-analysis where appropriate (Higgins et al., 2011).

The Cochrane Handbook was also consulted for guidance on the inclusion of non-randomised studies in instances where methods differ due to variations within study designs from the inclusion of randomised controlled trials (RCTs) alone (Reeves et al., 2008). Examples of these differences include: creating a search strategy for observational studies as these are required to be sensitive rather than specific and methods for assessing the methodological quality of the included studies (Reeves et al., 2008). Observational study designs lend themselves to different sources of potential bias, and therefore have their own methods/tools of quality assessment which should be utilized (Stroup, 2000).

As this was a systematic review of observational studies the review is reported in line with the Meta-Analyses of Observational Studies in Epidemiology (MOOSE) guidelines (Stroup et al., 2000). These guidelines were developed to ensure that systematic reviews and meta-analyses of observational studies are reported in a transparent and detailed manner to allow readers to evaluate the strengths and weaknesses of the review - and to be able to replicate the review if required.

A detailed systematic review protocol was developed before the review was conducted. This provided a detailed *a priori* description of the inclusion criteria, search strategy, data sources, method of data extraction and quality assessment, and also the anticipated method of data synthesis. The protocol is provided in appendix 3. The protocol was registered online with the international prospective register of systematic reviews (PROSPERO) (registration number CRD42015020703). This reduces the risk of duplicate reviews, and more importantly, allows other researchers to compare the

intended review methods and analyses with that conducted. This is important to minimise the possibility that researchers alter the analysis post-hoc to obtain results in keeping with pre-conceived ideas of the research area, and therefore, introduce bias.

3.3.1 Information sources

3.3.1.1 Data sources

The electronic databases searched were:

- MEDLINE In-Process & Other NON-Indexed Citations (R) (via OvidSP)
- PsycINFO (via OvidSP)
- EMBASE (via Ovid SP)
- CINAHL (via EBSCO)
- AIDSLINE (via EBSCO)
- Web of Science (via Thomson Reuters)

The electronic databases listed above were chosen because they are standard health-related bibliographic databases; they provide a large collection of published articles from around the world. No restrictions were placed on the searches in terms of publication status, publication date or language. Each database was searched between the date of inception and August 2015; the search was updated in September 2018 to ascertain whether any new research had been published since the initial search.

A number of additional sources were also searched including the following grey literature databases, dissertations and theses, and websites:

- Networked Digital Library of Theses and Dissertations
- Web of Science Conference Proceedings- Conference Proceedings Citation Index- Science (CPCI-S), Conference Proceedings Citation Index- Social Science & Humanities (CPCI-SSH)
- The British Library Electronic Theses Database (EThOS)
- ProQuest Dissertations and Theses
- OAISTER
- OpenGrey

This was done to ensure the search was as comprehensive as possible.

The search strategies used for the primary electronic databases were simplified for the grey literature databases as these databases did not accommodate long search strings. In addition to the above, reference lists of included studies were searched to ensure that no potential studies for inclusion were missed.

3.3.2 Search terms

The literature search strategies were developed to identify observational studies exploring sexual behaviours associated with the increased risk of contracting BBVs or STIs in adults with SMI. The search terms were constructed using MEDLINE and then adapted for the other databases. Specific search terms were identified by scanning key journal articles identified from preliminary searches of the literature and also from searching Medical Subject Headings (MeSH) terms for specific electronic databases. The search strategy did not include index terms relating to study design as many non-randomised studies are not indexed consistently in bibliographic databases, therefore increasing the likelihood of missing potentially relevant studies (Reeves et al., 2008). The Cochrane group for non-randomised studies (Reeves et al., 2008) also recommends that specific outcomes are not included in search strategies to ensure that any adverse or obscure outcomes are retrieved by the search. With this in mind, the search strategy was based on terms for two constructs connected by the Boolean term AND:

a) Severe mental illness terms
b) Blood borne virus or other sexually transmitted infection terms

The final search strategy for MEDLINE, which is provided in appendix 4, was checked for sensitivity by an information specialist from the Centre for Reviews and Dissemination at the University of York alongside clinical experts. The search strategy was designed to be sensitive rather than specific to capture all available literature related to this topic area (Reeves et al., 2008).

3.3.3 Study eligibility criteria

3.3.3.1 Population

The population of interest for this review were adults aged eighteen or over with a diagnosis of SMI. As discussed in Chapter 1 (section 1.1) there is no agreed definition of SMI, a pragmatic definition was adopted following guidance for improving the physical health care of people with SMI, a recent epidemiological study that aimed to operationalise the term SMI, and also from reviewing how SMI has been defined in other studies (Peckham et al., 2017; Ruggeri et al., 2018; White et al., 2008). Therefore, in line with definition adopted for this thesis, for the purpose of this review, SMI was defined as a documented diagnosis of Schizophrenia or delusional/psychotic illness (ICD F20, F21- F29 or DSM-equivalent) or bipolar disorder (ICD F31 or DSM-equivalent) (APA, 2013; WHO 2016).

To be included in this review the SMI-inclusive diagnosis needed to be clearly established by a structured clinical interview for establishing a DSM-IV or ICD-10 diagnosis (e.g. Structured Clinical Interview for DSM) (First et al., 2015), or made by a psychiatrist and have been documented in case notes. It was anticipated that studies would have a mixture of diagnoses. Therefore, this review included studies where the greatest proportion of the sample (over 75%) had a diagnosis of SMI as defined above as SMI comes with more profound and global impact on social functioning (Raj, 2013; Thornicroft et al., 2004). In addition to this, differing diagnoses could have an impact on a person's sexual activity. For example, some research suggests that a diagnosis of major depressive disorder (MDD) reduces the likelihood of a person engaging in 'high-risk' sexual behaviours due to decreased interest in sexual intercourse and sexual activity (Rogers et al., 2003; Rubb et al., 1993). However, there is also conflicting evidence that depression and hopelessness are associated with STIs (Chen et al., 2008). Therefore, MDD was not included in the definition of SMI used for this review as to ensure the results where pooled in a meta-analysis, were not artificially inflated or deflated.

3.3.3.2 Comparators

This systematic review included comparator populations that did not have a history of any mental illness. This may have been ascertained by undergoing a diagnostic clinical interview as part of a research study or by participants self-reporting no history of SMI.

3.3.3.3 Outcomes

The outcome of interest for this review were sexual behaviours associated with the increased likelihood of contracting or transmitting BBVs and/or STIs. Examples of these identified within the literature are defined above in section 3.2.1 of this chapter. In addition to the outcomes identified in section 3.2.1, whilst not risk behaviours, men who have sex with men (MSM) and women who have sex with women (WSW) are also reported within the literature as outcomes as these populations are considered to be at an increased risk of acquiring BBVs and STIs (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996). All tools (validated and non-validated) collecting data on these risk factors were included in the review.

3.3.3.4 Study designs

The study designs that were included in this review were prospective and retrospective comparative cohort studies, and case-control or nested case-control studies. Cross-sectional studies, case studies and case reports were excluded.

Cross-sectional studies were excluded from the review because it is not possible to establish a temporal relationship between the exposure and outcome (Kestenbaum, 2009). Cross-sectional studies measure exposure and outcome simultaneously, limiting the ability to draw valid conclusions about causality or any possible associations (Kestenbaum, 2009). Case studies and case reports were excluded from this review as they are generally used to generate hypotheses and also have a high potential of bias. (CRD, 2009).

3.3.4 Study Selection

In line with CRD guidelines (2009), study selection occurred in two stages using a piloted study selection form based on the inclusion criteria. The first stage of the study selection process was undertaken by two reviewers who worked independently: Samantha Gascoyne (SG) (author of this thesis) and Lucy Tindall (LT) (fellow PhD student). This involved an initial screening of all the titles and abstracts produced by the search which were then checked for relevance against the inclusion criteria detailed in section 3.3.3. If it was clear that an article did not meet the inclusion criteria for the review, then it was excluded. If there was any doubt, then the full paper was requested.

Full papers were obtained for studies that fulfilled the initial screen. The first and second reviewers worked independently to examine the full papers using a relevance checking form developed specifically for this review (appendix 5) against the inclusion criteria detailed in section 3.3.3. It is important that two people review the full papers at this stage as this increases the reliability of the studies included in the final systematic review. Approximately 8% of eligible studies would be missed if a single researcher undertook the selection process compared to all eligible studies being selected when more than one researcher is involved in the process (Edwards et al., 2002). Any disagreements were resolved by discussion and referred to an independent third reviewer where necessary [kappa = 0.4321, se= 0.0893].

Caution was taken when assessing eligible studies because there was potential for duplicate publications. Multiple citations may be published for the same study to report different findings such as different follow up stages or different outcome measures. Including multiple citations of the same study as separate studies could introduce bias to the results (e.g. results showing a false increase or decrease in association). Therefore, multiple citations were treated and included as a single study for this systematic review. These were noted when reporting the study selection to ensure transparency of the review process.

3.3.5 Data extraction

The data extraction process is crucial as it allows the reviewer to extract relevant data from the included studies so that the reviewer can critique and summarise the evidence in the systematic review (Liberati et al., 2009). A data extraction form was developed for this review (see appendix 6 for completed data extraction forms). This form was then piloted independently by the first and second reviewers (SG and LT) - extracting data from one study to ensure that all relevant data items (next section 3.3.6) had been captured.

This process was then repeated for each of the included studies to ensure that the extracted data was as reliable and as unbiased as possible (CRD, 2009; Liberati et al., 2009). As with study selection any discrepancies were discussed and resolved with an independent third reviewer where necessary.

3.3.6 Data Items

The data items extracted from each study included: study characteristics (study name, authors, year, location and setting of study); study design (case- control, cohort, sample size recruited, selection of cases/controls, cohort- length of follow up); study population characteristics (age, gender, sexuality, ethnicity, sample size recruited and analysed); data on the comparability of groups and confounding factors considered (matching for case-control studies); risk of bias (see section 3.3.7); sample size included in analysis; outcome data relating to behaviours associated with increased risk of BBV/STI infection (adjusted, unadjusted and raw data if available) and whether any statistical methods were used to control for potential confounding, and if so then which methods were used.

3.3.7 Quality assessment

The quality assessment of non-randomised studies is an important aspect of a robust systematic review of epidemiological studies (Stang, 2010). It is important to define what is meant by the term 'quality' and the assessment of quality in the context of undertaking this systematic review.

According to CRD guidelines (2009), the aim of quality assessment is to establish the extent to which the observed associations between exposure and outcome are likely to be an accurate reflection of the actual association. Studies of a low quality can lead to bias and therefore may produce an over/underestimation of association between outcome and the exposure of interest (Jepsen et al., 2004; Stang, 2010). Recent

guidance developed by the MOOSE group for the reporting of meta-analyses of observational studies recommend the assessment of study quality (Stroup et al., 2000).

There are a number of assessment tools for assessing the methodological quality of observational studies. Reeves et al. (2008) from the HIV Cochrane group suggest two tools: The Downs and Black instrument (1998) and the Newcastle Ottawa Scale (NOS) (Wells et al., 2000). There are strengths and limitations of both assessment tools that need to be considered. In terms of strengths, the Downs and Black scale (1998) highlights what reviewers should be considering in terms of the quality of epidemiological studies (Downs & Black 1998). A further strength of the scale is that the quality index had good test-retest reliability, internal consistency, and interrater reliability. However, some important limitations in relation to this review are that the Downs and Black instrument (1998) can be time consuming and lengthy, with twenty-seven separate items to apply. It also requires substantial epidemiological knowledge and has been found to be challenging when applied to case-control studies as some of the questions are not applicable to this study design, and these studies would be penalised in terms of their methodological quality score when not meeting certain criterion (MacLehose et al., 2000; Reeves et al., 2008). For systematic reviews of observational studies, in particular case-control and cohort studies, the NOS is the most frequently used and the authors have reported content validity for this tool (Wells et al., 2000). However, using the NOS can be a matter of subjectivity on the part of the reviewers depending on what had been reported by authors of observational studies, and how it was interpreted by researchers/reviewers. Despite its limitations, the NOS (Wells et al., 2000) was chosen to assess the methodological quality of the included studies in this review as it seemed more specific to cohort or case-control study designs.

The NOS contains eight items, categorised into three different constructs: selection of study groups, comparability of groups and ascertainment of exposure/outcome depending on study design (outcome- cohort studies or exposure- case-control studies). For each item, a series of response options are provided. The researcher is required to assign stars dependent on the quality of the primary studies. The higher quality studies are assigned a maximum of one star for each item, with the exception of the item related to comparability which allows the assignment of two stars. The NOS ranges between zero and nine stars, where higher quality studies are awarded a greater number of stars (Wells et al., 2000).

The quality assessment process was undertaken independently by two reviewers. Any disagreements were resolved through discussion [kappa = -0.2, SE 0.4082]. Completed quality assessment forms for all studies can be found in appendix 7.

3.3.8 Data synthesis

One of the main components of data synthesis takes the form of a narrative synthesis whereby the included studies are grouped and discussed according to reported themes (CRD, 2009).

The outcomes of interest in this review were sexual behaviours associated with the increased likelihood of contracting and/or transmitting BBVs and/or STIs. After scoping the literature it was anticipated that the studies meeting the inclusion criteria would mainly be case-control studies of which odds ratios are the only effect measure for dichotomous outcomes that can be estimated from this study design (Higgins & Green, 2011). Odds ratios are a measure of association that report the probability of an event occurring relative to the probability of an event not occurring (Higgins & Green, 2011). Therefore odds ratios (OR) (adjusted and/or unadjusted) and 95% confidence intervals (CI) were extracted or calculated for each of the included studies. Where studies did not report the information required (i.e. OR, standard errors or 95% confidence intervals) then these were calculated from the raw data provided.

When the included studies reported the same behaviours as outcomes, a random effects meta-analysis was undertaken in STATA version 13 (StataCorp, 2013). A random effects meta-analysis was used because it was assumed that the studies would differ in terms of a number of study characteristics. For example, after an initial scoping of the literature, there were a variety of SMI diagnoses and proportions of diagnoses within, and between each of the studies. Also, there were a number of different data collection tools used across the studies, all of which were non-validated questionnaires, therefore challenging the validity and reliability of the measures. Given these differences in populations and the measurement tools used, it was assumed that the true association would vary from study to study. A random effects model was used which makes this assumption, rather than a fixed effects model, which assumes that each study is estimating an effect size from a single, true effect estimate (Higgins & Green, 2011).

Heterogeneity was explored statistically using the x^2 (significance level P<0.05) and the I^2 statistic (Higgins et al. 2003) (where 0%-40% suggests low heterogeneity; 30%-60% may indicate moderate heterogeneity; 50%-90% may indicate heterogeneity; 75%-100% may indicate considerable heterogeneity). These categories are suggested to guide the interpretation of the I^2 statistic rather than provide definitive thresholds

(Higgins & Green, 2011). Heterogeneity will be used to aid interpretation and assess the robustness of findings.

3.3.9 Additional analyses

A number of pre-planned sub-group analyses and sensitivity analyses were specified in the systematic review protocol. It was anticipated that if there were sufficient studies, sensitivity analyses would be undertaken, including the strongest study designs to explore whether the significance of behaviours was dependent on including results from less robust study designs. Assessing publication bias using the funnel plot was also proposed if there were sufficient studies.

Sub-group meta-analyses were performed when the included studies had female-only or male-only populations.

3.4 Results

3.4.1 Results of the search

Electronic databases were initially searched during July and August 2015 and updated in September 2018 for observational studies exploring whether people with SMI are more likely to engage in sexual behaviours that are associated with the increased likelihood of BBVs/STIs infection compared to those with no history of SMI. The search identified 10,424 potentially relevant records. After duplicates were removed (n= 2,472) 7,952 records remained. No additional studies were found from reverse citation searches or grey literature searches. The screening of titles and abstracts were undertaken independently by two reviewers: 7,824 studies were excluded, and this left a total of 128 full text articles to be assessed. After two reviewers independently relevance-checked the remaining full papers, a total of eight papers were judged to be eligible for inclusion in the review. However, three of these were multiple citations of the same study, and so they were included as one publication. Therefore, a total of six unique records were included in the review. The PRISMA flow diagram is shown in Figure 3 on the following page.

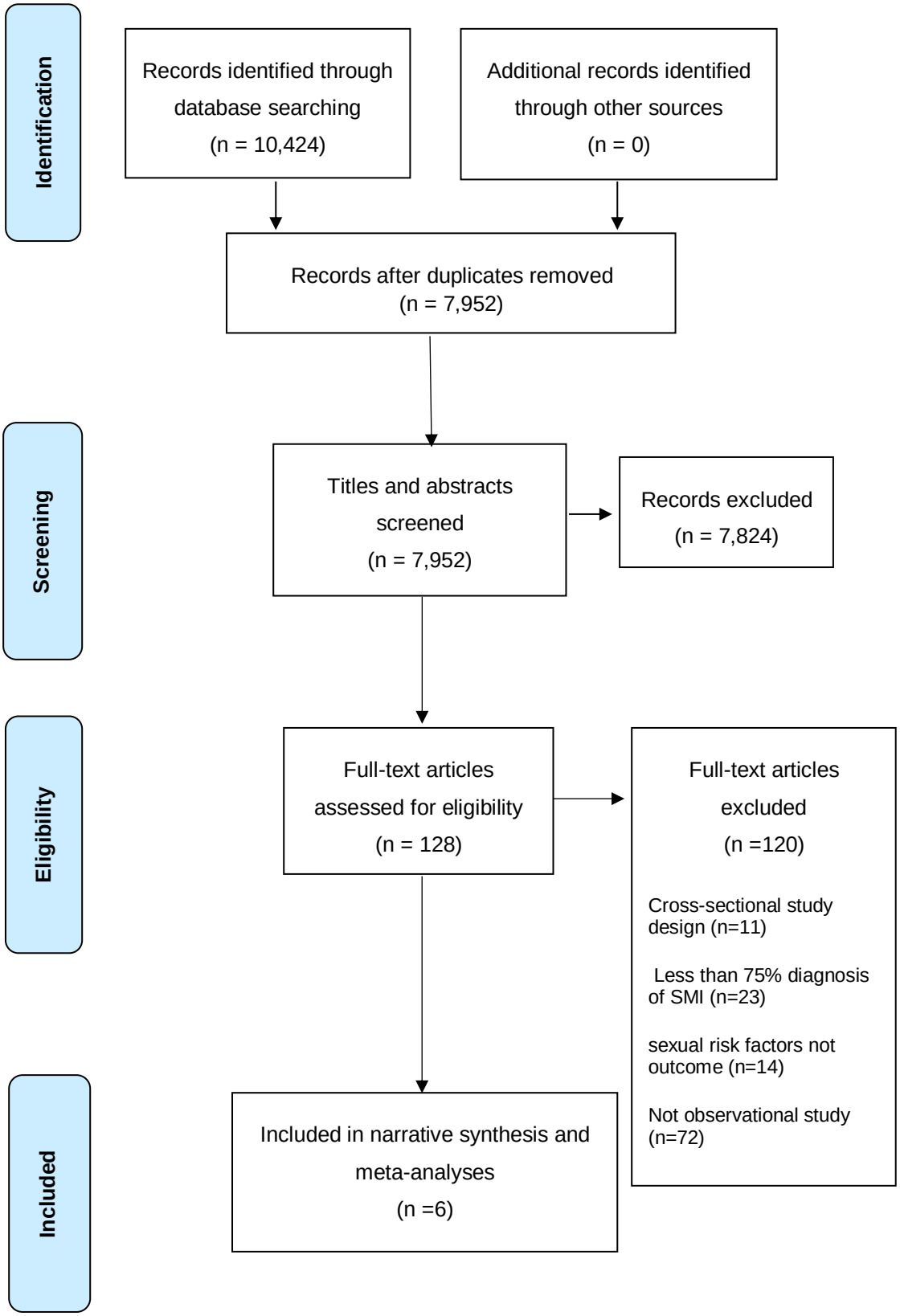


Figure 3 PRISMA flow diagram

3.4.2 Excluded studies

Out of the 128 full text articles assessed for inclusion in the review, 120 were excluded. Reasons for exclusion included, cross-sectional study designs (n=11), less than 75% of the population having a diagnosis of SMI (n=23), behaviour was not the outcome (n=14) and many of the papers were not observational studies (e.g. they were discussion papers or letters to editors) (n=72). Appendix 8 presents a full list of excluded articles and reasons for their exclusion.

3.4.3 Included studies

3.4.3.1 Study design

Six case-control studies met the inclusion criteria for the review (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996). Table 1 provides a summary of the descriptive characteristics of the included studies. A full data extraction table for each included study can be found in appendix 6.

Table 1 Summary characteristics of included studies

Study	Study design and setting	Cases	Controls	Outcome of interest
Brown et al. (2010, 2011a, 2011b)	**Study design:** Case-control **Country:** Australia, Melbourne **Setting:** Specialist youth mental health service. **Recruitment:** Cases- convenience sample from youth mental health services. Controls recruited through flyers in public locations.	**N=** 67 **Gender:** 19 females (28.4%), 48 males (71.6%). **Age:** 18-29 years, M=22.0 (SD=2.4) **Diagnosis:** First episode psychosis as defined by DSM-IV criteria obtained from participant's clinical file.	**N=** 48 **Gender:** 14 females (29.2%), 34 males (70.8%). **Age:** 18-29years M=21.8 (SD=3.6) **Diagnosis:** included if no history of psychosis or reported current mental health problems.	Sexual behavior as assessed using an adapted version of de Visser (2000) which included lifetime frequency of condom use with casual partner.
Coverdale et al. (1997)	**Study design:** Case-control **Country:** New Zealand, Auckland **Setting:** One inner city community mental health centre. **Recruitment:** Cases- Referral by clinical staff. Controls recruited from waiting rooms of a publicly funded general hospital.	**N=** 66 **Gender:** 66 females (100%) **Age:** 18-50years M=36.0 (SD=8.9) **Diagnosis:** patients with chronic mental illness documented by psychiatrist and diagnosis obtained from retrospective chart review. Schizophrenia or schizoaffective disorder: n= 34 (54%), Bipolar disorder: n=15 (23.8%), Major depression: n=6 (9.5%), other: n=8 (12.7%).	**N=** 66 **Gender:** 66 females (100%) **Age:** 18-50years M=36.2 (SD=8.8) **Diagnosis:** included if never seen psychiatrist/psychologist nor been treated for mental illness	STD risk behavior assessed using adapted versions of Kelly et al. (1992) and McKinnon et al. (1993) sexual risk behavior measures.
Coverdale et al. (2000)	**Study design:** Case-control **Country:** New Zealand, Auckland **Setting:** Inner city public community health centre. **Recruitment:** Cases- Referral by clinical staff. Controls recruited from waiting rooms of a publicly funded general hospital.	**N=** 92 **Gender:** 92 males (100%) **Age:** 18-51years, M=35.6 (SD= 8.2) **Diagnosis:** patients with chronic mental illness documented by psychiatrist and obtained from retrospective chart review. Schizophrenia or schizoaffective	**N=** 92 **Gender:** 92 males (100%) **Age:** 18-51years, M=35.3 (SD=8.2) **Diagnosis:** included if never seen psychiatrist/psychologist nor been treated for mental illness	STD risk behaviour assessed using adapted versions of Volvaka et al. (1992) and McKinnon et al. (1993) sexual risk behaviour measures.

		disorder: n= 58 (69%), Bipolar disorder: n=8 (10%), other psychotic disorders: n=9 (11%), Major depression: n=5 (6%), other: n=4 (5%).		

Table 1 Summary characteristics of included studies (continued)

Study	Study design and setting	Cases	Controls	Outcome of interest
Grassi et al. (1999)	**Study design:** Case-control **Country:** Italy, Northern region **Setting:** Acute psychiatric inpatient unit, S. Anna Hospital in Ferrara. **Recruitment:** Cases were referred by clinicians. Controls were recruited from the hospital waiting room.	**N=** 100 **Gender:** 56 males (56%), 44 females (44%) **Age:** 18-55 years, M=36.2 (9.4) **Diagnosis:** Psychiatric diagnosis assessed using the CIDI (1.1) according to ICD-10 criteria. Schizophrenia/schizotypal and delusional syndromes: n=65 (65%), affective syndromes: n=23 (23%), personality disorders n=12 (12%).	**N=** 90 **Gender:** Author reports controls being matched with cases on gender. Raw figures not reported. **Age:** Author reports controls being matched on age. Raw figures not reported. **Diagnosis:** Short psychiatric interview to confirm absence of current or previous mental illness.	HIV risk behaviour using HIV-RBT.
Koen et al. (2007)	**Study design:** Case-control **Country:** South Africa, Western Cape **Setting:** Associated psychiatric hospitals catchment area in the Western Cape. **Recruitment:** Cases were recruited from psychiatric units. The control group were a volunteer sample attending community health clinics for medical visits of any kind.	**N=** 43 **Gender:** 30 males (69.8%), 13 females (30.2%) **Age:** 18-65years, M=33.95 (SD=10.8). **Diagnosis:** Assessed for Schizophrenia defined as DSM-IV using DIGS (version 2.0)	**N=** 43 **Gender:** 30 males (69.8%), 13 females (30.2%) **Age:** 18-65years, M=34.5 (SD=10.4) **Diagnosis:** No details reported just described as 'healthy controls'	Sexual risk behaviour using the AIDS risk behaviour Assessment Questionnaire (ARBAQ).

Miller and Finnerty (1996)	**Study design:** Case-control **Country:** USA, area not reported **Setting:** Inpatient and outpatient medical and psychiatric services. **Recruitment:** Cases were mainly in outpatient services. Controls were recruited from inpatient and outpatient setting receiving care for physical health issues.	**N=** 44 **Gender:** 44 females (100%) **Age:** 18-45 years, M=30.8 (SD=7.7) **Diagnosis:** Serious mental illness using RDC as determined by SADS-L and chart reviews.	**N=** 50 **Gender:** 50 females (100%) **Age:** 18-45years, M=30.8 (SD=7.7) **Diagnosis:** No history of major psychotic or mood disorder as defined by RDC.	HIV risk behaviours using modified versions of existing measures.

Notes: AIDS= Acquired Immunodeficiency Syndrome; ARBAQ= AIDS risk behaviour assessment questionnaire; CIDI= Composite International Diagnostic Interview; DIGS= Diagnostic Interview for Genetic Studies; DSM-IV= Diagnostic and Statistical Manual of Mental Disorders (version 4); HIV= Human Immunodeficiency Virus; HIV-RBT= HIV-Risk Behaviour Test; ICD-10= International Classification of Diseases (version 10); M= mean; n= sample size; RDC= Research Diagnostic Criteria; SADS-L= Schedule for Affective Disorders and Schizophrenia- Lifetime Version; SD= standard deviation STD= sexually transmitted disease;

3.4.3.2 Sample size

Sample sizes from the included studies ranged from 43 in the SMI groups (Koen et al., 2007) to 100 (Grassi et al., 1999), and from 43 (Koen et al., 2007) to 92 (Coverdale et al., 2000) in the non-SMI groups. The total sample size across all studies for the SMI populations was 412, and the total sample size for the non-SMI population was 389 suggesting small sample sizes in each of the studies. The studies did not report the size of the population that the SMI groups were drawn from. None of the studies reported power calculations and therefore it is difficult to conclude whether they were statistically powered to detect a difference between SMI and those with no history of SMI.

3.4.3.3 Setting

One study was conducted in Australia (Brown et al., 2010, 2011a, 2011) and two studies were conducted in New Zealand (Coverdale et al., 1997; Coverdale et al., 2000). Single studies were conducted in South Africa (Koen et al., 2007), USA (Miller & Finnerty, 1996) and Italy (Grassi et al., 1999). With few observational studies meeting the inclusion criteria for this review, it suggests a lack of research in this area internationally.

In terms of SMI populations three of the studies were set in secondary care inpatient/outpatient psychiatric units (Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996). For the remaining three studies, the SMI population were recruited from community mental health centres (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000). The majority of the included studies recruited those with no history of mental illness from waiting rooms of general or community hospitals (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996). One study (Brown et al., 2010, 2011a, 2011b) recruited the participants with no history of mental illness through flyers in public locations.

3.4.3.4 Participants

As the study design for the included studies were all case-control studies, matching was part of the sampling strategy. Two studies by Coverdale et al. (1997, 2000) were female-only and male-only studies respectively and matched the people in the SMI and those with no history of mental illness based on ethnicity and age (within two years). The participants in the Grassi et al. (1999) study were matched on sex, age and socio-educational level. Koen et al. (2007) matched SMI and non-SMI groups on race, gender and age (within five years). Miller and Finnerty (1996) controlled for age, race, employment status, religion and level of education. Finally, Brown et al. (2010, 2011a,

2011b) report that their samples were closely matched on demographics without giving further details of the exact characteristics/demographics.

The age of participants ranged from 18 to 65, with a mean age of 32.4 years in both the case and control groups. However, it is worth noting the variation in age across studies. The participants in the Brown et al. study (2010, 2011a, 2011b) had a mean age of 22 years, whereas the mean ages of the participants in the other five studies were around 33 years of age. In terms of gender, three were gender specific studies, two were female only studies (Coverdale et al., 1997; Miller & Finnerty, 1996), and one was a male only study (Coverdale et al., 2000). The remaining three studies had both male and female participants, with the majority being female participants in two studies (Grassi et al., 1999; Koen et al., 2007). Brown et al. (2010, 2011a, 2011b) reported a male majority of approximately 71% in both the SMI and non-SMI groups.

All included studies had participants where the diagnosis of SMI was over 75% as defined as a documented diagnosis of schizophrenia or delusional/psychotic illness (ICD 10 F20 & F22 or DSM-equivalent) or bipolar disorder (ICD F31 or DSM-equivalent) (WHO, 2016; APA, 2013). Three studies identified such diagnoses through chart review or participant's clinical files (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000). Grassi et al. (1999) assessed psychiatric diagnoses as per ICD (WHO, 1992) criteria using the Composite International Diagnostic Interview (CIDI) version 1.1 (WHO, 1990). The participants in the Koen et al. (2007) study were required to have a diagnosis of Schizophrenia according to DSM-IV criteria (American Psychiatric Association, 1992) this was assessed using the Diagnostic Interview for Genetic Studies (DIGS) (Nurnberger et al. 1994). Miller and Finnerty (1996) used chart reviews to ascertain psychiatric diagnosis and also the Schedule for Affective Disorders and Schizophrenia- Lifetime version (SADS-L) (Endicott & Spitzer, 1978). For all the included studies the majority of participants met criteria for Schizophrenia, with bipolar disorder being the next most commonly reported diagnosis. For control participants to meet criteria for inclusion in the studies they must have had no history of psychiatric illness or contact with psychiatric services.

3.4.3.5 Outcome measures

The outcome of interest for this review were sexual behaviours associated with the increased likelihood of contracting or transmitting BBVs and/or STIs. The outcome measures used to collect data on these were different for each of the included studies. The majority of the tools used were adapted from existing measures. Brown et al. (2010, 2011a, 2011b) used an adapted version of de Visser (2000) which included lifetime frequency of condom use with a casual partner to measure sexual behaviour.

Two studies (Coverdale et al., 1997, Coverdale et al., 2000) adapted both Kelly et al. (1992) and McKinnon et al. (1993) tools to measure STD risk factors such as sexual trading and/or inconsistent condom use. One study (Miller & Finnerty, 1996) reported that they ascertained the level of HIV risk behaviours using a modified version of existing measures but did not report which measures were adapted. Two studies used risk measurement tools without adaptation (Grassi et al., 1999, Koen et al., 2007). Grassi et al. (1999) used the HIV-Risk Behaviour Test (HIV-RBT) (Carmen & Brady, 1990) and Koen et al. (2007) used the AIDS risk behaviour assessment questionnaire (ARBAQ, Kelly et al., 1992).

3.4.4 Methodological quality of included studies

The Newcastle Ottawa Scale (NOS) for assessing the risk of bias in epidemiological studies was used to assess the methodological quality of the studies in this review (Wells et al., 2000). The NOS is split into three sections: selection, comparability and exposure. For ease of reporting each of these will be discussed in turn below.

3.4.4.1 Selection

In terms of selection, there are four sub-sections, the first of these is adequate definition of cases (SMI population), whereby independent validation (clinical diagnostic interview or patient's medical records) is considered to be the most rigorous method of establishing a diagnosis in this instance. Four studies (Brown et al., 2010, 2011a, 2011b: Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996) defined their SMI samples' diagnoses by independent validation, using either a patient's medical records or by undertaking a diagnostic interview as part of the study. Two studies (Coverdale et al., 1997; Coverdale et al., 2000) used independent validation or referral by clinicians to define the diagnoses of SMI samples taking part in the studies.

The second sub-section is representativeness of the cases, where a random sample of defined cases is considered to minimise bias. All studies are considered to have potential for selection bias (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996).

The third sub-section of selection is the selection of controls (those with no history of mental illness), whereby community control subjects is regarded to minimise selection bias, hospital controls increases the possibility of bias. One study recruited their non-SMI participants from a community setting (Brown et al., 2010, 2011a, 2011b). The remaining five studies recruited their participants with no history of mental illness from general hospital waiting rooms or inpatient/outpatient settings for physical health issues

(Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007, Miller and Finnerty, 1996).

The fourth sub-section is the definition of controls, in this instance, those with no history of mental illness. Five studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Miller & Finnerty, 1996) reported control participants had no history of mental illness that was established by self-report or by clinical interview. However, one study (Miller & Finnerty, 1996) reported that some of the control participants did have diagnoses of phobias, although specific phobias were not reported. The participants in this study did not have a diagnosis of SMI as defined for this review. The Koen et al. (2007) study reported the control group as 'healthy controls' being matched to cases without giving details on how this was established.

3.4.4.2 Comparability

The second section is comparability of cases and controls at both the design and analysis stage. All six studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty. 1996) matched SMI and non-SMI subjects on a number of demographic factors detailed in section 2.3.4. Three studies (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999) controlled for important factors such as substance use disorders, this was controlled for at the design stage of the studies. The remaining three studies (Brown et al., 2010, 2011a, 2011b; Koen et al., 2007; Miller & Finnerty, 1996) did not report controlling for any factors outside of demographic features either at the design or analysis stage.

3.4.4.3 Exposure

The third section is exposure where there are three sub-sections. The first sub-section is ascertainment of exposure. Five studies (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996) used structured interviews to ascertain levels of engagement in behaviours associated with the increased risk of BBV/STI infection. However, the interviewers were not blind to case/control status, thus increasing the risk of potential bias. One study (Brown et al., 2010, 2011a, 2011b) ascertained level of exposure using self-report measures.

The second sub-section considers whether the same method of ascertainment was the same for cases and controls. All six studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996) used the same interview or questionnaire method for both the

SMI and control groups to ascertain the level of engagement in sexual behaviours associated with increased risk of BBV/STI infection.

The third and final sub-section is whether non-response rates were reported for both groups and whether there were any differences between the SMI and non-SMI groups. In two studies (Koen et al., 2007; Miller & Finnerty) all participants responded. In three studies (Brown et al., 2010; 2011a; 2011b, Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999) non-response rates were different between groups, however these rates were not reported.

3.4.4.4 Summary

In summary, the overall methodological quality of the included studies was assessed as being moderate, with studies scoring either four or five stars out of a possible total of nine. One thing each of the included studies did effectively was to utilise independent validation when selecting the SMI participants to confirm a current clinical diagnosis of SMI. Overall, the studies defined the SMI and those with no history of mental illness groups adequately, all of the studies controlled for important demographic factors at the design stage by matching. In addition, three studies also controlled for factors outside of demographics including substance-use disorder in the control group (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999). All studies used the same method of assessing outcome in both the SMI and no history of mental illness groups, and all were assigned a star for this sub-section.

However, of particular concern was that all studies were judged to be at risk of selection bias as the representativeness of the no history of mental illness group was not reported. Similarly, five studies recruited their control participants from hospital settings and thus, increasing the potential for selection bias (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996). Another area of concern was that some outcomes were assessed either using self-report measures which may introduce reporting bias due to the sensitive nature of the questions. Other outcomes were assessed using non-validated interviews and therefore we can't be certain of the validity or reliability of these interviews. In light of this, some caution is needed when interpreting the results.

Table 2 on the next page provides a summary of the methodological quality of the included studies, with their assigned stars, using the NOS assessment tool (Wells et al., 2000).

Table 2 NOS quality assessment for included studies

	Selection				**Comparability**	**Exposure**		
Study	**Is the case definition adequate?**	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
Brown et al. (2010, 2011a, 2011b)	a) yes, with independent validation ★	b) potential for selection biases or not stated	a) community controls ★	a) no history of disease ★	a) study controls for important factors (**age, gender**) ★	d) written self-report or medical record only	a) yes ★	c) rate different and no designation
Coverdale et al. (1997)	a) yes, with independent validation ★	b) potential for selection biases or not stated	b) hospital controls	a) no history of disease ★	a) study controls for important factors (**age, gender, SUD**) ★	c) structured interview not blinded to case/control status	a) yes ★	c) rate different and no designation

Coverdale et al. (2000)	a) yes, with independent validation ★	b) potential for selection biases or not stated	b) hospital controls	a) no history of disease ★	a) study controls for important factors (**age, gender, SUD**) ★	c) structured interview not blinded to case/control status	a) yes ★	c) rate different and no designation
Grassi et al. (1999)	a) yes, with independent ★ validation	b) potential for selection biases or not stated	b) hospital controls	a) no history of ★ disease	a) study controls for important factors (**age, gender, SUD**) ★	c) structured interview not blinded to case/control status	a) yes ★	c) rate different and no designation
Koen et al. (2007)	a) yes, with independent ★ validation	b) potential for selection biases or not stated	a) hospital controls	b) no description of source	a) study controls for important factors (**age, gender**) ★	c) structured interview not blinded to case/control status	a) yes ★	a) same rate for both ★ groups
Miller and Finnerty (1996)	a) yes, with independent ★ validation	b) potential for selection biases or not stated	b) hospital controls	a) no history of disease (no SMI but some phobia ★ diagnoses)	a) study controls for important factors (**age, gender**) ★	c) structured interview not blinded to case/control status	a) yes ★	a) same rate for both ★ groups

3.4.5 Narrative Synthesis and meta-analyses

Across the six studies, ten sexual behaviours associated with the increased likelihood of contracting or transmitting BBVs and/or STIs were consistently reported. These include: sexual trading; sex with a person who uses drugs; alcohol and/or drug use prior to sexual intercourse; sexual intercourse with someone known less than 24 hours; more than one sexual partner reported in the last 12 months; paid sex work; sex with someone who identifies themselves as bisexual; men who have sex with men, or women who have sex with women and inconsistent condom use. Table 3 below presents how the sexual behaviours associated with increased risk of BBV/STI infection were reported across studies.

Table 3 Overview of sexual risk behaviours reported across included studies

	Brown et al. (2010, 2011a, 2011b)	Coverdale et al. (1997)	Coverdale et al. (2000)	Grassi et al. (1999)	Koen et al. (2007)	Miller & Finnerty (1996)
Alcohol/drug use prior to sex	✓		✓	✓	✓	
Inconsistent condom use	✓			✓		
Men who have sex with men (MSM) or women who have sex with women (WSW)			✓			✓
More than one sexual partner (in 12 months)	✓	✓	✓	✓		
Paid sex work				✓		✓
Pressured into unwanted sex		✓	✓		✓	✓
Sex with a person who identifies themselves as bisexual		✓		✓		
Sex with a person who uses drugs	✓	✓	✓	✓	✓	
Sexual partner known for less than 24 hours		✓	✓	✓	✓	
Sexual Trading	✓	✓	✓	✓	✓	

For ease of reporting in this section the studies will be grouped and discussed according to the sexual behaviours reported in the included studies. However, there are likely to be complex interrelationships between the risk behaviours and these will be discussed when interpreting the results in the discussion chapter. As with the narrative synthesis the meta-analyses have been grouped by sexual risk behaviours

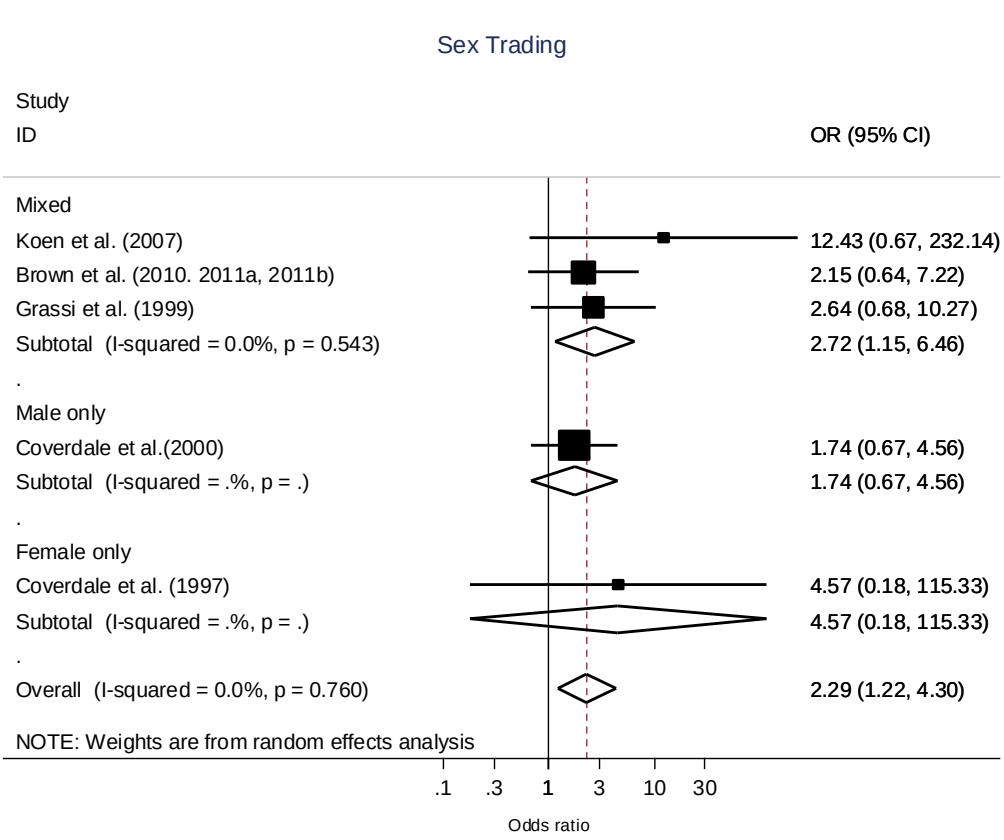
and also sub-grouped by gender specific studies. These are presented below, and each will be discussed in turn.

3.4.5.1 Sexual trading

Five studies reported on sexual trading, within each study with rates ranging from 2.9% to 20% for SMI populations and 0% to 13% of those with no history of mental illness. There was no evidence of a statistically significant difference between adults with SMI and those with no history of mental illness (Brown et al 2010., 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007). Brown et al. (2010, 2011a, 2011b) found that 16.7% of participants with SMI reported having traded sex in the past compared to 8.5% of those with no history of mental illness. Coverdale et al. (1997) found, in this female-only sample, that 2.9% of participants with SMI and 0% of those with no history of mental illness reported they had had sex for favours. In the male-only study (Coverdale et al, 2000) 20% of the SMI participants and 13% of with no history of mental illness reported having had sexual intercourse for money, drugs or favours. Grassi et al. (1999) reported that 8.3% of those with SMI and 3.3% of participants with no history of mental illness answered 'yes' to this behaviour. In line with the above four studies Koen et al. (2007) found that 11.6% of the SMI group and 0% of those with no history of mental illness had had sex for money, drugs or accommodation.

The overall pooled odds ratio for sexual trading was 2.29 (95% CI, 1.22, 4.30) and is displayed in figure 4 below. Pooling the studies in a meta-analysis found that there was evidence of a difference in sexual trading amongst adults with SMI compared to those with no history of mental illness. Given there were only single studies in male only and female only populations it is difficult to draw firm conclusions from these sub-groups, but they are displayed in figure 4 to show variation. The overall I^2 was 0%, which is considered to indicate no statistical heterogeneity (Higgins et al., 2003).

Figure 4 Forest plot of sexual trading in SMI and none SMI populations

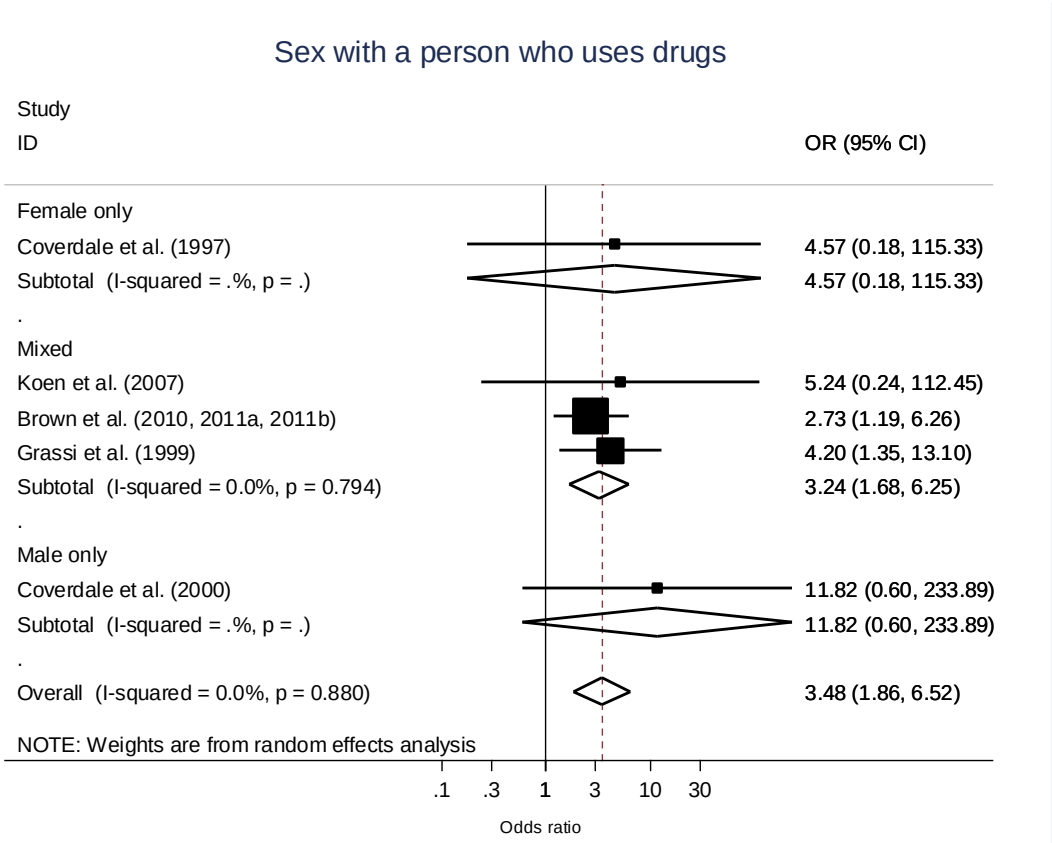


3.4.5.2 Sex with a person who uses drugs

Five studies reported on having sex with a drug user, with rates ranging from 2.9% to 44.8% for those with SMI and 0% to 22.9% for those with no history of mental illness (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007). Brown et al. (2010, 2011a, 2011b) found that 44.8% of the SMI group and 22.9% of those with no history of mental illness had had sex with someone who had taken drugs or alcohol prior to sex, which was a statistically significant difference, (x^2=5.82, *degrees of freedom (df) df*= 1, *p*=0.016). Similarly, Grassi et al. (1999) reported that participants with SMI (16.7%) significantly differed from those with no history of mental illness (4.5%) in reporting higher rates of sexual intercourse with an intravenous drug user (x^2 = 5.76, *df* =1, *p*= 0.016). In contrast, three studies (Coverdale et al., 1997; Coverdale et al., 2000; Koen et al., 2007) found a similar trend, although their results were not statistically significant. Coverdale et al. (1997) reported that 2.9% of those with SMI and 0% of those with no history of mental illness had had sex with an intravenous drug user. Coverdale et al. (2000) reported that 6% of participants with SMI had had sex with a suspected or known intravenous drug user compared to 0% of those with no history of mental illness. Koen et al. (2007) reported that 4.7% of the SMI group and 0% of the groupv with no history of mental illness had had sex with a partner who had used intravenous drugs.

The overall pooled odds ratio of people with SMI having sex with a person who uses drugs was 3.48 the odds of the non SMI population (95% CI, 1.86, 6.52, figure 5). Pooling the results in a meta-analysis identified that there was evidence of a difference in having sex with a drug user between those suggesting that people with SMI were more likely to have sex with a person who uses drugs compared to those with no history of mental illness. Given there were only single studies in male only and female only populations it is difficult to draw firm conclusions from these sub-groups but they are displayed in figure 5 to show variation. The overall I^2 was 0%, which is considered to indicate no statistical heterogeneity (Higgins et al., 2003).

Figure 5 Forest plot for having sex with someone who uses drugs in SMI and none SMI populations



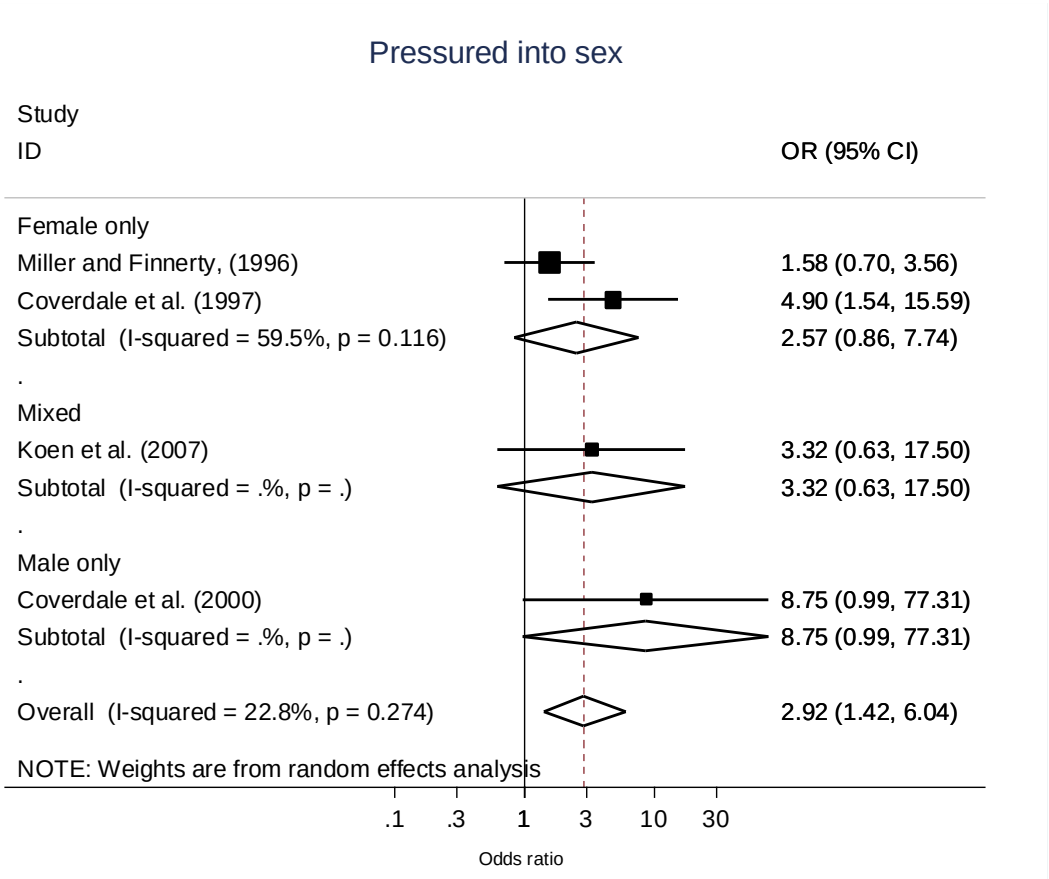
3.4.5.3 Pressured into unwanted sex

Four studies reported on the experience of being pressured into unwanted sex with rates ranging from 11% to 46.5% for those with SMI and 1% to 39.6% for those with no history of mental illness (Coverdale et al., 1997; Coverdale et al., 2000; Koen et al., 2007; Miller & Finnerty, 1996). Two studies found significant differences between the SMI and control populations for this experience (Coverdale et al., 1997; Coverdale et al., 2000), while two found non-significant results, although in the same direction of effect (Koen et al., 2007; Miller & Finnerty, 1996). Coverdale et al. (1997) reported that those with SMI (34.3%) were more likely to be pressured into having unwanted sexual

intercourse than those with no history of mental illness (7.7%), (x^2 = 10.3, *df* =1, *p*= 0.001). Coverdale et al. (2000) found that 11% of the SMI group reported that they had been pressured into having unwanted sexual intercourse compared to 1% of those with no history of mental illness (*p*= 0.016, Fishers Exact Test). Koen et al. (2007) found that more of the SMI sample (14%) compared to those with no history of mental illness (4.7%) reported being pressured into having unwanted sex. Miller and Finnerty (1996) found that 46.5% of the SMI sample reported being pressured into having unwanted sexual intercourse compared to 39.6% of those with no history of mental illness.

The overall pooled odds ratio for being pressured into unwanted sex was 2.92 (95% CI 1.42, 6.04, figure 6). Pooling the studies in a meta-analysis showed that there was an increase in the odds of those being pressured into unwanted sex between adults with SMI and those with no history of mental illness. The odds of being pressured into unwanted sex in adults with SMI was almost three times the odds of the control group. Given there was only a single study in the male population it is difficult to draw firm conclusions from this sub-group, but it is displayed in figure 6 to show variation. The overall I^2 was 22.8%, which is considered to indicate a low level of statistical heterogeneity (Higgins et al., 2003).

Figure 6 Forest plot for being pressured into unwanted sex in SMI and none SMI populations

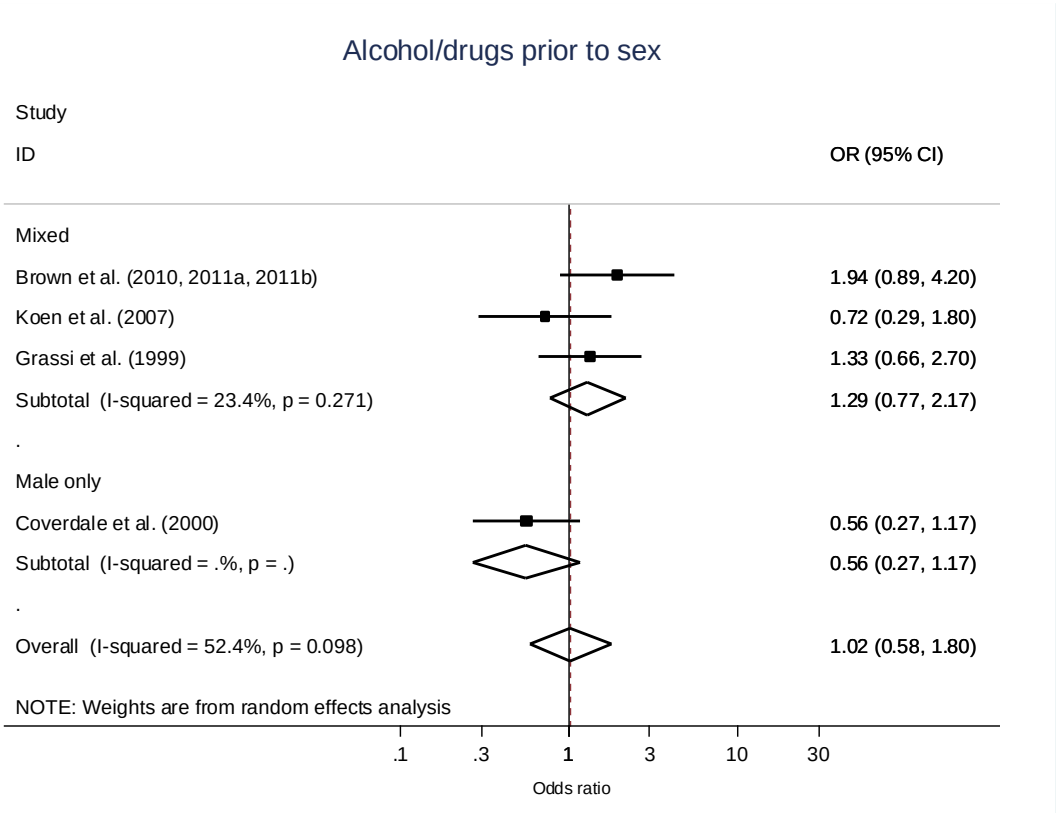


3.4.5.4 Alcohol/drug use prior to sex

The rates of consuming alcohol or drugs before engaging in sex ranged from 23.7% to 49.3% in the SMI samples and 18.8% to 37% for those with no history of mental illness (Grassi et al., 1999; Koen et al., 2007). Four studies reported on this behaviour (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007). Brown et al. (2010, 2011a, 2011b) found that 49.3% of participants with SMI compared to 33.3% of those with no history of mental illness reported using alcohol or drugs prior to having sex. Grassi et al. (1999) found a similar trend, 23.7% of those with SMI and 18.8% of those with no history of mental illness reported consuming alcohol or drugs before having sexual intercourse. Coverdale et al. (2000) and Koen et al. (2007) report conflicting trends. Coverdale et al. (2000) found that 36% of the SMI group and 37% of those with no history of mental illness reported using alcohol or drugs before having sex. Similarly, Koen et al. (2007) found that 27.9% of their SMI group compared to 34.9% of those with no history of mental illness answered 'yes' to consuming alcohol or drugs prior to having sexual intercourse.

The overall pooled odds ratio for consuming alcohol/drugs prior to sex was 1.02 (95% CI, 0.58, 1.80, figure 7). Pooling the studies in a meta-analysis suggest that there is no evidence of a difference in consuming alcohol or drugs prior to sex between people with SMI and those with no history of mental illness. However, it is worth noting that the results from the single male only study are on the negative side of 1 compared to the mixed gender studies but there are too few studies to draw firm conclusions. This is displayed in figure 7 to show variation. The overall I^2 was 52.4%, which is considered to indicate substantial levels of statistical heterogeneity (Higgins et al., 2003). Therefore, caution is needed when interpreting these results.

Figure 7 Forest plot for being pressured into unwanted sex in SMI and none SMI populations



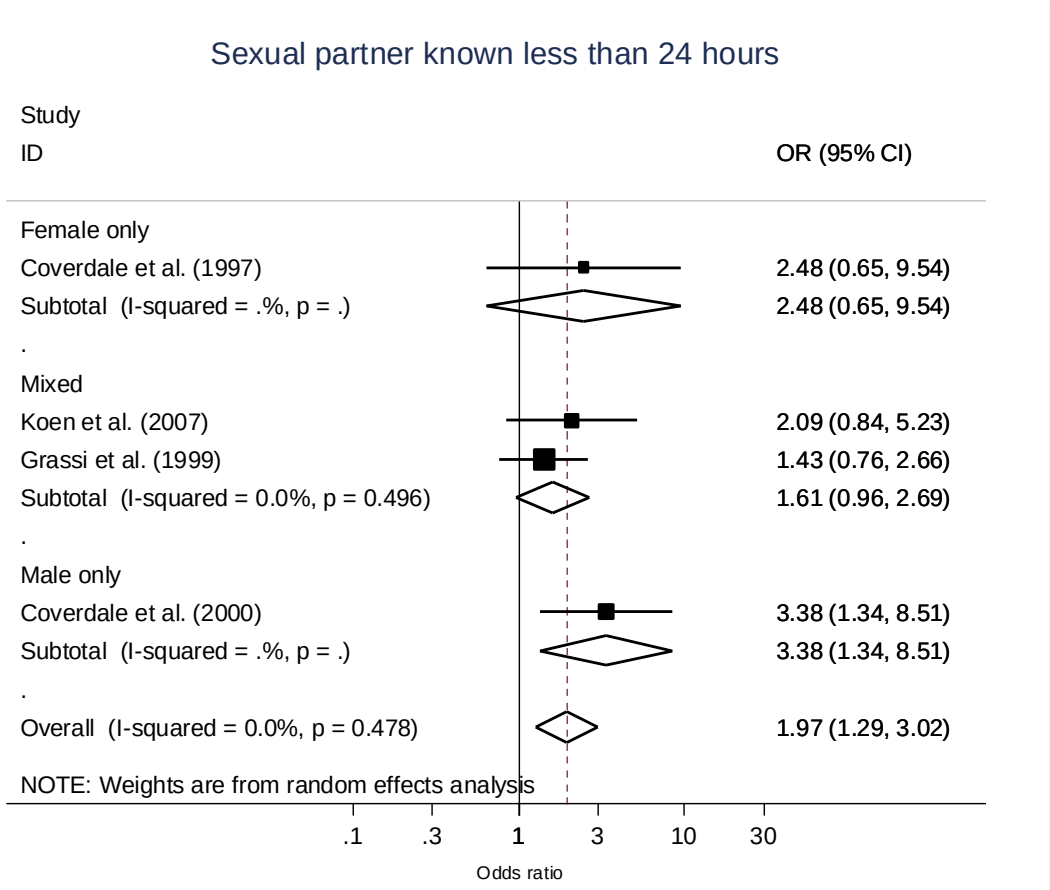
3.4.5.5 Sexual intercourse with someone known less than 24 hours

Four studies provided data on participants having sexual intercourse with someone known for less than 24 hours with rates ranging from 17.1% to 41.9% for SMI groups and 7.7% to 27.7% for those with no history of mental illness (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007). Coverdale et al. (2000) found a statistically significant difference between the SMI and those with no history of mental illness on this behaviour. A total of 32% of those with SMI reported having had sex with a person they had known less than 24 hours compared to 12% of those with no history of mental illness (x^2 = 7.45, *df* =1, *p*= 0.006) (Coverdale et al., 2000). Coverdale et al. (1997) found that 17.1% of those with SMI and 7.7% of those with no history of mental illness reported having had sex with someone they had known for less than 24 hours. In line with this Grassi et al. (1999) found that 35.4% of the SMI group and 27.7% of those with no history of mental illness reported having a sexual partner with someone they had known for less than 24 hours. Similarly, Koen et al. (2007) found that 41.9% of people with SMI and 25.6% of those with no history of mental illness answered 'yes' to this behaviour. However, none of the results reported in these three studies were statistically significant.

The overall pooled odds ratio for having sex with someone they've known less than 24 hours was 1.97 (95% CI, 1.29, 3.02, figure 8). Pooling the studies in a meta-analysis

found that the odds of a person with SMI reporting they had had sex with someone they had known for less than 24 hours were almost two times the odds of those with no history of mental illness. Given there were only single studies in male only and female only populations it is difficult to draw firm conclusions from these sub-groups but they are displayed in figure 8 to show variation. The overall I^2 was 0%, which is considered to indicate no statistical heterogeneity (Higgins et al., 2003).

Figure 8 Forest plot for sexual partner known for less than 24 hours in SMI and none SMI populations



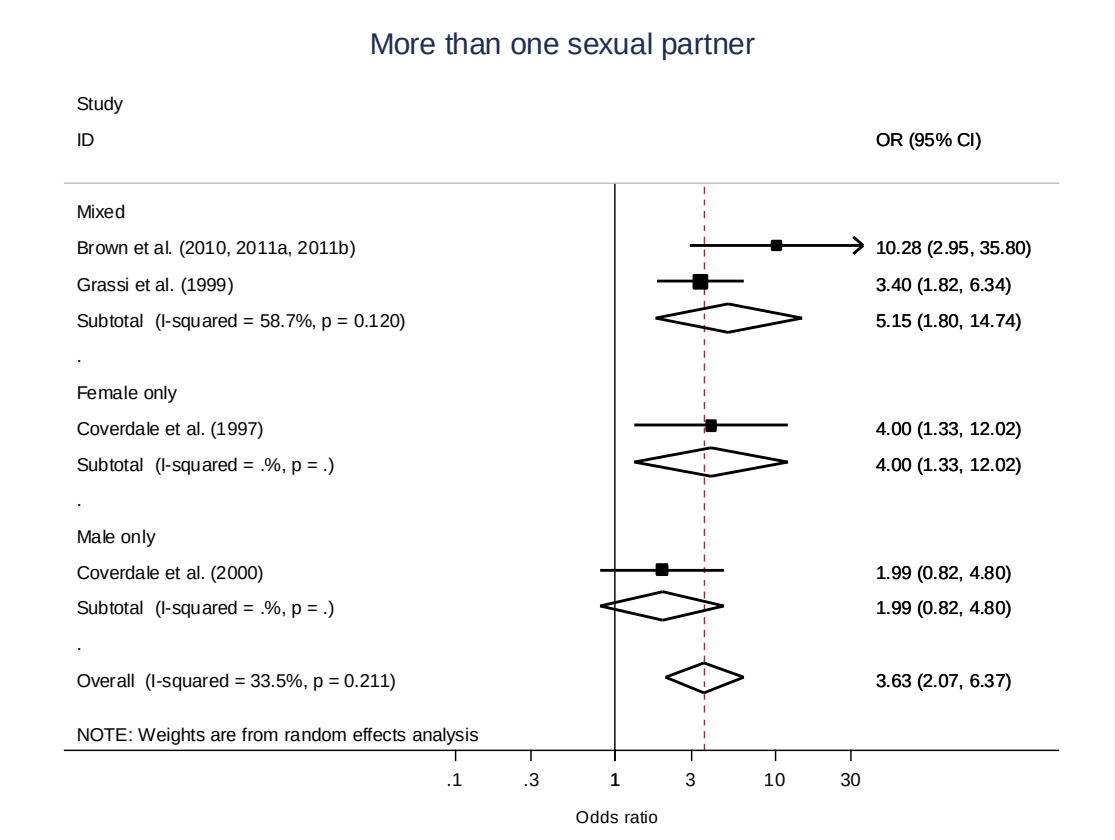
3.4.5.6 More than one sexual partner reported in a 12-month period

Four studies reported on the behaviour of more than one sexual partner in a 12-month period with rates ranging from 31% to 74.6% for the SMI populations, and 11.5% to 70.8% for those with no history of mental illness (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999). Coverdale et al. (1997) found a statistically significant difference between the SMI and those with no history of mental illness for this behaviour, 36.4% of the SMI group compared to 11.5%

of the those with no history of mental illness (x^2 = 11.5, *df* =1, *p*= 0.006). Grassi et al. (1999) also found a statistically significant difference; 53.1% of the adults with SMI compared to 30% of those with no history of mental illness reported having multiple sexual partners (x^2=9.27, *df*= 1, *p*< 0.01). Brown et al. (2010, 2011a, 2011b) found that 74.6% of the SMI sample and 70.8% of those with no history of mental illness reported that they had had more than three sexual partners, a non-statistically significant difference. Similarly, Coverdale et al. (2000) found a non-significant result, 31% of the SMI group and 19% of those with no history of mental illness reported having had sexual intercourse with more than one female.

The overall pooled odds ratio for having more than one sexual partner in a 12-month period was 3.63 (95% CI, 2.07, 6.37, figure 9). Pooling studies in a meta-analysis found that the odds of a person with SMI reporting more than one sexual partner in the previous 12 months was over three and a half time the odds of those with no history of mental illness. Given there were only single studies in male only and female only populations it is difficult to draw firm conclusions from these sub-groups but they are displayed in figure 9 to show variation. The overall I^2 was 33.5%, which is considered to indicate moderate levels of statistical heterogeneity (Higgins et al., 2003). Therefore, caution is needed when interpreting these results.

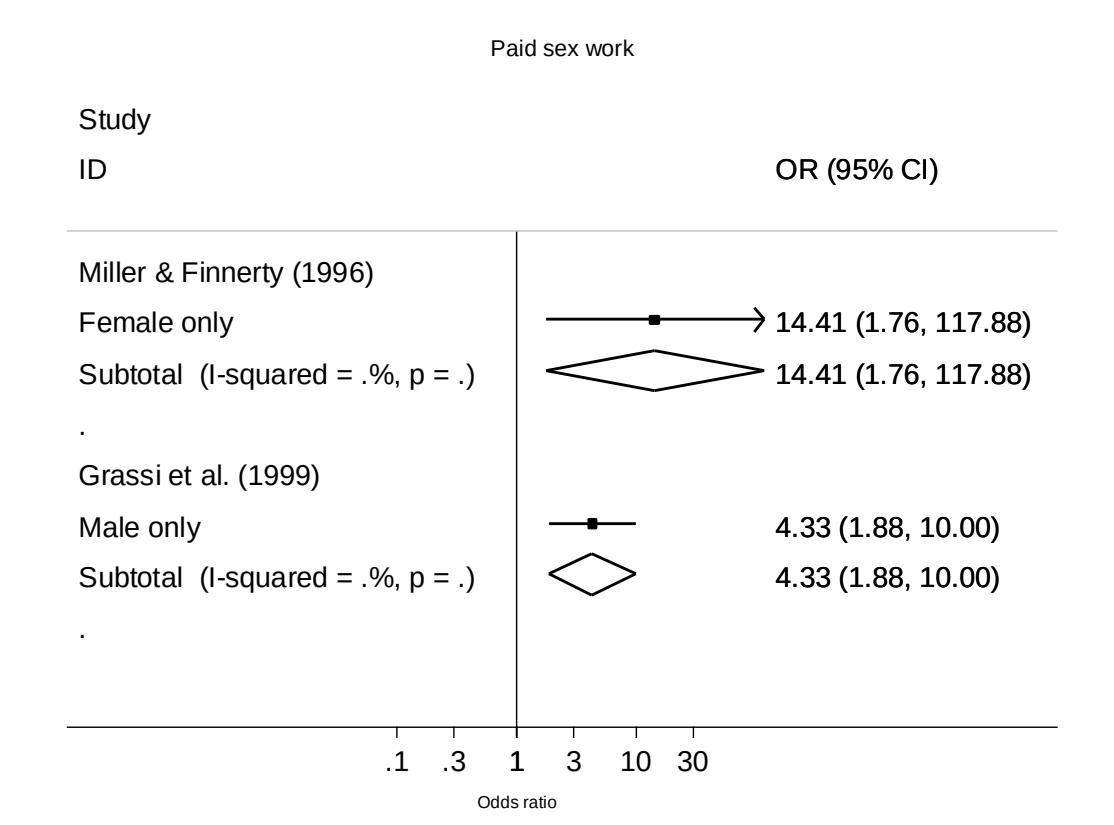
Figure 9 Forest plot for more than one sexual partner in 12 months in SMI and none SMI populations



3.4.5.7 Paid sex work

Two studies reported on this behaviour (Grassi et al., 1999; Miller & Finnerty, 1996) and both found statistically significant differences between the SMI group and those with no history of mental illness. In the Grassi et al. (1999) study 57% of those with SMI and 23.5% of those with no history of mental illness had engaged in sex work (x^2=11.1, *df*= 1, *p*< 0.01) (N.B. this behaviour only took into account the male sample). Miller and Finnerty (1996) found that 22.7% of females in the SMI population reported having engaged in sex work compared to 2% of females of those with no history of mental illness (x^2=7.8, *df*= 1, *p=0.*01). Given there were only single studies in male only and female only populations it is difficult to draw firm conclusions from these sub-groups, but they are displayed in a forest plot in figure 10 to show variation.

Figure 10 Forest plot for paid sex work in SMI and none SMI populations

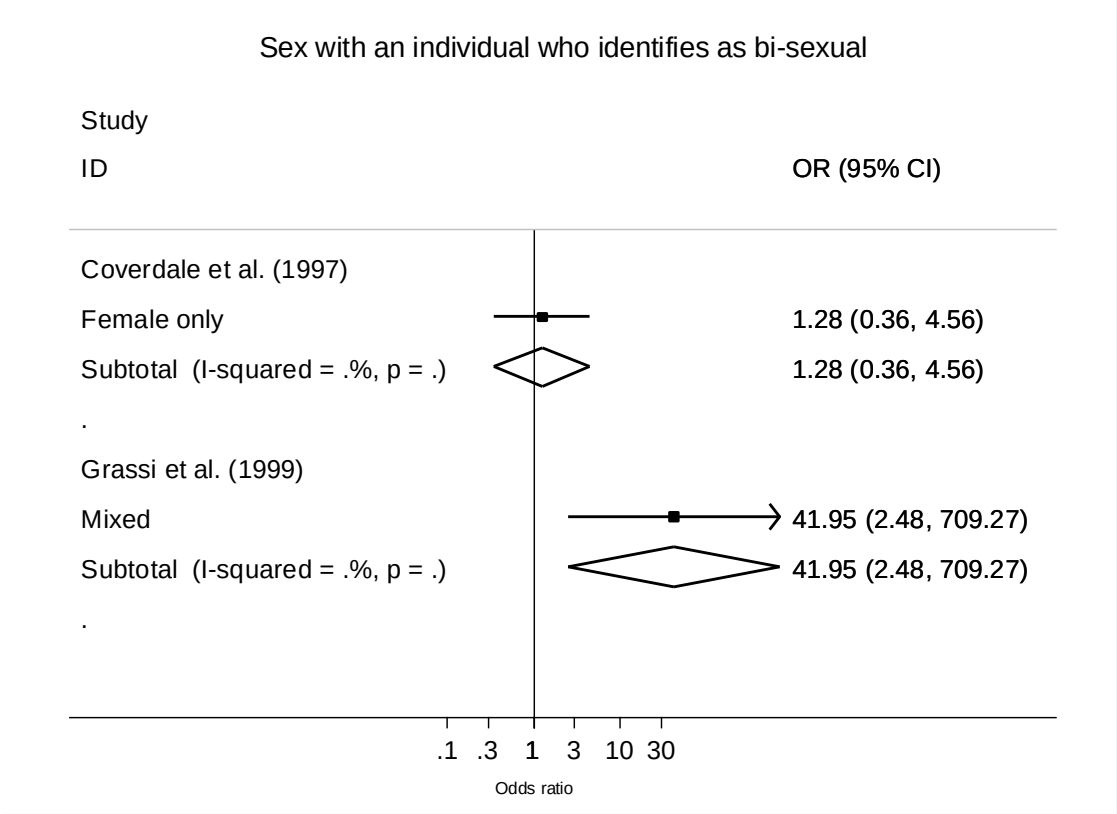


3.4.5.8 Sex with an individual who identifies themselves as bi-sexual

Two studies report on sex with a person who identifies as bi-sexual and found significant differences (Coverdale et al., 1997; Grassi et al., 1999). Coverdale et al. (1997) found that 14.3% of participants with SMI reported having sex with a 'suspected' bi-sexual compared to 1.9% of those with no history of mental illness (*p*=0.037, Fishers Exact Test). Grassi et al. (1999) found that 18.9% of the SMI group reported they had had sex with a bi-sexual partner compared to 0% of those with no history of mental

illness (x^2=16.22, *df*= 1, *p*< 0.01). Given there were only single studies in mixed populations and female only populations it is difficult to draw firm conclusions from these sub-groups, but they are displayed in figure 11 to show variation

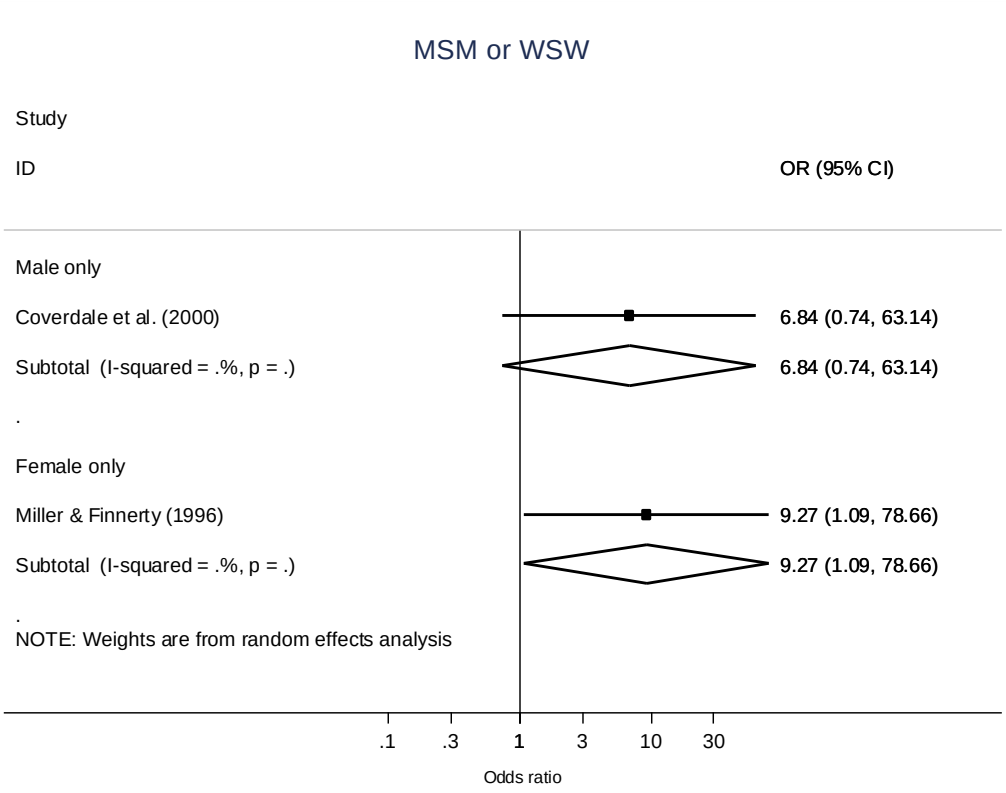
Figure 11 Forest plot for having sex with someone who identifies themselves as bi-sexual in SMI and none SMI populations



3.4.5.9 Men who have sex with men (MSM) or women who have sex with women (WSW)

Two studies reported on men who have sex with men, or women who have sex with women (Coverdale et al., 2000; Miller & Finnerty, 1996). In the male-only sample, Coverdale et al. (2000) found that 8% of the SMI sample and 1% of those with no history of mental illness had engaged in same sex sexual intercourse in the last year. In a female-only sample (Miller & Finnerty, 1996) 16.7% of women with SMI reported they had engaged in same sex sexual intercourse compared to 2% of those with no history of mental illness (x^2=4.5, *df*= 1, *p=0.*03). Given there were only single studies in male only and female only populations it is difficult to draw firm conclusions from these sub-groups, but they are displayed in figure 12 to show variation.

Figure 12 Forest plot for MSM or WSW in SMI and none SMI populations

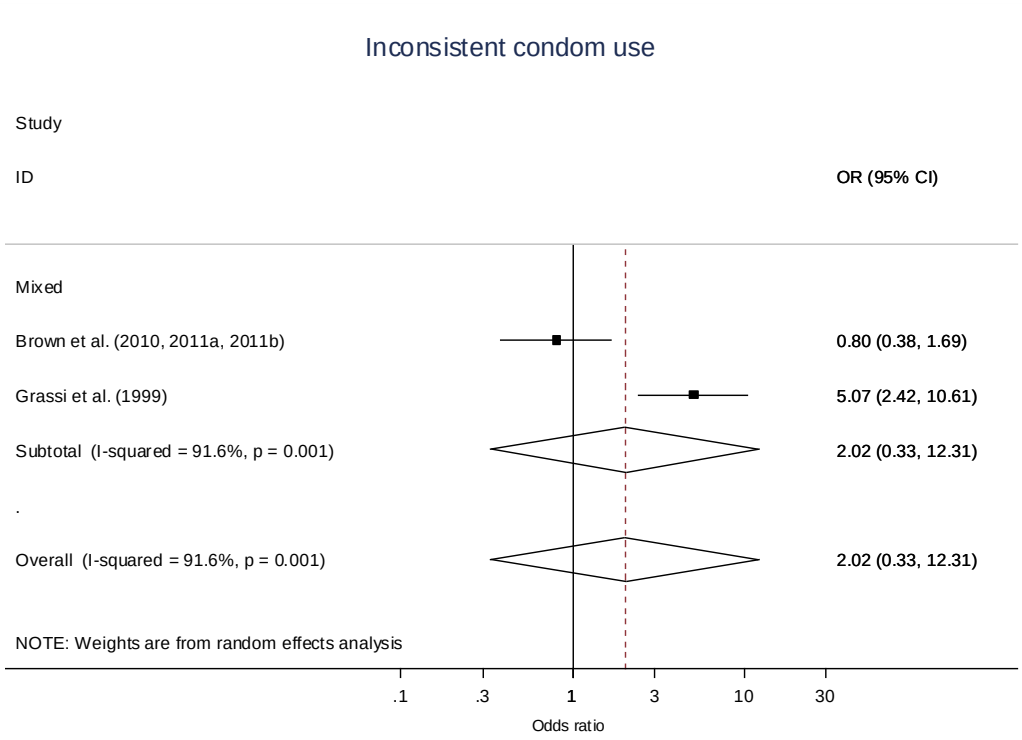


3.4.5.10 Inconsistent condom use

Two studies reported on this behaviour (Brown et al., 2010, 2011a 2011b; Grassi et al., 1999). Brown et al. (2010, 2011a, 2011b) reported that 52.3% of the SMI sample and 55.1% of those with no history of mental illness had engaged in unprotected sex at their last sexual encounter, a non-significant difference. Grassi et al. (1999) found a statistically significant difference where 43.3% of those with SMI reported 'never' using a condom during sex compared to 13.3% of those with no history of mental illness (x^2=21.4, *df*= 1, *p*< 0.01).

The overall pooled odds ratio for inconsistent condom use was 2.02 (95% CI, 0.33, 12.31, figure 13). Pooling the studies in a meta-analysis found that there was no evidence of a difference in inconsistent condom use between people with SMI and those with no history of mental illness. The overall I^2 was 91.6%, which is considered to indicate considerable levels of statistical heterogeneity (Higgins et al., 2003). Therefore, caution is needed when interpreting these results.

Figure 13 Forest plot for inconsistent condom use in SMI and none SMI populations



3.4.5.11 Summary

To summarise the results from the meta-analyses above, presented below are four forest plots to provide an over-arching visual aid for: overall pooled odds ratios for each sexual risk behaviour associated with BBV/STI infection, overall pooled odds ratios for each sexual risk behaviour associated with BBV/STI infection in for the male-only studies, female-only studies, and mixed population studies.

Figure 14 Forest plot for overall pooled odds ratios for each behaviour associated with BBV/STI infection in SMI and none SMI populations

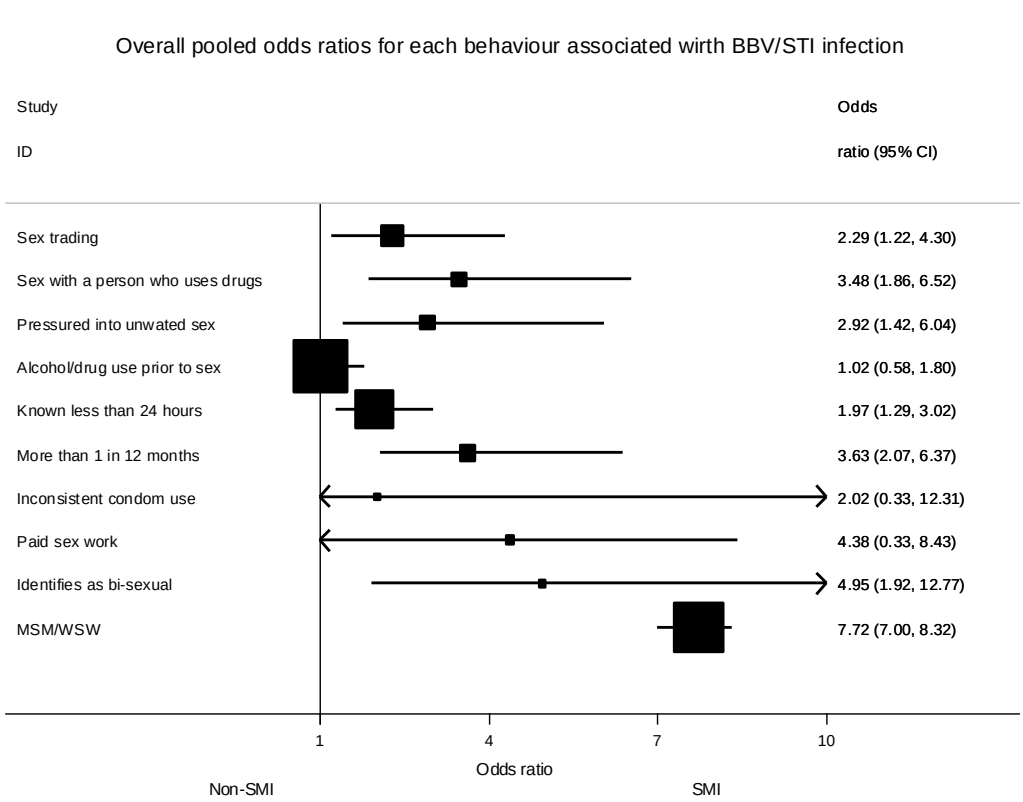


Figure 15 Forest plot for overall pooled odds ratios for each behaviour associated with BBV/STI infection in SMI and none SMI- male only studies

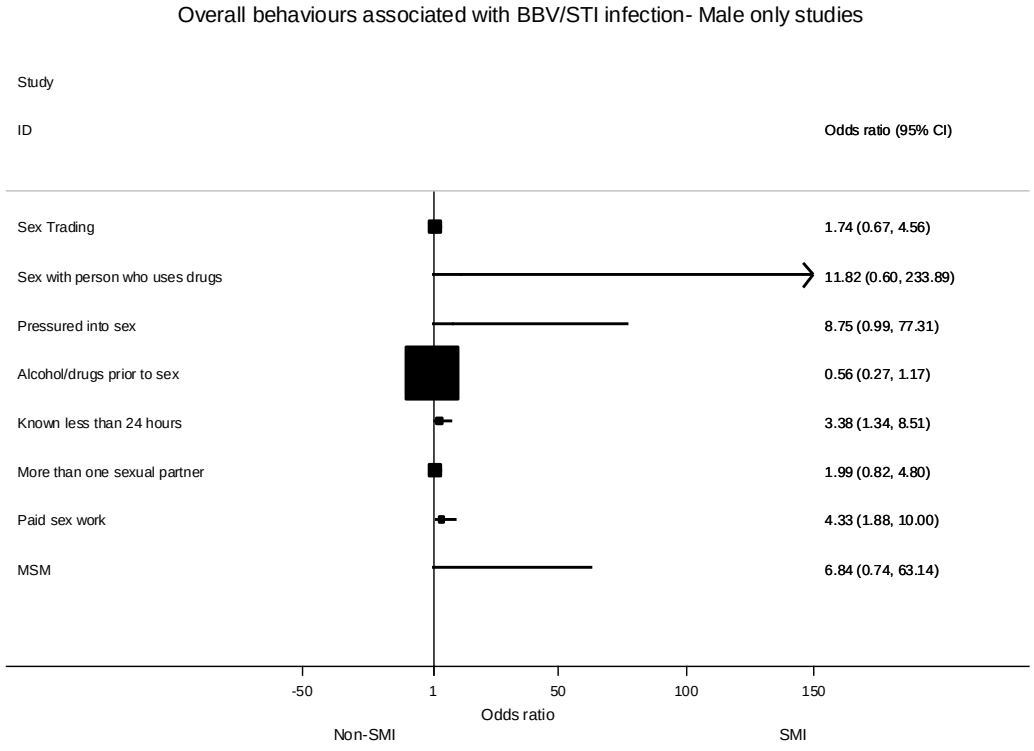


Figure 16 Forest plot for overall pooled odds ratios for each behaviour associated with BBV/STI infection in SMI and none SMI populations- female only studies

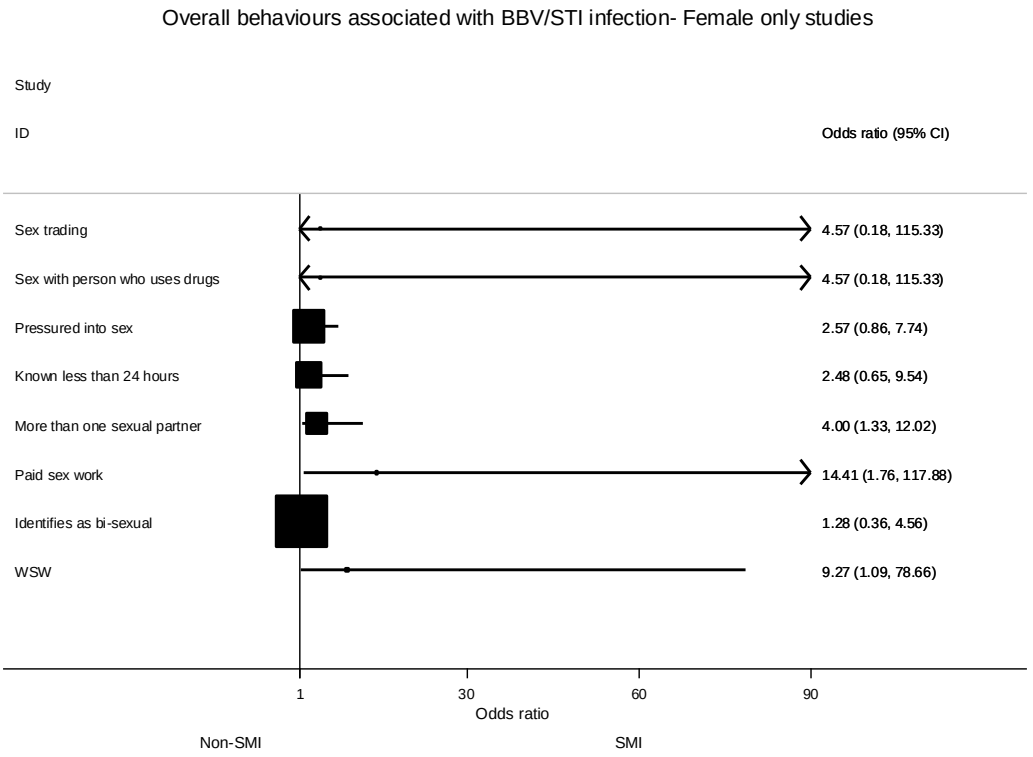
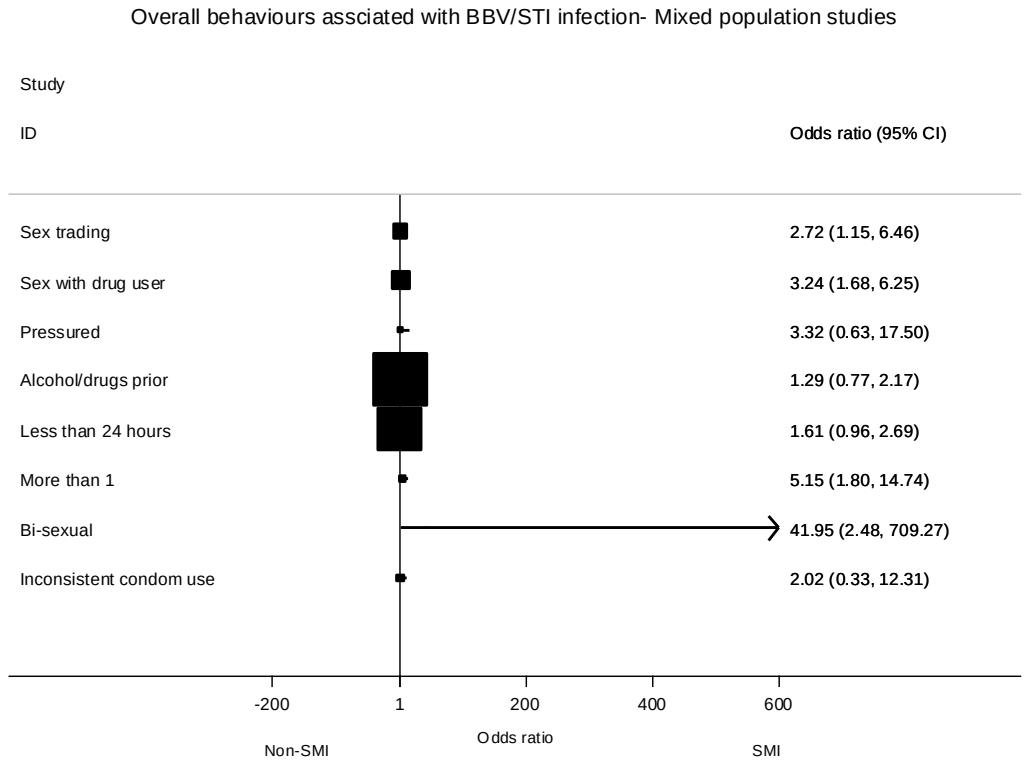


Figure 17 Forest plot for overall pooled odds ratios for each behaviour associated with BBV/STI infection in SMI and none SMI populations- mixed population studies



This section has summarised the evidence from the six-included case-control studies exploring sexual behaviours associated with increased risk of HIV/STI infection in adults with SMI, compared with those with no history of mental illness and also when sub-grouped by gender specific studies. The next section will interpret these results in light of the strengths and limitations of the included studies and the current systematic review methods.

3.5 Discussion

3.5.1 Summary of results

The aim of this systematic review was to examine sexual risk behaviours associated with the acquisition of BBVs or other STIs in adults with SMI. Six case-control studies (total n= 801; n=412 cases, n=389 controls) were included in the review. Common methodological flaws included selection bias, failing to use validated questionnaires or interviews, and failing to blind interviewers to case or control status.

Across the six included studies ten sexual risk behaviours were reported more than once. These included: sexual trading (n=5); sex with a person who uses drugs (n=5); alcohol and/or drug use prior to sexual intercourse (n=4); sexual intercourse with someone known less than 24 hours (n=4); more than one sexual partner reported in the last 12 months (n=4); paid sex work (n=2); pressured into unwanted sex (n=4); sex with someone who identifies themselves as bisexual (n=2); men who have sex with men or women who have sex with women (n=2); and inconsistent condom use (n=2). Evidence of significant differences between adults with SMI and those with no history of mental illness were found amongst five sexual risk behaviours, with only alcohol and/or drug use and inconsistent condom use finding little or no evidence of a difference between the cases and controls. It was not appropriate to combine the remaining three behaviours in meta-analyses as they were male-only, female-only or mixed population studies providing data on those behaviours.

When sexual risk behaviours across the studies were pooled, the behaviour most highly associated with SMI was that of ‘reporting more than one sexual partner in the last 12 months. Individuals with SMI had 3.63 (CI, 2.07, 6.37) the odds of reporting more than one sexual partner in the last 12 months compared to those with no history of mental illness. Individuals with SMI had 3.48 (CI, 1.86, 6.52) the odds of reporting having had sex with a person who uses drugs, and with regards to ‘sex trading’ participants with SMI had 2.29 (CI, 1.22, 4.30) the odds of reporting trading sex compared to those with no history of mental illness. In addition, cases had 2.92 (CI, 1.42, 6.04) the odds of reporting being ‘pressured into having unwanted sexual intercourse’, and 1.97 (CI, 1.29, 3.02) the odds more likely to have had sex with a person they had known for less than twenty-four hours compared to those with no history of mental illness. All of these results were statistically significant. With regards to the behaviour ‘alcohol and/or drug use prior to sex’ the meta-analysis suggested that people with SMI had similar odds to those with no history of mental illness 1.03 (CI, 0.71, 1.51) but this result was not statistically significant. For the sexual risk behavior ‘inconsistent condom use’ the pooled result suggests that people with SMI had 2.02

(CI, 0.33, 12.31) the odds of reporting 'Inconsistent condom' use to those with no history of mental illness, howev. In relation to men who have sex with men (MSM) and women who have sex with women (WSW), paid sex work and sex with an individual who identifies as a bisexual, SMI did appear to be a risk factor, however as the studies reporting on this were split by gender, the individual results were not combined in a meta-analysis.

3.5.2 Evaluation of the review methodology

3.5.2.1 Strengths of the current review

A detailed systematic review protocol was developed before the review was conducted (appendix 3). This provided a detailed *a priori* description of inclusion and exclusion criteria, search strategy, data sources, method of data extraction, method of quality assessment, and also the anticipated methods of data synthesis. As it is now good practice, the protocol for this systematic review was registered on PROSPERO, an international online database for protocols of systematic reviews in the fields of health and social care (registration number CRD42015020703).

A second strength of this systematic review was the extensive range of literature sources that were searched in order to try and capture all international literature (published or unpublished) relating to SMI and sexual behaviours associated with increased risk of BBV/STI infection. A total of six primary electronic databases were searched using specifically developed search strategies (an example of the MEDLINE search strategy is given in appendix 4) and additionally six grey literature databases were searched to try and identify any conference proceedings or dissertation and theses. In retrospect, if the search was to be performed again, all of the primary databases would still be searched, however the number of grey literature resources searched would be reduced to save time and resources as they did not yield any further studies eligible for inclusion in the systematic review.

A further strength of the systematic review was that two researchers independently screened all titles and abstracts from the electronic searches, and both independently screened full text articles against the inclusion and exclusion criteria on a pre-piloted relevance checking form (appendix 5). Once the eligible studies were confirmed, the same two researchers independently extracted pre-defined data items onto a pre-piloted data extraction form (appendix 6). This was to ensure that the data were as unbiased and as reliable as possible.

Finally, the methodological quality of included studies was assessed using the NOS (appendix 7). This tool is the most frequently used tool for systematic reviews of

observational studies, in particular case-control and cohort studies with reported content validity for this instrument (Wells et al., 2000). This was completed independently by two reviewers to ensure that this process was as unbiased as possible.

3.5.2.2 Limitations of the current review

Although this review has generated important information relating to sexual risk behaviours associated with the increased risk of BBV/STI infection in adults with SMI, a number of limitations need to be considered when interpreting the findings of this systematic review.

Firstly, although the searches were extensive, and the search strategy was designed to be sensitive and broad, only six unique records were found to meet the inclusion criteria out of a total of 10,424. Despite the research team trying to minimise the possibility of missed records, it cannot be ruled out that studies were missed when searching electronic databases or grey literature sources. This should also be considered within the context of the scoping reviews discussed in section 3.2.3 of this chapter, as those reviews found and included a larger number of studies, 51 in the case of Lagios and Deane review (2007). However, the same inclusion and exclusion criteria did not apply, for example, cross-sectional studies were a specific exclusion criterion for inclusion in this systematic review, in contrast to the Lagios and Deane review who included this study design (2007).

An additional limitation of the current review is that the author of one study was contacted as there was one aspect of this paper where the rationale was not clear for only asking men about paid sex work, and although an enquiry was sent to the lead author, no contact was made, however this paper was conducted nearly 20 years ago (Grassi et al., 1999).

A further limitation of the current review is that some caution is needed in interpreting the results of the meta-analyses due to the low number of studies included. There were also variations in sample, three studies were either male-only or female-only populations whilst the other were mixed gender populations with differing proportions of SMI diagnoses across studies. The results of the meta-analyses therefore should be interpreted with some caution.

3.5.3 Interpretation and evaluation of the evidence

Although the results of the meta-analyses provide some preliminary evidence that people with SMI are more likely to engage in sexual behaviours associated with

increased risk of BBV/STI infection compared to those with no history of mental illness, the results should be considered with caution due to the substantial differences in the designs of the included studies. Given these differences, the main focus should be on the narrative synthesis. However, there are a number of additional concerns that place limitations on the interpretation of both the meta-analysis and the narrative synthesis, these are discussed in section 3.5.3.2 below.

3.5.3.1 Strengths of the primary studies

The overall quality of the included studies was moderate with the majority of the studies scoring a total of four out of nine stars on the NOS (Wells et al., 2000). A number of strengths and limitations were identified and will be discussed in line with the NOS categories. One strength identified was that in all six studies, those with SMI were defined by independent validation through either a clinical interview or from information collected from patients' notes and clinical referral. This ensures that participants meet the right inclusion criteria for the studies, and allows for capacity to provide informed consent to be assessed. All six studies were assigned a star for this category.

A further strength of the included studies was the definition of those with no history of mental illness and five out of the six studies were assigned a star for this category. All control groups were defined as having no history of SMI. In two studies (Grassi et al., 1999; Miller & Finnerty, 1996) the non-SMI groups were administered a clinical interview to ensure they did not meet the diagnostic criteria for mental illness and had no history of mental illness. Those with no history of mental illness in three studies self-reported that they had no history of SMI (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000). In the Koen et al. (2007) study the control group was defined as 'healthy controls', however, there was no further information or evidence about how this was established. Due to the stigma surrounding SMI, those in the control group may not have felt able to report previous diagnoses honestly, meaning this study could not be assigned a star for quality on this category due to a potential source of reporting bias (Wainberg et al., 2016).

In terms of the comparability of cases and control groups at the design stage, all studies were assigned one star out of a possible two on the NOS (Wells et al., 2000). This was because all studies matched SMI and non-SMI groups on important factors. The participants in the Grassi et al. (1999) study were matched on sex, age and socio-educational level. Koen et al. (2007) matched SMI and those with no history of mental illness on race, gender and age (within five years). Miller and Finnerty (1996) controlled for age, race, employment status, religion and level of education. Finally, Brown et al. (2010, 2011a, 2011b) report that their samples were closely matched on

demographics. Three studies (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999) controlled for important factors such as substance use disorders, this was controlled for at the design stage of the studies. The remaining three studies (Brown et al., 2010, 2011a, 2011b; Koen et al., 2007; Miller & Finnerty, 1996) did not report controlling for any factors outside of demographic features either at the design or analysis stage. For example, the sample in the Brown et al. (2010, 2011a, 2011b) study, although not significant, had a greater proportion of those with SMI who had not completed high school, as socio-economic status was not controlled for, it could account for some of the differences between groups. Similarly, in the Coverdale et al. study (2000) socio-economic status was not controlled for in the analysis, the SMI group were more likely to receive benefits and less likely to be employed or married than those with no history of mental illness, and this may also account for some differences between groups.

All six studies (Brown et al., 2010; 2011a; 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996) were assigned a star as the outcomes of interest for the SMI and those with no history of mental illness groups in each study were ascertained using the same questionnaire/interview which allows us to directly compare the responses of both groups within studies.

Finally, a further strength of the Brown et al. (2010, 2011a, 2011b) study was that they used community samples for those with no history of mental illness group which increased the representativeness of the sample. This is the only study that was assigned a star for this category on the NOS as the other five included studies used hospital controls which increases the risk of selection bias.

3.5.3.2 Limitations of the primary studies

A number of limitations were evident in the included studies. As discussed in previous sections, the sample sizes in the majority of the included studies were small, with the smallest sample in one study being 42 for those with SMI and 43 for those without (Koen et al., 2007). None of the studies reported power calculations, the rationales for using small sample sizes, or the total pool of people the SMI population were sampled from. Studies with low or no statistical power can affect the precision results by either artificially inflating or deflating effect estimates, thus increasing the risk of biased results (Button *et al.,* 2013).

All six studies had the potential for selection bias or failed to provide sufficient information about this. Brown et al. (2010, 2011a, 2011b) used a convenience sample for the SMI group and females were under-represented in the sample. It is also

important to note that the sample in the Brown et al. (2010, 2011a, 2011b) study were young adults diagnosed with first-episode psychosis and currently in the recovery stage, therefore the results of this study are not generalisable to the SMI population. The remaining studies used volunteer samples (Coverdale et al., 1997; Coverdale et al., 2000, Grassi et al., Koen et al., 2007; Miller & Finnerty, 1996). Thus, it is not possible to establish the representativeness of the samples and therefore caution is needed when interpreting the results of the included studies, and also the meta-analyses.

In relation to the selection of those with no history of mental illness groups, five of the included studies recruited their samples from waiting rooms of general hospitals (Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996). With this in mind, it is difficult to draw any conclusions about how representative the control groups were of the general population.

Three of the included studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000) used self-report methods to establish that the control group had no history of SMI. Although this is considered an acceptable method by the NOS. A more rigorous method of establishing this would have been to administer a structured clinical interview to all control participants. The Koen et al. (2007) study did not provide any description on how a history of no SMI was established. Therefore, no stars from the NOS could be assigned to these studies for the selection of controls category.

An additional limitation of all of the included studies was that the questionnaires/interviews used to collect data on sexual risk behaviours were all adapted, and therefore were not in themselves validated assessment tools. Consequently, it is difficult to know whether the data collected was valid or reliable and makes interpreting the results difficult. Furthermore, another concern is the potential of reporting bias surrounding the reliability of the sexual health interview itself, and whether the SMI and non-SMI groups were reluctant to report engaging in sexual behaviours that they do not deem socially acceptable and put them at an increased risk of BBV/STI infection (Grassi et al., 1999).

A further limitation of three of the included studies was that non-response rate and missing data were not discussed and how these may have had an impact on the results of the studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000). With this in mind, it is not possible to determine whether there were any differences between the participants that did respond to the questions and the participants who didn't. This may have affected the results by either overestimating

or underestimating the overall association. In the Grassi et al., (1999) study although there are no descriptions about the difference between responders and non-responders, the authors acknowledge that the lack of complete assessments from the cases suggesting the results are not generalisable.

Although the review found some preliminary evidence that people with SMI are more likely to engage in different types of sexual risk behaviour compared to those without a history of mental illness, it is not possible to ascertain how robust the associations are between the sexual behaviours identified and the acquisition of BBV/STIs as none of the included studies reported on diagnoses of HIV and only two studies reported on previous diagnoses of STI's (Grassi et al., 1999, Miller & Finnerty, 1996). However, there is evidence more generally to support why some of these behaviours are associated with increased risk of BBVs and STIs (Cournos & McKinnon, 1993; Lagios & Deane, 2007; Sohler et al., 2000; Wainberg et al., 2008). Many of them increase the likelihood that unprotected sex will occur as people can be driven by desires and act impulsively (e.g. being under the influence of alcohol/drugs and forgetting condoms, being offered money or goods to have condomless sex, being coerced to have sex without a condom) (Brown et al., 2010, 2011a, 2011b; Cournos et al., 1994; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Guimarães et al., 2014; Koen et al., 2007; McKinnon et al., 1993; Miller & Finnerty, 1996; Pinto et al., 2007; Sohler et al., 2000; Wainberg et al., 2008).

3.5.4 Implications for methodological standards in future studies

Firstly, only six studies met the inclusion criteria for this review. Given that research suggests that people with SMI are at an increased risk of contracting BBVs or other STIs, more research is required to further investigate this relationship. This review has demonstrated a number of areas that need to be addressed in future research within this context. The assessment of the methodological quality of included studies highlighted common flaws. Within future studies researchers should aim to improve methodological standards and address some of the limitations identified to minimize the risk of bias. One suggestion would be to recruit larger sample sizes so the precision of the findings can be improved. This could be achieved by recruiting multiple controls per case participant which in turn would increase the sample size and thus the statistical power of the study. A second suggestion for future studies would be to use validated collection methods by way of questionnaires or structured interviews to ensure high quality data is collected and that findings from studies can be trusted. For all interviews, interviewers should be blind to case/control status and well trained in order to reduce interviewer bias. A final suggestion would be to address limitations with

regards to the potential for selection bias. Future studies should try and recruit a representative sample of participants with SMI by means of inviting all eligible people that meet the inclusion criteria. The potential for selection bias could also be reduced if the control groups were recruited from community settings rather than hospital settings.

3.5.5 Implications for reporting standards in future studies

All research should be reported in a transparent manner, so the intended audience can determine how the research was planned, how it was undertaken, what was actually found, and the conclusions that were drawn from the findings. However, according to von Elm et al. (2007) many observational studies do not report important information, or it is not reported clearly, making it difficult to draw reliable conclusions from the research. With this in mind the Strengthening the Reporting of Observational Studies in Epidemiological Statement (STROBE) checklist was developed to improve the transparency of reporting, and thus allowing critical appraisal of observational studies. The checklist consists of 22 items that can be applied to cohort, cross-sectional and case-control studies. In relation to the studies that were included in this review, many were undertaken before the development of the STROBE checklist. However, some examples of missing information from the included studies were: no description of sources of potential bias and how they would be addressed, no information in relation to how sample sizes were decided, and also missing data and how this may impact on the results were rarely discussed. To conclude, future studies within this context should be reported in line with the STROBE statement to ensure observational studies are consistently reported and lend themselves to critical appraisal.

3.6 Conclusion

A systematic review was undertaken to explore whether people with SMI are more likely to engage in sexual behaviours that are associated with increased risk of BBV/STI infection, compared to those without SMI. Six unique case-controls studies that met the inclusion criteria were included in this review. The results provide some preliminary evidence that people with SMI are more likely to engage in sexual behaviours that are associated with increased risk of BBV/STI infection compared to those without SMI. However, it is unlikely that SMI would be the single attributor to a willingness to engage in sexual behaviours that are associated with increased risk of HIV/STI infection. There are numerous factors which could directly impact on the engagement in such behaviours: socio-economic status, marital status, gender, comorbid substance use, and stage of illness.

The results of the systematic review support the findings of previous reviews (Cournos & McKinnon, 1997; Lagios & Deane, 2007) and highlights the lack of research in this subject area with limited studies from Europe, and specifically none in the UK. Therefore, there is a need for further rigorous epidemiological studies to be conducted. In addition to the need of robust epidemiological studies internationally, and given the paucity of research in this field in the UK, there is also a need to explore whether it would be feasible and/or acceptable to speak to people with SMI in the UK about their sexual health and behaviour. The studies included in this review, and also the scoping reviews did not provide any information on the feasibility or acceptability of undertaking research in this area with this population. This research will be vital in informing the development of future research by providing information on the ethics processes within the UK, recruitment processes, feedback on the acceptability of data collection measures, and also service user comfort in discussing their sexual health and behaviour. Further research in this field will allow the relationship between SMI and the increased risk of BBVs/STIs to be further understood which will then inform policy and practice in developing preventative strategies for this population in the UK.

3.7 Summary

This chapter has presented a systematic review to explore whether people with SMI are more likely to engage in sexual behaviours associated with increased risk of BBV/STI infection compared to those with no history of mental illness.

Building upon the findings of this chapter, the following chapter outlines the aims, methodology and results of an acceptability and feasibility study of assessing sexual risk behaviour measures in people with SMI in the UK.

Chapter 4. An acceptability and feasibility study of assessing sexual health and risk behaviour measures in people with severe mental illness in the UK.

The aims and methodology of an acceptability and feasibility study assessing sexual risk behaviour measures in people with severe mental illness (SMI) will be outlined in this chapter. Following an introduction to conducting feasibility studies, the rationale and aims of this study will be described. The chapter then presents a description of the study's methodology including; study design, recruitment, data collection methods, an in-depth description of the sexual risk behaviour measures utilised for data collection, and the analytic plan is described. This chapter also presents ethical considerations with regards to ethics processes and also those specifically in relation to sexual health interviewing. Finally, the results and discussion are presented.

4.1 Introduction

According to the National Institute for Health Research (NIHR) (2013), feasibility studies are conducted early in the research process to establish whether a question has the potential to be answered such as, 'is it possible to recruit people into a study using recruitment method X?'. Wuest et al. (2014) suggests that feasibility studies are important in exploring the issues around research methodology and context specific practicalities. They are often the pre-cursor to, and used to inform larger studies such as definitive Randomised Controlled Trials (RCTs) assessing the efficacy of an intervention (Eldridge et al., 2016). The NIHR guidance (2015) states that feasibility studies are used to estimate important factors needed in the design and development of a main study. These include:

- Number of eligible potential participant's
- Engagement of clinical staff in recruiting participants
- Willingness of participants to be randomised
- Time needed to collect and analyse data
- Ability to estimate sample size based from the standard deviation of the outcome measure when needed
- Suitability of proposed primary and secondary outcome measures

In support of this, Orsmond et al. (2015) suggest that feasibility studies are important to research as they are concerned with study processes rather than outcome to answer the question, 'can it be done?'. Orsmond et al. (2015) describes five objectives that should guide health researchers when undertaking feasibility studies:

1. Evaluation of recruitment capability and resulting sample characteristics
2. Evaluation and refinement of data collection procedures and outcome measures
3. Evaluation of acceptability and suitability of intervention and study procedures
4. Evaluation of resources and ability to manage and implement the study and intervention
5. Preliminary evaluation of participants responses to intervention

Objective one allows for researchers to explore whether it is possible to recruit the appropriate participants to a study, assess whether the eligibility criteria for the study is suitable or too restrictive, and also to be able to examine recruitment rates and determine whether the recruitment methods employed work, or whether new methods of recruitment need to be adopted. Objective two enables researchers to explore whether the data collection methods and outcome measures are suitable for the purpose of the study or whether they need to be amended for future studies. Similarly, objective three looks at study processes and data collection tools but from the perspective of study participants. Do participants engage with recruitment processes and do they find the method of recruitment and study documents acceptable? Objective four relates to whether the research team have the resources and skill set to be able to manage the study. Also, when undertaking primary research, organisational structures should be considered; does the organisation engage with the research? Do they have the capacity to accommodate the research study? Objective five is concerned with participants completing the outcome measures, do the outcome measures capture the information required to answer study questions? Is there any missing data? When undertaking a feasibility study, these objectives are important in guiding the learning process, and vital lessons can be learnt for informing larger future studies (Orsmond et al., 2015).

4.2 Rationale and aims

The results of the systematic review in the previous chapter highlight the lack of research exploring the intersection of SMI and sexual health, but it does provide some preliminary evidence that people with SMI are more likely to engage in sexual risk behaviours that are associated with blood borne viruses (BBVs) and sexually transmitted infections (STIs) compared to those with no history of mental illness. Engaging in ‘high risk’ sexual behaviours is one of the suggested explanations for the elevated prevalence of BBVs in the SMI population (Cournos & McKinnon, 1993; Lagios & Deane, 2007). Although the Lagios and Deane scoping review (2007) reported that few countries had prevalence data relating to BBVs and other STIs in the SMI population, a recent systematic review of prevalence studies reported that in the

USA the estimated prevalence of HIV in people with SMI was 6% compared to 0.6% in the general population with HIV (Hughes et al., 2015). Therefore, there is a need to be able to reliably assess those deemed to be at risk of contracting BBVs and/or STIs in this 'at risk' population. This will inform the development of effective interventions to promote positive sexual health and relationships.

In general, the majority of the research in this field has been undertaken in the USA. According to McKinnon et al. (1993) it was unclear within the literature as to whether it was possible to interview people with SMI about their sexual behaviour and ascertain reliable information, and also, whether discussing this would have a negative impact on their psychiatric symptoms. To explore this further, McKinnon et al. (1993) undertook a test-retest study to explore the reliability of conducting a sexual health interview in a psychiatric population using the Sexual Risk Behaviour Assessment Schedule (SERBAS). Thirty people volunteered to participate in this study. However, three of these were unable to be re-interviewed within the sixty-day time frame and so these were excluded, and a total of twenty-seven test-retest interviews were undertaken. McKinnon et al., (1993) reported high test-retest reliability with coefficients for risk related sexual behaviour in the previous six months ranging between 0.61 and 0.89 suggesting that reliable interviews regarding sexual risk behaviour can be obtained from people with SMI. McKinnon et al. (1993) also found that participants responded positively to the interview and reported that participants were happy to talk about a 'normal' aspect of life. The study reported that there were no adverse events, distress or discomfort expressed by the participants, and there was no exacerbation of psychiatric symptoms observed by the experienced researchers in response to sexually explicit questions and nobody wanted to terminate the interview prematurely (McKinnon et al., 1993). In support of this, reliability estimates ranging from 0.49 to 0.93 were found from a further test re-test study using the SERBAS with thirty-nine male participants with SMI (Sohler et al., 2000).

Although there is limited research in this field, a number of case-control and cross-sectional studies have been undertaken internationally in countries such as the USA, Brazil, New Zealand, South Africa and Italy, which suggests in these countries it is feasible to recruit people with SMI to studies exploring sexual health and behaviour however, there is limited information on the acceptability of undertaking this research in this population (Brown et al., 2010, 2011a, 2011b; Cournos et al., 1994; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Guimarães et al., 2014; Koen et al., 2007; McKinnon et al., 1993; Miller & Finnerty, 1996; Pinto et al., 2007; Sohler et al., 2000; Wainberg et al., 2008). Therefore, this study was developed to explore the

acceptability and feasibility of undertaking sexual health and behaviour research in people with SMI and was the first study to explore this in a UK population.

In line with the NIHR guidelines (2015) the overall aims of this feasibility study were to undertake a feasibility study to examine recruitment processes and get participant feedback on the acceptability of a sexual health interview. The main objectives of this research were:

1. To assess the feasibility of exploring sexual health and sexual risk behaviour by: quantitative assessment of numbers eligible, numbers consenting to participate, and number of questionnaire/interviews conducted.
2. To explore the acceptability of data collection measures used and the data collection method.

In addition to the main aims, the following secondary aims were also explored:

1. To explore the ethics processes of undertaking research in this novel area in the UK
2. To evaluate the completeness of the sexual health questionnaire and interview

4.3 Methodology

4.3.1 Study design

A feasibility study was undertaken for people meeting the eligibility criteria described below in section 4.3.2. The study was cross-sectional and comprised a quantitative interview with four separate sets of questions including three self-report questionnaires and a researcher led gold standard interview. The questionnaire/interviews were undertaken with service users meeting the inclusion criteria below within a community mental health team (CMHT) in one NHS site in England. Further information about the design and content of the self-report questionnaires and researcher led gold standard interview can be found in section 4.3.7.

4.3.1.1 Patient and Public Involvement

Patient and public involvement (PPI) is an essential component of Health Services Research (HSR) (Gray-Burrows et al., 2018). PPI ensures that research is conducted in collaboration with academics, healthcare professionals and people with lived experience of the health condition in question. Examples of involvement include developing or providing feedback on research study documentation, actively undertaking research activities such as interviews, and offering input on oversight committees such as a trial steering committee. Involving patients and the public in all aspects of the research process ensures the research is relevant to the needs of service user, and therefore the impact of the research is likely to be greater (Gray-Burrows et al., 2018).

As part of the wider NIHR Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC YH) workstream on SMI and sexual health, a stakeholder and PPI event was held in April 2015. A poster was issued to research and development teams within the region with a request that the poster be disseminated to service user groups within their NHS Trusts. The poster detailed the aims of the event which were:

- To discuss the assessment of sexuality, sexual health and behaviour, STIs, BBVs and family planning for people with SMI;
- To review the tools and procedures that are currently used for assessing these issues in the SMI population;
- To discuss the involvement, recruitment, enrolment and participation of people with SMI in research studies.

People who were either ‘experts by experience’ of mental health services, or carers of people with mental health problems were asked to contact the organisers and register their interest in the event.

A total of five people attended the event, two males and three females. As part of this event the PPI group were instrumental in the design and development of the protocol for the study presented within this chapter (latest version of the protocol in appendix 9). The PPI group advised on what should be included in participant information sheets (PIS), how to inform potential participants about the study, how to recruit and consent research participants in a comfortable and acceptable way, how best study data can be collected (self-report or researcher led) and the potential support requirements for people with SMI taking part in research (e.g. offering frequent breaks). The PPI group also reviewed and provided feedback on the acceptability of a questionnaire proposed for use in this study. The feedback was positive, and the PPI group suggested that although it was a self-report measure, the researcher should be present in case some of the terminology required clarification.

Throughout the development of the study and the process for obtaining ethical approval described in section 4.4, members of the PPI group were contacted via email for continued feedback on study documents. This feedback was used to ensure that the information given to potential participants was explicit in what the study involved as it could potentially trigger some difficult memories whereby people may have experienced prior sexual abuse/exploitation. This would allow participants to make a fully informed choice about participation.

4.3.2 Inclusion and exclusion criteria

To be included in this study, participants were required to be both:

- Over the age of 18 and
- On the caseload of one community mental health service with a diagnosis of schizophrenia, other psychotic/delusional disorders or bipolar disorder (F20, F21-29 & F31).

People were excluded from taking part in the study if they:

- Had a primary diagnosis of substance use;
- Had a primary diagnosis of cognitive impairment;
- Lacked capacity to consent as per the Mental Capacity Act (2005);
- Were non-English speaking participants;
- Were on the sex offenders register.

People with a primary diagnosis of substance use disorders were excluded from this study as the population of interest were those with SMI, and as explored in chapter 3,

section 3.2.1, using substances may increase the likelihood of engaging in sexual behaviours associated with increased risk of BBV/STI infection. Given the sensitive nature of this research, adults that had a primary diagnosis of cognitive impairment or lacked capacity to consent as per the Mental Capacity Act (2005) were excluded from this study. Adults with literacy difficulties were not excluded; in these instances, all study information and questionnaires were read out to participants. It was felt that the option of providing translated versions of study questionnaires and interview schedule would not be feasible due to the resources and scope of this study, and therefore non-English speaking participants were excluded from this study. It was a requirement of the NHS Research Ethics Committee (as discussed in section 4.4 of this chapter) that those on the sex offenders register be excluded from participating in this research in order to limit the potential risk to the researcher.

4.3.3 Sample size and sampling strategy

According to Billingham et al. (2013) there is limited guidance on the sample size requirements of feasibility studies and pilot randomised controlled trials (RCTs). They undertook an audit of sample sizes for feasibility and pilot studies registered with the clinical research network (CRN) in the UK and found that the sample sizes of feasibility studies and pilot RCTs ranged from 10-300 with a median of 36 participants (Billingham et al., 2013). With limited published guidance and the limited resources for this study it was expected that a volunteer sample of ten people (five men and five women) meeting the eligibility criteria would be recruited to take part in this study.

4.3.4 Recruitment methods

There were three different recruitment methods employed sequentially for this study, the rationale for multiple methods is described in section 4.4.4. Each of the recruitment strategies are discussed in turn below. It was anticipated that recruitment would take place over a two-month period in one NHS site; however, this was extended to a seven-month period from between January and July 2017, the rationale for the recruitment extension is discussed in detail in section 4.4.4.

4.3.4.1 Initial recruitment method

Prior to commencing this study, the subject area, the proposed method of screening and recruitment were discussed at CMHT and early intervention team (EIT) meetings within one NHS site in England. NHS trust communications networks were utilised to raise awareness of the study, and clinicians received (by email) information about recruitment processes and eligibility criteria. Where CMHT's agreed, clinical staff screened their caseloads for potentially eligible participants based on the inclusion and exclusion criteria described above. The total number of patients meeting the inclusion criteria on the caseload of the CMHT was unobtainable.

Potentially eligible participants received an information pack about the study via their case manager. This contained a detailed participant information sheet (appendix 10), a simplified leaflet with information about the study (appendix 11) and a consent to contact form (appendix 12). The case managers who gave out the information packs could explain the study, answer any questions raised and obtain consent for the researcher to contact the participant if they were interested in participating in the study.

4.3.4.2 Recruitment method two

To increase recruitment rates, a second method of recruitment was employed. Where care co-ordinators agreed, the researcher attended outpatient clinics such as clozapine and depot clinics. The researcher was able to hand out a simplified information leaflet (appendix 11), answer any questions the potential participants had, and provide them with a full information pack if they expressed an interest in taking part in the study.

4.3.4.3 Recruitment method three

A third recruitment method was employed during the study. There is a programme of research being undertaken at the University of York in the Mental Health and Addictions Research Group which is aiming to improve the health and wellbeing of people with SMI. The lifestyle, health and wellbeing study is a cohort study that aims to collect data on the lifestyle choices of people with SMI, and also to provide a cohort of people who would be interested in taking part in future research. This recruitment method involved mailing out information packs to people within the lifestyle, health and wellbeing cohort who consented to being contacted again about research. The information packs included the same information as the packs handed out by clinicians and the researcher but, also included a cover letter which explained that they had been invited to take part in this study as they had recently completed a lifestyle survey and had expressed an interest in participating in future research studies (appendix 13).

The total number of people recruited into the lifestyle, health and wellbeing cohort at the point of recruiting for this study was 2214 participant's, however, it was not known how many of these participant's consented to be contacted again about future research. After discussions with the cohort study team it was decided that mailing out to potential particpants in batches of ten would be most appropriate in order to be able to gauge interest in the study presented within this chapter and also to be mindful of the limited recruitment period.

4.3.5 Consent process and data collection

On receipt of a faxed or scanned and signed consent to contact form, the researcher contacted the potential participant directly by telephone to confirm they met the study

eligibility criteria, answer any questions the participant had and arrange an appointment to meet at a time and venue that was convenient for the participant.

On meeting with the researcher, a full oral explanation of the participant information leaflet was given, participants were given a further opportunity to clarify any points they did not understand or gain more information. If written informed consent was obtained (appendix 14) and the time was convenient for the participant, the questionnaire/interview session was conducted at the same time. However, if this was not convenient, a later date was booked. Where written informed consent was obtained, a copy of the consent form was given to the participant; a copy was also sent to their GP/case manager along with a letter (appendix 15) to inform them of their inclusion in the study with the participant's consent. A copy was also stored securely in the participant's personal data file.

The questionnaire/interview sessions were administered at one time point and were conducted face-to-face. There were a number of reasons the interviews were conducted face-to-face:

1. In case there were any literacy or comprehension issues that otherwise would mean individuals may not have been able to participate;
2. Some terminology about human sexual functioning or sexual practices may be unfamiliar to participants; at the beginning of the Sexual Risk Behaviour Assessment Schedule (SERBAS) interview, a dialogue took place between the researcher and participant to come to a mutual understanding about what the sexual terms in the interview meant, and how the participant referred to those behaviours;
3. The cultural meaning of certain behaviours could be explored, and any shame or guilt felt could be reduced in the interview, this would not have been possible if a written survey was used;
4. As the researcher was a trained interviewer with experience of mental health research, they were able to offer support if they perceived any discomfort, or the participants expressed discomfort with any questions; the interview could then be stopped and resumed at another session if required.

4.3.6 Data storage

The consent forms and contact details for participants were stored in a locked filing cabinet within a locked office at the University of York. No personal identifiable information was collected during the questionnaire/interviews sessions and all participants were allocated a unique participant ID for the study which was used when

analysing and reporting the data. The anonymised data were stored separately on a secure password protected server within a locked office at the University of York. Study data will be retained for a period of five years from the end of the study to comply with the Data Storage Policy at the University (2017). The processes of ensuring participant confidentiality, anonymity, data storage and reporting of data was explained to all participants in the participant information sheet and verbally at the beginning and end of the interviews.

4.3.7 Data collection tools design and content

There were four separate sections to the questionnaire/interview schedule for this study. It is important to note that as the secondary objective of this study was to evaluate the completeness of the sexual health questionnaire/interview (which questions were completed/not completed) participants could skip any questions that they did not feel comfortable answering.

The first section was a short self- report questionnaire (appendix 16) which collected minimal demographic information including: age, gender, sexuality, relationship status, mental health diagnosis and whether they were taking any antipsychotic medication.

The second section was a self-report questionnaire adapted from the National Survey of Sexual Attitudes and Lifestyles 3 (NATSAL 3). The NATSAL is a survey exploring the sexual attitudes and lifestyles of the British general population that was conducted in 1990 to 1991 (NATSAL 1), was repeated in 1999 to 2001 (NATSAL 2) and again between 2010 and 2012 (NATSAL 3). The NATSAL 3 data was collected using a computer assisted interview for the questions more sensitive in nature. The NATSAL 3 has five domains; health, family and learning about sex; first sexual experiences, contraception uses and sexual lifestyle, the more sensitive questions covering sexual behaviour, number of partners, sexual practices and sexual health; attitudes and risks and socio-demographic questions. The NATSAL used in this study was adapted from the computer assisted version to a self-report paper version containing 183 questions in total, taking approximately 30 minutes to complete (adapted version of NATSAL- appendix 17). Some of the sections were removed including, learning about sex, fertility testing and use of Viagra, as these were not directly relevant to the study objectives.

The third section of the data collection process took the form of a gold standard semi-structured interview, the Sexual Risk Behaviour Assessment Schedule for adults (SERBAS) which was administered by the researcher to examine recent sexual behaviours (full version of SERBAS- appendix 18) (Cournos et al., 2005). The

SERBAS was initially developed in New York for injecting drug users and then further adapted for psychiatric patients by a team of psychiatrists who worked in both inpatient units and community outpatient clinics (McKinnon et al., 1993). The SERBAS consists of 281 items and takes, on average, 45 minutes to complete depending on the amount and type of sexual behaviour that is reported (Sohler et al., 2000). The SERBAS begins with an exploration of the participant's terminology for sexual practices and behaviours which attempts to build a rapport between the participant and researcher, and also put the participant at ease (McKinnon et al., 1993). The SERBAS then screens for sexual activity before assessing in detail the recent and lifetime sexual practices of the participant (Sohler et al., 2000). This was the first time this interview had been administered in the UK SMI population and required the researcher to undergo training in its administration (as discussed in section 4.4.2).

Both the NATSAL and the SERBAS were used within this study to ensure that the ten 'high risk' sexual behaviours reported within the systematic review findings were covered within the data collection tools used for this study, as neither tool covered all risk factors individually.

The final part of the questionnaire/interview session was a short self-complete questionnaire about the participant's experience (acceptability) of the interview/questionnaire that was developed for this study (appendix 19). This included six open ended questions such as, *'why did this study interest you?'*, *'why did you agree to take part?', 'how did you find the overall experience?'* and *'how did you feel about completing the questionnaire/interview?'* There were also six closed questions on a Likert scale relating to what could have improved the experience including comfort, timing, privacy, relevance of questions and whether the participants felt they were in a safe and supportive environment.

The total number of questions included in the case report form was 463, however, the number of questions each of the participants answered depended on their levels of sexual activity and comfort in answering the questions.

4.4 Ethics

4.4.1 Ethical considerations

Due to the nature of this study it was important to consider all potential risks to participants as their well-being was of utmost importance. The main potential risk from participating in this study was the potential embarrassment of discussing sexual behaviour, sexual health and relationships. The researcher was also aware that people

with SMI who have experienced sexual abuse and/or exploitation may find this study distressing and may trigger difficult feelings. To minimise this, potential participants were informed in the information sheet and leaflet as well as verbally of the specific nature and content of the study prior to consent. The researcher ensured this was explicit in the participant information sheet, and although prior sexual abuse was not an exclusion criterion for the study, the content of the questionnaires and interview may trigger upsetting memories. All interviews were conducted in a private room to minimise embarrassment also. The researcher was trained in the delivery of the sexual health interview (see section 4.4.2) to ensure all participants felt as comfortable as possible.

Only people who have capacity to consent and in a stable phase of their illness were recruited into the study. In addition, as this was an opt-in study, people who participated chose to take part. However, as for all research, the researcher was mindful that people may become upset or angry during an interview. The researcher was also trained to terminate any interviews that become inappropriate. A clinical member of the supervision team was informed of any such instances. All the interviews took place on NHS Trust sites with staff in the vicinity of the interview room (which have a personal alarm).

Participants were also informed of their right to withdraw at any time and without having to give a reason at the beginning of the questionnaire/interview session.

The participants were not under any obligation to respond to questions that they did not want to answer. Participants were also offered breaks during the session if they were needed. The participants were fully de-briefed prior to leaving the session. Participants were asked whether they had any concerns or issues about topics covered during the questionnaire/interview session or as a result of taking part in the study in general. Any concerns raised were followed up with their key worker but only with consent of the participant. The only exception to this was if there was an issue that concerned significant risk to the participant or a third party. In this case, the risk protocol (appendix 20) would be enacted, see section 4.4.1.1.

Although this study was likely to be a low risk study, a number of procedures were in place to ensure the safety of the participant and researcher, these are described in detail below.

4.4.1.1 Risk protocol

As there is an elevated risk of suicide in those with SMI, a risk protocol was developed specifically for this study (Chesney et al., 2014). Possible risks related to the potential disclosure of suicidal thoughts, self-harm or other potential risks (e.g. domestic abuse, risk to others) were identified in the development stage of the risk protocol. The

researcher was an experienced mental health researcher and in addition had the support of senior mental health clinicians Professor Elizabeth Hughes (registered mental health nurse) and Professor Simon Gilbody (consultant psychiatrist).

If risk of suicide/self-harm was disclosed during the questionnaire/interview session the researcher explained to the participant the need to ask them some further questions, using the following phrase:

> *"You have mentioned <repeat participant's words used in interview>. I'm sorry that you're feeling this way right now. I would like to ask you a few more questions that will explore these thoughts and feelings further. Some of the questions are sensitive but they are very important in making sure you receive the right kind of support"*

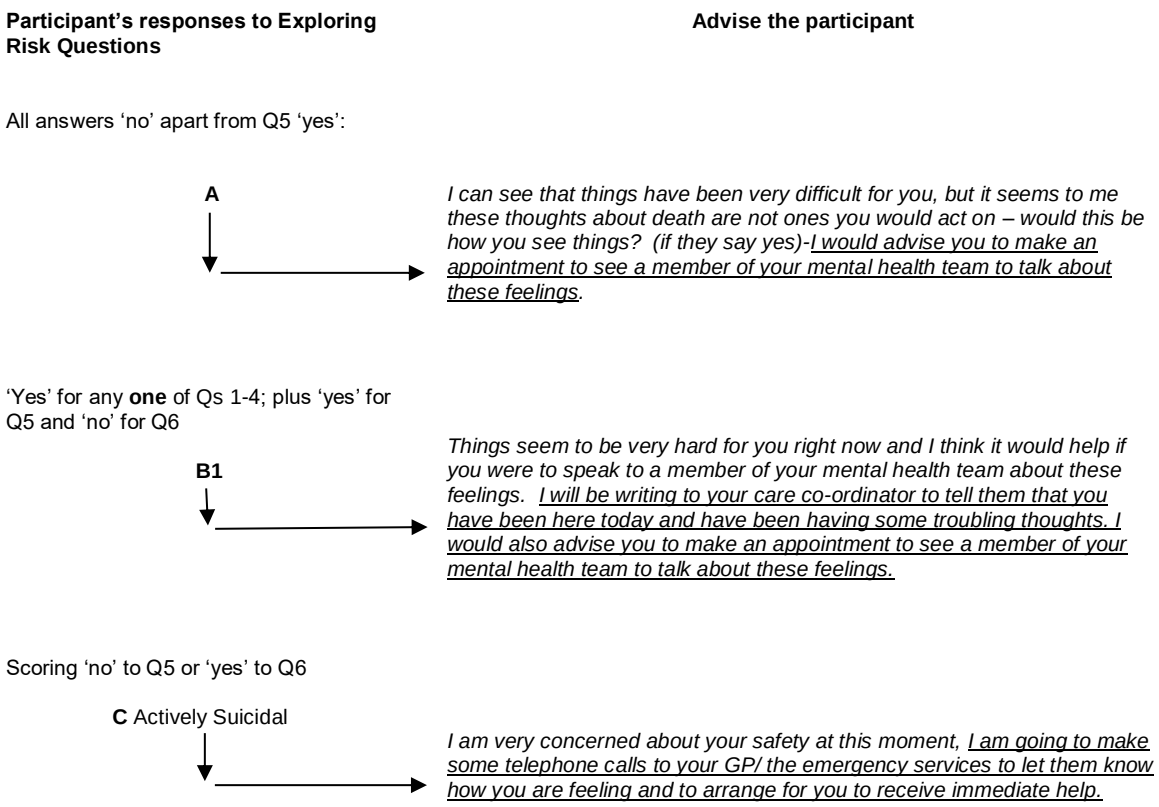
The researcher would then ask the participant the 'exploring risk questions' (see figure 18 below) and document verbatim the participant's responses to the probing question, and each of the six exploring risk questions to establish the level of risk.

Figure 18 Exploring risk questions

Probing question: "Can you tell me more about why you expressed suicidal thoughts/intent/plans? Details of disclosed thoughts (please record verbatim as far as possible)	
Plans	
1. Do you know how you would kill yourself? If **Yes** – details	Yes / No
2. Have you made any actual plans to end your life? If **Yes** – details	Yes / No
Actions	
3. Have you made any actual preparations to kill yourself? If **Yes** – details	Yes / No
4. Have you ever attempted suicide in the past? If **Yes** – details	Yes / No
Prevention	
5. Is there anything stopping you killing or harming yourself at the moment? If **Yes** – details	Yes / No
6. Do you feel that there is any immediate danger that you will harm or kill yourself? If **Yes** – details	Yes / No

The researcher would then follow the 'exploring risk questions guidance' to determine the possible level of risk and advise the participant of the outcome (see figure 19).

Figure 19 Exploring risk questions guidance



In instances where the level of risk was categorised as level C (immediate risk) the researcher would not leave the participant alone and would contact a supervisory clinician immediately. The clinician would discuss with the researcher the necessary action to take, which would include one or more of the following:

- Contact the participants care coordinator or the duty worker;
- Accompany the participant to accident and emergency (A&E) if the participant was on hospital premises. The researcher would not leave the participant until a clinician had taken responsibility for their care;
- If there was no A&E department on the premises, the researcher would call a taxi and accompany the participant to A&E and not leave them until a clinician had taken responsibility for their care.

In all instances of risk, the researcher would contact one of the senior mental health clinicians immediately following the assessment and inform them of the risk, the participant's responses to the exploring risk questions and the response following the exploring risk questions guidance. If the clinician advised that a letter needed to be sent to the participant's care co-ordinator/duty worker, a brief narrative summary of the

participant's response to the exploring risk questions would be completed along with any decisions, actions/lack of actions and the rationale. The letter would be signed by the researcher and countersigned by the clinician, and then sent to the participant's care team with a copy of the letter stored in the participant's personal non-data file.

In cases when other non-suicide risk issues needed to be explored (self-harm, domestic violence, risk to others) the researcher would contact the supervisory clinician for advice and ensure that any decisions, actions/lack of actions and the rationale were documented thoroughly. As with suicide risks any letters sent to care coordinators would be signed by the researcher and countersigned by the clinician, and then sent to the participant's care team with a copy of the letter stored in the participant's personal non-data file.

4.4.1.2 Lone-worker policy

As the questionnaire/interview sessions were to be conducted in a community location (i.e. premises of CMHT) a 'buddy' system was put in place to ensure the researchers safety (see lone-worker protocol, appendix 21). The 'buddy' was a member of the supervision team and needed to be contactable by telephone for the duration of the questionnaire/interview session. Before each visit the researcher would ensure the 'buddy' had the participant's ID number, the time and location of the session, and the researchers 'designated contact' contact details.

Immediately after the end of each questionnaire/interview session the researcher would contact the 'buddy' by telephone to confirm the session had been completed and that they were on their way back to the research site. It was anticipated that the sessions would take between 60 and 90 minutes, however, if there were any delays the researcher would contact the 'buddy' to inform them of the delay and advise them of an approximate time of completion.

In the event that the researcher was not in contact with their buddy by telephone 20 minutes after the questionnaire/interview session was due to end, the buddy would contact the researcher on their mobile phone. If the researcher did not answer their phone or did not contact the 'buddy' back within a further ten minutes, then the buddy would contact the participant using their home and/or mobile contact numbers. If the buddy was not able to contact the participant, they would attempt to contact the researcher's 'designated contact' by telephone to see if the researcher had been in contact with them. If the buddy had still been unable to contact the researcher, then the buddy would contact the local police and give them the location of the participant interview and explain the situation.

In the unlikely event, the researcher was being held against their will during the session, and was able to contact their buddy (either by telephone or text) but was unable to explain their situation, they would say “Can you cancel my meeting with Steve please?”

The buddy would then contact the local police immediately, providing them with the location of the questionnaire/interview session and explain the situation.

4.4.2 Interviewer training and supervision

The researcher received extensive training in administering the SERBAS interview schedule from Professor Karen McKinnon, who was an international collaborator and has over 30 years of experience of administering the tool in SMI populations in both America and Brazil. The training included an introduction to the SERBAS, a sex word synonym desensitisation exercise, orientation to the SERBAS structure and the responsibilities of the interviewer. The training also incorporated role-play in dyads of SERBAS administration, and particularly challenging scenarios that interviewers could face during the interview. This was followed by a homework assignment of audio-recording the complete SERBAS interview schedule and rating the quality of interviews. Professor McKinnon provided written feedback on the audio recording and there was a discussion for any difficulties faced. The scoring of the instrument was also discussed in detail. Professor McKinnon authorised the researcher as competent to undertake the sexual health interview, and provided ongoing supervision in its use throughout the duration of the study.

4.4.3 Ethical approval

Due to the nature of this feasibility study ethical approval was first sought from the Health Sciences Research Governance Committee (HSRGC) at the University of York. This involved submitting a study protocol (latest version of the protocol in appendix 9), an NHS ethics application form, all study documentation (appendices 10, 11, 12, 13, 14, 15, 16, 17, 18 and 19), risk protocol (appendix 20) and a lone worker policy (appendix 21). Once the application had been reviewed by the HSRGC, written feedback was received, and amendments were required before the application was approved and could be submitted to an NHS Research Ethics Board (REC). The initial HSRGC outcome and recommendations letter can be found in appendix 22 with the researcher’s responses to the board’s recommendations in appendix 23. Once the HSRGC had approved the ethics application for this study (appendix 24), all the documents were then submitted to the Liverpool Central NHS REC board for review. As this was the first study in the UK that proposed to ask people with SMI about their sexual health and sexual behaviours the NHS REC board was attended in person to answer any questions the committee members had about the study. The NHS REC

board requested a couple of clerical edits and an amendment to the demographic questionnaire to include a question regarding antipsychotic medication and sexual dysfunction, although this was not to be explored within this study, the NHS REC board felt it would provide a fuller picture of the population. They also requested that that any person who was on the sex offenders register be excluded from the study (appendix 25). This was to ensure the researcher wasn't taking any unnecessary risks to their own safety. These amendments were addressed and approval for the study was granted in June 2016 (appendix 26).

During this time, the NHS ethics process was changing, and all NHS ethical applications were also required to gain health research authority (HRA) approval. This central approval replaced the need for local research and development checks. The HRA granted approval for this study in November 2016 (appendix 27). It took nine months from the initial HSRGC application to obtain final approval from the HRA, and a further three months until the first participant was recruited

4.4.4 Ethical amendments

Several substantial and minor ethical amendments were made. The first substantial amendment proposed a number of changes to the original protocol to help increase recruitment rates. The first of these was to offer participant's a £10 voucher to thank them for taking their time to participate in the study. The second change proposed was that with the permission of care teams, the researcher was to attend outpatient clinics to hand out information relating to the study directly to service users, and answer any questions they may have had. This was to reduce the burden of time and resource on CMHT and EIT staff. A third change that was proposed was to mail out to a cohort of patients with severe mental illness who had taken part in the lifestyle, health and wellbeing cohort study and who had consented to be contacted again about research. Using a brief and simple survey method they proposed to assemble a large group of people with SMI and to measure a number of health-related behaviours and risk factors. In addition to these changes, a simplified PIS (appendix 28) was devised following feedback from CMHT and EIT staff members who had requested a simple and scripted way to introduce the study to service users meeting the inclusion criteria. The NHS REC board and the HRA granted approval for these changes in March 2017 (appendices 29 and 30).

A further substantial amendment was made to undertake a qualitative sub-study in addition to the quantitative service user interviews. It was proposed that a small sample of staff involved in the quantitative study would be invited to participate in a single semi-structured interview, to explore their perceived importance and acceptability of the subject of sexual health in relation to their service users. The interviews would also

explore the experiences and comfort in discussing issues around sexual health, and to identify any potential training needs. The NHS REC board and the HRA granted approval for this sub-study in May 2017 and a copy of approvals can be found in appendices 31 and 32. The qualitative study is discussed in detail in Chapter 5 of this thesis.

Three minor amendments were also made during this study. The first of these was to use the most recent version of the SERBAS interview schedule (Cournos et al., 2005). The differences between the two versions were minimal, for example, explicit questions around 'fisting' and 'rimming' activities had been removed. The second minor amendment was to add a second NHS site, as a potential participant outside the original NHS recruiting trust expressed an interest in taking part in the study. A third and final minor amendment was made to reflect changes in study documentation that were required for the mail out to people in the lifestyle, health and wellbeing cohort study who had consented to being contacted about future research. Each of these minor amendments required HRA approval which was granted before any of the changes were implemented. Copies of all approval letters can be found in appendices 33, 34 and 35. Table 4 provides an overview of the timescales associated with gaining ethical approval for all studies within this thesis.

Table 4 Overview of ethics timescale

	Mar 16	Apr 16	May 16	June 16	July 16	Aug 16	Sep 16	Oct 16	Nov 16	Dec 16	Jan 17	Feb 17	Mar 17	Apr 17	May 17
HSRGC approval															
Main NHS ethics															
Main HRA approval															
SA1															
SA2															
MA1															
MA2															
MA3															

SA= substantial amendment; MA= minor amendment

4.5 Analytic plan

4.5.1 Data cleaning

The majority of the questions in the four sections of the questionnaire/interview session were closed questions, and when certain questions were applicable the full dataset included 400 separate variables. This data was manually entered into SPSS version 24 (IMB Corp, 2016) by one researcher in the first instance, due to the number of variables and as considered a gold standard (Paulsen et al., 2012) a second researcher independently checked the raw data against the SPSS data set to minimise errors that could affect the study's results (Van den Broeck et al., 2005). As part of the data cleaning process, a number of errors that are commonly associated with questionnaires were specifically checked (Van den Broeck et al., 2005). These included data entry errors such as inputting 55 instead of 5, and missing values with no actual value. Data entry errors were double checked by the second researcher and amended where necessary, and a code value of 999 was assigned for all missing values.

4.5.2 Descriptive results

The flow of participants through the study are detailed in a Consolidated Standards of Reporting Trials (CONSORT) flow diagram (see figure 20). The number of people potentially eligible and approached, recruitment method used for approach, number of people consenting to be contacted and number of interviews completed will be summarised overall.

Due to the nature of this study all data will be presented descriptively, with no formal statistical analyses undertaken as the study was not statistically powered to detect an association. Categorical data will be presented using frequencies and percentages, and continuous data as means and standard deviations. There were a number of free text answers as part of the self-report acceptability questionnaire, these will be described narratively.

4.6 Results

This section of the chapter presents the narrative and descriptive results in line with the aims and objectives (outlined in section 4.2) of undertaking a feasibility study to examine recruitment processes and get participant feedback on the acceptability of a sexual health interview with people with SMI.

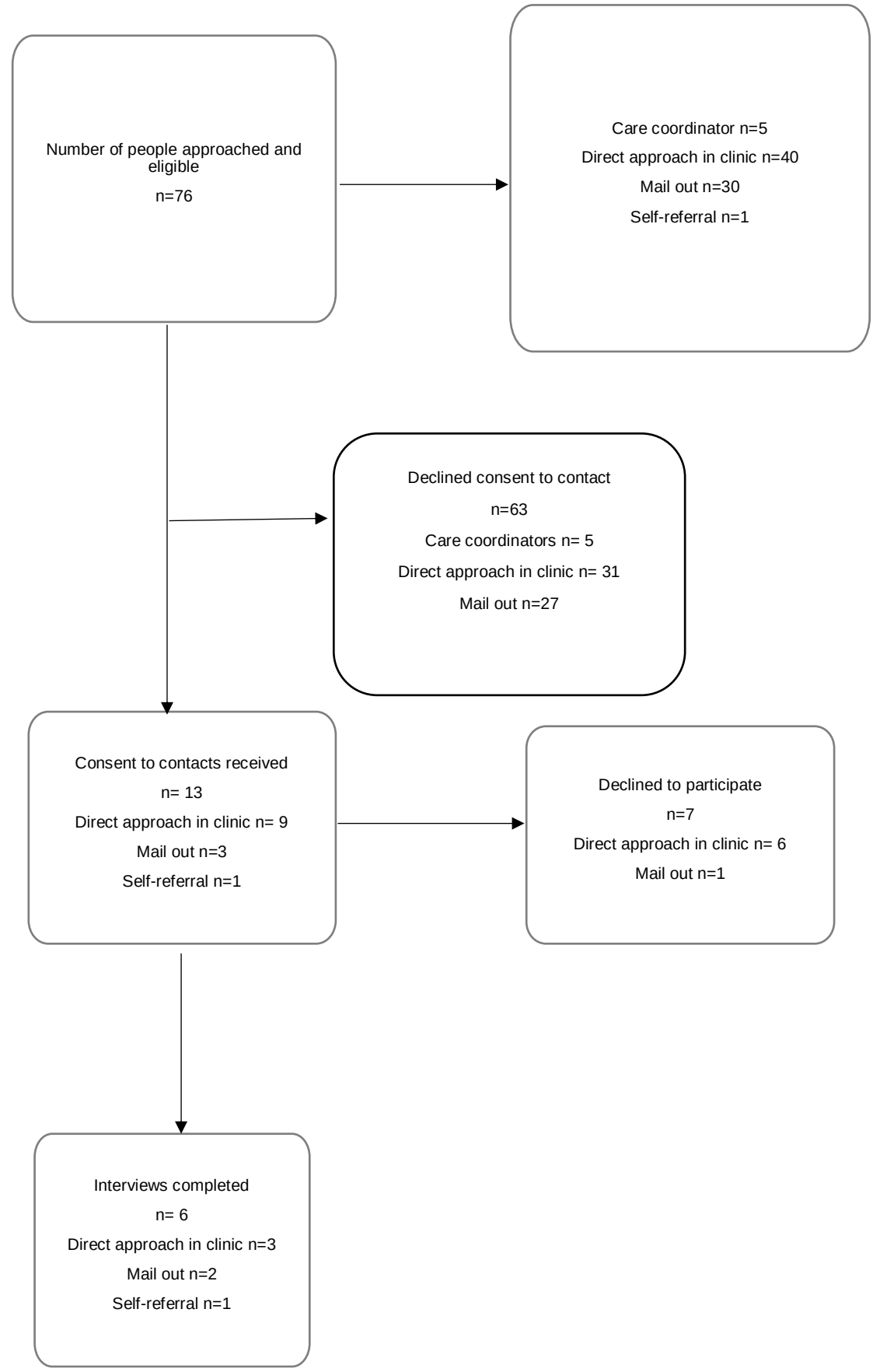
4.6.1 Setting

The questionnaire/interview sessions took place face-to-face at a time and location that was convenient to the participant. These were held on the premises of two NHS Trusts within England during office hours 9-5pm.

4.6.2 Recruitment processes and feasibility

A total of 76 people were approached and considered eligible, yielding 13 consent to contact forms (17.1%) and a total of six participants were consented and interviewed for this study (46.2%). As described in section 4.3.4 (recruitment methods) a number of recruitment strategies were employed due to poor recruitment rates. The initial recruitment method was for mental health professional key workers to screen their caseloads and hand out information packs to all of those meeting the study inclusion criteria. On receiving feedback from the CMHT, only five service users had been approached about the study and all had declined participation. A second recruitment method was employed whereby, with case manager's permission, the researcher was able to directly approach potentially eligible people in outpatient clinics. A total of 40 people were directly approached and given information about the study which yielded nine consent to contact forms (22.5%) to discuss the study further with the researcher. The final recruitment strategy employed involved mailing out information packs to people who have taken part in the lifestyle, health and wellbeing cohort study (University of York) and who consented to being contacted again about research. Thirty people were mailed out the study information with a total of three people returning a consent to contact form (10%). Figure 20 below is a summary of participant flow for the study.

Figure 20 CONSORT diagram for recruitment flow through the study



4.6.3 Participant characteristics

As can be seen in figure 20, six participants were recruited, consented and interviewed for this study. There was an equal number of men and women agreeing to take part, the majority were between the ages of 31 and 40 years old. One participant was aged between 18 and 30 years old, and one participant was aged between 41 and 50 years of age. Of the six participants, one reported they were in full time employment, one reported being a student, and four reported being unemployed. In terms of relationship status, one reported being married, one in a steady relationship, and four reported being single. All six participants reported being white British, a diagnosis of schizophrenia and being heterosexual. This is summarised in table 5 below.

Table 5 Summary of participant characteristics for acceptability and feasibility study

Participant Characteristics	Number	%
Age		
18-30	1	16.7
31-40	4	66.7
41-50	1	16.7
51-60	0	
60+	0	
Gender		
Male	3	50
Female	3	50
Other	0	0
Employment status		
Employed	1	16.7
Unemployed	4	66.7
College/university student	1	16.7
Retired	0	0
Relationship status		
Single	4	66.7
Married	1	16.7
Divorced/separated	0	0
In steady relationship	1	16.7
In casual relationship	0	0
Sexuality		
Heterosexual	6	100
Homosexual	0	0
Bisexual	0	0
Other	0	0
Diagnosis		
Schizophrenia	6	100
Ethnicity		
White British	6	100

4.6.4 Completeness of the sexual health questionnaire and interview

All six participants completed all aspects of the questionnaire and interview schedule that were relevant to their sexual lifestyle. Although two parts of the session were self-report measures (NATSAL and the acceptability questionnaire) all participant's reported feeling more comfortable with the researcher reading out all question and response options. There were no issues around literacy difficulties or needing to clarify terminology. There were no reports of discomfort answering any of the questions in the questionnaires or interview schedule.

4.6.4.1 Summary of findings from participant interviews

One participant reported that they had never engaged in any sexual activity. Of those that had been sexually active, 3 participants reported that it was over five years since they had engaged in any sexual activity, 1 participant reported that it was between 6 months and 1 year since they had had sexual intercourse, and 1 participant reported that they had had sexual intercourse within the 7 days preceeding the interview. Similarly, for oral sex, 3 participants reported that it was over 5 years since they had had oral sex, 1 participant reported that it was between 6 months and 1 year since they last had/received oral sex, and one participant reported giving oral sex in the 4 weeks preceeding the interview after taking drugs and consuming alcohol.

Of the participants that had been sexually active (current or past), 3 reported that they had never been to a sexual health clinic and 2 reported that they had visited a sexual health clinic but that it was over ten years ago. Two participants reported a history of STIs and all participants reported that they had never been tested for HIV.

4.6.5 Acceptability of data collection measures and method

The final section of the questionnaire/interview session was a short self-report acceptability questionnaire devised for the purpose of this study. As above, the participants felt more comfortable answering the questions if they were read out to them.

In response to asking the participants about the length of the interview, where on average the questionnaire/interview session took 45 minutes to complete, the majority of participants reported that it was just about the right length of time. Participants were asked about their comfort answering the questions during the questionnaire/interview session, with most of the participants reported feeling comfortable during the session. One participant reported they felt some-what uncomfortable. When asked whether the interviews were undertaken in a safe and supportive environment, all participants said they felt that it was conducted in a safe and supportive environment. Similarly, the

majority of participants felt the interviews were private. All interviews were arranged so that they were undertaken at a time and location that was convenient to the participant; five reported it was very convenient and one reported it was convenient. The participants were also asked how relevant they felt the questions were to them; all the participants felt the questions were either ‘very relevant’ or ‘relevant’. As this is a new area of research in the UK, all participants were asked whether they had discussed this subject area with anyone else; one participant said they had discussed these topics with a friend, two reported that they had discussed with ‘another person’ but no one within their care team, and three reported they had not discussed this subject with anyone else at all. These results are summarised in table 6 below.

In order to get more feedback, participants were also asked a number of free text questions. The first of these was, *“Why did this study interest you, why did you agree to take part?”* All participants stated that they wanted to help, and two also reported that they wanted to find out more as it wasn’t something they had discussed before. The second free text question asked, “*how did you find the overall experience? How did you feel about completing the questionnaire/interview?”* one participant reported feeling a little awkward, one participant stated that it was not as bad as they thought it was going to be, three said that they felt comfortable answering all of the questions and one participant expressed relief that they had had the opportunity to discuss this topic, as they had felt unable to talk about it with anyone in the past. The final free text question was, “*how can we improve how we collect this important data in the future?*” all six participants had no suggestions on improving the data collection method or further comments on the measures of data collection used.

Table 6 Summary of responses to acceptability questionnaire

Acceptability of data collection measures and method		
	Number	**%**
Length of interview		
Far too long	0	0
Somewhat too long	1	16.7
Just the right time	4	66.7
Not long enough	1	16.7
Comfort during interview		
Very comfortable	3	50
Comfortable	2	33.3
Somewhat uncomfortable	1	16.7
Uncomfortable	0	0
Interview undertaken in safe and supportive environment		
Very safe and supportive environment	5	83.3
Safe and supportive environment	1	16.7
Somewhat unsafe and unsupportive environment	0	0
Not at all safe and supportive environment	0	0
Privacy during interview		
Very private	5	83.3
Private	1	16.7
Somewhat private	0	0
Not at all private	0	0
Convenience of interview location		
Very convenient	5	83.3
Convenient	1	16.7
Somewhat convenient	0	0
Not at all convenient	0	0
Relevance of questions		
Very relevant	1	16.7
Relevant	5	83.3
Somewhat irrelevant	0	0
Not at all relevant	0	0
Discussed this subject with anyone else		
Partner	0	0
Friend	1	16.7
Keyworker	0	0
GP	0	0
Psychiatrist	0	0
Other	2	33.3
N/A	3	50

4.6.5 The ethics processes

This is one of the first empirical studies in the UK to explore the sexual health and behaviours of people with SMI and therefore, one of the first study to navigate the ethical processes of a departmental university ethics board, an NHS REC board and the HRA in the UK with this subject area.

As described in section 4.4.3 all relevant study documentation was submitted to the HSRGC for review as per the University of York's guidelines for students. The initial response of the HSRGC was that of non-approval. Table 7 below summarises the recommendations from the HSRGC along with the amendments/responses from the researcher.

Table 7 Summary of recommendations from HSRGC and researcher responses

Recommendations from the HSRGC	Response and actions from researcher
1. The committee thought it unrealistic that the questionnaire/interview would only take 60 minutes.	This was increased to approximately 90minutes, to take into account the differing levels of sexual activity. This was also amended on the participant information sheet.
2. Large parts of the data collection tool are basically surveys; why would these need to be administered 1-1 and face-to-face given the sensitive nature of the questions.	Section 3 of the questionnaire/interview session was a gold standard interview validated to be administered face-to-face, which is led by an experienced mental health researcher trained to undertake the interview. Sections 1, 2 and 4 will be self-completed by the participant. Due to the nature of questions, the researcher will be present to ensure the participant is comfortable at all times, to support or seek support (from duty worker or study clinicians) on behalf of the participant if the questions trigger difficult memories, or to clarify any of the terminology within the self-report questionnaires.
3. The various parts of the Data Collection Tool don't seem entirely coherent (e.g., repetition of questions) or appropriate (e.g., 'Please keep in mind that the hospital staff will not have access to any of the answers you give me').	Section 3 of the interview is a validated gold standard interview and so the script and questions are to remain exactly as presented by the author (from whom we have written permission to use the interview). This example is part of the gold-standard interview '(e.g., 'Please keep in mind that the hospital staff will not have access to any of the answers you give me').' Some of the questions are repetitive but are asked in different ways and cover a number of different 'high risk' sexual behaviours identified within the literature.

After resubmitting the amended relevant documentation and addressing the questions posed by the HSRGC, the study was approved. As the population of interest was to be

recruited from a CMHT in one NHS site in England, the study required approval from the NHS REC. As described in section 4.4.3 the NHS REC meeting was attended in person to answer any questions about the study. The NHS REC board requested that 'any person on the sex offenders register' be excluded from the study to ensure the researcher wasn't taking any unnecessary risks to their own safety. The request was added to the list of exclusion criteria (section 4.3.2) and the study was approved.

4.6.5.1 Risk and lone-working

Despite robust protocols being in place to protect both the participants and the researcher, there were no instances where the risk protocol or the lone worker protocol had to be activated. There were also no occasions in which any interview had to be terminated through discomfort or inappropriate behaviour.

4.6.6 Engaging NHS professionals in accessing and recruiting people with SMI to a research study

Although not an *a priori* aim of this study, one key finding from this study was the difficulty in engaging NHS professionals in accessing and recruiting patients with SMI to a study about sexual health and behaviour. This process began by visiting a CMHT in one NHS site in the UK after ethical approval had been sought, but whilst awaiting HRA approval. This was an opportunity to provide the team with the contextual background and rationale for this study as well as the methodology employed. The initial recruitment method of caseload screening was explained (discussed in section 4.3.4.1) with emphasis on the inclusion and exclusion criteria. There was an opportunity for all staff members to ask the researcher questions. The CMHT confirmed they had the capacity and capability to undertake the research in their site.

Once HRA approval had been granted, the researcher visited the CMHT to provide them with relevant study documentation and participant information packs. This provided a further opportunity for the team to ask the researcher questions. It was agreed that the researcher would email the contact person each week for weekly updates.

At one of the weekly updates, the CMHT contact informed the researcher that there had been no interest in the study at present, but other members of the team had raised some concerns about the need to ask personal questions and potentially leave participants distressed. There was also discomfort expressed about introducing the study to patients meeting the inclusion criteria. It was agreed that the researcher would attend a further team meeting to reassure them about the purpose of the study. It was also agreed that the researcher would provide the team with a simplified information

sheet which would provide them with a consistent way to introduce the study to potential participants.

The researcher attended a further team meeting to reassure the team that the study had been scrutinised and approved by three ethical bodies (HSGRC, NHS REC and HRA). The CMHT members were provided with a simplified information sheet for them to be able to introduce the study in a consistent manner to patients meeting the eligibility criteria. One person reported they had spoken to five of their patients and they had declined participation. No further questions were asked of the researcher at this meeting. However, after a number of weeks of no recruitment activity, a substantial ethical amendment was submitted to the NHS REC to approve recruitment methods two and three (as discussed in section 4.3.4.2 and 4.3.4.3). These alternative recruitment methods did lead to some recruitment activity with the first participant being recruited in March 2017, and the final participant recruited in July 2017.

4.7 Discussion

This section of the chapter describes a summary of the study's main findings in line with the study objectives. The strengths and limitations of this primary study will be discussed in line with the current research literature and conclusions drawn with these in mind.

4.7.1 Summary of findings

A total of 76 people were approached and eligible, yielding 13 consent to contact forms and a total of six participants were consented and interviewed for this study which gives a recruitment rate of 8%. As described in section 4.3.4, a number of different recruitment methods were employed to increase recruitment rates. The direct approach method of recruitment yielded the most consent to contact to consent ratio of 25%, with a total of four participants being recruited via this method.

In relation to the acceptability of the data collection measures used, the majority of the participants reported that they felt comfortable throughout the questionnaire/interview session. In support of previous research in this area all participants engaged well with the subject area, there was no discomfort witnessed during the interviews and there were no instances where the questionnaire/interview session had to be terminated for any reason. All participants reported that they felt the questions were 'relevant' to them, and that all interviews were undertaken in a safe and supportive environment. All aspects of the questionnaire and interview schedule that were relevant to their lifestyle were completed of which 2 participants reported being sexually active within the 4 weeks preceeding the interview, there was no missing data and nobody refused to answer specific questions.

Considering this was one of the first UK studies to explore this subject area, the guidance, support and recommendations received from both the PPI group, and also international collaborator Professor Karen McKinnon were instrumental in navigating a number of different ethical processes successfully.

One important lesson learnt from this study is that engaging clinical staff members with the research process and the subject area is vital in ensuring they feel comfortable in discussing research with their patients, but also to ensure that patients have access to information about research, which is, their ethical right (Department of Health and Social Care, 2015).

4.7.2 Strengths of the current study

This is the first empirical study to explore the acceptability and feasibility of undertaking sexual health and behaviour research in people with SMI in the UK. Whilst this area of

research has been neglected thus far in the UK, this study provides useful insights into conducting research in an under researched area within the NHS, and the processes involved in doing so, the results of this study will help to inform future research in this area.

One of the major strengths of this study was that it was designed following the findings of the systematic review undertaken in chapter 3. The systematic review found that ten sexual behaviours associated with increased risk of BBV/STI infection had been consistently reported within the epidemiological literature, these included: sexual trading; sex with a person who uses drugs; alcohol and/or drug use prior to sexual intercourse; sexual intercourse with someone known less than 24 hours; more than one sexual partner reported in the last 12 months; paid sex work; sex with someone who identifies themselves as bisexual; men who have sex with men or women who have sex with women, and inconsistent condom use. However, the six case-control studies included in the systematic review did not use validated measures to collect their data. This study collected data on sexual health and sexual risk behaviour using both a gold-standard interview (SERBAS), and validated self-report measures from the NATSAL to ensure the data collected was valid and reliable. These two measures were chosen to reflect the sexual behaviours identified in the systematic review as neither tool covered all risk factors individually.

As this was one of the first studies to explore the intersection of SMI and sexual health from a patient perspective in the UK, it was crucial to get input and feedback from a PPI group. A focus group was held in April 2015 to get advice on recruitment strategies and study documentation. The feedback received on the study documentation was instrumental in ensuring that potential participants were fully informed of what the study would involve, therefore, helping to maximise the comfort of those who chose to take part. This input was also crucial when preparing the study for the ethics process.

In line with this being the one of the first studies in the UK to explore this subject area, this was also one of the first studies to navigate both the University of York (HSRGC) and the NHS's processes and approvals. Advice was sought from international collaborator Professor Karen McKinnon who has been undertaking this research in the USA for over 30 years. Professor McKinnon advised that all patient facing documents be explicit about what the study entails, and also to provide examples of the types of questions they may be asked, to ensure that potential participants were able to make a fully informed decision about their participation in the study. The patient facing documents were approved with no amendments required by either the HSGRC or the NHS REC board. Advice was also sought from Professor McKinnon when the original ethics application was not approved by the HSRGC, specifically in relation to why the

questionnaire/interview session had to be completed face-to-face given the 'sensitive' nature of the questions. In response to the HSRGC's concerns, further clarification was offered that it was necessary to conduct the questionnaire sessions face-to-face as one section (SERBAS) was a gold standard interview that was validated for face-to-face administration. It was also emphasised that the researcher was an experienced mental health researcher, and face-to-face sessions would allow the researcher to pick up on any discomfort and support where any clarifications were needed in terms of terminology. These clarifications ensured that the application was approved. In addition to this, it is important to note that although the HSRGC had some initial concerns about the study, none of the issues they raised were realised during data collection. However, one point to consider is that the small scope of this study allowed the researcher time to undertake the questionnaire/interview session face-to-face, this may not be possible in larger scale studies.

A further strength of this study was that despite the sample size, the participants who did take part in the study engaged well with the questionnaire/interview session, and all questions relevant to their sexual lifestyle were answered.

4.7.3 Limitations of the current study

One of the main limitations of this study was poor recruitments rates. According to a cross-sectional study examining proportions of patients with psychosis willing to take part in research, they found that two thirds of people with psychosis were willing to take part in research (Patel et al., 2017). However, the proportion of people with SMI willing to take part in this study was approximately 8%. Despite employing different recruitment methods at different points in the study, it still appeared to be difficult to access and get study information to potentially eligible participants. If this study was to be conducted again and on a larger scale, more than one NHS Trust and one CMHT would have to be approached in order to increase the pool of potentially eligible patients. A further recruitment method option would have been to consider recruiting patients via primary care, this would have increased the pool of potentially eligible participants receiving information packs substantially, this may be feasible for a larger scale study, however, this was not feasible within the scope of the study presented in the chapter. A broader definition of SMI may also have helped to increase recruitment rates, however as much of the existing literature does not include diagnoses such as personality disorders. If future studies were to include these, it would be important for them to consider how this could impact on the results, and how this would fit within the context of the wider literature.

Furthermore, some members of staff within the CMHT reported that they had handed the study information packs to people meeting the inclusion criteria, but they had all declined participation. Other staff members expressed they did not feel comfortable talking to their patients about this subject area and that they didn't feel comfortable or confident enough to explain the study. In response to this, the researcher provided CMHT staff a simple script to use to enable them to introduce the study, and to ensure they covered the key aspects of the study in a consistent manner. Although this was positively received by the CMHT staff, there were no participants recruited via this strategy, resulting in two further methods of recruitment being employed. It is important to consider whether the mental health professionals were acting as gatekeepers in the research process. Gatekeeping is defined when a third party prevents access to someone or something (Holloway & Galvin, 2016). Within the research context, gatekeeping occurs when potential participants are considered to be 'vulnerable' by the clinicians involved in their care, and as a result deny them the opportunity to take part in research (Patterson et al., 2010). Despite health research undergoing rigorous ethical review, and it being an ethical right for people to have a choice about whether to take part in research or not, gatekeeping is still problematic within health research across all fields (Howard et al., 2009; McDaid et al., 2006; Tooher et al., 2008). Given that staff openly voiced their discomfort in talking to patients about this subject area, it cannot be ruled out that gatekeeping was at play here.

In addition to this, a further limitation of the study was that the initial recruitment target of ten was not achieved and this sample size was on the lower end of sample sizes for feasibility studies (Billingham et al., 2013). However, if the recruitment target of 10 had been reached, the findings of the study would still be subject to bias (Etz & Arroyo, 2015). For example, it would not be possible to generalise the findings of the study presented within this chapter too widely as it is not possible to infer how representative the responses of the questionnaire/interview would be of the wider SMI population in the UK.

Another limitation of this study was that despite the researcher undergoing desensitisation training, and training in the use of the SERBAS interview schedule, the authors of the SERBAS state that considerable training of between 15 and 20 hours is required to ensure the reliability and validity of the interview is maintained (McKinnon et al., 1993). Due to the scope of this study and the time and resource implications this was not possible, the researcher received approximately five hours training in total and supervision when necessary from Professor Karen McKinnon. However, there was no

evidence from the data that the SERBAS had been administered incorrectly. Furthermore, the researcher was an experienced mental health researcher who has experience of undertaking other gold standard interview schedules, for example the Structured Clinical Interview for DSM IV (SCID) (First et al., 2015), the Mini-International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998) and the Clinical Interview Schedule Revised (CIS-R) (Lewis et al., 1992).

A further limitation to be considered is the potential of reporting bias surrounding the reliability of the sexual health interview itself, and whether participants were reluctant to report engaging in sexual behaviours associated with the increased risk of BBV/STI infection that they do not deem socially acceptable (Grassi et al., 1999). There are several factors that may undermine the reliability of responses from this population including cognitive impairment, substance use and a history of sexual abuse which should be considered when drawing conclusions (Elkington et al., 2010). Although not within the remit of this study due to time and resources, researchers should consider conducting a test re-test study to explore whether it is possible to elicit reliable responses from a UK SMI population as has been shown in the USA (McKinnon et al., 1993; Sohler et al., 2000).

It is also important to consider the potential for sampling bias as the study included a small number of participant's who volunteered to take part, and received a financial reward for their participation. As the participants self-selected themselves to take part, it cannot be ruled out that the characteristics and sexual lifestyles of those who declined to participate would be different to those who consented to the study. However, although this study recruited a volunteer sample, the findings add important new knowledge about the acceptability and feasibility of exploring the sexual health and behaviour of people with SMI in the UK.

4.7.4 Conclusions

This study was undertaken to explore the acceptability and feasibility of recruiting people with SMI to a study about sexual health and assessment of sexual risk behaviour in the UK. Six participants meeting the inclusion criteria were recruited into this study, and completed all aspects of the questionnaire/interview session that were relevant to their sexual lifestyle. A number of recruitment methods were required to access and recruit people with SMI to this study, and this would need to be considered for planning larger scale research in this subject area. The study was also a first for ethics boards both locally at the University of York HSRGC and nationally at NHS REC and HRA, whereby, with minor iterations the study was approved and deemed acceptable and an important piece of research. Although it was found that it was

difficult to engage clinical staff with this subject, the results do provide some preliminary evidence that exploring the sexual health and behaviours of people with SMI in the UK is acceptable, which supports the international literature in this field. The data collection tools used were considered appropriate with participants feeling the questions were relevant to them.

It can be concluded that after approaching one caseload of a CMHT and 30 people in a lifestyle, health and wellbeing cohort that it was feasible to speak to six people with SMI about their sexual health and behaviour, which included answering a maximum of 463 questions depending on their sexual lifestyle. In addition, the processes and data collection measures used were acceptable to this small sample.

4.8 Summary

This chapter has presented a feasibility study to explore whether it is feasible and acceptable to speak to people with SMI in the UK about their sexual health and behaviour.

Building upon the findings of this chapter, and given some of the challenges faced in recruitment, the following chapter outlines the aims, methodology and results of a qualitative interview study exploring the views of mental health professionals in relation to the sexual health and relationship needs of their service users.

Chapter 5. Qualitative interview study exploring the views of mental health professionals in relation to the sexual health and relationship needs of people with severe mental illness.

This chapter describes a qualitative interview study which explored the views of mental health professionals in relation to the sexual health and relationship needs of people with severe mental illness (SMI). Following an introduction to the qualitative research method, the rationale and aims of this study will be described. The chapter then presents a description of the study's method including; design, recruitment methods, ethical considerations and the approach to data analysis. Finally, the results and the discussion are presented.

5.1 Introduction

According to Green and Thorogood (2018), the application of qualitative methods to Health Services Research (HSR) originated in the social sciences and humanities, but is now firmly rooted within HSR, and provides enhanced evidence to health care practitioners, policy-makers and funders. Qualitative research aims to understand and interpret social phenomena rather than quantify them (Green & Thorogood, 2018). There are a number of different qualitative methods that can be utilised, but this section will be focusing on the qualitative interview, which is the most common data collection method in qualitative research (Jamshed, 2014). The purpose of the qualitative interview is to explore the attitudes, beliefs, perceptions and experiences of individuals in relation to specific social phenomena (Gill et al., 2008). Therefore, research interviews are considered to be most appropriate in areas where little is known about the subject of interest, and also when exploring sensitive topics in which participants may not feel comfortable discussing in a group environment (i.e. focus groups) (Gill et al., 2008).

There are a number of different types of qualitative interviews, however the most common referred to in the literature are structured, unstructured and semi-structured interviews (Green & Thorogood, 2018). Structured interviews are fundamentally questionnaires administered verbally using pre-defined questions (Gill et al., 2008). These are often scripted and do not allow for flexibility with follow-up questions where further detail may be required. As a result, structured interviews are generally simple and quick to administer, however, there is no scope to collect in-depth information (Gill et al., 2008). In contrast, the unstructured qualitative interview usually begins with an open question and develop based on the interviewee's response. As there is usually little guidance on what to talk about for this type of interview, they can present a

challenge to both the interviewer and the respondent (Gill et al., 2008). In addition to this, they are often time-consuming and are considered to be most appropriate when substantial depth on a subject area is required (Gill et al., 2008). The third type of qualitative interview is the semi-structured interview which are widely used within health research, and are organised around a set of pre-defined, open-ended questions whereby other questions can often emerge (DiCicco-Bloom & Crabtree, 2006). This approach allows the interviewer the flexibility to explore participant's responses further when they raise important information or when clarification is needed (Gill et al., 2008).

5.2 Rationale and aims

This thesis aims to explore the intersection between mental health and sexual health in people with SMI, particularly in relation to sexual behaviours associated with the increased risk of contracting a blood borne virus (BBVs) and/or sexually transmitted infection (STIs) in the UK. The two previous empirical chapters within this thesis have explored the behaviours of people with SMI in relation to their sexual health; the first empirical chapter from the perspective of the international literature, by way of a systematic review and meta-analyses, which provided some preliminary evidence that people with SMI are more likely to engage in sexual risk behaviours such as sex trading compared to those with no history of mental illness.

The second study explored the acceptability and feasibility of conducting research into the sexual health and behaviour of people with SMI in the UK, by consulting with users of community mental health services in one NHS Trust in England. The study found that exploring the sexual health and behaviours of people with SMI in the UK is acceptable, the data collection tools used in the questionnaire/interview session were considered appropriate, and the participants felt the questions were relevant to them, which supports the limited research in this area conducted outside of the UK (Brown et al., 2010, 2011a, 2011b; Cournos et al., 1994; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Guimarães et al., 2014; Koen et al., 2007; McKinnon et al., 1993; Miller & Finnerty, 1996; Pinto et al., 2007; Sohler et al., 2000; Wainberg et al., 2008). However, the findings also indicated that it was not feasible to use the initial recruitment strategy of care coordinators screening their caseloads for potentially eligible participants, and approaching them directly to offer them a study information pack. As discussed in chapter 4 section 4.4.4, a number of ethical amendments were made to the initial recruitment strategy to reduce the burden on NHS mental health professionals, and also to try and increase uptake to the feasibility study. Feedback from mental health professionals at team meetings suggested that they had experienced some discomfort talking to service users about research around sexual

health and sexual practices. There were also concerns raised about the appropriateness of the research to service users. This qualitative study aimed to explore these views in further detail.

Previous research by Kautz et al. (1990) describes four factors why general nurses do not discuss sexual health, behaviour and sexuality with patients that have physical health concerns such as cancer:

1. Knowledge- sexual health and behaviour is not on the nursing curriculum.
2. Professional role- nurses do not feel that addressing these issues is part of their role, that there are limitations in terms of their workload, and also the moral values of nurses differing to those of their patients.
3. Attitudes- nurses feel that patients are not well enough to talk about sex and in doing so could trigger anxiety.
4. Comfort with sexuality- talking about sex can be uncomfortable for nurses and it can be difficult asking colleagues for support with this.

However, there is limited research exploring the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI (Gray et al., 2002). One study, a cross-sectional survey was undertaken in London with NHS mental health professionals to examine their knowledge, attitudes and practice around sexual health in patients with SMI (Hughes & Gray, 2009). The survey was distributed to 650 mental health professionals, of which 283 people responded, yielding a response rate of 44%. In contrast to general nurses, it was reported that 224 (80%) of respondents felt that sexual health promotion was part of their role, and only 14% reported that they felt uncomfortable discussing sexual health issues. Although the majority of respondents (86%) reported that they felt comfortable discussing sexual health and behaviour, 70% stated that they rarely do this as part of routine clinical practice. With regards to knowledge about human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS), 72% of the respondents did not consider that people with SMI were more likely to engage in ‘high risk’ sexual behaviours, nor to have a diagnosis of HIV/AIDS compared to the general population (Hughes & Gray, 2009).

A qualitative study conducted in Australia found that of the 14 mental health nurses who were interviewed, the majority stated that they would avoid the subject of sexual health with service users (Quinn et al., 2011). The reasons given for this avoidance included the nurses not feeling that it was part of their role to support service users with their sexual health, there were some concerns over blurring professional boundaries, and it was also felt that the sexual health of their service users was not a priority (Quinn

et al., 2011). Recently, four focus groups were undertaken in two NHS sites providing mental health services in England in which a total of 27 mental health professionals took part (Hughes et al, 2017). The focus groups found that mental health professionals tended to avoid the subject of sexual health in order to protect service users from distress or embarrassment. However, the focus groups also identified that staff are aware of the sexual health needs of people with SMI, but they didn't feel comfortable broaching the subject of sexual health with patients due to their lack of knowledge and confidence in dealing with issues related to sexual health (Hughes et al., 2017). Training needs were also highlighted with respondents suggesting that sexual health should feature on the undergraduate nursing curriculum as well as post-qualification professional development (Hughes et al., 2017). More specific training should be given including information on the transmission, symptoms and treatments of STIs and BBVs as well as an awareness of local sexual health service provision (Hughes et al., 2017).

5.2.1 UK policy

In recent years there have been a number of government initiatives and policies to try and ensure that people with SMI are receiving high quality care for their physical health needs. The Five Year Forward View for Mental Health report (2016) proposes an integrated mental health and physical health care approach, and makes recommendations to try and help reduce the health inequalities people with SMI face. The report states that there are currently almost half a million people with SMI registered with a GP, and the proportion of these people receiving annual physical health checks ranges from between 62% and 82% (Mental Health Taskforce Strategy, 2016).

Despite there being new UK government policy and guidelines to try and achieve parity of esteem between mental and physical healthcare, the sexual health and relationship needs of people with SMI are still somewhat neglected from the agenda. The Department of Health and Public Health England published an action document for mental health nurses, with the view of improving the physical health of people with mental health problems in 2016. Within this document, there are brief guidelines for the sexual and reproductive health of people with mental health problems. The action document highlights key elements such as; increased risk of BBVs and STIs, increased risk of exploitation, physical and sexual violence, engaging in 'high risk' sexual behaviours and also increased rates of unintended pregnancy within this population (DOH, 2016). In order for mental health professionals to provide holistic recovery orientated care, they need to support people with SMI with their sexual health and

relationship needs (Dein & Williams, 2008; Eklund & Östman, 2010). It is crucial that this is incorporated into mental health policy to assist mental health nurses in supporting their service users, and a number of actions are proposed within the guidance. These are summarised in table 8 below.

Table 8 Summary of actions for supporting service users with their sexual health (DoH, 2016)

Action	Supporting information
Sexual health assessment	Include sexual health as part of comprehensive nursing assessments.
Non-judgemental approach	Be mindful of own attitudes to this subject and be respectful of service user's attitudes and actions.
Provide information of STIs and BBVs	Be able to provide accurate information on how STIs and BBVs are acquired and transmitted.
Sexual dysfunction	Ask service users about sexual function in relation to medication.
Unintended pregnancy	Provide guidance and information on contraception to reduce the risk of unintended pregnancies.
Emergency contraception	Ensure female service users are aware that emergency contraception is available from local pharmacies.
Local sexual health services	Be able to signpost service users to local sexual health services and support them if necessary.

5.2.2 The role of mental health professionals in assessing the sexual health of service users

According to Moore et al. (2013) nurses are in the ideal position to provide guidance and support in relation to sexuality, sexual health, and relationship needs of mental health service users due to the ongoing nature of contact and care. Despite this, a study undertaken by McCann (2010) sought to explore the views and opinions of people with SMI in relation to sexual relationships in the UK. McCann found that 83% of respondents reported that they were interested in having sexual relationships. Despite people with SMI being able to fully express their desires and expectations in relation to sexual relationships, 43% of mental health professionals were unable to identify whether their service users had these needs (McCann, 2010). When considering the bio-psycho-social model of health care the sexual health and relationship needs of those with SMI should be considered (Sakeld, 2015).

A continuing professional development (CPD) article was published in 2015 to guide mental health nurses in assessing the sexual health of people with mental health problems, and also to allow them to reflect on their current practice (Salkeld, 2015). The aim of the CPD article was to:

1. Outline the importance of sexuality and sexual health when assessing the physical health care needs of people with a mental health diagnosis;
2. Determine a relationship between high risk sexual behaviours and people with a mental health diagnosis;
3. Explore the effects of psychotropic medication on sexual function, activity and satisfaction;
4. Explore the need for improved sexual health assessment and the role of the mental health nurse in conducting this.

In addition to providing mental health nurses with context about the importance of sexuality and the sexual health of mental health service users, it also provides a description of how medication, alcohol, and drugs can impact upon service users and their sexual health and behaviour, before suggesting factors that need to be considered when assessing the sexual health of service users with mental health problems. In line with improving the physical health of people with mental health problems action document for mental health nurses, the recommendations are similar (DOH, 2016). The CPD article suggests that when mental health nurses assess the sexual health needs of their service users they should:

- Not make assumptions about the person or situation;
- Not make judgements and allow stereotypical views effect their judgement;
- Ask for clarification if necessary;
- Use the same terminology as the service user to encourage comfort in discussing such issues;
- Reinforce confidentiality and privacy

There has been very limited research exploring the views of mental health professionals specifically in relation to the sexual health and relationship needs of people with SMI in the UK. The small amount of research that has been conducted in this area has been mainly by cross-sectional surveys or focus groups (Hughes & Gray, 2009; Hughes et al., 2017). However, as discussed in section 5.1 of this chapter, in-depth interviews may be a more appropriate data collection method given the sensitive nature of this subject (Gill et al., 2008). One study conducted in Australia undertook semi-structured interviews to explore whether sexuality and sexual health were

discussed with service users in clinical practice from the perspective of mental health nurses only (Quinn et al., 2011). Therefore, the study presented in this chapter was designed to explore whether in-depth semi-structured interviews with the wider mental health profession support or conflict with the existing research literature in this area.

The study was developed for two reasons, the first as a result of the difficulties with recruitment in the acceptability and feasibility study with service users, and second after receiving feedback from mental health professionals at team meetings with regards to the topic area as discussed above.

The overall aims of this study were to explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI. The main objectives of this research were:

1. To explore the perceived importance of sexual health and relationship needs of people with SMI to mental health professionals;
2. To explore the perceptions of 'high risk' sexual behaviour in the SMI population from mental health professionals point of view;
3. To explore the views and attitudes of mental health professionals to supporting service users with issues surrounding sexual health and relationship needs.

In addition to the main objectives, the following secondary objectives were also explored:

1. Potential barriers for undertaking research in this area;
2. Facilitators and barriers for mental health professionals in relation to discussing sexual health and relationship needs of service users.

5.3 Methods section

5.3.1 Study design

Semi-structured qualitative interviews with a wide range of mental health professionals (senior community mental health nurses, social workers, occupational therapists, clinical psychologists, cognitive behavioural therapists and team leaders) were conducted within a community mental health team (CMHT) and early intervention team (EIT) within one NHS site in England. Further information about the design and content of the topic guide can be found in section 5.3.5.

5.3.2 Sampling strategy and sample size

A sample is defined as “the set of actual data sources that are drawn from a larger population of potential data sources”, (Morgan, 2008, pg. 789). According to Morgan (2008) sampling is a two-stage process. The first stage is defining the population of interest by means of specifying eligibility criteria for inclusion in the sample. The second stage is to select the sample, of which there are two main approaches, probability sampling and nonprobability sampling (Morgan, 2008). Probability sampling focuses on the size of a group within a population to determine how many participants will be included in the sample, whereas, nonprobability sampling focuses on selecting participants based on them meeting pre-specified criteria (Morgan, 2008). Convenience sampling is a type of nonprobability sampling in which participants who meet specific criteria, are easily accessible and are willing to participate in the research study (Etikan et al., 2016). The participants recruited for this study were a convenience sample and were from the same site used for the acceptability and feasibility study presented in chapter 4.

In relation to the sample size for this study, the emphasis of qualitative interviews is to focus on collecting high quality, in-depth information about a specific subject area and is more suited to small sample sizes (Morgan, 2008). Therefore, it is acceptable for qualitative researchers to use data saturation to determine sample size rather than collect more data than can be analysed, and data that does not produce new results (Morgan, 2008). There are varying definitions of data saturation in qualitative research, particularly in relation to the qualitative interview (Faulkner et al., 2017; Saunders et al., 2018). For the purposes of this study data saturation was defined as the point in the data collection process where no new information is discovered in the data analysis signifying that data collection process can end (Faulkner et al., 2017; Saunders et al., 2018). Achieving data saturation can provide the researcher with some confidence that continued the data collection would yield similar results and therefore confirm the

emerging themes in the data set (Faulkner et al., 2017). Consequently, data for this study was collected until data saturation was reached.

5.3.3 Inclusion criteria

The inclusion criteria for this qualitative study were mental health professionals within one locality of one NHS trust in England that were involved in the initial recruitment strategy for the service user acceptability and feasibility questionnaire/interviews discussed in chapter 4. To avoid any confusion between the service user participants that took part in the acceptability and feasibility study presented in chapter 4 of this thesis, the mental health professionals that agreed to be interviewed as part of this study will be referred to as staff participants throughout the remainder of this chapter.

5.3.4 Recruitment

An initial recruitment email was sent to two key mental health professional contacts within the one locality of NHS Trust where the service user interviews had taken place. This email included information about the staff qualitative interviews and attached a copy of the participant information sheet (PIS) (appendix 36) which detailed the purpose of the study, the processes involved with participation and specific procedures including, protecting confidentiality, anonymity of data and interview data storage. The PIS also provided contact details of the researcher if any questions arose. The two key contacts forwarded the recruitment email and PIS to their colleagues who had been involved in the initial recruitment strategy for the acceptability and feasibility service user study. Only when staff members had voiced an interest to one of the key contacts in taking part in an interview, were the contact details of these staff members shared with the researcher. The researcher contacted each of the interested parties by email, thanked them for their interest, and asked if they had any questions about the study or interview process. If they were happy to participate they were asked to share several dates and times they were available to be interviewed. The interviews were then arranged at a mutually convenient time.

5.3.5 Interview design and content

Interviews were semi-structured and conducted face-to-face at a time and location convenient to the staff participants. The interviews were mainly conducted on a one to one basis, however, in one instance due to NHS time and resource restraints one interview was conducted with two mental health professionals at the same time. The aims of the study were explained at the start of each interview and the staff participants were asked to confirm that they had read the PIS. All staff participants were reminded that the interview would be audio-recorded and that during the transcription process

any personal identifiable information would be anonymised by allocating each staff participant a unique ID number. It was explained that direct quotations may be used within this thesis, in publications and at conference dissemination events but they would be reported anonymously. Staff participants were given the opportunity to ask any questions they may have in relation to the study, and reminded that they have the right to withdraw from the study at any time and without giving a reason. It was only at this point were staff participants asked to provide written informed consent (appendix 37). All interviewees were also asked whether they would like to receive a summary of the results of the study.

A topic guide provided the basis for the semi-structured interviews (appendix 38). The research question was guided by feedback received from the mental health professionals during the service user acceptability and feasibility study initial recruitment process. In turn, the feedback informed the design of the interview schedule/topic guide in collaboration with the supervisory team and an experienced qualitative researcher within the Mental Health and Addictions Research Group at the University of York. To explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI, the topic guide included broad questions such as their 'perceived importance of the subject area' as a clinician, and their 'perception of risk behaviour in this population'. More focused questions were asked in relation to their current practice in discussing sexual health and behaviour, specifically whether service users brought up these issues and their comfort as clinicians in supporting them in this aspect of their care. As the sexual health and behaviour of people with SMI is a relatively new research area in the UK, the interviews provided an opportunity to ask mental health professionals about potential barriers to research in this area, and also to identify any facilitators to enable them to better support service users with these issues.

The topic guide was used to ensure that all staff participants were asked the same questions to allow for comparisons to be made throughout analysis and reporting. The wordings of the questions were fluid rather than fixed, this was to enable the researcher to use the participant's terminology. This was also to allow for clarification of terms and probing where necessary.

At the end of each interview the staff participants were thanked for their time and asked if they had any feedback or questions. Interviewees were informed that they could ask questions following the interview using the researcher's contact details provided to them.

5.4 Ethical considerations

Ethical approval for this qualitative study was granted by the Liverpool Central NHS Research Ethics board and the Health Research Authority in May 2017 (appendices 31 and 32). As this was a substantial amendment to the acceptability and feasibility study described in chapter 4 (section 4.4.4) the University of York, Health Sciences Research Governance Committee were notified of this amendment and approvals for their records along with the relevant supporting documentation.

Consent forms and contact details (email addresses only) for staff participants were stored in a locked filing cabinet within a locked office at the University of York. All identifiable information within the interviews were anonymised and staff participants were allocated a unique participant ID for the study which was used when analysing and reporting the data. The anonymised interview data transcripts were stored separately on a password protected secure server within a locked office at the University of York. Study data will be retained for a period of five years from the end of the study to comply with the Data Storage Policy at the University (2017). The process of participant confidentiality, anonymity, data storage and reporting of data was explained to all staff participants in the (PIS) and verbally at the beginning and end of the interviews. Staff participants were also informed of their right to withdraw at any time and without having to give a reason. For reporting purposes, the NHS site where the staff interviews were undertaken will be referred to in the thesis as 'the site,' to protect the confidentiality of the trust and staff participants.

5.5 Approach to data analysis

According to Braun and Clarke (2006) a key part of the qualitative research process is actively deciding which theoretical framework, and method of analysis match with what the research question aims to find out. With this in mind, thematic analysis was chosen as the method of analysis for this study. This was undertaken from a realist approach which aims to report the experiences, meaning and reality of participants in relation to a specific phenomenon (Braun & Clarke, 2006). Thematic analysis differs from other methods such as grounded theory and interpretative phenomenological approach as although they each seek to identify and describe patterns within the data, thematic analysis is not theoretically driven (McLeod, 2011). This approach is therefore considered to be an accessible analytic method, particularly to those with limited experience in qualitative methods (Braun & Clarke, 2006; Nowell et al., 2017).

5.5.1 Thematic analysis

The method of analysis chosen for this study was thematic analysis. Thematic analysis is one of the most widely used qualitative approaches to analysing interviews. Thematic analysis is a strategy whereby data can be divided, placed in categories, summarised and reconstructed to allow key features of a data set to be captured (Ayres, 2008). This method of analysis was chosen as one researcher would be conducting the analysis on this study and this method allows researchers to be flexible when identifying, analysing and reporting themes which provides an in-depth interpretation of the data (Braun & Clarke, 2006). Despite the flexibility of thematic analysis, it is essential that researchers follow the available guidance to ensure that analyses are undertaken with scientific rigor without minimising the flexibility of the approach (Antaki et al. 2003). In addition to this, the transparent description of analysis and reporting processes of research is crucial, and is one thing that is often criticised in qualitative research as it is difficult to evaluate and synthesise findings (Braun and Clarke, 2006). Therefore, the comprehensive guidance for conducting thematic analysis published by Braun and Clarke (2006) was used to guide the analysis of the data collected in this study. The stages of thematic analysis are described in detail below, and a summary can be found in table 9.

5.5.1.1 Familiarisation with the data

According to Braun and Clarke (2006) when data is collected by the researchers themselves, some initial thoughts on analytic interests may be generated. Despite this, their guidelines state that a vital part of the analysis is for the researcher to immerse themselves in the data set, which usually involves repeated reading of the data to ensure the researcher becomes familiar with the depth of the data (Braun & Clarke, 2006). Although it is acknowledged that becoming familiar with the data can be time-consuming, it is considered to be a crucial part of the analysis (Braun & Clarke, 2006). In this study, the repeated reading stage involved the researcher being active in the process by means of searching for patterns within the data, and also by making notes about initial thoughts that aided later stages of the analysis process.

Another vital part of the familiarisation process when working with qualitative data such as interviews, is the transcription of the data. When interviews have been audio-recorded, the data need to be transcribed into a written format so that thematic analysis can be conducted. As with the repeated reading process, although the transcription of data can be time-consuming, it is considered a key component of researchers familiarising themselves with the data due to the attention to detail required (Bird, 2005). Although this is considered to be best practice, it is acknowledged that there

may be times when it is not feasible for a researcher to transcribe their data. In the case of this study, due to limited time and resources, the transcription of interviews was outsourced to a professional transcription company. However, upon receipt of the transcripts as recommended by Braun and Clarke (2006), the familiarisation process took place by checking transcripts against the original audio recordings for accuracy.

5.5.1.2 Generation of initial codes

The second stage of thematic analysis is the generation of initial codes which involves dividing the raw data into basic segments which are of interest, and in relation to the phenomena being explored. The generation of initial codes for this study were derived from an inductive approach meaning that codes and themes arise from what is in the data set rather than deductively, whereby a researcher would approach the data with ideas and concepts that would be used to code and interpret the data (Braun & Clarke, 2006). An inductive approach was chosen as this was the first time in-depth semi-structured interviews had been conducted in relation to this subject, therefore, it was important that the coding process was approached with no pre-conceieved ideas about the data.

For this stage of thematic analysis Braun and Clarke (2006) suggest three main areas of advice;

1. Code for as many themes as possible
2. Keep some of the surrounding context
3. Code extracts of data into as many different themes as they fit into
4. No data set is without inconsistencies – don't ignore these in the coding process

The coding of extracts in this study was undertaken without the assistance of analysis software such as N-Vivo due to the small dataset, this involved working through the data set in a systematic manner to identify interesting concepts and patterns across the data set. This was performed by writing notes on the text and using highlighters to identify potential themes. At the end of this stage the researcher had generated a long list of codes that were identified across the data set.

5.5.1.3 Searching for themes

Stage three of thematic analysis re-engages the researcher at the broader level of themes within the data set rather than individual codes. This involved organising the coded data extracts into potential themes to begin considering how different codes combine. It is at this point where the significance of themes become apparent. This was done by creating mind maps using the notes and highlighted extracts of data from

the previous stage. These were cut up and grouped together where patterns/themes appeared to be forming, colour coded post-it notes were also used to show where sub-themes were beginning to emerge.

5.5.1.4 Reviewing the themes

According to Braun and Clarke (2006) it is at this stage that the data within themes should begin to form a meaningful narrative whilst there should be a clear distinction between themes. Braun and Clarke (2006) suggest there should be two levels to this stage;

1. Review the coded extracts - this involved re-reading all the coded extracts of data to ensure they form a clear pattern. Decisions were made as to whether codes fitted within themes or whether new themes or sub themes needed to be created.
2. Reviewing themes in relation to the entire data set - this involved re-reading the entire data set to determine whether the themes and the thematic mind map (stage 3) reflected the data set as a whole and present an accurate representation.

At the end of this stage it should be clear what the main themes within the data set are, and the narrative across and within themes become apparent.

5.5.1.5 Defining and naming the themes

This stage involved defining and refining themes. Braun and Clarke (2006) describe this as identifying the features of what the story of particular themes tell, as well as the themes overall narrative. A detailed analysis was conducted for each theme with consideration being paid to how the narrative within each theme fitted within the broader narrative of the data and the research objectives. As part of the refinement process, sub-themes were confirmed to provide structure to larger, more complex themes. This is the stage where the titles of themes and sub-themes were finalised for the final analysis and report writing.

5.5.1.6 Writing the results

The final stage of thematic analysis is the preparation of the final write up, whether that be for a report, for publication, or as in this instance as part of a thesis. The role of presenting findings is to present a succinct, logical narrative of the data within and across themes, whereby quotations are used to highlight particular areas of interest. It is also essential that the narrative provides more than a description of the data, but

rather contributes to the research question (Braun & Clarke, 2006). The findings of this study are reported in the next section of this chapter, section 5.6.

Table 9 Summary of the stages of thematic analysis reproduced from Braun & Clarke (2006)

Stage		**Description of the process**
1.	Familiarisation with the data	Transcribe data (where possible), read and re-read and write down initial thoughts
2.	Generation of initial codes	From the entire data set, code the data in a systematic fashion, assigning relevant data to each code.
3.	Searching for themes	Collate codes into potential themes with all relevant data
4.	Reviewing the themes	Review the themes to check if they work with the coded extracts and the overall data set to produce a thematic 'map' of the analysis.
5.	Defining and naming the themes	Ongoing analysis to refine and name the themes and the overall narrative of the analysis
6.	Writing the results	Select extracts that relate back to the analysis, research questions and literature to produce the final report

5.6 Results

Following an overview of staff participant characteristics, this section of the chapter presents the findings of the qualitative interviews. For ease of reporting the findings have been separated into two sections; 1) Findings directly associated with supporting service users with their sexual health, and; 2) Findings associated with staff and organisational processes.

It is important to note that throughout the interviews some staff participants spoke anecdotally about the experiences of their service users, some of which raised potential safeguarding issues. The researcher was assured that local NHS safeguarding procedures were followed in these instances.

5.6.1 Participant Characteristics

Seven out of a total of 22 staff participants took part in the semi-structured interviews including a clinical psychologist, an occupational therapist, a cognitive behavioural therapist, two social workers and two mental health nurses (one of which was a CMHT team manager). The sample consisted of three men and four women. Interviews took place between May and July 2017, and lasted 40 minutes on average, ranging from 27 minutes to 59 minutes. All of the staff participants had been involved in team meetings introducing the acceptability and feasibility study, and involved in discussion about the initial recruitment strategy; as described in chapter 4 of this thesis.

5.6.2 Findings directly associated with supporting service users with their sexual health

5.6.2.1 Importance of sexual health and relationships

Sexual health, behaviour and relationships were perceived as being an integral part of the lives of people with SMI. Staff participants expressed that they were aware of their service users having sexual relationships, and acknowledged that having good relationships and intimacy was important to their service users:

> *"yeah, relationships and what happens in relationships, is something that I think is critical to people's lives and recovery. And I guess people's sexual lives are an integral part of life, for most people"* ***[SP001, clinical psychologist, male].***

Despite all staff participants perceiving that the sexual health and behaviour needs of people with SMI are important this was not always reflected in their clinical practice. However, being involved in recruitment for the acceptability and feasibility study, taking part in the interview, and raising this subject directly highlighted the importance of this topic area:

"It just draws your attention to, and maybe my colleagues are as well, the embodiment of the problem that you've highlighted when you asked me the question, is this stuff important, I said, yeah definitely and what do you do about it, well, no, not a great deal really. As a clinician it's important but I don't seem to do anything with that importance and focus on other things, and it makes you reflect and then hopefully you start to in your own way meet the need that you've highlighted" ***[SP006, cognitive behavioural therapist, male].***

Staff participants also stated that it would be useful to gather information from service users about their relationships as this would help clinicians to see what their relationships are like during periods of ill health, and how they view those relationships when they are feeling better.

Abuse in relationships

Vulnerability and abuse in relationships was a common theme throughout the interviews in relation to service users with SMI. Clinicians reported that the majority of the female and a lot of male patients on their caseloads had often had unwanted sexual experiences, and oppressive or traumatic relationships including violence which can contribute to a cycle of trauma:

"When people from potentially very early ages, have had their bodies taken over by other people, rape, incest, all this kind of stuff, and then go through life not valuing themselves, or having that kind of respect for themselves, that then affects their sexual activities and creates that cycle whereby usually men, identify women, and exploiting that, taking advantage of that" ***[SP001, clinical psychologist, male].***

"a history of sexual trauma and sexual abuse, and sometimes there's a repeat pattern with abusive partners and things, kind of self-limiting behaviours type thing. There's a vulnerability to that, the skewed attachments that people develop in terms of personality and attracting the wrong people" ***[SP004, social worker, male].***

One staff participant described how one patient they had worked with had had a lengthy history of violent abuse and how that now affects their current relationships:

"I worked with one particular lady with horrific history of abuse which I won't go into detail, but she'd actually seek out the abuse. She was quite vulnerable" ***[SP004, social worker, male].***

Another staff participant described how one of their service users had been admitted to a psychiatric hospital three times within a year which was blamed on their diagnosis of schizophrenia, however, each admission was preceded by her being raped by her husband. It was also highlighted that service users do not use the term 'abuse' or 'abusive relationship' when talking to clinicians, they often talk about stress within a relationship, and it is the role of the clinician to pick up on these subtle cues and ask further questions around topics such as domestic abuse. This enables them to gather more information and be able to support their patient as they are often in unequal relationships or living with perpetrators of violence. One staff participant described that a core part of their role was to support service users who had experienced sexual abuse in order to help them have more power in relationships, and more control over their bodies which they felt was a central aspect of recovery. Although the majority of the staff participants described how a history of sexual abuse can lead to a lifetime cycle of abusive relationships, and how this can affect their mental health, one staff participant stated that some of their service users won't have sex or enter into relationships because they have experienced abuse.

5.6.2.2 Supporting service users with sexual health, behaviour and relationships

A number of sub-themes were identified during the analysis process, these include; talking about sexual health, behaviour and relationships; working with service users around sexual health, and patient discomfort. These will be discussed in turn below.

Talking about sexual health, behaviour and relationships

In relation to talking about sexual health, behaviour and relationships with service users there were differing accounts of whether these conversations were clinician led or whether service users brought the subject up:

> *"I would have waited [for] people to bring it up. I know other people bring it up. It's a sensitive one isn't it? I know one of our OTs [occupational therapists] who's not here today, she's very up front about discussing it. But then she's felt that our psychiatrist has discussed it when he shouldn't. I think it's one of his listed questions that he asks people, and he's just being thorough. Sometimes that's appropriate, somebody wants to discuss it, and sometimes it's not. It's knowing how to do it sensitively isn't it?"* ***[SP003, community mental health nurse, female].***

The overarching philosophy of the clinicians interviewed was to give control back to the service users, and for patients to dictate the process and what they want to talk about. However, at the same time, if staff were aware of service users engaging in risky

sexual practices, or if they could be at risk of exploitation, they aimed to provide them with a space that gives them a choice about whether they want to talk about it or not. In line with this, staff participants also highlighted the importance of being really attentive and aware of the subtle cues that service users might give and the need to take up the invitation to discuss these sensitive issues.

> *"getting into a really ethical dilemma, on the one hand, I suppose my philosophy is to really give control back to the client to dictate the process and what they want to talk about, but at the same time, I know people are engaging in risk sexual practices or might be at risk of exploitation, how to then bring that up in a way that gives them choice about whether they want to talk about it or not"* ***[SP001, clincal psychologist, male].***

One staff participant reported that service users often share the information indirectly, and it can take time for them to build up a rapport with their clinical team, and thus for them to feel comfortable discussing such issues. In support of this another staff participant explained that these conversations can happen naturally, for example, if someone expresses negative thoughts about a relationship, this can lead to more direct questions being asked.

> *"There's been situations where they've talked about relationships being abusive but not, they don't use that term, they start off the conversation about the stresses within the relationship and as you ask more questions, you know, it comes to light that's there's an abusive relationship there, a controlling relationship".* ***[SP002, community mental health nurse, female].***

One area where the clinicians felt they were lacking in clinical practice is when service users are in long term relationships or single, although, they acknowledged that they should still be speaking to them about sex and intimacy:

> *"I think that's where I lack, if somebody isn't in a relationship, I should be still trying to talk to them about sex and intimacy, because it is also…somebody not having sex…you know, it's not just about, oh that's going to cause problems in itself, can't it? I think that's an area where I lack, somebody who is in a relationship I seem to be more practical and talk about it"* ***[SP005, occupational therapist female].***

One staff participant however, reported that they had supported a number of single service users with online dating profiles at their request as they had expressed a desire to meet someone for a relationship.

Two staff participants felt that there were issues around gender and asking questions about sexual health and behaviour. One of the male staff participants didn't feel that it was appropriate for him to be talking to his younger female service users about this subject:

> *"we didn't talk very much about sexual practice or sexual health because of me being an older…not old but an older male compared to a 16 year-old, not that I'm that old. So, no, it didn't come up very often in the context outside of being a sexual abuse survivor. We talked about it more openly in that context than I would if I was working with someone that was depressed, for example."* ***[SP006, cognitive behavioural therapist, male].***

Similarly, one of the female participants recalled:

> *"there was a young lad on the depot [injectable long acting antipsychotic] and I think he had got a female care coordinator and they weren't able to sort of ask him about his function [sexual dysfunction] of being on the depot…So they involved one of the support workers who was obviously male, went out and just put it in terms that, you know, I think he said something like can you still knock one out [reach orgasm] or something? but yes, it took a while to sort of go and ask that question because it needed to be delivered to that client's understanding"* ***[SP002, community mental health nurse, female].***

One staff participant reported that one of their female service users had had many sexual partners and they were able to have transparent conversations around sexual health and lifestyle as well as contraception. Another male staff participant stated that they had had many conversations with male service users to ask if they were using condoms and had given them advice on practising safe sex. A third staff participant described how even though some service users do not feel comfortable conversing about past sexual experiences, it is still crucial to open up the space to enable those conversations to happen.

> *"one of our male clients has had two admissions and before both [admissions] mentioned stuff around their dad, and they've never said that their dad abused them, but reading between the lines. But yeah, I've often said, I just want to bury this, and then they've ended up getting admitted. And we're kind of almost going through that process again, but before I came to our service, they'd been seeing a private sex therapist around sex addiction, and very rarely will they speak to us about this. And I guess I've been trying to say, if you want to speak about this, it's fine, and we'll try to, but they almost don't, and I suppose the interesting thing*

is, is in five years of seeing that private therapist, it was only before they got admitted the first time, that they even alluded to some kind of abuse. But, I suppose the question I have is, well, I would assume that if someone has had some kind of sex addiction, what's happened there? They've had so many years and experiences where it's not been talked about, that, do we just perpetuate that, or do we say, oh this is something that might be relevant to you, do you want to talk about it? And yeah, just kind of keep opening up that space for people" ***[SP001, clinical psychologist, male].***

A further comment to make is that a couple of staff participants drew a parallel between talking about sexual health and behaviour with service users today, and how talking about hearing voices was viewed forty years ago and the stigma that was associated with it. One staff participant described how doctor's entries in patient notes regarding sexual relations were a reflection on the service user's mental health, and was considered a sign they were deteriorating which suggests that sexual expression is seen as part of the illness. The clinicians expressed that talking about auditory or visual hallucinations is now completely normalised within their professions, and hoped that the same would happen when talking about sexual health behaviour and relationships with service users in the future.

Working with service users around sexual health

Although staff participants described how it can be difficult to open up conversations about sexual health behaviour and relationships with service users, clinicians also found they are constantly risk assessing behaviour and the information they get, as service users will often disclose that they have a number of sexual partners. This will often lead to conversations about safe sex and whether their partners are consenting:

"and sometimes it might be that there's been a change in other behaviours that would suggest that they are worried about something or something is troubling them, that actually you sort of learn to pick up on those patterns as a bit of an indicator that we need to go down this other road because that normally suggests that they are worried about it" ***[SP002, community mental health nurse, female].***

"sometimes I think it's important to be really attentive and aware of the cues that they might be inviting you into a conversation. And yeah, they're going to be very obscure things that you have to be very attentive to. And I suppose, if you pick up on something, then obviously how you respond to that, just responding to it, and giving that space that if they want to say something more they can do.

But again, if they don't want to, then they don't, then that's their choice" ***[SP001, clinical psychologist, male].***

One staff participant gave an example of how they had tried to minimise risk, one of their service users had told them that their housing situation had become unstable and they had been 'sofa surfing' (staying with numerous friends or family members as they didn't have their own place to stay) and had been asked for sexual favours in return. Once this disclosure had been made the staff participant helped to resolve the housing issue and therefore minimised the risk of exploitation of this individual. This highlights how important these conversations can be in this setting and population. One staff participant explained how a number of their service users had approached her to ask whether she would attend a GP appointment with them as they were concerned that their sexual health wouldn't be taken seriously, as they thought the GP would view their lack of libido as normal because of their mental health condition. In contrast, a staff participant reported that one service user they supported had disclosed that they were dissatisfied with their sex life, but when asked this question by a psychiatrist they told them they were satisfied with their sex life. When challenged the service user explained that she felt as though if she had told the psychiatrist the truth (feeling dissatisfied with her sex life) they would have thought that she was becoming unwell.

One staff participant also highlighted that although people often think of the impact that being in a negative relationship can have on a person's mental health, they neglect to think of service users who are single, who would like to be in a relationship, and whom potentially feel isolated as a result:

"you know, I said, do you want a relationship, well in fact, no, he said to me, I would like to meet someone, and I said, how are you doing that? He was saying about being on an Internet website and I was saying like, what's on your profile, do you feel like you've sold yourself. He hadn't, so we talked about me supporting him doing that" ***[SP005, occupational therapist, female].***

Patient discomfort

Three staff participants reported that they had experienced service users feeling uncomfortable or embarrassed when trying to talk to them about their sexual health and behaviour:

"I could see in their non verbals that they were just absolutely like so embarrassed that the thought of discussing it was just not an option" ***[SP002, community mental health nurse, female].***

"but I'm thinking of one person that said, I'm absolutely alarmed that the doctor has asked me about my libido, why has that got anything to do with him. I do wonder if the doctor explained what that was and probably in relation to medication. He was so disgusted that he'd even been asked. I don't even think if…it's his perception about that as an individual isn't it that didn't want to discuss that, but I think that's kind of stuck with me that" ***[SP005, occupational therapist, female].***

"I see this other man that came…comes in to see me. He's in the police force and he…I think he must be nearly 7 foot tall, really big, strapping lad. And he were absolutely horrified that our psychiatrist had to ask him about his sexual health. He just said, I'm not coming no more to have treatment. It don't work. It don't make no difference. I'm not going to be humiliated like that anymore. And that's all he'd said to him. So I don't know why that were, or whether he, you know, would have preferred a female to ask him. I just don't know" ***[SP007, social worker, female].***

In support of this, a staff participant stated that they felt that nine out of ten service users would feel uncomfortable discussing their sexual health and behaviour with their mental healthcare team:

"I know that it's important and I know that the public health, it might be a massive issue with it but we are quite a conservative society I think in a lot of ways and to ask, I think, maybe nine out ten of our service users would say that, oh I don't want to be asked those questions again" ***[SP005, occupational therapist, female].***

5.6.2.3 Sexual risk behaviours

All of the staff participants reported that they felt the client group they worked with would be more likely to engage in 'high risk' sexual behaviours meaning an increased likelihood of contracting a BBV or STI:

"Absolutely, yeah, males and females. The… I would say mainly the females that I've worked with that have been quite unwell have been quite promiscuous, not taking precautions whatsoever" ***[SP007, social worker, female].***

One staff participant described how one of their service users with a previous history of abuse met someone from an internet dating website, and the meeting resulted in the patient being sexually assaulted; however, the service user continued to use the internet site and has disclosed numerous sexual partners to her mental healthcare

team. Another staff participant described how one of their female service users was allowing a male friend to sleep on her sofa and he was using cannabis at her property, and she didn't feel able to tell him to leave, although it later transpired that they were having unprotected sex as the service user became pregnant.

The normalisation of pornography was raised by one staff participant. As pornography is more accepted within today's culture, this can be reflected in some people's sexual practice. Therefore, what certain people may consider risky sexual practice may not be considered risky to others depending on past sexual experiences:

> *"with the normalisation of pornography in culture and often almost misogynistic, almost verging on violent types of pornography, then that's reflected in some people's sexual practices… okay, you don't necessarily make a judgement, some people might genuinely enjoy that, that's fine, but some people, these things might be happening, because they don't really want it but they don't feel able to say no, or whatever else"* ***[SP001, clinical psychologist, male]'***

Several staff participants spoke about how risks can change through stages of the mental illness, and how people were more likely to engage in 'high risk' sexual behaviours if they were unwell:

> *"If somebody was, you know, really sexually active and had had a number of partner [s] in the past few months then, you know, that was sort of put forward that, you know, these bipolar are they being manic, is this a manic phase?"* ***[SP002, community mental health nurse, female].***

Although staff participants described that they are aware of the increased sexual risk behaviours in the SMI population, they also acknowledge that this is not as high on their agenda as it should be. In contrast, staff participants reported that in drug and alcohol services this is high on their agenda as people tend to live chaotic lifestyles, and service users were often putting themselves in vulnerable situations by exchanging sex for drugs.

> ***"****I mean, because in terms of physical health and statistics would show, I think it would follow then that there'd be other vulnerabilities in terms of sexual health and people leading a chaotic lifestyle, almost as drug misuse, alcohol misuse, and I think the drugs and alcohol are linked to increase in STIs in populations where there's a lot of substance misuse and that****" [SP004, social worker, male].***

Despite there being a large number of service users with a dual diagnosis of SMI and alcohol and/or drug misuse within the CMHT, this issue is still neglected.

5.6.3 Findings associated with staff and organisational processes related to supporting service users with their sexual health

5.6.3.1 Is it legitimate to have conversations about sexual health with service users?

One of the main themes that emerged when interviewing staff participants about personal and organisational barriers to talking to service users about their sexual health and behaviour, was the legitimacy and moral considerations around this. One staff participant reported that it can be difficult to know how to initiate these conversations with service users as often, the service users dictate the therapeutic process. After being involved in the feasibility study presented in chapter 4, staff felt that it would be a challenge to bring this subject up whilst still giving service users a choice about whether they want to discuss this or not:

> *"there's been some really interesting discussions in our team recently around whether people want to talk about this, or whether it's ethical to talk about this, or how do we feel about asking certain questions?"* ***[SP001, clinical psychologist, male].***

A second issue raised was whether service users actually feel that these are legitimate conversations to be having with members of their clinical team, whilst another participant stated that the team were faced with many safeguarding considerations, and felt that asking one more difficult question would not be problematic. However, in contrast to this the majority of staff participants felt that there was a consensus that if service users had experienced a traumatic history of abuse then asking these questions could lead to a cycle of them being re-traumatised. In one instance a staff participant explained that the reason he had consented to take part in the interview was due to his concern that asking service users explicit questions about sexual practice could trigger upsetting memories:

> *"I've agreed to do all this is because I was…I don't know what the right word is, concerned probably that asking sexually explicit…explicit questions about sexual practice may, for some of our clients, be triggering in some way"* ***[SP006, cognitive behavioural therapist, male].***

Despite this, everyone agreed that although a high proportion of people with SMI have experienced trauma and/or abuse which may precede their mental illness, not addressing the issue also presents an ethical dilemma.

One staff participant also gave an example of why in certain circumstances they may not be the appropriate person to be having such conversations with service users:

> *"I'm thinking about a client I'm seeing at the moment and there's no inappropriateness, but it's kind of, you can tell that I'm a positive female [a role model], you know, he'll say, we've got a lot in common me and you haven't we. I think there's that in my mind as well, that to bring that [sex and relationships] up with him then may be quite…if I were to say, you know, talking about such and such and such, but that's not a…and kind of, he might, what are you saying that to me for, he reads into a lot of things"* ***[SP005, occupational therapist, female].***

Another staff participant also described an incident which had occurred within their service which had raised the question of whether it was moral or ethical to be talking to service users about sexual health and behaviour:

> *"I would say a barrier for me would be somebody…a member of staff did lose their job a few years ago and he'd been discussing sex inappropriately with a service user. I can remember this had an impact on me a few years ago because I thought oh god, what's okay to discuss and what's not okay to discuss, and I don't know what he had discussed, but to have lost his job it probably was inappropriate completely. So that could be a barrier, just being a bit unsure about what's all right to discuss and what's not all right"* ***[SP003, community mental health nurse, female].***

5.6.3.2 Experiencing and managing discomfort

Throughout the interviews a common sub-theme was that of mental health professionals themselves experiencing some discomfort talking about issues of sexual health and behaviour, not only during the acceptability and feasibility study in chapter 4 but also in clinical practice. One participant felt the terms sexual health and sexual practice were quite intrusive but was unsure how to overcome this issue as they felt it related to the UK being a reserved society:

> *"at one time we had like a comprehensive assessment that were almost like a tick box. And it was really embarrassing 'cause you were meeting a person for the first time and had to talk about sexual health and it were like, oh, is she for real?"* ***[SP007, social worker, female].***

One staff participant described that in a previous job it was part of their role to assess the quality of life of service users, and one of the questions was whether a person was satisfied with their sex life. Despite the staff participant themselves saying that they felt

comfortable asking the question, they reported that their colleagues had expressed the view that it was not appropriate to ask service users the question. Another staff participant stated that they felt these questions would be better asked if the mental health professional and service user were the same gender.

Although staff participants expressed how they have or would have felt uncomfortable when discussing sexual health with service users, they also acknowledged that there was a need to be able to manage this discomfort in order to be able to support their service users. One staff participant reported that it is often staff themselves that were the barrier. The staff participants were unwilling to talk about sexual health and behaviour with another person stating that there needs to be a change in culture and the way that they work with people. One staff participant reported that there had been a change in attitudes to sexual health in their service due to the appointment of a new psychiatrist:

> *"I think it's been better since we've had this psychiatrist that we have now, because I think from where he's come from I think he's done a lot of work on that subject. So I think I've had a few people that have kind of come to me, males in particular, have said, oh, I'm very keen on what that psychiatrist said. I saw him for the first time and he asked me about me sex life. So I think there's aspect to it but I think there's also…he is very interested and I think he does kind of get it"* ***[SP007, social worker, female].***

In support of this, one staff participant felt that one way to manage feelings of staff and patient discomfort would be to normalise the conversation, and expressed that working with people with SMI did not always need to be about medication management and care plans but could be about normal aspects of life too. In addition to this, another person reported that they felt they could raise these conversations more easily with service users they have built a rapport with as they can raise this in a more jovial sense rather than formally. Participants also felt that the more they do something the easier it gets and the more confident they feel in their practice.

One staff participant also described how engaging with the feasibility study had been a positive experience and had started to open up conversations within the team about how best to approach and address the subject of sexual health and behaviour.

According to one staff participant, approximately one in four women in the general population has received unwanted sexual attention/contact. They felt that as the majority of the CMHT work force is female there may be colleagues within the team that have had a personal experience of this. Therefore, staff members with personal

experience are reluctant to speak with service users about this due to that experience, but also in an attempt to protect both themselves and the service user. In addition to this, another staff participant stated that rather than it being a personal experience of unwanted sexual attention/contact, it could be more generally about the staff members own relationship with sex that influences if and how they approach this subject with others in clinical practice.

5.6.3.4 The "medical" health care model in mental health

Two staff participants described how the "medical model" of mental health care could be a potential barrier in supporting service users with their sexual health and behaviour. One staff participant expressed how the "medical model" only allowed mental health professionals to work with service users at a surface level leaving the more complex issues to be ignored. For example, mental health care focuses on managing crises, getting service users admitted to a ward and ensuring they are on the correct psychiatric medication rather than asking what has led to the admission. In addition, a staff participant described how the "medical model" can treat people as sexless particularly in relation to males and sexual dysfunction:

> *"and I think there's probably a distorted view of when symptoms are in remission from a biological medical model and a psychiatric viewpoint, the symptoms might be in remission but there's a whole load of other problems in terms of lethargy and people's libido being flattened and all that. But it [antidepressant medication] seems effective, but at what cost"* ***[SP004, social worker, male].***

Integrated care

Two staff participants expressed how physical health and mental health need to be integrated more so that patients are treated holistically. Two examples of how this has worked in previous services are presented:

> *"when I was newly qualified, well, I was in the drug and alcohol team, we had the HIV counsellors in our office for certain days of the week, we worked really closely with them. There was a lot of [inaudible] and a lot of outreach work"* ***[SP003, community mental health nurse, female].***

> *"we did used to have like a specialist nurse and everybody used to ring her for advice and that were just amazing. We don't have that anymore, do we? We don't have that luxury anymore"* ***[SP007, social worker, female].***

5.6.3.4 Is sexual health part of a mental health professional's role?

The majority of staff participants felt that supporting service users with their sexual health behaviour and relationships was part of their role, as it was their job to understand everything about their service user in order to be able to work with them holistically. One staff participant explained how this involved constantly risk assessing whether patients are exposing themselves to risky situations and whether they have capacity and are consenting to these situations. If risks are present, then care plans can be implemented and risks managed.

As part of this, the mental health professionals felt that they would be the best person to support service users with their sexual health in the first instance, as they had spent a number of months/years building up trust and a therapeutic relationship with the patient, therefore if they were to disclose such information, it would not be a coincidence:

> *"I think if they were initially coming to us then yes to support them and I'd give them that option, do you want me to support you or do you want us to make phone contact or do you want us to signpost you, and that sort of thing"* ***[SP002, community mental health nurse, female].***

In contrast to this, one staff participant did not feel they were the best person to support service users due to their lack of knowledge of the area, but felt that their role was more of a facilitator in helping service users to access other appropriate services. To concur with this, one staff participant described how they had been to visit a service user and had not felt able to support them appropriately:

> *"I know this sounds absolutely bizarre. But this man had got really…he were a homosexual and he'd got really bad ulcers in his mouth. And he said to me just during conversation, I've not been in a sexual relationship for a number of year but I've kind of got all these ulcers in my mouth, so would I still be able to pass this virus onto people? And I couldn't answer him and I just thought, how…that's like really bad, isn't it, that I've not been able to say to him…give him advice about it?"* ***[SP007, social worker, female].***

Workload

Three staff participants expressed that the workload of mental health professionals could also be a barrier as to why the area of sexual health and behaviour was neglected. One staff participant explained how the initial mental health assessment when a patient is referred to a CMHT contains between 200 and 300 tick box questions

which had to be completed in a short time-frame, and therefore did not feel that asking about sexual health in this format would be the correct space to gather this information. Another staff participant also commented that the amount of mandatory training they have to attend can also make fitting in new areas of discussion difficult:

> *"I mean these times that we are really really busy and we've got, you know, reports to do and stuff like that, but I think we try and accommodate as much as we can"* ***[SP002, community mental health nurse, female].***

In addition to this, two staff participants raised the issue of the lack of government policy guiding this area and reported that the number of care standards they are already expected to meet was incredibly high. Therefore, the area of sexual health can be neglected. Despite this, they were both in agreement that it needs to be brought to the forefront of clinical practice.

Advocating to other services

Six staff participants felt that they would be comfortable advocating service users to external services if they raised an issue around sexual health that they felt unable to support the service user with. In addition, they would also offer to accompany the service user to any appointments. One staff participant stated that discussing access to sexual health services was not as common as other physical health services. Another staff participant however, reported that they were currently working with a service user in relation to their sexual health. One staff participant felt that although they would be comfortable to advocate to external health care services, they felt that mental health care and physical health care were very far removed from one another:

> *"I would have to start googling services because I wouldn't be familiar with where they were now"* ***[SP003, community mental health nurse, female].***

5.6.3.5 Training needs

Six out of the seven people who were interviewed stated that they had received no formal training in sexual health as this had not been part of their undergraduate curriculums or their continuing professional development. This resulted in staff members feeling unsure as to whether these are legitimate conversations to be having with their service users. One staff participant stated that they had received training on this subject, and in particular the language that should be used throughout their undergraduate and postgraduate training. However, all seven staff participants expressed that there was a definite training need in relation to this subject area:

"there's definitely a training need, because I suppose when you're in that environment and you're doing a course for a few hours it brings it to the forefront of your mind and you start discussing it and then people feel more confident about taking that back to the teams wouldn't they? I wonder if there's a way of bringing it in with other training that's already in existence" ***[SP003, community mental health nurse, female].***

A number of staff participants suggested that it would be a good idea to have a forum whereby someone external facilitates conversations around sexual health and behaviour. Thus allowing staff members to explore how to approach the subject of sexual health and how would be best to support their service users. One person felt that having these discussions informally within the team would feel like they had permission to discuss these issues with their patients:

"maybe just something that is quite informal that would sort of give us the permission to say that it is okay because yes, we know that everybody has got those sexual needs and its part of my Maslow's hierarchy of needs and all like that, you know, so we are aware of that" ***[SP002, community mental health nurse, female].***

One staff participant stated that providing an open forum for these conversations may start a process of desensitisation. A number of other staff participants stated that they felt a form of desensitisation training would be useful:

"I think there's something around, the desensitisation training might become quite useful, 'cause I suppose you're just getting practitioners to tolerate what they might perceive or experience as something quite awkward, or something that's not part of routine practice" ***[SP001, clinical psychologist, male].***

Supervision

A sub-theme of training needs that emerged through the analysis process was staff supervision. A number of staff participants felt that supervision would be a helpful way to support staff in processing difficult information, or when they are inexperienced in dealing with particular issues:

"that people by and large, I don't think people [staff members], to a certain amount they're desensitised to the trauma type stories, but since I've been in this team, I've been in this team nearly four years, and I guess with that systemic way of working, doing lots of joint work, and colleagues saying, they've been working for 30 to 40 years, it's like, oh, can you help me with this bit of work, because I've never heard clients that have said they've been

abused or whatever? I've never worked with clients that have been abused. It's like, of course you have. You know? But you've not been asking the questions, and it's just 'cause I'm asking the question and you're with me, that this is happening" ***[SP001, clinical psychologist, male].***

It was also reported that supervision is often a good arena for staff to become aware and reflect on their own responses to situations rather than the responses of the service user they are working with. Similarly, a different staff participant stated that in a previous place of work they used to have a buddy system in place for when staff members had experienced a difficult or uncomfortable session with a service user, they were able to talk things through and get support from a colleague.

Suggestions for sexual health awareness

Whilst discussing training needs with staff participants a number of suggestions were made. One staff participant stated that a course for clinicians on the basics of BBVs and STIs in terms of transmission, symptoms and treatment would be really useful. A second staff participant also reported that information is key. Figures regarding prevalence of disease would work as a shock tactic for clinicians and a justification for why mental health professionals need to be aware of these risks and having these conversations with their service users. Another suggestion made was to provide service users with information leaflets:

"I wonder about leaflets and things like that. You know when we first get involved with somebody, if we had a leaflet…not just on sexual health. You know, leaflets on different things that we can support and say these are some things, but we will kind of maybe just ask you if you need any support with. Then you can refer back to the leaflet and say, you know, you remember that I gave you these leaflets and this is one of the things that we said we might just ask you about. If you do want any support with sexual health and relationships and then if somebody said, no thanks, then you know, fine, but that might open up something for them to talk about and then you can refer to the leaflet again, can't you" ***[SP005, occupational therapist, female].***

Another staff participant suggested that an external person attending a family and friends group would open up conversations about sexual health and behaviour, and so service users would be aware that their clinical team are able to support them in this area if needed. Two staff participants suggested incorporating sexual health checks as part of the physical health care checks that service users receive as this would ensure sexual health care becomes part of routine practice.

5.7 Discussion

This section of the chapter describes a summary of the study's main findings in relation to the study objectives. The strengths and limitations of this study will be discussed in line with the current research literature, and conclusions drawn with these in mind.

5.7.1 Summary of findings

Seven mental health professionals were recruited by convenience sampling to participate in the semi-structured qualitative interviews. The interviews lasted for 40 minutes on average, and data were collected until data saturation was reached. A total of eight themes were identified across the data set; the importance of sexual health behaviour and relationships; supporting service users around their sexual health behaviour and relationships; sexual risk behaviour; whether it is ethical to have conversations about sexual health with service users; experiencing and managing discomfort; the "medical" health care model in mental health; whether sexual health should be part of a mental health professional's role, and training needs.

It was perceived by all staff participants that the sexual health and relationship needs of their service users were an important aspect of their patient's lives and often an integral part of their recovery. They expressed how people with SMI have often experienced traumatic and abusive relationships in the past, and how these experiences often mean service users become involved in a cycle of negative relationships, leaving them vulnerable and open to exploitation, which in turn has a negative impact on their mental health. However, the mental health professionals felt that providing service users with an open forum to raise these issues gave them a choice to seek support as the majority of staff participants felt that asking sexually explicit questions might trigger and re-traumatise participants. This contrasts with the findings of McKinnon et al. (1993) who found that people with SMI responded positively to questions about their sexual health, and reported that service users were happy to talk about a 'normal' aspect of life. The study reported that there were no adverse events, distress or discomfort expressed by those with SMI, there was no exacerbation of psychiatric symptoms. Similarly, McCann (2010) sought to explore the views and opinions of people with SMI in relation to sexual relationships in the UK. McCann found that 83% of respondents reported that they were interested in having sexual relationships. Despite people with SMI being able to fully express their desires and expectations in relation to sexual relationships, 43% of mental health professionals were unable to identify whether their service users had these needs (McCann, 2010). In support of the previous research in this field, the service users interviewed as part of the acceptability and feasibility study (described in chapter 4) did not report any feelings of discomfort or distress when

asked explicit questions about their sexual health and behaviour. However, there were instances whereby staff participants reported that patients described feeling “disgusted” and “humiliated” about being asked about their sexual health which contrasts with the findings of the international literature.

The findings of this study suggest that mental health professionals are aware that people with SMI are more likely than the general population to engage in ‘high risk’ sexual behaviours. This contradicts the findings of Hughes and Gray (2009) who found that 72% of the mental health professionals in their sample did not consider that people with SMI were more likely to engage in ‘high risk’ sexual behaviours, and were not more likely to have a diagnosis of HIV/AIDS compared to the general population. However, the findings of this study support those that were found in the more recent Hughes et al. (2017) focus groups. Hughes et al. (2017) found that the mental health professionals that took part in the focus groups were aware that service users may engage in behaviours such as condomless sex, paid sex work and having sexual intercourse with multiple partners. Not only were the staff participants interviewed in this study risk aware, particularly in relation to service users with a dual diagnosis, they provide examples of particular risks that have been disclosed to them in practice (e.g. sofa surfing). Interestingly, although staff participant’s identified a couple of behaviours associated with the increased risk of BBV/STI infection found in the systematic review presented in chapter 3 of this thesis (i.e. sexual trading, use of alcohol and/or drugs), they also identified things such as pornography and online dating of which there is limited evidence for in the literature in relation to people with SMI. Despite the staff participants in this study being aware of this increased risk, they still acknowledged that this was not high on their agenda and often neglected in their clinical practice. Although staff participants felt this area is neglected in their day to day practice, throughout the interviews there were many examples of how staff participants had supported their service users around their sexual health behaviour and relationships, whether that be by sign posting to other services, attending appointments with their service users, providing advice around safe sex, or supporting single service users seeking relationships.

Despite the examples described above, a common theme throughout the interviews was to question whether it is ethical and legitimate to have conversations about sexual health and behaviour with service users. Staff participants felt that broaching this subject with service users could be difficult due to triggering difficult memories as discussed above. This finding supports that of Hughes et al. (2017) who found that mental health professionals tended to avoid the subject of sexual health in order to protect service users from distress or embarrassment. Gender issues were also raised,

questions were raised about the appropriateness of female staff members speaking to men, or vice versa about these issues as the intention may be misconstrued by the service user. Despite this, there was a consensus that not addressing the issue also presents an ethical dilemma. The ethics of not asking these questions are more profound in terms of missing a safeguarding issue, or not being able to prevent an STI.

There was a consistent message throughout the interviews that staff felt uncomfortable raising and discussing issues around sexual health and behaviour with their service users because this has never been part of their normal practice. This is supported by previous survey data that found that 86% of the respondents reported feeling comfortable discussing sexual health and behaviour, but 70% stated that they rarely do this as part of routine clinical practice (Hughes & Gray 2009). Previous research has also found that mental health professionals tend to avoid the subject of sexual health as they don't feel comfortable broaching the subject (Quinn et al., 2011; Hughes et al., 2017). Although the staff participants in this study expressed how they have, or would have felt uncomfortable when raising or discussing the subject of sexual health, they also acknowledged that there was a need to be able to manage this discomfort in order to be able to support their service users.

A further barrier identified in supporting service users with their sexual health, was the "medical model" of mental health care. Although staff participants were talking abut the bio-psycho-social model of care that underpins all medical and nursing training, they felt that mental health nursing focused on the medical at the expense of the psycho-social factors, only allowing mental health professionals to work with service users at a surface level, leaving the more complex issues to be ignored. The staff participants expressed how the "medical model" does not allow much flexibility to ask the deeper questions that may help understand what precedes an acute episode of illness. Despite this, it was found that the majority of staff participants felt that the sexual health of service users was part of their role as mental health professionals, and that they were the best person to support them. This supports the 80% of respondents in the Hughes and Gray (2009) survey who felt that sexual health promotion was part of their role. However, this contradicts the findings of Kautz et al. (1990) who found that general nurses do not feel that supporting patients with their sexual health was part of their role. In support of Kautz et al. (1990) and in relation to mental health nurses, Quinn et al. (2011) found that mental health nurses reported avoiding the subject of sexual health because they did not feel it was part of their role, and they also felt that the sexual health of their service users was not a priority.

One consistent finding from this study was that there was a definite training need in relation to sexual health. All but one staff participant reported receiving no training at

undergraduate or post graduate level. Training needs were highlighted in relation to approaching the subject of sexual health and managing their own discomfort in relation to the subject area, but also in relation to knowledge. Staff participants did not feel confident or able to support service users as they did not have a basic knowledge of the symptoms, transmission and treatment of STIs and BBVs. This finding supports that of Hughes et al. (2017) whose respondents suggested that sexual health should feature on the undergraduate nursing curriculums as well as post qualification professional development training. They also highlighted the need for information on STIs and BBVs and an awareness of local service provision (Hughes et al., 2017). In addition to this, staff participants raised the issue of the lack of government policy guiding this area. There are national guidelines in place stating that non-specialist settings should be asking about sexual health and behaviour, however, it is unclear as to whether these are being implemented but staff participants reported that they are already expected to meet a high number of care standards (DoH, 2016; DoH, 2018).

5.7.2 Strengths of the current study

This is the first UK study to my knowledge to explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI by undertaking semi-structured qualitative interviews. This research has added to the sparse national and international literature, this study provides useful insights into: whether mental health professionals view the sexual health and behaviour of their service users as important; whether they are aware of the increased 'high risk' sexual behaviour in the SMI population; processes for supporting service users with these issues; barriers for undertaking research in this area, and in highlighting training needs. Therefore, the results of this study will help to inform future research in this area, particularly in relation to engaging mental health professionals in sexual health and behaviour research, and also in developing training programmes to ensure that mental health professionals feel comfortable and confident to support their service users in this area.

One of the major strengths of this study was that it was undertaken as a direct result of the findings of the acceptability and feasibility service user study in chapter 4. In summary, no participants were recruited from care coordinators screening their caseloads for people meeting the eligibility criteria. Feedback from mental health professionals at team meetings also suggested that there was some discomfort talking to service users about research around sexual health and sexual practices. There were also concerns raised about the appropriateness of the research to service users. Therefore, this provided an opportunity to gain a more in-depth understanding of

potential barriers to supporting patients in this area and provisions and requirements for training, which, are of importance when engaging NHS mental health professionals in future research studies in this area.

In addition to this, although during the acceptability and feasibility study it appeared challenging to engage the mental health professionals with research into sexual health, behaviour and relationships, they were willing to participate and engage with the qualitative interviews. They were willing to share their views and experience in relation to this subject as well as provide valuable feedback and suggestions for future research and training ideas with data saturation being achieved by the sixth interview.

Given the diverse nature of CMHTs across different NHS Trusts it is not possible to state how representative the views of this CMHT would be in relation to the wider mental health workforce. However, the wide range of professionals that took part in these interviews should be considered a strength of this study as this ensures that the perspectives from different professions are captured within the data set (1 clinical psychologist, 1 occupational therapist, 1 cognitive behavioural therapist, 2 social workers and 2 mental health nurses).

A further strength of this study was the fluid nature of the interview. For example, when speaking to some mental health professionals, it became apparent that when speaking about the perception of sexual risk in people with SMI, their perception of this was sexual dysfunction as a side effect of taking anti-psychotic medication, rather than potential sexual health assessment needs or that people with SMI are more likely than the general population to engage in behaviours associated with increased risk of BBV/STI infection.

5.7.3 Limitations of the current study

Although this study was the first UK study to explore the perspectives of mental health professionals in relation to the sexual health and behaviour of people with SMI by conducting semi-structured interviews, the findings should be interpreted with some caution. One important thing to consider is the responses that participants gave in the interviews may have been influenced by their prior experiences of engaging in the acceptability and feasibility study in chapter 4, and therefore may have expressed feelings they thought the researcher wanted to hear. Also, the interviews were undertaken in one site in the UK, therefore the findings may not be reflective of the views of all mental health professionals working within the NHS. Despite this, the themes that emerged from the semi-structured interviews were aligned with the

findings of previous research in this area in both the UK and Australia (Hughes et al., 2017; McCann, 2010; Quinn et al., 2011).

A further limitation of this study was that nonprobability convenience sampling was used to recruit participants. According to Etikan et al., (2016) data obtained from a convenience sample is likely to be biased, and a researcher is unable to determine whether the convenience sample is representative of the population of interest. Therefore, this impedes the researcher's ability to draw inferences about a population and, therefore the research may lack transferability/external validity. Although there are potential biases when using a convenience sample, the sample for this study were recruited for a specific purpose; they had been involved in the team meetings and initial recruitment strategy for the acceptability and feasibility study, therefore there was only a small population to sample from (staff team comprising a total of 22 people), and data were collected until data saturation was achieved.

Furthermore, the coding of transcripts for this study was undertaken by one researcher (the author of this thesis), which given the subjective nature of qualitative analysis could be seen as a limitation of this study. However, although the analysis was undertaken by one researcher, the codes/themes were shared regularly with the supervision team to ensure that the emerging findings were grounded in the original data.

In addition, outsourcing the transcription of the interview data to an external company is a limitation of this study. According to the guidance published by Braun and Clarke (2006) the transcription of data is a vital part of conducting thematic analysis in terms of the researcher familiarising themselves with the data. Although this was not possible due to the time restraints and the lack of resources within this study, each transcription was checked against the original recording to ensure consistency as advised by Braun and Clarke (2006).

5.7.4 Conclusions

Seven mental health professionals took part in semi-structured qualitative interviews to explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI. All of the staff participants had been involved in team meetings introducing the study and the initial recruitment strategy for the acceptability and feasibility study described in chapter 4 of this thesis. The findings of this study suggest that mental health professionals perceive the sexual health needs and relationships of their service users as vital, and as an integral part of their recovery. Despite staff participants being risk aware in relation to sexual practices, and

providing examples of supporting service users with these issues, this is not high on their agenda and is not considered as part of their routine practice.

A number of barriers were identified in terms of both supporting service users with their sexual health, and also undertaking research in this area including; the legitimacy of these conversations with service users; staff discomfort; workload and training needs. The lack of training around sexual health and behaviour has been highlighted and is supported by other literature in the field. Therefore, it is important that this is considered to be part of both undergraduate and postgraduate nursing programmes to ensure nursing students are aware of the importance of this area, and to equip them with feeling comfortable and confident in supporting service users with these issues.

To conclude, this is the first UK study to explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI by in depth semi-structured interviews. This study has identified training needs in line with other research in the area, therefore, a training package should be developed to enable mental health professionals to feel comfortable and confident in supporting service users with their sexual health behaviour and relationships. Furthermore, there are national guidelines in place stating that non-specialist settings should be asking about sexual health and behaviour, however, it is unclear as to whether this is being implemented (DoH, 2016; DoH, 2018). These guidelines should be implemented to ensure that a sexual risk behaviour assessment is part of every psychiatric assessment to identify individuals at risk of contracting a BBV or other STI. This in turn will enable mental health professionals to provide or advocate appropriate HIV prevention strategies which some would argue is an ethical obligation of their role (Koen et al., 2007).

5.8 Summary

This study used semi-structured interviews with mental health professionals to explore their views on the sexual health and relationship needs of people with SMI in the UK.

Building upon the findings of chapters 4 and 5, the following chapter explores the acceptability and experiences of people with severe mental illness (SMI) who took part in the Randomised Evaluation of Sexual Health Promotion Effectiveness informing Care and Treatment (RESPECT): a feasibility study of an intervention aimed at improving the sexual health of people with SMI within community mental health teams (CMHTs) in the UK (Hughes et al., 2016).

Chapter 6. Exploring the acceptability and experiences of people with SMI participating in the RESPECT study in the UK.

This chapter presents the rationale, aims and objectives for a study exploring the acceptability and experiences of people with severe mental illness (SMI) who took part in the Randomised Evaluation of Sexual Health Promotion Effectiveness informing Care and Treatment (RESPECT): a feasibility study of an intervention aimed at improving the sexual health of people with SMI within community mental health teams (CMHTs) in the UK (Hughes et al., 2016). Following the rationale, aims and objectives, the chapter will then present the study's methodology including; study design, recruitment methods, consent processes, data collection methods and tools and processes for obtaining ethical approval. The analytic plan is then presented which provides a description of the methods used for the analysis of survey and free text responses. Finally, the results and discussion are presented.

6.1 Rationale and aims

Despite the increased focus of the comorbid physical health needs of people with SMI, the sexual health needs of people with SMI are neglected from health policy and agenda (DoH. 2010). Of particular concern is the increased risk of contracting blood borne viruses (BBVs) or other sexually transmitted infections (STIs) within this population, whereby global prevalence rates of HIV, hepatitis B and C infections in the USA were found to range from 1.7% to 5% compared to 0.3% to 0.4% in the general population (Hughes et al., 2015). The evidence in chapter 2 of this thesis, and in line with previous research in this field, suggests that one explanation for these elevated rates of BBVs and STIs is as a result of people with SMI engaging in sexual behaviours associated with the increased risk of BBV/STI infection. These behaviours include sexual trading; sex with a person who uses drugs; alcohol and/or drug use prior to sexual intercourse; sexual intercourse with someone known less than 24 hours; more than one sexual partner reported in the last 12 months; pressured into unwanted sex; paid sex work; sex with someone who identifies themselves as bisexual; men who have sex with men or women who have sex with women, and inconsistent condom use when compared with the general population (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996;).

Research on this subject in the UK is in its infancy, with the feasibility study undertaken in chapter 3 of this thesis being one of the first UK studies to explore the acceptability and feasibility of recruiting people with SMI to a study about sexual health and behaviour. Despite challenges in engaging clinical staff with this subject, and the need

for a number of recruitment methods being employed, six participants were recruited which provides some preliminary evidence that exploring the sexual health and behaviour of people with SMI in the UK is acceptable, thus supporting the international literature that people with SMI will engage in sexual health research (Brown et al., 2010, 2011a, 2011b; Cournos et al., 1994; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Guimarães et al., 2014; Koen et al., 2007; McKinnon et al., 1993; Miller & Finnerty, 1996; Pinto et al., 2007; Sohler et al., 2000; Wainberg et al., 2008). The data collection tools used were considered appropriate with participants and they reported that the questions were relevant to them. Despite this, additional data from the UK is required to be able to explore the acceptability of undertaking sexual health research in the SMI population further.

A feasibility randomised controlled trial (RCT), the RESPECT study has recently been conducted in the UK (Hughes et al., 2016). It is also important to note that the author of this thesis, Samantha Gascoyne, was the Trial Coordinator for this RCT. The objective of the RESPECT study was to establish whether it is feasible to recruit people with SMI to a sexual health promotion intervention RCT, the first study of its kind in the UK (Hughes et al., 2016). This chapter builds on the preliminary findings of the feasibility study presented in chapter 4 of this thesis. It aims to explore the acceptability of people with SMI in the UK receiving information about the RESPECT study using data collected from a baseline feedback questionnaire, and experiences of people with SMI in the UK who took part in the RESPECT study using data from the exit feedback questionnaire (BFQ and EFQ respectively). The main objectives of this research were:

1. To explore the acceptability of people with SMI being approached to take part in a sexual health promotion intervention RCT.
2. To explore the experiences of those who participated in the RESPECT study
3. To explore reasons for non-participation in the RESPECT study.

6.2 Methodology

6.2.1 Study design

A two-stage survey of trial participants was undertaken for people meeting the eligibility criteria described below in section 6.2.2. The BFQ and EFQ data were collected from service users within a community mental health team (CMHT) in five NHS sites in England. Further information about the design and content of the self-report questionnaires included in this analysis can be found in section 6.2.7.

6.2.2 Inclusion and exclusion criteria

To be eligible to receive a study information pack about the RESPECT study, potential participants were required to be both:

- Over the age of 18 and
- On the caseload of one the four-included community mental health services with a diagnosis of schizophrenia, other psychotic/delusional disorders or bipolar disorder (F20, F21-29 & F31).

People were excluded from taking part in the study if they:

- Had a primary diagnosis of substance use;
- Had a primary diagnosis of cognitive impairment;
- Lacked capacity to consent as per the Mental Capacity Act (2005);
- Were non-English speaking participants;
- Were on the sex offenders register.

6.2.5 Recruitment methods

There were two main recruitment methods utilised simultaneously in the RESPECT study; caseload screening and self-referral, both are outlined briefly below.

6.2.5.1 Caseload screening

At each recruiting site researchers from the Clinical Research Network (CRN) worked with the NHS clinical staff in CMHTs to promote the study and undertake case load screening for potentially eligible participants using the eligibility criteria outlined above in section 6.2.2. Clinical staff were then asked to provide a study information pack in person or by post to those identified as potentially eligible. This information pack included an invitation letter, the Patient Information Sheet (PIS), a consent to contact form (CTC), a baseline feedback questionnaire (BFQ), and two freepost envelopes (one addressed to York Trials Unit (YTU), and one to the University of Huddersfield). Potentially eligible participants were asked to send all CTC back to YTU using a

freepost envelope, and all BFQ back to the University of Huddersfield in a separate envelope.

On receipt of a CTC at YTU, a member of the research team would make contact with the potential participant to explain the study, and with their verbal consent allow for eligibility screening to be carried out by one of the CRN clinical study officers to ensure the potential participant met the eligibility criteria for inclusion in the study. If and when this had been confirmed, a researcher would contact the potential participant to arrange a meeting to undertake informed consent, and if that was agreed, to also undertake baseline data collection. Potential participants were also able to verbally agree to be contacted, and this was communicated to the research team by the CRN staff.

6.2.5.2 Self-referral

The second recruitment method into the RESPECT study was by self-referral either by email, the website form or via telephone. Self-referrals were processed in the same way as a CTC described above. Self-referring participants were informed by the research team that they would be unable to participate in the study without prior agreement from their case manager to ensure there were no factors that could affect them participating (i.e. one of the exclusion criteria). In addition, local CRN staff and RESPECT researchers also attended various service user groups/events, for example, recovery colleges, creative groups and clinics to give out leaflets themselves. At those events, consent to contact could be obtained either verbally or with the consent to contact form. This method of recruitment ensured all potentially eligible participants received information about the study and had the opportunity to take part.

6.2.6 Consent process and data collection

Where eligibility was confirmed by the NHS Trust site, a RESPECT researcher arranged a convenient time and location to meet with the potential participant. At this meeting, the RESPECT researcher explained the study in full, and gave the potential participant the opportunity to ask questions. Potential participants were assured of confidentiality regarding the information they provided as part of the research, and the boundaries of that confidentiality (i.e. under what circumstances that may have to be breached, e.g. disclosure of being a risk to themselves or others). They were also given a localised information sheet with local sexual health services and contact details. They were informed that participation was voluntary and that they could withdraw from the intervention and/or data collection at any point without affecting their care, and without having to give a reason. They were also informed that if randomly

allocated to the sexual health intervention that they could withdraw from the intervention at any point but still have the option of staying in the study and completing the follow-up questionnaires. If willing, written informed consent was obtained and baseline data collected.

The primary objective of the RESPECT study was to demonstrate the feasibility of recruiting people with SMI to a sexual health promotion intervention RCT. In addition, all potential participants who received an initial study information pack were asked to complete a BFQ to collect data on the reasons why people chose to, or declined to take part in the RESPECT study. They could return this at any point after receiving this information, and all data received until the recruitment end date (March 2018) was included in the analysis.All participants who did take part in the study (irrespective of randomised group) were also asked to complete an EFQ to share their experiences of taking part in the research study. These are the focus of this study and the content of both questionnaires are described in the next section.

6.2.7 Data collection tools design and content

The BFQ and the EFQ were both developed specifically for the RESPECT study and received patient and public involvement (PPI) input, from suggestions and feedback from the initial drafts to the finalised versions of the questionnaires.

Initially the BFQ (version 1.2) was a 21 item self-report questionnaire to explore reasons for participation and non-participation in the RESPECT study. This included questions such as, "*who explained most of the RESPECT study to you?", "Did you read the participant information sheet?".* It also contained five free text response questions such as, *"Did you have any comments on the participant information sheet?"* and *"If you have any other reasons for taking part or not please write below".* In addition to this, version 1.2 of the BFQ contained 11 statements which participants were asked to rate on a five-point Likert scale ranging from "strongly disagree", to "strongly agree". Examples of the statements included, *"I understand what the RESPECT study is about", "the idea of randomisation worried me",* and *"I was satisfied that either group could be suitable for me".*

Due to the length of version 1.2 of the BFQ (appendix 39), and in an attempt to increase response rates, the Trial Management Group and PPI members identified the key items of importance and interest from version 1.2 of the BFQ and used these in the revised,shorter BFQ (seven item) (version 1.3, appendix 40) self-report questionnaire. This contained four closed questions with the option of 'agree' or 'disagree' responses, for example, '*I understood what the RESPECT study was about', 'The idea of*

randomisation worried me'. The BFQ also asked three open ended questions, for example, '*Did any other information help you make your decision',* and *'If you are NOT taking part it would be really helpful if you could tell us the main reason why'*.

Demographic information was not collected as part of either version of the BFQ, the rationale for this was because it was considered a pre-recruitment questionnaire and it was suggested by the REC as a way of collecting views on the relevance of the subject area and recruitment process prior to people consenting to take part in the RESPECT study. The BFQ was designed to obtain data from both those who declined to take part and those who later consented to take part in the RESPECT study.

The EFQ (appendix 41) was a 14 item self-report questionnaire. This contained five closed questions which required a 'yes' or 'no' response. Examples of these questions included, *'Did you stay in the study until the end?',* and *'Is there anything that you wish you had known about the RESPECT study before you agreed to take part?* There were also two open questions which asked participants to explain their answers to the closed questions. In addition to these, there were seven closed questions on a five-point Likert scale relating to their experiences of taking part in the RESPECT study ranging from 'strongly agree' to 'strongly disagree', for example, *'Taking part in RESPECT was helpful for me', 'The questionnaires were easy to complete',* and *'I understood what the RESPECT study was about'*.

6.2.8 Data storage

Due to the nature of this study, no personal identifiable information was collected. All participants were allocated a unique participant ID for the study which was used when analysing and reporting the data. The processes for ensuring participant confidentiality, anonymity, data storage and reporting of data is detailed in chapter 4, section 4.3.6 in line with the Data Storage Policy at the University of York (2017).

6.3 Ethics

6.3.1 Ethical approval

As the RESPECT study was a National Institute Health Research portfolio study, and the sponsor for this study was the University of Huddersfield, all study documentation was sent to the East Midlands Derby Research Ethics Committee (REC), Huddersfield University Ethics Board, and the Health Sciences Research Governance Committee (HSRGC) at the University of York in parallel for review. Ethical approval was granted by the East Midlands Derby Research Ethics Committee, REC reference: 16/EM/0334

on 30th September 2016, and the Health Research Authority (HRA) on 16th November 2016.

6.4 Analytic plan

6.4.1 Data cleaning

There was a mixture of closed and free text questions in both the BFQ and the EFQ. This data was manually entered into SPSS version 24 (IMB Corp, 2016). As there were two versions of the BFQ (v1.2 and v1.3) the data sets were entered and analysed separately to avoid confusion where there was an overlap of questions across versions. The data was entered by one researcher in the first instance, and as considered good practice, a second researcher independently checked 10% of the raw data against the SPSS data set to minimise errors that could affect the study's results (Van den Broeck et al., 2005). As part of the data cleaning process, a number of errors that are commonly associated with questionnaires were specifically checked for as described in chapter 4 section 4.5.1 (Van den Broeck et al., 2005). These included data entry errors such as inputting 55 instead of 5, and missing values with no actual value. Data entry errors were double checked by the second researcher and amended where necessary, and a code value of 999 was assigned for all missing values.

6.4.2 Descriptive results

Due to the nature of this study, all data will be presented descriptively with no formal statistical analyses undertaken as the study was not statistically powered to detect an association. Categorical data are presented using frequencies and percentages, and continuous data as means and standard deviations. There were a number of free text survey questions as part of the BFQs and EFQs, these will be described narratively to add depth to the data.

6.5 Results

This section of the chapter presents the findings of the descriptive and narrative results for the baseline feedback questionnaires (version 1.2 and 1.3) and the exit feedback questionnaires. For ease of reporting the findings have been separated into three sections; 1) BFQ (version 1.2); 2) BFQ (version 1.3); 3) EFQ.

Due to a lack of accurate screening data, it was unknown how many eligible potential participants received the study information pack containing the either versions of the BFQ either via their care coordinator or through the post. Therefore, data relating to the total number of people approached to provide feedback is unobtainable.

6.5.1 Baseline feedback questionnaire (version 1.2)

Each potential participant that received a RESPECT study information pack was asked to complete a BFQ to gain an insight about the acceptability of receiving information about taking part in the RESPECT study. Ten people completed version 1.2 of the BFQ, and of those seven were fully completed (70.0%). Table ten below provides a summary of the responses.

Table 10 Summary of responses to the RESPECT baseline feedback questionnaire (version 1.2)

	Number	%
Who explained most of the RESPECT study to you		
Researcher Mental health worker Post	1 5 2	10 50 20
Are you taking part in the RESPECT study		
Yes No	6 4	60 40
I understand what the RESPECT study is about		
Agree Strongly agree	5 3	50 30
I understand the differences between the two groups in the study (sexual health sessions plus care as usual OR care as usual)		
Strongly disagree Agree Strongly agree	1 6 1	10 60 10

I was satisfied that either group could be suitable for me		
Strongly disagree Neither agree nor disagree Agree Strongly agree	1 2 4 1	10 20 40 10
I wanted to have care as usual rather than the sexual health sessions		
Strongly disagree Disagree Neither agree nor disagree Agree	1 3 1 2	10 30 10 20
I was encouraged by some family/friends to take part		
Strongly disagree Disagree Neither agree nor disagree Agree	2 3 1 1	20 30 10 10
I understood how my care would be chosen (by chance, at random) as part of the study		
Strongly disagree Agree Strongly agree	1 3 3	10 30 30
The idea of randomisation worried me		
Strongly disagree Disagree Neither agree nor disagree	3 3 1	30 30 10
I trusted the person explaining the study		
Disagree Agree Strongly agree	1 4 2	10 40 20
I wanted to help with the research		
Strongly disagree Neither agree nor disagree Agree Strongly agree	1 1 2 3	10 10 20 30
I feel that others with the same difficulties as me will benefit from the study results		
Strongly disagree Neither agree nor disagree Agree Strongly agree	1 1 2 3	10 10 20 30

I found it difficult to participate in the study due to practical reasons (childcare, travel, time out of my day		
Strongly disagree Disagree Agree	1 5 1	10 50 1
Did you read the participant information sheet?		
Yes	8	80
If yes, was it helpful?		
Yes	8	80
Was the amount of information in it…		
Too little Just right Too much	1 6 1	10 60 10

6.5.1.2 Baseline feedback questionnaire (version 1.3)

One hundred and fifty BFQ (version 1.3) were completed, however, one of these was completed by a care coordinator who reported not handing out packs to potentially eligible participants as they thought it would exacerbate symptoms of paranoia. A second one was also completed but at the three-month follow up visit, therefore, these have not been included in the descriptive results meaning a total of 148 BFQs (version 1.3) were included in the analysis. A total of 55 people (37.2%) fully completed the form (completed questions 1-4 as 5-7 may have been N/A). Table 11 below provides a summary of responses to the closed questions on the BFQ (version 1.3).

Table 11 Summary of responses to the RESPECT baseline feedback questionnaire (version 1.3)

	Number	%
I understand what the RESPECT study is about		
Agree Disagree	89 1	60.0 0.7
The idea of randomisation worried me		
Agree Disagree	25 60	16.9 40.5
I feel that others with similar needs as me will benefit from the results of the study		
Agree Disagree	86 0	59.3 0
I found it difficult to participate in the study due to practical reasons (childcare, travel, time out of my day)		

Agree	15	10.1
Disagree	67	45.3

With regards to the free text response questions, around one third (27.2%; n=43) of participants reported other information that had helped them make their decision whether to participate, the most commonly reported source of extra information was their own desire to learn more about sexual health, and some people reported that this was due to their own personal experiences of contracting sexual diseases and/or being in exploitative relationships. Other information sources that were used to aid decision making were the PIS and study leaflet. Study specific reasons for wanting to take part included the flexibility of meetings, the researcher's positive attitude, and being able to talk through the study with family members and members of their clinical team. More general reasons for wanting to take part in the RESPECT study were to contribute to mental health research and to be able to give something back to the NHS.

Although in version 1.3 of the BFQ, respondents weren't asked directly if they had chosen to take part in the RESPECT study (as in version 1.2 of BFQ), they were asked, "If you are NOT taking part it would be really helpful if you could tell us the main reason why", therefore responses to this question were taken to be indicative of those who had chosen not to take part in the RESPECT study, n=67 (42.4%). The most common reason for people declining to take part was that they didn't feel the study was relevant to them (n=37). The majority of people who stated that the reason they didn't feel the study was relevant to them was because they weren't currently sexually active/in a relationship and hadn't been for 'some time' (n=15). Ten people also reported that they were married, and therefore not engaging in casual sex as why the RESPECT study was not relevant to them. Other specific reasons why the study wasn't relevant included, 'feeling too old' (n=8) or, feeling that they had enough knowledge on the topic (n=4). The second most commonly reported reason for non-participation was not wanting to discuss the topic of sexual health (n=15), with nine people stating that they were not comfortable discussing the topic of sexual health, and six people stating they weren't interested in the subject. Other reasons for non-participation included time limitations or other pressures taking priority (n=6) and being unhappy with the data collection process (n=4). Two respondents specifically commented that the baseline appointment time of up to two hours as indicated by the PIS had deterred them from taking part.

Approximately one quarter of respondents (25.8%, n=38 respondents) gave details when asked for any other comments about the study. The most common response was

support of the study (n=19) even if they were not taking part, some people expressed what a good idea they thought the study was, and that they were pleased that the 'elephant in the room of psychiatry' was finally being discussed. Other comments included feedback about how it could be improved such as having a separate intervention for sexual health knowledge (n=1), and there separately being more of a relational intervention (n=1), having the option of just one session rather than 3 (n=1), making the questionnaires more accessible (n=2).

6.5.2 RESPECT exit feedback questionnaire

At the six-month follow-up visit trial participants were asked to complete an EFQ to gain an insight about their experiences of taking part in the RESPECT study. From a sample of 72 trial participants, a total of 45 people completed the EFQ (62.5%) and of those, 43 were fully completed (95.5%). Table 12 below provides a summary of the responses.

Table 12 Summary of responses to the RESPECT exit feedback questionnaire

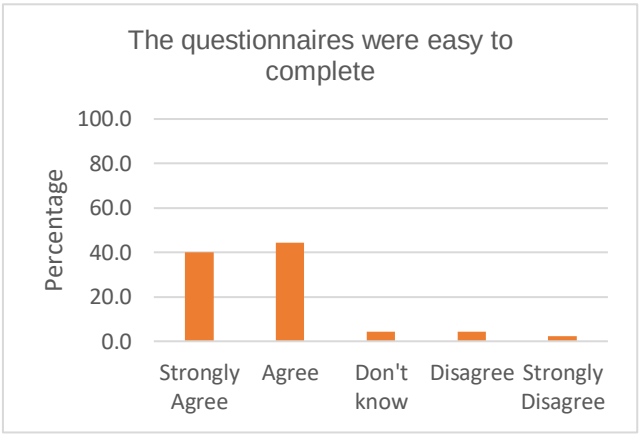
	Number	%
Did you stay in the study until the end?		
Yes No	45 0	100 0
Do you think it was a good idea to take part in the RESPECT study?		
Yes No	45 0	100 0
Did you have any negative experiences?		
Yes No	2 43	4.4 95.6
Is there anything you wish you'd known about the RESPECT study before you agreed to take part?		
Yes No	2 43	4.4 95.6
Would you recommend taking part in this study to others?		
Yes No	43 2	95.6 4.4

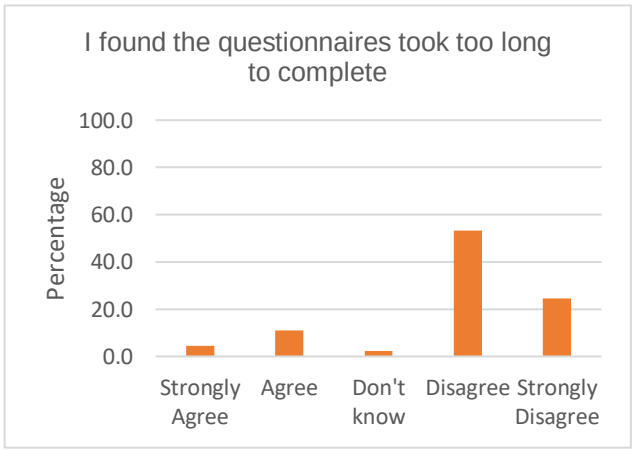
Although the majority of responses were positive and in support of the research field of mental health and sexual health, two people (4.44%) reported that they would not recommend taking part in the study to others as they felt the study had not been worthwhile due to not contributing to positive societal change, and that it had not stopped sexual diseases from continuing to be transmitted. Other reasons for not recommending the study were that the questions were more personal than they

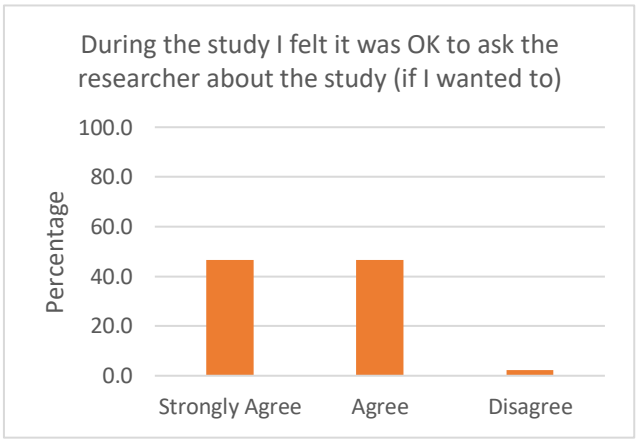
thought they would be, and that the intervention had not been personalised to the specific STI that the participant had contracted.

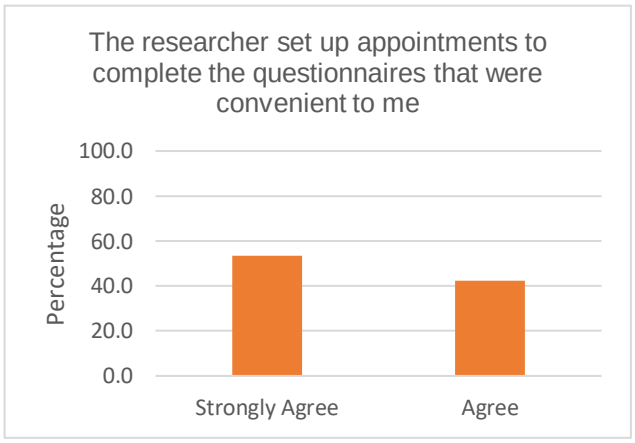
Participants were asked to rate seven statements about their participation in the RESPECT study on a five-point Likert scale ranging from, ‘strongly disagree’ to ‘strongly agree’. Overall respondents felt that RESPECT had been helpful (93%; n=40), that the questionnaires were easy to complete (88.4%; n= 38), that they felt it was OK to ask the researcher questions about the study if they wanted to (97.6%; n=42), that the researcher set up appointments at a convenient time (100%; n=43), that they understood what the RESPECT study was about (95.3%; n=41), and that they understood what it meant to be randomised (81.4%; n=35). Most respondents disagreed with the statement that the questionnaires took too long to complete (81.4%; n=35). A summary of these responses are displayed in figure 21 below.

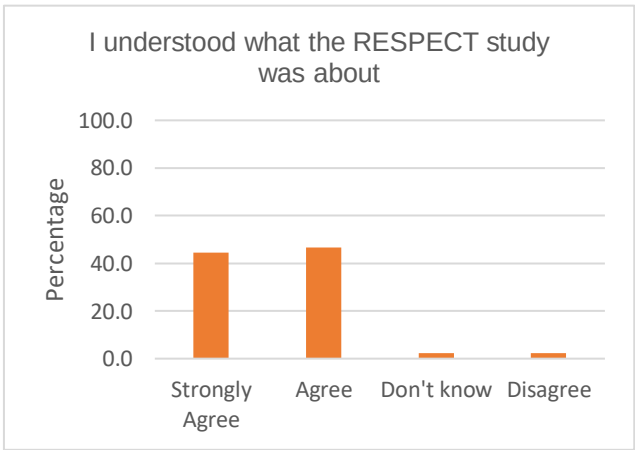
Figure 21 Summary of responses to RESPECT exit feedback questionnaire statements

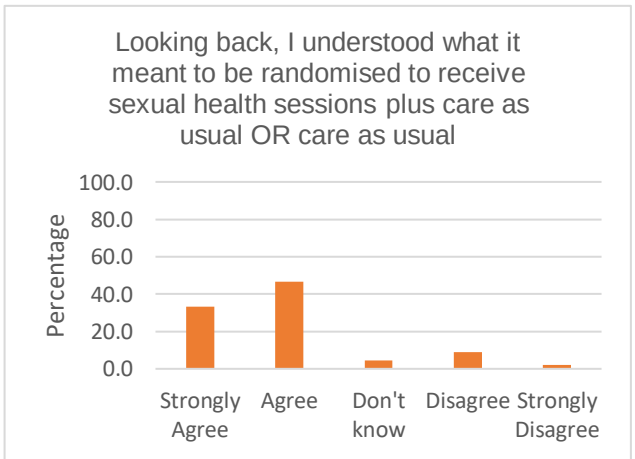












In addition to this, participants were also asked a couple of open ended questions as part of the EFQ. The first of these was in relation to question three in table 12 and asked, "*if you had any negative experiences, what could have been done (or has been done) to help you?"* One participant stated that although not negative, "I definitely had to question my intentions when reflecting on past sexual experiences, so good insightful questions", a second participant reported they felt a "fear of what the questions would be and revealing myself to someone, but everyone was really excellent, the researcher went through it all with me", and similarly another participant stated that they didn't like some of the questions but realised the importance of these, "some of them were personal but I suppose it's essential".

The second open ended question asked participants to explain their answer to whether they would recommend taking part in this study to others, of which 73.3% provided a written response. The most commonly reported reasons for recommending the study were the value participants placed on gaining information about sexual health and relationships (n=14), and how they had enjoyed the experience (n=6), in particular of opening up a taboo conversation (n=6). Other reasons included that it had felt good to give back and contribute to NHS mental health services (n=2), and that they had found the researchers and interventionists to be non-judgemental and friendly (n=2).

6.6 Discussion

The previous section presented the narrative and descriptive results in line with the aims and objectives (outlined in section 6.1) to explore the acceptability of people with SMI in the UK receiving information about the RESPECT study using data collected from a BFQ, and experiences of people with SMI in the UK who took part in the RESPECT study using data from the EFQ (Hughes et al., 2016). This section of the chapter describes a summary of the study's main findings in line with the study objectives. The strengths and limitations of this primary study will be discussed in line with the current research literature, and conclusions drawn with these in mind.

6.6.1 Summary of findings

One hundred and fifty-eight BFQs in total (versions 1.2 and 1.3) were either fully competed or partially completed by potential participants who were given study information packs about the RESPECT study. Regardless of whether people chose to take part in the RESPECT study or not, the overall consensus was that discussing sexual health and relationships with service users with SMI was a positive step, and a need that wasn't currently being met in clinical practice referring to it as the "elephant in the room of psychiatry".

From the information provided in the study information packs, approximately two thirds of the respondents felt that they understood what the RESPECT study was about (62%; n=98), and they felt that the study's results would be beneficial to people with similar needs as themselves (59.5%; n=94). In relation to 'randomisation' the majority of respondents reported feeling comfortable with this process (41.7%; n=66), with 15.8% (n=25) reporting that they felt 'worried' about this aspect of the study. Overall, respondents found the study design and processes acceptable, with only 10.1% (n=16) reporting that participation would be difficult due to practical issues (e.g. time commitments).

With regards to the EFQ a sample of 72 trial participants, a total of 45 people completed the exit feedback questionnaire (62.5%) and of those, 43 were fully completed (95.5%). Overall respondents felt that RESPECT had been helpful (93%; n=40), that the questionnaires were easy to complete (88.4%; n= 38), that they felt it was OK to ask the researcher questions about the study if they wanted to (97.6%; n=42), that the researcher set up appointments at a convenient time (100%; n=43), that they understood what the RESPECT study was about (95.3%; n=41), and that they understood what it meant to be randomised (81.4%; n=35). Most respondents

disagreed with the statement that the questionnaires took too long to complete (81.4%; n=35).

The findings of this study build upon the evidence presented in chapter 4 of this thesis and provides further evidence that it is acceptable to speak to people with SMI about their sexual health and behaviour in the UK, and when they do, they report a positive experience.

6.6.2 Strengths of the current study

This is the first RCT in the UK to explore whether it is feasible to recruit people with SMI to a sexual health promotion intervention study. As part of the recruitment process, all of those that were contacted about taking part in the RESPECT study were asked to complete a BFQ which collected acceptability data on being approached to take part in a study to do with sexual health. The results of this study build upon the evidence presented within chapter 4 of this thesis and provides further useful insights into conducting research in an under researched area within NHS settings. Therefore, the results of this study will help to further inform future research in this area.

One of the strengths of this study was that after receiving feedback that the initial version of the BFQ (version 1.2) was too long (21 items) from participant's and mental health professionals, this was revised to a shorter and simpler (7 item) version (1.3) to try and increase the likelihood of this being completed regardless of whether people chose to take part in the study or not.

Furthermore, it is important to note that even those people who chose not to take part in the RESPECT study were provided with an opportunity to provide feedback on the nature of the study, and information provided to them in the participant information pack. This is allowed the study to collate reasons for non-participation in the trial which is crucial when planning to do further research in this area within the UK.

A major strength of this study was that the majority of participants reported that they had understood what the RESPECT study was about, they felt the study was relevant to their population and that the results would benefit people with similar needs as themselves, suggesting that it is acceptable to ask people with SMI about their sexual health and relationship needs, and provide them with knowledge and skills to equip them to stay safe and free of STIs and BBVs in relationships by the way of health promotion sessions.

A further strength of this study was that people who did consent to take part in the RESPECT study were also provided with an opportunity to provide feedback on their experiences of being part of the trial by completing an EFQ at the six-month follow up

visit. The majority of participants who completed the EFQ engaged well with the study and stayed in it until the end and reported that they would recommend the study to others suggesting that participating in the RESPECT study was a positive experience.

6.6.3 Limitations of the current study

It is important to consider the potential for selection bias within this study as although 158 people completed the BFQ, and 45 trial participants completed the EFQ, the participants volunteered to provide feedback. As the participants self-selected themselves to provide feedback or take part, it cannot be ruled out that the feedback of non-responders would be different to those who did provide feedback regardless of whether they consented to take part in the RESPECT study or not. Additionally, with regards to the BFQ, as demographic information wasn't collected, it was not possible to explore the potential differences between those who consented to take part and those who declined to take part in the RESPECT study. Therefore, it is not possible to generalise the findings of this questionnaire to the wider SMI population. Despite this, the findings add important new knowledge about the acceptability of undertaking sexual health and behaviour research in people with SMI.

A further limitation of this study was that although the BFQ was shortened to try and increase response rates, it is important to consider that the removal of certain questions may have affected the overall quality of the findings as important information could have been missed (e.g. "I understood the differences between the two groups in the study"). Despite this the BFQ was suggested to the study team by the REC as a way of collecting views on the RESPECT recruitment processes, and therefore the findings would only be relevant to the RESPECT study rather than the wider research context.

Furthermore, it is also important to be aware that the acceptability data collected as part of the RESPECT study is not necessarily reflective of the population being studied as a whole. It is possible that those who provided feedback on the RESPECT study at baseline or upon completion of the trial may be individuals who have the strongest opinions, and have the most vested interest in sharing their stories because they want to effect change in society's attitudes towards the sexual lifestyles of people with SMI and the stigma attached to this as discussed in chapter 1 (section 1.3.2). With this in mind, it should be noted that the people who completed the BFQ and/or EFQ are not necessarily reflective of all viewpoints.

Similarly, in relation to the EFQ, although it a strength that this information was collected upon completion of the trial. It is important to note that not all trial participants

completed this questionnaire. Therefore, it is not possible to ascertain whether the responses with regards to experiences of being involved in the RESPECT study would be different for completers versus non-completers of the EFQ. The results of the EFQ should be interpreted with this in mind.

In addition to this, for the people who completed either version of the BFQ and who consented to take part in the RESPECT study, their responses to both the BFQ and EFQ were not linked to their trial participant ID. Therefore, the responses to these questionnaires could not have been explored further in relation to their demographics. In specific relation to the EFQ, it would have been interesting to compare the demographics and trial allocation for those who completed the EFQ and those who did not to see if there were any consistent differences.

6.6.4 Conclusions

This study was undertaken to explore the acceptability of people with SMI in the UK receiving information about the RESPECT study using data collected from a BFQ, and experiences of people with SMI in the UK who took part in the RESPECT study using data from the EFQ. One hundred and fifty-five BFQs were either fully or partially completed dependent upon their participation in the RESPECT study, and 45 EFQs were completed for those participants who consented to take part in the trial. This study found that it is acceptable to speak to people about their sexual health and behaviour in the UK, and when engaging in research in this area, they report this as a positive experience that they feel will benefit people within the SMI population. This study also provides vital and novel evidence for the reasons that people chose not to take part in the RESPECT study but also this particular area of research which, where possible should be taken into account in future research studies conducted within the UK.

To conclude, this study builds upon the evidence presented in chapter 4 of this thesis, and provides further evidence that it is acceptable to speak to people with SMI about their sexual health and behaviour in the UK, and when they do, they report a positive experience. Further research would need to incorporate the findings of this study and those presented in chapter 4 as this would be invaluable to inform the design and conduct of future research in this field.

6.7 Summary

This chapter explored the acceptability and experiences of people with SMI who took part in the Randomised Evaluation of Sexual Health Promotion Effectiveness informing Care and Treatment (RESPECT): a feasibility study of an intervention aimed at

improving the sexual health of people with SMI within community mental health teams (CMHTs) in the UK (Hughes et al., 2016).

The findings for the thesis are synthesised in the next chapter which will consider the key findings in relation to the overall aims of the thesis before discussing the suggestions for future research, recommendations for policy and practice, and the strengths and limitations of the thesis as a whole.

7.0 General discussion

The overall aim of this thesis was to begin to explore the intersection between severe mental illness (SMI) sexual health, and sexual behaviours associated with the increased risk of BBV/STI infection, with a specific focus on the acceptability of undertaking sexual health and behaviour research in people with SMI in the UK. The empirical research chapters within this thesis (chapters 3-6) include their own independent discussion sections. This chapter synthesises the key findings followed by a discussion of the challenges associated with conducting research in this area. The strengths and limitations of the thesis are then presented followed by recommendations for future research, policy and practice. Finally, a discussion of the thesis dissemination plan and overall conclusions are provided.

7.1 Key findings

The empirical chapters within this thesis have employed a range of methods including a systematic review, an acceptability and feasibility study, semi-structured qualitative interviews, and analysis of acceptability survey data collected as part of the RESPECT study. Table 13 summarises the key findings from the empirical chapters to address the aims of this thesis which were:

- To explore sexual behaviours associated with the increased risk of BBV/STI infection in people with SMI.
- To explore whether it is feasible to undertake sexual health and behaviour research in a population of people with SMI.
- To explore whether it is acceptable to undertake sexual health and behaviour research in a population of people with SMI.
- To explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI.

Each of these aims are then discussed in the subsequent sections of this chapter.

Table 13 Summary of key findings

Thesis aim (chapter)	Method used	Summary of key findings
To explore sexual behaviours associated with the increased risk of BBV/STI infection in people with no history of mental illness. **(3)**	Systematic review	Of the 6 case-control studies included in the review, ten sexual behaviours associated with the increased likelihood of BBV/STI infection were reported, including: sexual trading; sex with a person who uses drugs; alcohol and/or drug use prior to sexual intercourse; sexual intercourse with someone known less than twenty-four hours; more than one sexual partner reported in the last twelve months; paid sex work; pressured into unwanted sex; sex with someone who identifies themselves as bisexual; men who have sex with men or women who have sex with women and inconsistent condom use. Overall, the results provide some preliminary evidence that people SMI are more likely to engage in 'high risk' sexual behaviours compared to people with no history of mental illness. However, the results should be interpreted with caution given the substantial differences in the outcomes collected and the varying quality of the included studies.
Exploring whether it is feasible to undertake sexual health and behaviour research in a population of people with SMI **(4)**	Acceptability and feasibility study	A total of 76 people were approached and considered eligible, yielding thirteen consent to contact forms (17.1%) and a total of six participants were consented and interviewed for this study (46.2%). Three different recruitments strategies were employed sequentially due to poor recruitment rates. The findings of this study suggest that after approaching one caseload of a CMHT and 30 people in a lifestyle, health and wellbeing cohort that it was feasible to speak to six people with SMI about their sexual health and behaviour, which included answering a maximum of 463 questions depending on their sexual lifestyle. In addition, the processes and data collection measures used were acceptable to this small sample.
Exploring whether it is acceptable to undertake sexual health and behaviour research in a population of people with SMI (4 & 6)	Acceptability and feasibility study and analysis of acceptability survey data as collected as part of the RESPECT study	The findings of the acceptability data collected in chapters 4 and 6 provide some preliminary evidence that it is acceptable to speak to people with SMI about their sexual health and behaviour. The majority of the participants reported that they felt comfortable throughout the questionnaire/interview session, felt that the questions were relevant to them and this research is beneficial to people with SMI. The acceptability and feasibility study (chapter 4) also found that all aspects of the questionnaire and interview schedule that were relevant to their lifestyle were completed, there was no missing data and no

		refusal to answer specific questions suggesting that the data collection tools were also deemed acceptable.
Exploring the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI **(5)**	Qualitative interviews	Findings revealed factors directly associated with supporting service users with their sexual health and findings associated with staff and organisational processes. Mental health professionals perceive the sexual health needs and relationships of their service users as vital and as an integral part of their recovery. Despite them being risk aware in relation to sexual practices and providing examples of supporting service users with these issues, this was not high on their agenda and not considered as part of their routine practice. A number of barriers were identified in terms of both supporting service users with their sexual health and also undertaking research in this area including; the legitimacy of these conversations with service users; staff discomfort; workload and training needs. The lack of knowledge and training around sexual health and behaviour was also highlighted.

7.1.1 Behaviours associated with the increased risk of BBV/STI infection in people with SMI.

This thesis aimed to explore the sexual behaviours associated with the increased likelihood of BBV/STI infection in people with SMI. One of the concerns raised within the international literature is that BBVs and STIs are more prevalent in this population (Hughes et al., 2015). One suggestion within the international literature is that people with SMI are more likely to engage in sexual behaviours associated with the increased likelihood of contracting a BBV or STI compared to those with no history of mental illness. This thesis provides further support for this, in that when collating evidence in relation to this by way of systematic review and meta-analyses (chapter 3), it was found that people with SMI are more likely to engage in sexual behaviours associated with the increased likelihood of BBV/STI infection such as, sexual trading and paid sex work when compared to people with no history of mental illness. In contrast, the findings in chapter 4 of this thesis found that two out of six participants reported being sexually active within the four weeks preceding the interview of which only one participant reported having unprotected oral sex after consuming alcohol and/or drugs. However, taken within the context of the wider literature these findings should be interpreted with some caution due to the limited sample size.

One limitation of this thesis, is that although data about the sexual lifestyles and behaviours of participants was collected using validated measures as part of the

acceptability and feasibility study in chapter 4, it was not possible to further explore this data due to the small sample size, and the potential of being able to identify the participants from their data and demographics.

Also, in relation to the behaviours of people with SMI, although the mental health professionals who took part in the qualitative interviews in chapter 5 of this thesis acknowledged that they felt their service users were more likely to engage in 'high risk' sexual practices, they reported things such as online dating, hyper-sexuality in acute illness, pornography, and dual diagnosis, rather than and in contrast to those reported within the systematic review, and those identified from the scoping reviews (Cournos & McKinnon, 1997; Lagios and Deane, 2007; McCann, 2003).

7.1.2 Feasibility of undertaking sexual health and behaviour research in a population of people with SMI

This thesis aimed to explore whether it is feasible to undertake sexual health and behaviour research in a population of people with SMI in the UK. The feasibility of this area of research has been demonstrated in a number of countries internationally, for example, Brazil, Italy, South Africa, but with the majority of the work undertaken in the USA. However, the research presented in this thesis was one of the first times it has been explored in the UK. An attempt to begin exploring this should be considered a strength of this thesis as it is considered to be a taboo subject that is often put in the 'difficult box', with many people holding the view that people with SMI do not engage in sexual intercourse, which is contradicted by the literature within this field. A further strength of this thesis was that input was sought from those who have been leading research in this field for the last 30 years, Professor Karen McKinnon and Professor Francine Cournos. They provided guidance on the recruitment methods and recruitment materials for the study presented within chapter 4 of this thesis.

There were challenges in undertaking this work in relation to engaging mental health professionals with research in this subject area, as they felt that it wasn't appropriate for this population, and could have a negative impact on their psychiatric symptoms. Within the literature this could be defined as 'gatekeeping' which is when a third party prevents access to someone or something (Holloway & Galvin, 2016). Within the research context, gatekeeping occurs when potential participants are considered to be 'vulnerable' by the clinicians involved in their care, and as a result deny them the opportunity to take part in research (Patterson et al., 2010). Within the context of this thesis,

people with SMI were denied the right to receive information about a research study exploring the acceptability and feasibility of undertaking research in the area of sexual health and behaviour (Borschmann et al., 2014). Whilst it is important to acknowledge the expertise of mental health professionals and their role in advocating for service users, it is vital that people with SMI are able to make their own decisions, not only in relation to their care but also about their right to be informed about, and take part in research (Borschmann et al., 2014). Despite this, a number of important lessons were learnt and would be important to consider when planning future research. For example, some mental health professionals were selecting whom to provide study information packs to based on whether they 'thought' they would be interested, rather than those people meeting the eligibility criteria, or some mental health professionals were not willing to hand out study information packs as they did not feel the research was appropriate for people with SMI. This is despite the international literature suggesting otherwise, rigorous ethical review, and it being an ethical right for people to have the choice about whether to take part in research or not. Despite the Department of Health's commitment to implement evidenced based health services, recruitment to research remains problematic in both general and psychiatric populations, and thus gatekeeping signifies the disconnect between clinical practice and research (Department of Health, 2001; Howard et al., 2009; McDaid et al., 2006; Patterson et al., 2010). In order to address this and to prevent gatekeeping in the future, it is important to engage clinical staff in the research process. Previous research suggests that clinical staff may hold negative attitudes towards research because it is likely to increase their workload, they are unaware of the types of research being undertaken with their patient population, they are research naïve, have never received any research training, and in some instances do not believe in the advantages of evidence-based practice (Mickan et al., 2016; Patterson et al., 2010). Therefore, it is crucial that researchers engage with clinicians as early in the research process as possible and to maintain that engagement from the initiation of ideas, study design, implementation of the project and the dissemination of research findings (Patterson et al., 2010). With regards to research training, there is evidence that a multi-layered approach including; service research champions, mentoring, group workshops, protected time, opportunities for collaboration and feedback are effective in building capacity to undertake research (Cooke et al.,2009; Grimshaw et al., 2012; Haines et al., 2004; Mazmanian et al., 2016). Without these steps it seems unlikely that the government's plan to implement evidenced based health services will be achieved.

Despite the sample recruited in the acceptability and feasibility being less than the overall target (six people rather than ten), a number of recruitment methods (as described in chapter 4, section 4.3.4) were employed to provide study information to people with SMI directly to see if that would aid recruitment. If there had not been the time constraints of doing this work as part of a PhD project, and also delays with ethical approval as discussed below, this thesis provides preliminary evidence that when people with SMI are provided with study information directly, it is feasible to recruit people with SMI to research concerning their sexual health and behaviour in the UK. In order to improve recruitment rates for future studies, it would be worth considering approaching more than one NHS Trust and one CMHT in order to increase the pool of potentially eligible patients that could be approached. A further recruitment method option would be to consider recruiting patients via primary care, this would increase the pool of potentially eligible participants receiving information packs substantially, however, this wasn't feasible within the scope of this PhD. A broader definition of SMI may also help to increase recruitment rates, however as much of the existing literature does not include diagnoses such as personality disorders, it would be important for future studies to consider how this could impact on the results, and how this would fit within the context of the wider literature.

The study presented in chapter 4 was one of the first studies in the UK to attempt to navigate both a University departmental ethics board (HSRGC), and the NHS Research Ethics Committee (REC) in relation to gaining approval to undertake research in this area. In preparation for submitting to both ethics boards a patient and public focus group was undertaken to gain feedback on study documentation including the participant invitation letter, participant information sheet (PIS), consent form, and data collection forms. They provided guidance on the content of the invitation letter and the PIS to ensure that they were as informative as possible, and explicit about the questions the study would be asking, in order for the people receiving the information to be able to make a fully informed decision with regards to their participation in the research. This was particularly important given this population are more likely to have experienced sexual abuse, exploitation or trauma, which in turn may have had an impact on their decision to take part in this research.

In light of the lack of evidence in the UK, collaboration was also sought from Professor Karen McKinnon and Professor Francine Cournos who have been undertaking research in this area in the USA and Brazil for over 30 years. Their support and expertise were instrumental in being able to navigate the process for obtaining ethical approval for the studies presented in chapters 4 and 5. In addition to this, feedback on all documents and the ethics application was sought from Professor Karen McKinnon.

When submitting this research for ethical review, each of the two ethics boards and their individual processes posed different challenges. In the first instance, the HSRGC did not grant approval for the study. A number of issues were raised. The first issue that was raised by HSRGC was that the committee felt it was unrealistic that the questionnaire/interview session would take one hour, a second concern was that the questionnaire/interview session was to be administered one to one and in person given the explicit and sensitive nature of the questions, and a third concern raised was they felt the data collection tools were repetitive and not always appropriate. Before approval was given, each of these items needed to be addressed as discussed in section 4.6.5 of chapter 4 of this thesis. The process for obtaining ethical approval from the HSRGC took approximately three months.

The challenges faced by the NHS REC board and the HRA were different to those as described above. The NHS REC board asked for addition of 'those on the sex offenders register' to be added as an exclusion criteria and approval was granted. Although obtaining approval from the REC board was relatively straight forward, this was a point in time when research processes in the UK were being streamlined and a new central system for approving research in NHS sites was launched, the Health Research Authority (HRA) approval process. Due to prioritising large, national, multi-centre, National Institute of Health Research (NIHR) portfolio studies, it took six months for the HRA to approve the studies presented in chapters 4 and 5.

Although there were challenges whilst navigating the ethics process in undertaking research in this area in the UK, much of this was due to changes within the ethics structure within the UK at the time of obtaining approval, and could not have been avoided. With regards to the concerns raised by the HSRGC, although none of their concerns were realised when undertaking the questionnaire/interview sessions they did provide valuable insight into what issues need to be thought through when planning an ethical application for future research in this area. This learning was evident as this experience was able to directly guide the ethical application of the RESPECT study described in chapter 6, ensuring a more straight forward route to obtaining ethical approval which should be considered a strength of this thesis.

7.1.3 The acceptability of undertaking sexual health and behaviour research in a population of people with SMI.

A further aim of this thesis was to explore whether it is acceptable to undertake sexual health and behaviour research in people with SMI in the UK. Although previous research studies have explored the sexual health and behaviour of people with SMI internationally, demonstrating it is feasible to recruit this population to research in this

area as discussed above (section 7.1.2), this thesis is the first to explicitly ask people in this population whether it is acceptable to ask about their sexual health behaviour, and relationship needs as part of a research study.

The literature suggests that participants respond positively to questionnaires and/or interviews, and report that participants were happy to talk about a 'normal' aspect of life. In addition, there is no reported evidence of any adverse events, distress or discomfort expressed by the participants, and no reported exacerbation of psychiatric symptoms observed by the researchers in response to sexually explicit questions.

The findings of this thesis provide further evidence to support previous research in this area and also preliminary evidence that this finding can be translated to the UK. A patient and public involvement group with lived experience of SMI were happy to engage with this research, they reviewed the patient facing documentation devised for the study presented in chapter 4 of this thesis to ensure that the information was acceptable to people with SMI. Furthermore, the interview/questionnaire sessions conducted in chapter 4 of this thesis were used to get feedback on the data collection tools, and although participants in this research study were advised that they did not have to answer questions if they felt uncomfortable, all aspects of the questionnaire and interview schedule that were relevant to their lifestyle were completed with no refusal to answer any of the questions, and there was no evidence of discomfort and no requests to terminate the interview prematurely.

With regards to service users being asked direct questions about the acceptability of undertaking research in this area (chapter 4 and 6), the findings of this thesis provides preliminary evidence that it is acceptable to speak to the SMI population about their sexual health behaviour, and relationship needs in the UK, thus supporting the international literature.

7.1.4 The views of mental health professionals in relation to the sexual health and relationship needs of people with SMI.

The final aim of this thesis was to explore the views of mental health professionals in relation to the sexual health and relationship needs of people with SMI. Given the challenges of engaging the mental health professionals in helping to identify and hand out study information packs to potentially eligible participants as discussed in section 7.1.2, the semi-structured qualitative interviews were undertaken as a direct result of those findings.

The findings of this thesis suggest that mental health professionals perceive the sexual health needs and relationship needs of their service users as important, and an integral part of their recovery, however, this is not high on their agenda and is not considered as part of their routine practice. Although the attitudes of mental health professionals within the literature are generally positive, and believe that it is part of their role to undertake physical health checks such as checking blood pressure and weight as well as providing dietary and exercise advice, there is still some hesitance and a lack of confidence when asked about supporting people with smoking cessation or sexual health (Howard & Gamble 2011; Hughes & Gray 2009; Nash, 2005; Robson et al., 2013). These findings are supported by the wider literature within the context of sexual health but also in other areas of physical health (Hughes & Gray, 2009; Hughes et al., 2017; Katz et al., 1990; Quinn et al., 2011; Robson et al., 2013). Previous research has found that nurses who receive post-registration training in physical health care display higher levels of confidence increased knowledge and more positive attitudes when providing support and advice about physical health conditions (Huh et al.,2012 Robson et al., 2013).

This thesis has identified training needs within the mental health workforce in line with other research in the area (Hughes & Gray 2009; Hughes et al., 2017; Quin et al., 2011; Robson et al., 2013). Previous research has found that nurses who receive post-registration training in physical health care display higher levels of confidence, increased knowledge and more positive attitudes when providing support and advice about physical health conditions (Huh et al.,2012 Robson et al., 2013). Therefore, in order for mental health professionals to feel comfortable and confident in supporting service users with their sexual health, there is a need for mandatory training to include the more ‘taboo’ aspects of physical health care.

7.2 Recommendations

7.2.1 Recommendations for future research

Given the scarcity of evidence exploring the intersection of severe mental illness and sexual health and behaviour in the UK, future research will need to adopt a range of observational, experimental and qualitative methods to build upon the existing UK evidence. Given that at present, the UK does not have any specific prevalence data for BBVs or other STIs for an SMI population, future research should seek to obtain this data to explore whether rates of infections for people with SMI are elevated in the UK as suggested by international prevalence data. Future research should also consider rigorous longitudinal epidemiological studies, as despite preliminary evidence that people with SMI are more likely to engage in ‘high risk’ sexual behaviours compared to

those with no history of mental illness, it is unlikely that SMI would be the single attributor to a willingness to engage in 'high risk' sexual behaviours, there are numerous factors which could directly impact on the engagement in such behaviours: socio-economic status, marital status, gender, comorbid substance use, and stage of illness. A longitudinal cohort study would allow these factors to be explored in detail providing an accurate UK context to this important research area.

In addition to this, there is a need to be able to assess people deemed to be at risk of contracting BBVs or other STIs. Although this thesis used a national survey (NATSAL) and a gold-standard interview schedule (SERBAS) to ask questions about sexual risk behaviour (chapter 4), it must be acknowledged that it would not be feasible to use these tools in clinical practice. The recommended training time for using the SERBAS is approximately 20 hours, and the length of time to complete both of these measures approximately is between 60 and 90 minutes dependent on levels of sexual activity, it would not be clinically or cost effective to use these to assess risk, given the workload and time constraints placed on mental health professionals. Therefore, future research should look to develop and validate a short sexual risk behaviour measure that incorporates the risk behaviours reported in the findings of the systematic review presented in chapter 3 of this thesis which could form part of the psychiatric assessment.

As highlighted by this thesis (chapters 4 and 5) it can be challenging to engage clinical staff in a novel research area. Future research should seek to explore how best to engage clinical staff in the research process and integrate into clinical practice, especially when the research is asking difficult questions about a subject that could be potentially uncomfortable for some. In addition to this, the qualitative interviews with mental health professionals highlighted a training need in relation to this subject area.

7.2.1.1 Immediate next steps for this body of research

An immediate next step for this body of research based on the findings of this thesis would be to develop a training intervention that could be delivered to all mental health professionals. As a number of the qualitative interviews highlighted, staff do not feel comfortable or confident in discussing the sexual health or behaviour with their service users. In addition, a recurring theme was that they didn't know whether these were legitimate conversations to be having with people with SMI. Therefore, a training intervention should look to include elements of desensitisation in order to begin to break down the discomfort of talking about this subject area. There were a number of YouTube videos created as part of RESPECT, service users and carers spoke about how it was acceptable to talk to them about their sexual health and behaviour.

Incorporating these into the training package alongside recent health policy would hopefully provide some reassurance to mental health professionals about the legitimacy of such having such conversations. Another aspect to be considered for the training intervention would be knowledge. From the qualitative interviews, staff felt that they didn't know enough about STIs and BBVs in terms of symptoms, transmission, treatment and available local services in order to be able to support their service users. Providing this information in a brief, easily accessible format would hopefully address the confidence issues that mental health professionals have voiced both within chapter 5 of this thesis, and also the wider literature.

7.2.2 Recommendations for policy and practice

Chapter 5 of this thesis identified that mental health professionals were uncertain whether supporting their service users with their sexual health and relationship needs was part of their role. NHS policy drivers therefore, need to make staff aware that this is a legitimate conversation to be having with service users and provide guidance, training and support to enable mental health professionals to feel comfortable and confident to support people with SMI with this area of their physical health.

Until recently the sexual health and relationship needs of people with SMI have been missing from NHS policy and health agenda. Whilst the research presented in this thesis was being conducted, the Department of Health and Public Health England published in 2016 an action document for mental health nurses with the view of improving the physical health of people with mental health problems in the UK. Within this document, there are brief guidelines for the sexual and reproductive health of people with mental health problems. The action document highlights key elements such as; increased risk of BBVs and STIs, increased risk of exploitation, physical and sexual violence, engaging in 'high risk' sexual behaviours, and also increased rates of unintended pregnancy within this population (DOH, 2016). Similarly, as discussed in chapter 5 (section 5.2.2), a continuing professional development article was published in 2015 to guide mental health nurses in assessing the sexual health of people with mental health problems, and also to allow them to reflect on their current practice (Salkeld, 2015). However, it is unknown how accessible and how widely these documents have been disseminated to mental health professionals and whether in fact these are being implemented in practice.

Despite there being variations in international health care systems, there is a consensus that the segregation of mental and physical health care is a barrier to people with SMI engaging with health services for their physical health needs. Therefore, there is a need to address international policy both in public health and

mental health nursing to ensure that the physical health needs of people with SMI are consistently being assessed, managed and monitored by the appropriate services and thus beginning to address the physical health disparities and mortality gap in this population.

Furthermore, the sexual health and relationship needs of people with SMI are currently neglected on undergraduate and postgraduate mental health nursing programmes, this would be a vital addition to the curriculum in order to address some of the legitimacy, comfort, confidence and ethical issues expressed during the qualitative interviews in chapter 5 of this thesis.

7.4 Dissemination

In addition to impacting on research through the publication and submission of findings to academic journals (appendix 1), this thesis has been presented at numerous events hosted by numerous organisations, including an invited talk at the International Academy of Mental Health and Law Conference (2017), and World Mental Health Day (2018) at the University of York, presentations at the SeXY seminar at the University of Sunderland (2015), Departmental seminar at the University of York (2015), CLAHRC-YH dissemination events (2016, 2017) and also a poster presentation at the Society of Social Medicine (2016). The findings of this thesis will continue to be disseminated in the academic arena.

Furthermore, it is important the findings of this thesis are disseminated to mental health professionals given the applied nature of this research, and their involvement in the different aspects of this thesis. Summaries of the findings will be disseminated to the service user participants, and also to the NHS trusts that were involved in this research as they may not be aware of, be readers of, or have access to academic publications. The findings of this thesis will also be disseminated via email, utilising the mental health research network. This will ensure that all professions involved in supporting people with SMI have access to these research findings.

7.5 Conclusions

This thesis has begun to explore the intersection between severe mental illness, sexual health and sexual risk-taking behaviour, with a specific focus on the acceptability of undertaking sexual health and behaviour research in people with SMI in the UK. This thesis highlights the limited research evidence in the subject area, specifically in the UK. Within the UK context, this thesis provides evidence that it is acceptable to speak to the SMI population about their sexual health and behaviour as well as preliminary evidence that it is feasible to recruit people with SMI to research in this area.

Priorities for policy drivers include bringing the sexual health and relationship needs to the forefront of guidance for mental health professionals to ensure they aware of the legitimacy of supporting their service users with this aspect of their physical health. The findings from this thesis inform both research and policy and aim to provide a foundation on which to build future research in the UK which will in turn inform future NHS policy.

Appendices

Appendix 1- Published paper in Journal of Psychiatric and Mental Health Nursing

The sexual health and relationship needs of people with severe mental illness.

This paper will explore the sexual health and relationship needs of people with severe mental illness (SMI), as well as develop an argument that positive intimate relationships are a fundamental human right for all, including those with mental health issues.

"Sexual health" as defined by the World Health Organisation (WHO) (2006) is a global term which is not just about being free from sexually transmitted infections, but also about the right to a safe and satisfying relationship, and being able to express ones sexuality. More specifically, it is a right to choose to be sexually active (or not) or to choose to have sexually intimate relationships along with access to information and care in relation to sexual health (World Health Organization, 2006). It is also a human rights issue, not just a health issue where people with serious mental illness (SMI) have just as much right to have an intimate relationship (of their choosing) as anyone else. (Dixon-Mueller et al., 2009, Berer, 2004, Perlin, 2008).

Sexual health is a global health priority for all. The latest WHO figures of the global prevalence and incidence of chlamydia, gonorrhea, trichomoniasis, and syphilis in adult women and men report nearly one million new infections each day (Newman et al., 2015). These infections can cause infertility and other health consequences (Gottlieb et al., 2014). Strains of infections are emerging that are resistant to antibiotics (Ndowa et al., 2012). There is also a global human immunodeficiency virus (HIV) epidemic, the WHO estimate that there were approximately thirty-seven million people living with HIV at the end of 2014, with roughly two million new infections diagnosed worldwide in 2014 (WHO, 2015). Certain groups have been identified as particularly vulnerable to contracting sexually transmitted infections and blood borne viruses (BBVs) such as men who have sex with men, people who inject drugs, sex workers and people from high prevalence geographical areas such as sub-Saharan Africa (Department of

Health, 2013). There is another vulnerable group who should be considered as a high-risk group: people with SMI (Lagios, 2007). However, the sexual health and relationship needs of this group seems to have been missed off the health agenda (Hughes et al., 2015).

We therefore argue that promotion of sexual health falls into the remit of holistic mental health care, and we further argue that mental health nurses have a clear role to play in this.

Historically, people with mental illness would be incarcerated for life in asylums, a practice that continued into the 20th century. Their human rights and citizenship marginalized, and with respect to their sexuality, the general consensus was one that considered them to be asexual (Dobal & Torkelson, 2004). As such, there was no consideration towards the development of sexual health or reproductive health policy (Dobal & Torkelson, 2004). Despite being segregated by gender, people would manage to form relationships in spite of the regime. The closure of the asylums and the advent of "care in the community" has offered people with SMI more personal freedoms in their adult relationships, however, it has also exposed them to some risks in those relationships too. These include drugs and alcohol (Ford et al. (2003)), exposure to sexual exploitation (Elliot et al., 2004), as well as abusive intimate partners (King et al., 2008). In this transition from institutional care to integration into the community, it is questionable how much mental health services have focused on life skills in order to live well in communities, as opposed to the prevailing focus on psychiatric symptom relief (McCann, 2010a). There is an attitude of low expectation on recovery outcomes both from people who live with mental illness themselves as well as those who provide the service. We see this reflected in low rates of employment of people with serious mental illness as well (Mueser et al., 2001; Henderson et al., 2005). The recovery movement (Boardman & Friedli, 2012) promotes the concept of developing a meaning and purpose in life within the challenges of managing a chronic mental health condition. However, a criticism of the recovery movement is that it has

failed to emphasise sexual expression and sexual relationships. Mental health Policy in the UK, Ireland and Australia also fail to acknowledge the importance of sexuality, sexual relationships and sexual health. In the absence of adequate support the sexual health and relationship needs of people with SMI have been overlooked and ignored (Deegan, 2001). For mental health nurses to provide recovery orientated care, in the context of human sexuality they need to support people with SMI with their sexual health and relationship needs (Dein & Williams, 2008; Eklund & Östman, 2010), and the importance of this area of care should be incorporated into mental health policy.

Whilst this topic area has largely been ignored, there are some studies which highlight some of the key concerns regarding sexual health in this population:

- Whilst pregnancy rates are low; the rate of un-intended pregnancy is higher than in the general population (Miller & Finnerty, 1996).
- People with SMI are more likely to experience inter partner violence (IPV) (20% of women with SMI reported IPV compared to 5.3% without and 6.9% of men with SMI reported IPV compared to 3.1% without) (Khalifeh et al., 2015).
- People with SMI are also more likely to experience exploitative or coercive sex (Coverdale et al., 1997; Coverdale et al., 2000; Koen et al., 2007; Miller & Finnerty, 1996) (see risk behaviour section below).
- The prevalence of HIV, hepatitis b and hepatitis c are elevated in this population– this is an objective risk marker for sexual risk taking (as well as intravenous drug use) (Hughes et al., 2015).

In sum, it seems that people with SMI are facing real difficulties in relationships including domestic violence, lack of access (or use) of contraceptives, and risk of BBVs; of which HIV and hepatitis B are sexually transmitted. It is important to raise awareness not only of the increased prevalence of violence and infection in this group, it is also important for mental health nurses (and the other health and social care professionals) to understand the circumstances and risk factors related to these

unwanted consequences and be able to screen, educate and intervene if risk behaviours are identified.

Risk Behaviour

All sexual activity carries some element of risk of infection, unintended pregnancy and other health risks (Brown et al., 2011a, 2011b; Grassi et al., 1999). However, we know that some sexual behaviours carry higher risks than others. For example, anal sex (condomless) is more likely to lead to anal and rectal tears and bleeding. This means that the HIV virus (and other infections) can more easily enter the blood stream from body fluids of the other person (such as semen and vaginal fluid). In addition to sexual transmission, some BBVs such as hepatitis C are transmitted by sharing injecting equipment and can also be transmitted via sharing of household equipment such as toothbrushes and razors if the virus is in dried blood (Sawayama et al., 2000). This has specific implications for educating people about avoiding sharing razors and toothbrushes (in hospital wards or shared accommodation for example).

Whilst there are many studies that have identified rates and types of risk behaviours engaged in by adults with SMI, only 6 studies have provided comparative data with the general population. A number of sexual behaviours that are considered 'high risk' in terms of contracting a BBV or other STIs were consistently reported in six case-control studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007; Miller & Finnerty, 1996).

1. Substance use- Substance use is common in the general population as well as in people with SMI. Of specific interest is intoxication with drugs or alcohol when sex occurs. It can significantly impair a person's capacity to consider or use condoms (Weinhardt et al., 2001). However it seems that in the general population (as well as SMI) that substance intoxication at the time of sexual activity is fairly common (Brown

et al. (2010, 2011a, 2011b). Grassi et al. (1999) Coverdale et al. (2000) Koen et al. (2007)).

An additional factor to consider is sexual partners who are substance users 'sex with a partner who uses drugs' (Brown et al., 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999; Koen et al., 2007). Brown et al. (2010, 2011a, 2011b) found that twice as many (44.8%) people with SMI, compared with a non-SMI group had had sex with someone who had taken drugs or alcohol prior to sex ($p< 0.05$). Grassi et al. (1999) also reported higher rates of sex with a partner who uses drugs in an SMI population (16.7%) compared to a non-SMI group (4.5%) ($p=0.016$). Similar trends were also reported in other studies, however, their results were not statistically significant (Coverdale et al., 1997; Coverdale et al., 2000; Koen et al., 2007). This indicates the importance of not just asking about the individual's risk behaviours but also about the behaviours of the people that they have sex with (long term partners as well as more casual encounters).

2. Exploitative or coercive sex- Coverdale et al. (1997) reported that people with SMI were significantly more likely to report being pressured into sex compared with non-SMI group (34.3% v 7.7% p=0.001). Coverdale et al. (2000) found that 11% of people with SMI reported that they had been pressured into having unwanted sexual intercourse compared to 1% of the control group ($p= 0.016$). Other studies that compared SMI and non-SMI groups found non-significant results although, continued trends where people with SMI reported being pressured into unwanted sex more often than the control groups (Koen et al., 2007; Miller & Finnerty, 1996).

3. Sex trading- This involves sexual acts being exchanged for a commodity (often drugs, a place to stay, a meal etc.). This has been found to be more common in people with SMI (Brown et al 2010, 2011a, 2011b; Coverdale et al., 1997; Coverdale et al., 2000; Grassi et al., 1999). Koen et al., 2007 reported higher rates in SMI but this didn't reach statistical significance.

4. Multiple sexual partners (reported within a 12-month period) - Hyper-sexuality phases of illness may increase the risk of having multiple sexual partners (Meade et al., 2008). Coverdale et al. (1997) found a statistically significant difference between cases and controls for this risk behaviour, 36.4% of cases compared to 11.5% of the controls (p= 0.006). Grassi et al. (1999) also found a statistically significant difference; 53.1% of adults with SMI compared to 30% of the control group reported having multiple sexual partners (p< 0.01). Two other studies (Brown et al., 2010, 2011a, 2011b; Coverdale et al. 2000) also found that people with SMI were more likely to report multiple sexual partners in a twelve-month period than healthy controls. However, the results were not statistically significant.

This evidence suggests that people with SMI are more likely to engage in 'high risk' sexual behaviours and as such, are more at risk of contracting a BBV or other STI. The elevated prevalence rates of HIV and other STIs provide objective evidence that there is a real need to address sexual health in mental health. The following sections will address the perceptions of sexuality and expression in people with SMI and then we will consider the role of mental health nurses in promoting positive sexual relationships and lifestyles.

Perceptions of Sexuality and Expression in people with SMI

There are two stereotypes 'over-sexed' and 'under-sexed' that exist when we consider adult mental health and sex. The experience of 'over-sexed' has been acknowledged by Judd et al. (2009) for both men and women as a characteristic from psychotic disorders and bipolar disorder. In contrast, 'Under-sexed' is frequently seen for people experiencing depression, and as discussed by Krebs (2007) is poorly recognised and treated by health professionals. As with any stereotype, the truth lies somewhere in the middle and consistent with other stereotypes, should not be considered as universal truths. Sexual desire and expression can be seen as symptoms of mental illness and dismissed as such. This is especially true for people who express a desire to

transition to another gender (transgender), and in order to do this have to undergo psychiatric assessment to “prove” that this is not simply the manifestation of a mental illness (Drescher, Cohen-Kettenis and Winter, 2012).

The role of Mental Health Nurses in Promoting Sexual Health

Despite the emerging evidence of sexual health and relationship needs, the area of sexual health in mental health nursing has received limited attention.

McCann (2010a) undertook a study, which explicitly sought services user’s views and opinions regarding intimate relationships in a mental health service in North London, UK. The majority of respondents (90%) felt that they had needs in relation to sexual expression and 83% were interested in having intimate relationships (McCann 2010a). Although 43% of staff were unable to say whether their clients had intimacy needs, the clients themselves were fully able to articulate their hopes and expectations on the topic (McCann 2010b). In terms of psychosocial aspects of recovery, holistic assessments of need should include intimate relationships and address the person’s desires and wishes around forming and maintaining meaningful relationships (Government of Scotland, 2006).

In another UK study, Hughes and Gray (2009) undertook a survey of mental health staff about their knowledge and practice in relation to HIV and schizophrenia in a large mental health care provider in South London. The response rate was 44% (n=283) and half the respondents were registered nurses. The majority (80%) agreed that it was part of their role to discuss sexual health and that only 14% agreed that they felt uncomfortable discussing sexual health issues. Yet despite this, only 30% reported that they routinely discussed sexual health. The vast majority of respondents (81%) said that they did not assess for sexual side-effects of medication. There was a range of responses to clinical scenarios that suggested a lack of consistency of approach in the workforce. Around 2/3 of the respondents felt they needed access to more training and information on sexual health and topics suggested included challenging attitudes

to sexual health, communication skills to help feel more comfortable in talking about this topic, as well as more information on infections such as hepatitis B and C, and ethical issues and dilemmas.

Quinn and colleagues have examined this issue in Australia and found that (like McCann and Hughes and Gray studies in the UK) nurses in mental health settings tend to avoid starting a dialogue about sexual health and rarely addressed it in their role (Quinn et al., 2011) even though these mental health nurses were aware of the sexual health problems experienced by people with a SMI (Quinn et al., 2011).

However, in a further study Quinn was able to demonstrate that a specific training session on sexual health, could have an impact on nurse's behavior. They found that after training nurses increased their dialogue around sexual health describing the change process with a 5-As framework (Quinn et al., 2013). The 5-As framework acknowledges the difficulties and avoidance for nurses in including sexual health in care. The change process relying on education, awareness building and permission to engage with people regarding sexual health issues. The practice evolves, acknowledging the importance of sexual health for people with SMI, becoming part of the nurses' routine repertoire (Quinn et al., 2013). Whilst promising, its design, as well as being delivered in one service in Australia, limit the implications of this study. However, this is an area that needs to be explored in further studies.

Conclusion

Sexual health needs are significant in people with SMI, yet have not been addressed in assessment and care planning in mental health. There is an important role for mental health nurses in promoting safe and accepting environments for people with SMI, ensuring that they have access to information and adequate sexual health assessment to promote optimal sexual health. Research has indicated areas where need is greatest. The next step is to develop assessment tools and interventions that will meet this need in order to promote sexual health in the widest sense and to empower people

with SMI to have safe, satisfying and supportive intimate relationships. The locus of care is firmly established in the community and in order for people to thrive and live independent lives, then the area of sexuality and sexual expression should be recognized, emerge from the shadows and be firmly placed on the activities of living agenda. Whilst evidence suggests that mental health nurses tend to avoid talking about sexual health and relationship issues with service users, they are aware of their sexual health needs. Nurses are well placed to not only discuss sexual matters, but to enable people to develop the necessary life skills to promote sexual expression and to impact positively upon a person's recovery experience. Further research is needed to develop pragmatic interventions to be delivered in mental health services, as well as supporting staff to feel more comfortable in talking about sex and relationships.

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Appendix 2- AMSTAR 2 Checklist

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:
- ☐ Population
- ☐ Intervention
- ☐ Comparator group
- ☐ Outcome

Optional (recommended)
- ☐ Timeframe for follow-up

☐ Yes
☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:
The authors state that they had a written protocol or guide that included ALL the following:
- ☐ review question(s)
- ☐ a search strategy
- ☐ inclusion/exclusion criteria
- ☐ a risk of bias assessment

For Yes:
As for partial yes, plus the protocol should be registered and should also have specified:
- ☐ a meta-analysis/synthesis plan, if appropriate, *and*
- ☐ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

☐ Yes
☐ Partial Yes
☐ No

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:
- ☐ *Explanation for* including only RCTs
- ☐ OR *Explanation for* including only NRSI
- ☐ OR *Explanation for* including both RCTs and NRSI

☐ Yes
☐ No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):
- ☐ searched at least 2 databases (relevant to research question)
- ☐ provided key word and/or search strategy
- ☐ justified publication restrictions (e.g. language)

For Yes, should also have (all the following):
- ☐ searched the reference lists / bibliographies of included studies
- ☐ searched trial/study registries
- ☐ included/consulted content experts in the field
- ☐ where relevant, searched for grey literature
- ☐ conducted search within 24 months of completion of the review

☐ Yes
☐ Partial Yes
☐ No

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:
- ☐ at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include
- ☐ OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer.

☐ Yes
☐ No

Appendix 2- AMSTAR 2 Checklist continued

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

6. Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:
- ☐ at least two reviewers achieved consensus on which data to extract from included studies
- ☐ OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer.

☐ Yes
☐ No

7. Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes:
- ☐ provided a list of all potentially relevant studies that were read in full-text form but excluded from the review

For Yes, must also have:
- ☐ Justified the exclusion from the review of each potentially relevant study

☐ Yes
☐ Partial Yes
☐ No

8. Did the review authors describe the included studies in adequate detail?

For Partial Yes (ALL the following):
- ☐ described populations
- ☐ described interventions
- ☐ described comparators
- ☐ described outcomes
- ☐ described research designs

For Yes, should also have ALL the following:
- ☐ described population in detail
- ☐ described intervention in detail (including doses where relevant)
- ☐ described comparator in detail (including doses where relevant)
- ☐ described study's setting
- ☐ timeframe for follow-up

☐ Yes
☐ Partial Yes
☐ No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from
- ☐ unconcealed allocation, *and*
- ☐ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all-cause mortality)

For Yes, must also have assessed RoB from:
- ☐ allocation sequence that was not truly random, *and*
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

☐ Yes
☐ Partial Yes
☐ No
☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:
- ☐ from confounding, *and*
- ☐ from selection bias

For Yes, must also have assessed RoB:
- ☐ methods used to ascertain exposures and outcomes, *and*
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

☐ Yes
☐ Partial Yes
☐ No
☐ Includes only RCTs

10. Did the review authors report on the sources of funding for the studies included in the review?

For Yes
- ☐ Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information but it was not reported by study authors also qualifies

☐ Yes
☐ No

Appendix 2- AMSTAR 2 Checklist continued

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

RCTs

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
  - ☐ AND investigated the causes of any heterogeneity

☐ Yes
☐ No
☐ No meta-analysis conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
  - ☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available
  - ☐ AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review

☐ Yes
☐ No
☐ No meta-analysis conducted

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

☐ Yes
☐ No
☐ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

☐ Yes
☐ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
- ☐ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

☐ Yes
☐ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

☐ Yes
☐ No
☐ No meta-analysis conducted

Appendix 2- AMSTAR 2 Checklist continued

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- ☐ The authors reported no competing interests OR
- ☐ The authors described their funding sources and how they managed potential conflicts of interest

☐ Yes
☐ No

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Appendix 3- Registered systematic review protocol

Sexual risk behaviours associated with blood borne viruses and other sexually transmitted infections amongst adults with severe mental illness: protocol for a systematic review and meta-analysis of observational studies

1.1 Registration

In accordance with PRISMA-P guidelines (Shamseer et al., 2015) the systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) at http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015020703 (registration number CRD42015020703).

1.2 Authors

Named contact: Samantha J Gascoyne

Named contact email: samantha.gascoyne@york.ac.uk

Named contact address: Mental Health and Addictions Research Group

Department of Health Sciences

University of York

Heslington

YO10 5DD

Named contact phone number: +44 (0)1904 321103

Review Team Members and their organizational affiliations

Samantha Gascoyne,[1] Professor Simon Gilbody,[1,2] Professor Elizabeth Hughes,[3] Professor Catherine Hewitt[1], , Lucy Tindall,[1]

[1] Department of Health Sciences, University of York

[2] Hull and York Medical School

[3] University of Huddersfield and South West Yorkshire Partnership NHS Foundation Trust

1.3 Funding Sources/ sponsor

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1.4 Conflict of Interest

None known

2. Introduction

2.1 Aims of the review

The aim of this systematic review is to explore sexual risk behaviours associated with blood borne viruses and other sexually transmitted infections amongst adults with severe mental illness.

2.2 Condition or domain being studied

Severe mental illness (SMI)(defined by a diagnosis of mental illness that is persistent, disabling and requiring specialised psychiatry input (outpatient, community and/or inpatient admissions), Human Immunodeficiency Virus (HIV), Hepatitis B, Hepatitis C and other Sexually Transmitted Infections (STIs). This review concentrates on sexual risk behaviours. Sexual risk behaviours include acts such as unprotected sexual practices (anal, vaginal and oral intercourse), sexual trading (money, alcohol, drugs, cigarettes or accommodation) and paid sex work. However, this list is not exhaustive.

3. Methods

This review of evidence will be undertaken systematically following the guidelines by the Centre for Reviews and Dissemination for undertaking systematic reviews in health care (2009) and reported in line with the PRISMA statement (Liberati et al., 2009) and the MOOSE guidelines (Stroup et al., 2000).

3.1 Eligibility Criteria

Studies will be selected for inclusion in the review according to the criteria defined below.

3.1.1 Population

The population of interest for this review will be adults aged eighteen or over.

3.1.2 Exposure

The exposure considered in this review is adults with severe mental illness. For the purpose of this review severe mental illness is defined as a documented diagnosis of schizophrenia or delusional/psychotic illness (ICD 10 F20.9 & F22 or DSM-equivalent) or bipolar disorder (ICD F31 or DSM-equivalent) (APA, 2013; WHO, 2016). This SMI-inclusive diagnosis will need to have been made by a psychiatrist and be documented in case notes. It is anticipated that studies will have a mixture of diagnoses. Therefore, this review will include studies where the greatest proportion of the population (over 75%) has a diagnosis of severe mental illness.

3.1.3 Comparators/controls

The comparator population for this review are people with no history of severe mental illness.

3.1.4 Outcomes

The outcomes of interest for this review were sexual risk behaviours and the relevant odds ratios or relative risk estimates. These included engaging in unprotected sexual practices (vaginal, anal and oral intercourse), sexual trading (money, alcohol, drugs, cigarettes or accommodation) and paid sex work. However, this is not an exhaustive list. All tools (validated and non-validated) measuring sexual risk behaviours will be included in the review.

3.1.5 Study designs

The study designs included in this review will include prospective and retrospective comparative cohort studies, case-control or nested case-control studies and case cohort studies. Cross-sectional studies, case studies and case reports will be excluded.

3.2 Information sources

Broad sensitive literature search strategies will be developed in order to capture all relevant studies. The literature search strategy will be constructed in MEDLINE using medical subject headings (MeSH) and free text words. This will be adapted where necessary for other electronic databases. The search strategy will be based on terms for two constructs: SMI terms and BBV and other sexually transmitted infection terms.

The Search will consist of the following elements: searching electronic databases, checking reference lists of studies or reviews from retrieved papers, reverse citation

searches will be undertaken for any previous major review papers and grey literature resources will be searched.

The following electronic databases will be searched; AIDSLINE, CIHNAL, EMBASE, PsychINFO, MEDLINE in process and other Non-Indexed Citations and Web of Science. Grey literature resources will be searched to cover websites, conference proceedings and abstracts and dissertations and theses. Contact with experts in the field will also be made if necessary. There will be no date restrictions placed on the search. The review will include papers in all languages if a translation is available. In order to reduce publication bias wherever possible the review will include all relevant studies irrespective of publication status.

3.3 Study selection process

The results yielded by the literature search will be exported to an EndNote online library. In line with CRD guidelines (2009) study selection will occur in two stages using a study selection form developed for this review based on the inclusion criteria detailed in section 3.1. After deduplication the titles and abstracts will be independently reviewed for relevance by two reviewers in order to meet the inclusion criteria. For studies that appear to meet the inclusion criteria full papers will be independently reviewed by two reviewers using a piloted study selection form developed for this review and again the decision to include or exclude studies will be made on the inclusion criteria detailed below. Disagreements at both stages will be resolved by discussion and referred to an independent third reviewer if necessary.

Caution will be taken when assessing eligible studies as there may be multiple citations of particular studies. Multiple citations will be treated and included as single studies for this systematic review. These will be noted when reporting the study selection to ensure transparency of the review process.

3.4 Data collection process

The data extraction process will be undertaken independently by two reviewers using a data extraction form developed for this review. This will be piloted before the review begins. Extracted data will include demographic information, exposure details, methodological information and reported participant outcomes. Reviewers will resolve disagreements by discussion and referred to a third reviewer if necessary.

3.4 Data items

The data items from each study will include, study characteristics (study name, authors, year, location and setting of study), study design (sample size recruited, sample size included in analysis, selection of cases/controls, cohort- length of follow up), study population characteristics (age, gender, sexuality, ethnicity, diagnosis and method of diagnosis of SMI and BBV where appropriate), data on the comparability of groups and confounding factors considered, details of exposure of interest (sexually risky behaviour), risk of bias (see section 3.5) and outcome data (both adjusted and unadjusted multiple effect estimates if available, statistical methods used for controlling for potential confounding).

3.5 Risk of bias in individual studies

To assess the potential risk of bias within the included studies the methodological quality of primary studies will be assessed using the Newcastle-Ottawa Scale (NOS) (Wells et al., 2000) for assessing the quality of non-randomised studies in meta-analyses. This will be undertaken independently by two reviewers. Any disagreements will be resolved through discussion or referred to a third reviewer where necessary.

3.6 Data synthesis

Data will be tabulated and discussed in a narrative review. If studies are sufficiently homogeneous in terms of population, exposure, comparator and outcomes, meta-analyses will be undertaken using statistical software such as STATA. Heterogeneity will be explored statistically using the x^2 (significance level P<0.05) and the I^2 statistic (where 0% to 30% may not be important; 30%-50% may represent moderate heterogeneity; 50%-75% may represent substantial heterogeneity; 75%-100% may represent considerable heterogeneity). If statistical heterogeneity is observed (I^2 >50% or p<0.05) then a random effects meta-analysis model will be employed.

Where the included studies report adjusted odds ratios or risk ratios they will be pooled in a random effects meta-analysis to explore the overall association estimate. If studies report both adjusted and unadjusted odd ratios and risk ratios, all data will be extracted and sub-group analysis will be undertaken.

If statistical heterogeneity is substantial the results will take the form of a narrative synthesis where the relationships between and within the included studies will be explored.

3.6.1 Pre-planned analysis of subgroups

Subgroup meta-analyses will be performed to explore the differences in overall effect estimates if there are sufficient studies that report both unadjusted and adjusted effect estimates.

If there are sufficient studies sensitivity analyses will be undertaken including the strongest study designs to explore whether the significance of risk factors was dependent on including results from less robust study designs.

Publication bias will be assessed using the funnel plot if there are a sufficient number of studies to do so.

4. Dissemination

The review is being undertaken as part of a PhD with the aim of publication in a high quality, health-related peer reviewed journal.

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Appendix 4- Search strategy for MEDLINE

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

1 ((chronic$ or sever$ or persist$ or serious$) adj3 mental$ adj3 (ill$ or disorder$)).ti,ab.

2 exp Schizophrenia/

3 (schizophreni$ or hebephreni$ or oligophreni$ or psychotic$ or psychosis or psychoses).ti,ab.

4 delusional disorder$.ti,ab.

5 Paranoid Disorders/

6 exp Psychotic Disorders/

7 (paranoia or paranoid disorder$).ti,ab.

8 exp Bipolar Disorder/

9 ((bipolar or bi polar) adj3 (disorder$ or depress$ or ill$)).ti,ab.

10 (hypomania$ or mania$ or manic$).ti,ab.

11 (((cyclothymi$ or rapid or ultradian) adj3 cycl$) or RCBD).ti,ab.

12 or/1-11

13 exp Sexually Transmitted Diseases/

14 (sexually transmitted disease$ or STD or STDs).ti,ab.

15 (sexually transmitted infection$ or STI or STIs).ti,ab.

16 Chlamydia.ti,ab.

17 Gonorrhea$.ti,ab.

18 Syphil?is.ti,ab.

19 Genital Herpes.ti,ab.

20 Blood-Borne Pathogens/

21 (BBV or BBVs).ti,ab.

22 (blood borne virus$ or bloodborne virus$).ti,ab.

23 (blood born virus$ or bloodborn virus$).ti,ab.

24 HIV infections/

25 human immunodeficiency virus.ti,ab.

26 HIV.ti,ab.

27 exp Hepatitis C/

28 hep c.ti,ab.

29 hepatitis c.ti,ab.

30 HCV.ti,ab.

31 Hepacivirus/

32 exp Hepatitis B/

33 hepatitis B.ti,ab.

34 Hepatitis B virus/

35 HBV.ti,ab.

36 or/13-35

37 12 and 36

Key:

/= indexing term (MeSH heading- Medical subject headings)

exp= exploded MeSH heading

$= truncation

?- embedded truncation

.ti,ab.= terms in either title or abstract fields

adj= terms adjacent to eachother (same order)

adj3= terms within three words of each other (any order)

Appendix 5- Example relevance checking form

Inclusion/exclusion Criteria		
Diagnosis of SMI (over 75%)	Yes	No
Sexual risk behaviour in population is measured	Yes	No
Sexual risk behaviour in comparator group measured	Yes	No
Is there a comparator group?	Yes	No
Is it an observational study?	Yes	No
Cross-sectional study?	Yes	No

Rated by:	SG	LT	LH
Rated by third party?	Yes	No	
Decision	Included	Excluded	
Reason for exclusion:			

Appendix 6- Completed data extraction forms for case-control studies included in systematic review

Study characteristics (authors and year)	Brown et al. (2010, 2011a,2011b)
Study site (location)	Australia, Melbourne
Number of cases and controls	Cases n=67 Controls n=48
Sources and selection of cases and controls	Cases- convenience sample with first episode psychosis from youth mental health services. Controls- Fliers in public locations
Population characteristics (age, gender, SMI diagnosis, method of diagnosis	**Cases**: Gender: 19 females (28.4%), 48 males (71.6%), Age: 18-29years, M=22.0 (SD=2.4), Diagnosis: First episode psychosis as defined by DSM-IV criteria obtained from participants clinical file. **Controls:** Gender: 14 females (29.2%), 34 males (70.8%), Age: 18-29years M=21.8 (SD=3.6), Diagnosis**:** included if no history of psychosis or reported current mental health problems.
Comparability of groups and confounding factors considered	Groups 'closely' matched but criteria not defined in report.
Non-response rate?	N/A
Data collection/interview (measure used)	Sexual behavior as assessed using an adapted version of de Visser (2000) which included lifetime frequency of condom use with casual partner.
Confounding factors controlled for in analysis	For condom use- controlled for age, sex, education and employment.
Outcome data (Raw data)	Sex trading: cases 16.7%, controls 8.5% Sex with drug user: cases 44.8%, controls 22.9%. Alcohol/drugs prior to sex: cases 49.3%, controls 33.3%. More than one sexual partner: cases 74.6%, controls 70.8%. Inconsistent condom use (never): cases 52.3%, controls 55.1%.
Statistical methods used for potential confounding	Bivariate analysis, T-test and

Appendix 6- Completed data extraction forms for case-control studies included in systematic review continued

Study characteristics (authors and year)	Coverdale et al. (1997)
Study site (location)	New Zealand, Auckland
Number of cases and controls	Cases n=66 Controls n=66
Sources and selection of cases and controls	**Cases**- Referral by clinical staff from community mental health centre. **Controls**- recruited from waiting rooms of publically funded general hospital
Population characteristics (age, gender, SMI diagnosis, method of diagnosis	**Cases**: 66 females (100%), Age: 18-50, M=36.0 (SD=8.9), Diagnosis: obtained from retrospective chart review. Schizophrenia or schizoaffective disorder (54%), Bipolar disorder (23.8%), Major depression (9.5%), Other (12.7%). **Controls:** 66 females (100%), Age: 18-50, M=36.2 (SD=8.8), Diagnosis: included if never seen psychiatrist/psychologist nor been treated for mental illness.
Comparability of groups and confounding factors considered	Matched on gender, ethnicity and age (within 2 years)
Non-response rate?	Only sexually active participants were asked about risk behaviour- cases 35, controls 52.
Data collection/interview (measure used)	Semi-structured interview-STD risk behaviour assessed using adapted versions of Kelly et al. (1992) and McKinnon et al. (1993) sexual risk behaviour measures.
Confounding factors controlled for in analysis	Controlled for substance use disorder and marriage
Outcome data (Raw data)	Sex trading: cases 2.9%, controls 0% Sex with drug user: cases 2.9%, controls 0% Pressured into sex: cases 34.3%, controls 7.7% Sex with partner known less than 24hours: cases 17.1%, controls 7.7% More than one sexual partner: cases 36.4%, controls 11.5% Sex with a ‘suspected’ bi-sexual: cases 14.3%, controls 1.9%
Statistical methods used for potential confounding	Not reported

Appendix 6- Completed data extraction forms for case-control studies included in systematic review continued

Study characteristics (authors and year)	Coverdale et al. (2000)
Study site (location)	New Zealand, Auckland
Number of cases and controls	Cases n=92 Controls n=92
Sources and selection of cases and controls	**Cases**- Referral by clinical staff from community mental health centre. **Controls**- recruited from waiting rooms of publically funded general hospital
Population characteristics (age, gender, SMI diagnosis, method of diagnosis	**Cases**: 92 males (100%), Age: 18-51, M=35.6 (SD=8.2), Diagnosis: obtained from retrospective chart review. Schizophrenia or schizoaffective disorder (69%), Bipolar disorder (10%), other psychotic disorders (11%), Major depression (6%), Other (5%). **Controls:** 92 males (100%), Age 18-51, M=35.3 (SD=8.2), Diagnosis: included if never seen psychiatrist/psychologist nor been treated for mental illness
Comparability of groups and confounding factors considered	Excluded on substance use disorder Matched on gender, ethnicity, age (within 2 years).
Non-response rate?	Only sexually active participants were asked about risk behaviour- cases 49, controls 78.
Data collection/interview (measure used)	STD risk behaviour assessed using adapted versions of Volvaka et al. (1992) and McKinnon et al. (1993) sexual risk behaviour measures.
Confounding factors controlled for in analysis	Not reported
Outcome data (Raw data)	Sex trading: cases 20%, controls 13% Sex with drug user: cases 6%, controls 0% Pressured into sex: cases 11%, controls 1% Alcohol/drug use prior to sex: cases 36%, controls 37% Sex with partner known less than 24 hours: cases 32%, controls 12% More than one sexual partner: cases 31%, controls 19% Homosexual sex: cases 8%, controls 1%
Statistical methods used for potential confounding	Not reported

Appendix 6- Completed data extraction forms for case-control studies included in systematic review continued

Study characteristics (authors and year)	Grassi et al. (1999)
Study site (location)	Northern Italy
Number of cases and controls	Cases n=100 Controls n= 90
Sources and selection of cases and controls	**Cases**- Acute inpatient ward **Controls**- recruited from waiting rooms of a hospital
Population characteristics (age, gender, SMI diagnosis, method of diagnosis	**Cases**: 56 males (56%), 44 females (44%), Age: 18-55, M=36.2 (SD=9.4), Diagnosis: Psychiatric diagnosis assessed using the CIDI (1.1) according to ICD-10 criteria. Schizophrenia/schizotypal and delusional syndromes: n=65 (65%), affective syndromes: n=23 (23%), personality disorders n=12 (12%). **Controls:** Matched as above. Diagnosis: short psychiatric interview to confirm absence of current or previous mental illness.
Comparability of groups and confounding factors considered	Excluded on substance use disorder. Matched on age and gender.
Non-response rate?	N/A
Data collection/interview (measure used)	HIV risk behaviour using HIV-RBT
Confounding factors controlled for in analysis	Not reported
Outcome data (Raw data)	Sex trading: cases 8.3%, controls 3.3% Sex with a drug user, cases 16.7%, controls 4.5% Alcohol/drugs prior to sex: cases 23.7%, controls 18.8% Sex with partner known less than 24 hours: cases 35.4%, controls 27.7% More than one sexual partner: cases 53.1%, controls 30% Prostitution: cases 57%, control 23.5% Sex with a 'suspected' bi-sexual: cases 18.9%, controls 0% Inconsistent condom use (never): cases 43.3%, controls 13.3%
Statistical methods used for potential confounding	Not reported

Appendix 6- Completed data extraction forms for case-control studies included in systematic review continued

Study characteristics (authors and year)	Koen et al. (2007)
Study site (location)	South Africa Western Cape
Number of cases and controls	Cases n= 43 Controls n= 43
Sources and selection of cases and controls	**Cases-** recruited from psychiatric units. **Controls-** volunteer sample attending community health clinics for medical visits of any kind.
Population characteristics (age, gender, SMI diagnosis, method of diagnosis	**Cases**: 30 males (69.8%), 13 females (30.2%), Age: 18-65, M=33.95 (SD=10.8), Diagnosis: Assessed for Schizophrenia defined as DSM-IV using DIGS (version 2.0) **Controls:** 30 males (69.8%), 13 females (30.2%), Age: 18-65, M=34.5 (SD=10.4), Diagnosis: No details reported on inclusion or exclusion criteria for controls.
Comparability of groups and confounding factors considered	Matched on gender, race and age (within 5 years)
Non-response rate?	N/A
Data collection/interview (measure used)	Sexual risk behaviour using the AIDS risk behaviour Assessment Questionnaire (ARBAQ).
Confounding factors controlled for in analysis	Not reported
Outcome data (Raw data)	Sex trading: cases 11.6%, controls 0% Sex with a drug user: cases 4.7%, controls 0% Pressured into sex: cases 14%, controls 4.7% Alcohol/drugs prior to sex: cases 27.9%, controls 34.9% Sex with partner known for less than 24 hours: cases 41.9%, controls 25.6%
Statistical methods used for potential confounding	Not reported

Appendix 6- Completed data extraction forms for case-control studies included in systematic review continued

Study characteristics (authors and year)	Miller & Finnerty (1996)
Study site (location)	USA- area not reported
Number of cases and controls	Cases n=44 Controls n=50
Sources and selection of cases and controls	**Cases-** Inpatient and outpatient medical and psychiatric services. **Controls-** recruited from clinical setting for non-chronic physical illness.
Population characteristics (age, gender, SMI diagnosis, method of diagnosis	**Cases**: 44 females (100%), Age: 18-45 years, M=30.8 (SD=7.7), Diagnosis: Serious mental illness using RDC as determined by SADS-L and chart reviews. **Controls:** 50 females (100%), Age: 18-45years, M=30.8 (SD=7.7), Diagnosis: No history of major psychotic or mood disorder as defined by RDC.
Comparability of groups and confounding factors considered	Matched on age, race, education, employment status and religion
Non-response rate?	N/A
Data collection/interview (measure used)	HIV risk behaviours using modified versions of existing measures.
Confounding factors controlled for in analysis	Not reported
Outcome data (Raw data)	Pressured into sex: cases 46.5%, controls 39.6% Prostitution: cases 22.7%, controls 2% Homosexual sex: cases 16.7%, controls, 2%
Statistical methods used for potential confounding	Not reported

Appendix 7- Quality assessment for case-control studies (Newcastle-Ottawa Scale)

Study **(authors, year) Brown et al. (2010, 2011a, 2011b)**							
Selection				**Comparability**	**Exposure**		
Is the case definition adequate?	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
a) yes, with independent validation ★ b) yes, (e.g. record linkage or based on self-report) c) no description	a) consecutive or obviously representative series of cases **b) potential for selection biases or not stated** ★	**a) community controls** ★ b) hospital controls c) no description	**a) no history of disease** ★ b) no description of source	**a) study controls for important factors (age, gender, SUD etc.)** ★ b) study controls for any additional factors	a) secure record (clinical records) b) structured interview where blind to case/control status c) structured interview not blinded to case/control status **d) written self-report or medical record only** ★ e) no description	a) yes ★ b) no	a) same rate for both groups b) non-respondents described **c) rate different and no designation** ★

Appendix 7- Quality assessment for case-control studies (Newcastle-Ottawa Scale) continued

Study **(authors, year) Coverdale et al. (1997)**							
Selection				**Comparability**	**Exposure**		
Is the case definition adequate?	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
a) yes, with independent validation ★ b) yes, (e.g. record linkage or based on self-report) c) no description	a) consecutive or obviously representative series of cases **b) potential for selection biases or not stated** ★	a) community controls **b) hospital controls** ★ c) no description	**a) no history of disease** ★ b) no description of source	**a) study controls for important factors (age, gender, SUD etc.)** ★ b) study controls for any additional factors	a) secure record (clinical records) b) structured interview where blind to case/control status **c) structured interview not blinded to case/control status** ★ d) written self-report or medical record only e) no description	**a) yes** ★ b) no	a) same rate for both groups b) non-respondents described **c) rate different and no designation** ★

Appendix 7- Quality assessment for case-control studies (Newcastle-Ottawa Scale) continued

Study **(authors, year) Coverdale et al. (2000)**							
Selection				**Comparability**	**Exposure**		
Is the case definition adequate?	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
a) yes, with independent validation ★ b) yes, (e.g. record linkage or based on self-report) c) no description	a) consecutive or obviously representative series of cases **b) potential for selection biases or not stated** ★	a) community controls **b) hospital controls** ★ c) no description	**a) no history of disease** ★ b) no description of source	**a) study controls for important factors (age, gender, SUD etc.)** ★ b) study controls for any additional factors	a) secure record (clinical records) b) structured interview where blind to case/control status **c) structured interview not blinded to case/control status** d) written self-report or medical record only e) no description	**a) yes** ★ b) no	a) same rate for both groups b) non-respondents described **c) rate different and no designation** ★

Appendix 7- Quality assessment for case-control studies (Newcastle-Ottawa Scale) continued

Study **(authors, year) Grassi et al. (1999)**							
Selection				**Comparability**	**Exposure**		
Is the case definition adequate?	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
a) yes, with independent validation ★ b) yes, (e.g. record linkage or based on self-report) c) no description	a) consecutive or obviously representative series of cases **b) potential for selection biases or not stated** ★	a) community controls **b) hospital controls** ★ c) no description	**a) no history of disease** ★ b) no description of source	**a) study controls for important factors (age, gender, SUD etc.)** ★ b) study controls for any additional factors	a) secure record (clinical records) b) structured interview where blind to case/control status **c) structured interview not blinded to case/control status** ★ d) written self-report or medical record only e) no description	**a) yes** ★ b) no	a) same rate for both groups b) non-respondents described **c) rate different and no designation** ★

Appendix 7- Quality assessment for case-control studies (Newcastle-Ottawa Scale) continued

Study **(authors, year) Koen et al. (2007)**							
Selection				**Comparability**	**Exposure**		
Is the case definition adequate?	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
a) yes, with independent validation ★ b) yes, (e.g. record linkage or based on self-report) c) no description	a) consecutive or obviously representative series of cases **b) potential for selection biases or not stated** ★	a) community controls **b) hospital controls** ★ c) no description	a) no history of disease **b) no description of source** ★	**a) study controls for important factors (age, gender, SUD etc.)** ★ b) study controls for any additional factors	a) secure record (clinical records) b) structured interview where blind to case/control status **c) structured interview not blinded to case/control status** ★ d) written self-report or medical record only e) no description	**a) yes** ★ b) no	**a) same rate for both groups** ★ b) non-respondents described c) rate different and no designation

Appendix 7- Quality assessment for case-control studies (Newcastle-Ottawa Scale) continued

Study **(authors, year) Miller & Finnerty (1996)**							
Selection				**Comparability**	**Exposure**		
Is the case definition adequate?	**Representativeness of the cases**	**Selection of controls**	**Definition of controls**	**Comparability of cases and controls on the basis of the design or analysis**	**Ascertainment of exposure**	**Same method of ascertainment for cases and controls**	**Non-response rate**
a) yes, with independent validation ★ b) yes, (e.g. record linkage or based on self-report) c) no description	a) consecutive or obviously representative series of cases **b) potential for selection biases or not stated** ★	a) community controls **b) hospital controls** ★ c) no description	**a) no history of disease** ★ b) no description of source	**a) study controls for important factors (age, gender, SUD etc.)** ★ b) study controls for any additional factors	a) secure record (clinical records) b) structured interview where blind to case/control status **c) structured interview not blinded to case/control status** ★ d) written self-report or medical record only e) no description	a) yes ★ b) no	**a) same rate for both groups** ★ b) non-respondents described c) rate different and no designation

Appendix 8- Excluded studies with reasons for exclusion

Study	Reason for exclusion
Aral (2004)	Editorial response
Berkman et al. (2005)	RCT
Blalock and Wood (2015)	Theoretical report
Bonfils et al. (2015)	Risk behaviour not outcome
Brown et al. (2008)	Clinical implications paper
Buchanan et al. (2006)	Cross-sectional, No SMI
Brunette et al. (1999)	Less than 75% SMI- urban vs rural not c/c
Butterfield et al. (2004)	Cross-sectional
Butterfield et al. (2003)	Not observational study
Carey et al. (1997)	Literature review
Carey et al. (1999)	Not observational study- Archival data
Carey et al. (2001)	Less than 75% SMI- majority MDD 34%
Carey et al. (2004)	Less than 75% SMI- not c/x
Cates et al. (1994)	Not observational study
Chandra et al. (2003)	Less than 75% SMI- main MDD 58%
Checkley et al. (1996)	Review article
Chuang and Atkinson (1996)	Not observational study
Cividini et al. (1997)	Less than 75% SMI
Collins et al. (2008)	Not observational study
Cournos et al. (1994)	Not observational study
Cournos et al. (1993)	Not observational study
Cournos and McKinnon (1997)	Book chapter- not observational study
Cournos et al. (2001)	Discussion paper
Cournos et al. (2005)	Discussion paper

Coverdale (1996)	Discussion paper
Davidson et al. (2001)	Not observational
De Hert et al. (2009)	Letter to editor
De Hert et al. (2011)	Cross-sectional study
Dickerson et al. (2004)	Less than 75% SMI- risk not outcome
Dutra et al. (2014)	Cross-sectional
Dyer and McGuiness (2008)	Discussion paper
Elkington et al. (2010)	Not observational study
Essock et al. (2003)	Not observational study
Fishman et al. (1996)	Discussion paper
Freeman and Thom (2006)	Editorial
Gonzalez-Torres et al. (2010)	Less than 75% SMI- no validated measure
Goodman and Fallot (1998)	Not self-report risk behaviour
Grassi (1996)	Discussion paper
Guimarães et al. (2010)	Cross-sectional
Hariri et al. (2011a)	Not observational study
Hariri et al. (2011a)	Less than 75% SMI
Henning et al. (2012)	Prevalence study
Hercus et al. (2005)	Discussion paper
Hutchinson and Simeon (1999)	No risk behaviour outcome
Irwin et al. (2006)	Not SMI population

Appendix 8- Excluded studies with reasons for exclusion continued

Study	Reason for exclusion
Jonsson et al. (2011)	Cross-sectional- no validated tool
Kalichman et al. (1994)	Not observational study
Kalichman et al. (2005)	Less than 75% SMI- not validated tool
Karadaĝ et al. (2004)	Not observational study
Katz et al. (1994)	Not observational study
Kelly et al. (1992)	Not observational study
Kelly et al. (1995)	Less than 75% SMI?
Koen et al. (2007)	Not observational study
Kimhi et al. (1997)	Risk behaviour not outcome
King et al. (2008)	Not observational study
Knox et al (1994)	Less than 75% SMI- MDD and mood disorder ex bipolar main
Lacey et al. (2007)	Not observational study
Levounis et al. (2002)	Not observational study
Lommerse et al. (2013)	Cross-sectional- not all have SMI
Loue et al. (2011)	Major depression diagnosis
Loue et al. (2012)	Cross-sectional- not all had SMI
Majer et al. (2015)	Not SMI population
Maling et al. (2011)	Not observational study
Mason et al. (1995)	Discussion paper
McCann (2010)	Risk behaviour not outcome
McDermot et al. (1994)	Less than 75% SMI
McKinnon (1997)	Letter to editor
McKinnon et al. (1997)	Discussion paper
McKinnon et al. (2001)	Not observational study

McKinnon et al. (1996)	Not observational study
McKinnon and Rosner (2000)	Discussion chapter
Meade (2006)	Less than 75% SMI
Meade et al. (2011)	Not observational study
Meade et al. (2008)	Not observational study
Meade and Sikkema (2007)	Less than 75% SMI
Meade and Sikkema (2005)	Less than 75% SMI
Meade et al. (2009)	Less than 75% SMI
Meade et al. (2012)	Less than 75% SMI
Meade and Weiss (2007)	Review of literature
Meyer et al. (1995)	No validated risk behaviour outcome measure
Miller and Conover (1995)	No validated measure of sexual risk behaviour
Myers et al. (1997)	Not all of population have mental illness
NGwena (2011)	Not observational study
Ogunsemi et al. (2006)	Not observational study
Osher et al. (2003a)	Risk behaviour not outcome
Osher et al. (2003b)	Not observational study
Otto-Salaj et al. (1998)	Not observational study
Otto-Salaj and Stevenson (2001)	Discussion paper
Özcan et al. (2013)	Risk behaviour not an outcome
Pearson et al. (2008)	Less than 75% SMI

Appendix 8- Excluded studies with reasons for exclusion continued

Study	Reason for exclusion
Peixoto et al. (2014)	Cross-sectional
Prince et al. (2012)	Risk behaviour not outcome
Rahav et al. (1998)	Not observational study
Raja and Azzoni (2003)	Risk behaviour not an outcome
Randolph et al. (2007)	Not observational study
Rasch et al. (2013)	Less than 75% SMI
Ribeiro et al. (2012)	Not all SMI
Rosenberg et al. (2005)	Not observational study
Rosenberg et al. (2001)	Risk behaviour not an outcome
Rosenberg et al. (2003)	No validated measure of sexual risk behaviour
Safren et al. (2011)	Discussion paper
Schadè et al. (2013)	Depression only diagnosis
Sherba and Singer (2010)	Less than 75% SMI
Sollie et al. (1997)	Discussion paper
Stewart et al. (1994)	Not observational study
Strauss et al. (2006)	Cross-sectional study
Susser et al. (1997)	RCT
Swartz et al. (2003)	No validated measure of sexual risk behaviour
Thompson et al. (1997)	Not observational study
Tubman et al. (2003)	Cross-sectional- no validated measure of risk
Tucker et al. (2003)	Less than 75% SMI
Volavka et al. (1991)	Not observational study
Volavka et al (1992)	Not observational study

Wainberg, McKinnon (2008)	Not observational study
Weinhart et al. (1998)	Less than 75% SMI
Weinhart et al. (2001)	Less than 75% SMI
Weinhartj et al. (2002)	Not observational study
Woody et al. (1997)	No SMI diagnosis
Wright and Gayman (2005)	Not observational study

Appendix 9- Current protocol for acceptability and feasibility study (V4.0 27.04.17)

Feasibility and acceptability study of sexual risk behaviour in adults with severe mental illness in the UK: study protocol.

Miss Samantha Gascoyne[1], Professor Simon Gilbody[1], Professor Catherine Hewitt[1], Professor Elizabeth Hughes[2] and Professor Karen McKinnon[3].

Affiliations

[1] Department of Health Sciences, University of York, Heslington, York, YO10 5DD.

[2] Human and Health Sciences, University of Huddersfield, Queensgate, Huddersfield, HD1 3DH.

[3] Department of Psychiatry, Columbia University College of Physicians and Surgeons, New York, USA.

1.0 Background and Rationale

People with severe mental illness (SMI) experience significant inequalities in physical health and die on average 15-20 years earlier than the general population (BMA, 2014). In order to address this, physical health is higher on the health policy and practice agenda (DoH, 2010). However, sexual health is neglected from this. The World Health Organisation defines sexual health as “a state of physical, mental and social wellbeing in relation to sexuality. It requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free from coercion, discrimination and violence”, (WHO, 2006). Research evidence suggests that the sexual health of people with SMI is poor. There are a number of areas of concern:

- High levels of exploitation and violence in sexual relationships (intimate partner violence- IPV) (Howard et al., 2010a; Khalifeh et al., 2015)
- Stigma, leading to engagement in higher sexual risk behaviours (Elkington et al., 2010)
- People with SMI include key risk groups including men who have sex with men, and sex workers (and sex-trading) (Meade et al., 2009).
- An elevated risk of Blood Borne Viruses (BBVs), and other sexually transmitted infections (STI) (Hughes et al., 2015)
- Reduced use and access to contraceptives and higher levels of terminations of pregnancy (Coverdale et al., 1997; Matevosyan, 2009; Seeman and Ross, 2011)

Global prevalence rates of people with SMI have indicated a greater risk of HIV, Hepatitis B and C infections compared with expected rates found in the general population (Hughes et al., 2015). There is limited prevalence data from Europe. However, a recent meta-analysis found a pooled prevalence rate of HIV in the USA to be 6% in people with SMI compared with general population infection of around 0.6% in the USA (Hughes et al., 2015).

In addition, research has shown that people with SMI are sexually active, and some engage in ‘high risk’ sexual behaviours including unprotected sex, multiple partners, sex trading and sex work as well as risks associated with drug use itself (intoxication, impairing decision-making or leading to being exploited whilst under the influence) (Elkington et al., 2010; McKinnon et al., 2001; Meade et al., 2009). The link between SMI and high risk sexual behaviour is complex and likely to be influenced by unstable psychiatric symptoms (such as hyper-sexuality), comorbid drug and alcohol problems,

and sexual abuse and exploitation (McKinnon et al., 2001; Meade et al., 2008). Many of the studies have been undertaken in the USA with a very different set of cultural, organisational and socio-economic factors to the UK.

Sexual health issues are rarely discussed with service users in mental health settings (Hughes and Gray, 2009, McCann, 2010a, Quinn et al., 2011, Lagios and Deane, 2011). Hughes and Gray (2009) undertook a survey of mental health staff regarding their knowledge, attitudes and practice related to HIV and schizophrenia (the only UK survey related to this area). The main finding was that whilst staff reported feeling "comfortable" talking about sexual issues, they rarely did this in routine care. In addition, mental health staff also failed to perceive that people with schizophrenia may be at a higher risk of infection with BBVs.

Untreated sexually transmitted infections can lead to significant health problems (HPV can lead to cervical cancer; other STIs can result in infertility) and BBVs such as Hepatitis B and C can result in premature death. Co-morbidity of HIV and a serious mental illness such as schizophrenia poses particular challenges for both users and services even where efficacious HIV prevention strategies have been tested (McKinnon et al., 1999); in particular engagement with services and treatment adherence, as well as the psychiatric and neurological consequences compounding a pre-existing mental health problem (Angelino and Treisman, 2008). Early diagnosis and treatment has resulted in people living well with HIV and also has the potential to reduce onwards transmission. However many people are receiving late diagnosis for HIV and starting treatment after the point of maximum benefit (HPA, 2012). In addition, service users themselves value positive sexual relationships (McCann, 2010a) yet due to 'self-stigma' they feel limited in their choices of sexual partners and therefore end up being exposed to harmful relationships (Elkington et al., 2010; Wainberg et al., in press).

There is a need for us to be able to reliably assess those deemed to be at risk of contracting blood borne viruses and other STIs in this 'at risk' population in order for us to develop an intervention to promote positive sexual health and relationships. Much of the research in this field has be undertaken in the USA and Brazil (Cournos et al., 1994; Guimarães et al., 2014; McKinnon et al., 1993; Wainberg et al., 2008) and has demonstrated feasibility and acceptability with populations of people with SMI in those countries and also the studies did not experience any adverse events or exacerbation of symptoms as a result of participation in these studies (McKinnon et al., 1993).

As part of the Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC YH) there is a programme of research led by Professor Liz Hughes on improving the sexual health of people SMI. As part of this there is a three year funded studentship (Sam Gascoyne) which aims to examine the intersection between mental health and sexual health in people with severe mental health problems. In addition, Professor Hughes is chief investigator of a feasibility trial of an intervention to promote sexual health in people with SMI. However, this research has never been done in the UK and we need to consult with service users on the most effective ways of recruitment to a study related to this topic, as well as optimising comfort in undertaking an assessment of sexual health. Hence a small pilot study will be undertaken to inform the CLAHRC YH sexual health research programme.

2. Research Objectives

The overall aim is to undertake a small pilot study to examine recruitment processes, and get participant feedback on the acceptability of a sexual health interview.

2.1 Main objectives

1. Assess the feasibility and acceptability of undertaking a study of sexual risk behaviours by: assessment of numbers eligible, number consenting to participate and number of completed questionnaire/interviews.

2. Explore acceptability of data collection measures used and data collection method.

2.2 Secondary Objectives

So, In addition to the main aims, the following secondary aim will also be met by this study:

3. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused).

3. Methods

Potentially eligible participants will be identified by clinical staff in inpatient settings or community mental health services in the South West Yorkshire Partnership Foundation NHS Trust. The researcher will discuss the project both in team meetings and with individual staff and ask the teams to approach people on their caseloads who potentially meet inclusion criteria. The staff will have leaflets and a pack to give out to

people for initial information. If care co-ordinators agree then the researcher will attend outpatient clinics (clozapine/depot) to answer any questions potential participants may have about the research study.
A second recruitment method will be to mail out to people who have taken part in the Yorkshire Health and Wellbeing cohort study and who consented to being contacted again about research.

3.1 Inclusion and exclusion criteria

Inclusion criteria

- People over the age of 18
- Adults on the caseload of community mental health services with a diagnosis of schizophrenia, other psychotic/delusional disorders or bipolar disorder.

Exclusion criteria

- Adults with a primary diagnosis of substance use
- Adults with a primary diagnosis of cognitive impairment
- Those who lack capacity to consent as per the Mental Capacity Act
- Non-English speaking participants
- Those who on the sex offenders register

Adults with literacy difficulties will not be excluded; in these instances all study information and questionnaires will be read out to them.

We feel the option of providing translated versions of study questionnaires and interview schedule would not be feasible due to the scope of this small study.

3.2 Recruitment and consent

Recruitment will take place over a two month period in one study site, the South West Yorkshire Partnership Foundation NHS Trust. It is expected that a convenience sample of five men and five women with an eligible diagnosis will be recruited to take part in this study lasting approximately 60 minutes.

Potentially eligible participants will receive an information pack about the study via their case manager. This will contain a detailed participant information sheet (appendix 1) a simplified leaflet with information about the study (appendix 2) and a consent to contact form (appendix 3). The case manager who gives them the pack will be able to explain the study and obtain consent to contact. NHS trust communications networks will be utilised to raise awareness of the study and clinicians will receive (by email) information

about recruitment and eligibility, as well as information at team meetings. If care co-ordinators agree then the researcher will attend outpatient clinics (clozapine/depot) to answer any questions potential participants may have about the research study**.** A second recruitment method will be to mail out to people who have taken part in the Yorkshire Health and Wellbeing cohort study and who consented to being contacted again about research. This will include the same information as the packs handed out by clinicians but will also include a cover letter.

On receipt of a faxed or scanned signed consent to contact form the researcher will contact the person directly by telephone to confirm eligibility, and arrange for an appointment to meet at a mutually convenient time and venue.

The participant information sheet will provide contact details of the research team should participants wish to request further information about the study or ask any questions before providing their written consent.

On meeting with the researcher, a full oral explanation of the participant information leaflet will be given, participants will have a further opportunity to clarify any points they did not understand, or gain more information. If written informed consent is given (appendix 3- consent form) and the time is convenient for the participant, the questionnaire/interview session will also be done at the same time. However, if this is not convenient, a later date will be booked.

A copy of the consent form will be given to the participant; a copy will also be sent to their GP/case manager along with a letter (appendix 4) to inform them of their inclusion in the study with the participant's consent. A copy will also be stored securely in the participants' personal data file.

3.4 Data collection

As this is a feasibility and acceptability study, data will be collected from each participant at one time point by the researcher. The questionnaire/interview session will involve four parts (appendix 5- questionnaire/interview schedule), the first of which is a self-report questionnaire collecting minimal biographic and demographic information.

The second section is a self-report questionnaire, with questions about sexual lifestyle and attitudes. This has been adapted from the National Survey of Sexual Attitudes and Lifestyles 3 (NATSAL 3) which is a national general population British survey which began in 1990. The NATSAL has been adapted from a computer version to a self-

report paper version. Some of the domains have also been removed including, learning about sex, fertility testing and use of Viagra, as these are not directly relevant to the study objectives.

The third part of the interview session will take the form of a gold standard semi-structured interview, the sexual risk behaviour assessment schedule for adults (SERBAS) administered by the researcher to examine recent sexual behaviours. The SERBAS has high test re-test and inter-rater reliability (McKinnon et al., 1993). The SERBAS was initially developed in New York for injection drug users and then further adapted for psychiatric patients by a team of psychiatrists who worked in both inpatient units and community outpatient clinics. This will be the first time this interview has been administered in the UK SMI population.

The final part of the interview session will be a short self-complete questionnaire about the participant's experience (acceptability) of the interview/questionnaire session developed for this study.

The questionnaire/interview session will take place face to face at a time and location convenient to the participant (expected locations are health service, locations in the community or participant's homes). If the interview is to be conducted at a participant's home, then the researcher will seek advice about the safety of doing so from the key worker first. The researcher will follow a lone-worker policy as the questionnaire/interview session will be conducted on a one to one basis. Researcher protocols will also be in place for the disclosure of risks such as suicide and self-harm (appendix 6).

3.5 Primary outcomes

As this is a pilot feasibility study the primary outcome will be in line with the study objectives:

1. Recruitment rates: Quantitative assessment of the feasibility of the research will be assessed by numbers eligible, numbers consenting to participate and number of completed questionnaire/interviews.
2. Acceptability of the research will be assessed from outcomes of the experience/acceptability questionnaire and from in depth single interviews with mental health professionals.

3.6 Secondary outcomes

1. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused/missing data)

3.7 Data analysis

Due to the nature of this study all data will be presented descriptively with no formal statistical analyses undertaken as the study is not statistically powered to detect an association.

4.0 Qualitative study

In-depth single interviews will also be conducted among a purposive sample of between 5 and 7 mental health professionals (subject to data saturation), including diversity in age, professional grade and experience. The sample of mental health professionals will be recruited from the community mental health teams from South West Yorkshire Partnership NHS Foundation Trust that helped to recruit service users to the quantitative part of this PhD project. The interviews will explore their perceived importance of the subject of sexual health in relation to their service users, experience and comfort in discussing issues around sexual health and to identify any potential training needs. It is anticipated the interviews will last approximately thirty minutes.

The community mental health teams will be sent an information leaflet and a consent form by email. Before interviews commenced, written informed consent was obtained from all participants. The interviews will take place face to face where possible or over the telephone if more convenient.

All interviews with mental health professionals will be audio-recorded (subject to consent), transcribed verbatim and anonymised. Analysis will be undertaken by an individual researcher (SG- PhD student) using thematic analysis.

5. Withdrawal

Withdrawal can occur at any stage of the study following consent at the request of the participant. All personal information and data collected will be securely destroyed following the request to withdraw from the study.

6. Ethical issues

6.1 Anticipated risks and benefits

The well-being of our potential participants is of utmost importance, therefore, they will be approached about the study by a member of their care team in the first instance to confirm eligibility and to ensure they are able to provide informed written consent. A participant information leaflet will be provided with the contact details of the researcher

should a potential participant wish to ask further questions about the study before deciding whether to take part or not. Only when a consent to contact form has been received by the researcher will they then make contact by telephone with the potential participant. The researcher will contact the participant to arrange to meet at a time and place convenient to the participant. At this meeting, the researcher will give a full oral explanation of the study before obtaining informed written consent. If no consent to contact form is received, no contact will be made.

The main ethical issue from participating is potential embarrassment regarding discussing sexual behaviour, sexual health and relationships. We will also be aware that some people who have experienced sexual abuse and exploitation may find this study distressing and may trigger difficult feelings. In order to minimise this, people will be informed of the specific nature and content of the study prior to consent. We have made this point clear in the participant information sheet that the content may trigger upsetting memories.

Further ethical issues may relate to the potential disclosure of suicidal thoughts, self-harm or other potential risks (e.g. domestic abuse, risk to others). The researcher is an experienced mental health researcher and in addition has the support of senior mental health clinicians Professor Elizabeth Hughes (registered mental health nurse) and Professor Simon Gilbody (consultant psychiatrist). Hughes or Gilbody will be available by telephone for every interview scheduled. Also, within community mental health teams, a duty worker is on call at all times and the researcher will have the contact details of the duty worker when undertaking interviews. A detailed risk protocol will be in place to deal with such instances.

The questionnaire/interview session will take place face to face at a time and location convenient to the participant. This will be held within the premises of the South West Yorkshire Partnership NHS Trust during office hours 9-5pm. The questionnaire/interview session will be administered face to face due to the nature of the questionnaire and interview. The researcher will be there in case of any literacy or comprehension issues. Also some terminology regarding human sexual activity may be unfamiliar to some participants, therefore the researcher is there for clarification of terminology and to ensure they are as comfortable as possible.

There are no anticipated risks associated with the staff interviews.

6.2 Informing participants of anticipated risks and benefits

The participant information sheet will provide potential participants with information about the possible benefits and any known risks of taking part in the study. As the questionnaire/interview involves discussing some potentially sensitive topics, the participant information sheet will provide examples of areas that are covered in the questionnaire/interview. The participant information sheet suggests potential participants may wish to discuss their participation in this study with friends, family, GP or mental health professional. The participant information sheet also informs the participant that they will be given a £10 voucher for their time.

6.3 Obtaining consent

Potential participants will receive an information pack about the study from their case manager. The pack will contain a participant information sheet and a consent to contact form. The participant information sheet provides contact details for a member of the research team in the event a potential participant requests further information about the study. Consent to contact will be received prior to the potential participant being contacted by the researcher. A full oral explanation of the study will be given by the researcher before obtaining written informed consent and prior to any questionnaire/interview session taking place.

6.4 Retention of study documentation

All data will be stored for a minimum of five years at the University of York after the end of the final analysis of the study. Study data will be stored in accordance with the Department of Health Sciences Data Security Policy at the University of York. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records and will be destroyed securely at the end of the study. All electronic records will be stored on a password protected server within the Department of Health Sciences at the University of York. All personal information will be destroyed securely at the end of the study.

7. Public and patient involvement

Patient and public involvement (PPI) have contributed to the design and conduct of the proposed study and were all individuals with lived experience of SMI. A focus group was held in April 2015 to get advice on recruitment strategies, study documentation and data collection tools. This has been instrumental in the design of the study and the development of the study protocol. This study is designed to facilitate direct involvement in the recruitment and implementation of a sexual health interview to maximise recruitment and comfort in future studies.

8.0 Research governance

The study will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 Helsinki Declaration. Participants will not receive any financial incentive to participate in this study. The explicit wishes of the participant will be respected including the right to withdraw at any time. The interest of the participant will prevail over those of science and society. Provision will be made by the sponsor.

8.1 Suicide, self-harm and other potential risks

The participant's eligible for this study will have diagnoses consistent with severe mental illness (Bipolar disorder/Schizophrenia/Schizoaffective disorder or other psychotic disorder). There is a possible risk of suicide, self-harm or disclosures of other types of risk (e.g. domestic abuse, risk to other people). All participants will be subject to their usual GP care and community mental health services. However, we will follow good clinical practice in monitoring such risks during researcher encounters with study participants. Where any risks are disclosed, we will follow the study suicide/self-harm and other potential risk protocol (see appendix 6).

9.0 Study management

9.1 Study sponsorship

The University of York will act as the sponsor for this study

Dr Michael Barber
Intellectual Property Manager
University of York,
Research Innovation Centre,
York Science Park,
York,
YO10 5DG

9.2 Indemnity

Normal NHS indemnity procedures will apply. The University of York will also provide relevant cover.

9.3 Funding

This project is being funded as part of an NIHR CLAHRC PhD studentship.

9.4 Study management and responsibilities

The Chief Investigator (Miss Samantha Gascoyne) will have overall responsibility for the day to day running of the study. As this is part of a PhD project, Samantha will be supported by the academic supervisory team (Professor Liz Hughes, Professor Simon Gilbody and Professor Catherine Hewitt) who are all senior health researchers with significant experience of leadership. This supervisory team are also collaborating on the wider HTA funded RESPECT study as part of the CLAHRC YH programme of research. Professor Liz Hughes and Professor Simon Gilbody will be the clinical contacts where clinical advice is deemed necessary (as per risk protocol, see appendix 6). Professor Catherine Hewitt will provide statistical guidance where necessary. Professor Karen McKinnon is an international collaborator who will provide training and supervision on the use of the SERBAS interview schedule, with over twenty years of experience of administering the tool in an SMI population in both America and Brazil.

10. Dissemination

The findings from this study whilst not definitive, will inform how this population feel about discussing their sexual lifestyles and sexual behaviours. The findings will also provide feedback on the data collection methods and tools used and thereby inform future studies on sexual risk behaviour.

We will publish a report in a peer reviewed journal, produce a summary of the study for clinician and service user audiences, as well as informing the wider study (Samantha Gascoyne PhD) and HTA RESPECT study development. We will present the findings at conferences as an effective way of disseminating findings to key audiences of mental health professionals.

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Feasibility and acceptability study of sexual risk behaviour in adults with severe mental illness in the UK: study protocol.

Miss Samantha Gascoyne[1], Professor Simon Gilbody[1], Professor Catherine Hewitt[1], Professor Elizabeth Hughes[2] and Professor Karen McKinnon[3].

Affiliations

[1] Department of Health Sciences, University of York, Heslington, York, YO10 5DD.

[2] Human and Health Sciences, University of Huddersfield, Queensgate, Huddersfield, HD1 3DH.

[3] Department of Psychiatry, Columbia University College of Physicians and Surgeons, New York, USA.

1.0 Background and Rationale

People with severe mental illness (SMI) experience significant inequalities in physical health and die on average 15-20 years earlier than the general population (BMA, 2014). In order to address this, physical health is higher on the health policy and practice agenda (DoH, 2010). However, sexual health is neglected from this. The World Health Organisation defines sexual health as “a state of physical, mental and social wellbeing in relation to sexuality. It requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free from coercion, discrimination and violence”, (WHO, 2006). Research evidence suggests that the sexual health of people with SMI is poor. There are a number of areas of concern:

- High levels of exploitation and violence in sexual relationships (intimate partner violence- IPV) (Howard et al., 2010a; Khalifeh et al., 2015)
- Stigma, leading to engagement in higher sexual risk behaviours (Elkington et al., 2010)
- People with SMI include key risk groups including men who have sex with men, and sex workers (and sex-trading) (Meade et al., 2009).
- An elevated risk of Blood Borne Viruses (BBVs), and other sexually transmitted infections (STI) (Hughes et al., 2015)
- Reduced use and access to contraceptives and higher levels of terminations of pregnancy (Coverdale et al., 1997; Matevosyan, 2009; Seeman and Ross, 2011)

Global prevalence rates of people with SMI have indicated a greater risk of HIV, Hepatitis B and C infections compared with expected rates found in the general population (Hughes et al., 2015). There is limited prevalence data from Europe. However, a recent meta-analysis found a pooled prevalence rate of HIV in the USA to be 6% in people with SMI compared with general population infection of around 0.6% in the USA (Hughes et al., 2015).

In addition, research has shown that people with SMI are sexually active, and some engage in ‘high risk’ sexual behaviours including unprotected sex, multiple partners, sex trading and sex work as well as risks associated with drug use itself (intoxication, impairing decision-making or leading to being exploited whilst under the influence) (Elkington et al., 2010; McKinnon et al., 2001; Meade et al., 2009). The link between

SMI and high risk sexual behaviour is complex and likely to be influenced by unstable psychiatric symptoms (such as hyper-sexuality), comorbid drug and alcohol problems, and sexual abuse and exploitation (McKinnon et al., 2001; Meade et al., 2008). Many of the studies have been undertaken in the USA with a very different set of cultural, organisational and socio-economic factors to the UK.

Sexual health issues are rarely discussed with service users in mental health settings (Hughes and Gray, 2009, McCann, 2010a, Quinn et al., 2011, Lagios and Deane, 2011). Hughes and Gray (2009) undertook a survey of mental health staff regarding their knowledge, attitudes and practice related to HIV and schizophrenia (the only UK survey related to this area). The main finding was that whilst staff reported feeling "comfortable" talking about sexual issues, they rarely did this in routine care. In addition, mental health staff also failed to perceive that people with schizophrenia may be at a higher risk of infection with BBVs.

Untreated sexually transmitted infections can lead to significant health problems (HPV can lead to cervical cancer; other STIs can result in infertility) and BBVs such as Hepatitis B and C can result in premature death. Co-morbidity of HIV and a serious mental illness such as schizophrenia poses particular challenges for both users and services even where efficacious HIV prevention strategies have been tested (McKinnon et al., 1999); in particular engagement with services and treatment adherence, as well as the psychiatric and neurological consequences compounding a pre-existing mental health problem (Angelino and Treisman, 2008). Early diagnosis and treatment has resulted in people living well with HIV and also has the potential to reduce onwards transmission. However many people are receiving late diagnosis for HIV and starting treatment after the point of maximum benefit (HPA, 2012). In addition, service users themselves value positive sexual relationships (McCann, 2010a) yet due to 'self-stigma' they feel limited in their choices of sexual partners and therefore end up being exposed to harmful relationships (Elkington et al., 2010; Wainberg et al., in press).

There is a need for us to be able to reliably assess those deemed to be at risk of contracting blood borne viruses and other STIs in this 'at risk' population in order for us to develop an intervention to promote positive sexual health and relationships. Much of the research in this field has be undertaken in the USA and Brazil (Cournos et al., 1994; Guimarães et al., 2014; McKinnon et al., 1993; Wainberg et al., 2008) and has demonstrated feasibility and acceptability with populations of people with SMI in those

countries and also the studies did not experience any adverse events or exacerbation of symptoms as a result of participation in these studies (McKinnon et al., 1993).

As part of the Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC YH) there is a programme of research led by Professor Liz Hughes on improving the sexual health of people SMI. As part of this there is a three year funded studentship (Sam Gascoyne) which aims to examine the intersection between mental health and sexual health in people with severe mental health problems. In addition, Professor Hughes is chief investigator of a feasibility trial of an intervention to promote sexual health in people with SMI. However, this research has never been done in the UK and we need to consult with service users on the most effective ways of recruitment to a study related to this topic, as well as optimising comfort in undertaking an assessment of sexual health. Hence a small pilot study will be undertaken to inform the CLAHRC YH sexual health research programme.

2. Research Objectives

The overall aim is to undertake a small pilot study to examine recruitment processes, and get participant feedback on the acceptability of a sexual health interview.

2.1 Main objectives

3. Assess the feasibility and acceptability of undertaking a study of sexual risk behaviours by: assessment of numbers eligible, number consenting to participate and number of completed questionnaire/interviews.
4. Explore acceptability of data collection measures used and data collection method.

2.2 Secondary Objectives

So, In addition to the main aims, the following secondary aim will also be met by this study:

3. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused).

3. Methods

Potentially eligible participants will be identified by clinical staff in inpatient settings or community mental health services in the South West Yorkshire Partnership Foundation NHS Trust. The researcher will discuss the project both in team meetings and with

individual staff and ask the teams to approach people on their caseloads who potentially meet inclusion criteria. The staff will have **leaflets and** a pack to give out to people for initial information. **If care co-ordinators agree then the researcher will attend outpatient clinics (clozapine/depot) to answer any questions potential participants may have about the research study.**

A second recruitment method will be to mail out to people who have taken part in the Yorkshire Health and Wellbeing cohort study and who consented to being contacted again about research.

3.1 Inclusion and exclusion criteria

Inclusion criteria

- People over the age of 18
- Adults on the caseload of community mental health services with a diagnosis of schizophrenia, other psychotic/delusional disorders or bipolar disorder.

Exclusion criteria

- Adults with a primary diagnosis of substance use
- Adults with a primary diagnosis of cognitive impairment
- Those who lack capacity to consent as per the Mental Capacity Act
- Non-English speaking participants
- Those who on the sex offenders register

Adults with literacy difficulties will not be excluded; in these instances all study information and questionnaires will be read out to them.

We feel the option of providing translated versions of study questionnaires and interview schedule would not be feasible due to the scope of this small study.

3.2 Recruitment and consent

Recruitment will take place over a two month period in one study site, the South West Yorkshire Partnership Foundation NHS Trust. It is expected that a convenience sample of five men and five women with an eligible diagnosis will be recruited to take part in this study lasting approximately 60 minutes.

Potentially eligible participants will receive an information pack about the study via their case manager. This will contain a detailed participant information sheet (appendix 1) a **simplified leaflet with information about the study (appendix 2)** and a consent to

contact form (appendix **3**). The case manager who gives them the pack will be able to explain the study and obtain consent to contact. NHS trust communications networks will be utilised to raise awareness of the study and clinicians will receive (by email) information about recruitment and eligibility, as well as information at team meetings. **If care co-ordinators agree then the researcher will attend outpatient clinics (clozapine/depot) to answer any questions potential participants may have about the research study. A second recruitment method will be to mail out to people who have taken part in the Yorkshire Health and Wellbeing cohort study and who consented to being contacted again about research.**

On receipt of a faxed or scanned signed consent to contact form the researcher will contact the person directly by telephone to confirm eligibility, and arrange for an appointment to meet at a mutually convenient time and venue.

The participant information sheet will provide contact details of the research team should participants wish to request further information about the study or ask any questions before providing their written consent.

On meeting with the researcher, a full oral explanation of the participant information leaflet will be given, participants will have a further opportunity to clarify any points they did not understand, or gain more information. If written informed consent is given (appendix 3- consent form) and the time is convenient for the participant, the questionnaire/interview session will also be done at the same time. However, if this is not convenient, a later date will be booked.

A copy of the consent form will be given to the participant, a copy will also be sent to their GP/case manager along with a letter (appendix 4) to inform them of their inclusion in the study with the participants consent. A copy will also be stored securely in the participants personal data file.

3.4 Data collection

As this is a feasibility and acceptability study, data will be collected from each participant at one time point by the researcher. The questionnaire/interview session will involve four parts (appendix 5- questionnaire/interview schedule), the first of which is a self-report questionnaire collecting minimal biographic and demographic information.

The second section is a self-report questionnaire, with questions about sexual lifestyle and attitudes. This has been adapted from the National Survey of Sexual Attitudes and

Lifestyles 3 (NATSAL 3) which is a national general population British survey which began in 1990. The NATSAL has been adapted from a computer version to a self-report paper version. Some of the domains have also been removed including, learning about sex, fertility testing and use of Viagra, as these are not directly relevant to the study objectives.

The third part of the interview session will take the form of a gold standard semi-structured interview, the sexual risk behaviour assessment schedule for adults (SERBAS) administered by the researcher to examine recent sexual behaviours. The SERBAS has high test re-test and inter-rater reliability (McKinnon et al., 1993). The SERBAS was initially developed in New York for injection drug users and then further adapted for psychiatric patients by a team of psychiatrists who worked in both inpatient units and community outpatient clinics. This will be the first time this interview has been administered in the UK SMI population.

The final part of the interview session will be a short self-complete questionnaire about the participant's experience (acceptability) of the interview/questionnaire session developed for this study.

The questionnaire/interview session will take place face to face at a time and location convenient to the participant (expected locations are health service, locations in the community or participant's homes). If the interview is to be conducted at a participant's home, then the researcher will seek advice about the safety of doing so from the key worker first. The researcher will follow a lone-worker policy as the questionnaire/interview session will be conducted on a one to one basis. Researcher protocols will also be in place for the disclosure of risks such as suicide and self-harm (appendix 6).

3.5 Primary outcomes

As this is a pilot feasibility study the primary outcome will be in line with the study objectives:

1. Recruitment rates: Quantitative assessment of the feasibility of the research will be assessed by numbers eligible, numbers consenting to participate and number of completed questionnaire/interviews.
2. Acceptability of the research will be assessed from outcomes of the experience/acceptability questionnaire.

3.6 Secondary outcomes

1. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused/missing data)

4. Data analysis

Due to the nature of this study all data will be presented descriptively with no formal statistical analyses undertaken as the study is not statistically powered to detect an association.

5. Withdrawal

Withdrawal can occur at any stage of the study following consent at the request of the participant. All personal information and data collected will be securely destroyed following the request to withdraw from the study.

6. Ethical issues

6.1 Anticipated risks and benefits

The well-being of our potential participants is of utmost importance, therefore, they will be approached about the study by a member of their care team in the first instance to confirm eligibility and to ensure they are able to provide informed written consent. A participant information leaflet will be provided with the contact details of the researcher should a potential participant wish to ask further questions about the study before deciding whether to take part or not. Only when a consent to contact form has been received by the researcher will they then make contact by telephone with the potential participant. The researcher will contact the participant to arrange to meet at a time and place convenient to the participant. At this meeting, the researcher will give a full oral explanation of the study before obtaining informed written consent. If no consent to contact form is received, no contact will be made.

The main ethical issue from participating is potential embarrassment regarding discussing sexual behaviour, sexual health and relationships. We will also be aware that some people who have experienced sexual abuse and exploitation may find this study distressing and may trigger difficult feelings. In order to minimise this, people will be informed of the specific nature and content of the study prior to consent. We have made this point clear in the participant information sheet that the content may trigger upsetting memories.

Further ethical issues may relate to the potential disclosure of suicidal thoughts, self-harm or other potential risks (e.g. domestic abuse, risk to others). The researcher is an

experienced mental health researcher and in addition has the support of senior mental health clinicians Professor Elizabeth Hughes (registered mental health nurse) and Professor Simon Gilbody (consultant psychiatrist). Hughes or Gilbody will be available by telephone for every interview scheduled. Also, within community mental health teams, a duty worker is on call at all times and the researcher will have the contact details of the duty worker when undertaking interviews. A detailed risk protocol will be in place to deal with such instances.

The questionnaire/interview session will take place face to face at a time and location convenient to the participant. This will be held within the premises of the South West Yorkshire Partnership NHS Trust during office hours 9-5pm. The questionnaire/interview session will be administered face to face due to the nature of the questionnaire and interview. The researcher will be there in case of any literacy or comprehension issues. Also some terminology regarding human sexual activity may be unfamiliar to some participants, therefore the researcher is there for clarification of terminology and to ensure they are as comfortable as possible.

6.2 Informing participants of anticipated risks and benefits

The participant information sheet will provide potential participants with information about the possible benefits and any known risks of taking part in the study. As the questionnaire/interview involves discussing some potentially sensitive topics, the participant information sheet will provide examples of areas that are covered in the questionnaire/interview. The participant information sheet suggests potential participants may wish to discuss their participation in this study with friends, family, GP or mental health professional. **The participant information sheet also informs the participant that they will be given a £10 voucher for their time.**

6.3 Obtaining consent

Potential participants will receive an information pack about the study from their case manager. The pack will contain a participant information sheet and a consent to contact form. The participant information sheet provides contact details for a member of the research team in the event a potential participant requests further information about the study. Consent to contact will be received prior to the potential participant being contacted by the researcher. A full oral explanation of the study will be given by the researcher before obtaining written informed consent and prior to any questionnaire/interview session taking place.

6.4 Retention of study documentation

All data will be stored for a minimum of five years at the University of York after the end of the final analysis of the study. Study data will be stored in accordance with the Department of Health Sciences Data Security Policy at the University of York. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records and will be destroyed securely at the end of the study. All electronic records will be stored on a password protected server within the Department of Health Sciences at the University of York. All personal information will be destroyed securely at the end of the study.

7. Public and patient involvement

Patient and public involvement (PPI) have contributed to the design and conduct of the proposed study and were all individuals with lived experience of SMI. A focus group was held in April 2015 to get advice on recruitment strategies, study documentation and data collection tools. This has been instrumental in the design of the study and the development of the study protocol. This study is designed to facilitate direct involvement in the recruitment and implementation of a sexual health interview to maximise recruitment and comfort in future studies.

8.0 Research governance

The study will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 Helsinki Declaration. Participants will not receive any financial incentive to participate in this study. The explicit wishes of the participant will be respected including the right to withdraw at any time. The interest of the participant will prevail over those of science and society. Provision will be made by the sponsor.

8.1 Suicide, self-harm and other potential risks

The participant's eligible for this study will have diagnoses consistent with severe mental illness (Bipolar disorder/Schizophrenia/Schizoaffective disorder or other psychotic disorder). There is a possible risk of suicide, self-harm or disclosures of other types of risk (e.g. domestic abuse, risk to other people). All participants will be subject to their usual GP care and community mental health services. However, we will follow good clinical practice in monitoring such risks during researcher encounters with study participants. Where any risks are disclosed, we will follow the study suicide/self-harm and other potential risk protocol (see appendix 6).

9.0 Study management

9.1 Study sponsorship

The University of York will act as the sponsor for this study

Sue Final
Intellectual Property Manager
University of York,
Research Innovation Centre,
York Science Park,
York,
YO10 5DG

9.2 Indemnity

Normal NHS indemnity procedures will apply. The University of York will also provide relevant cover.

9.3 Funding

This project is being funded as part of an NIHR CLAHRC PhD studentship.

9.4 Study management and responsibilities

The Chief Investigator (Miss Samantha Gascoyne) will have overall responsibility for the day to day running of the study. As this is part of a PhD project, Samantha will be supported by the academic supervisory team (Professor Liz Hughes, Professor Simon Gilbody and Professor Catherine Hewitt) who are all senior health researchers with significant experience of leadership. This supervisory team are also collaborating on the wider HTA funded RESPECT study as part of the CLAHRC YH programme of research. Professor Liz Hughes and Professor Simon Gilbody will be the clinical contacts where clinical advice is deemed necessary (as per risk protocol, see appendix 6). Professor Catherine Hewitt will provide statistical guidance where necessary. Professor Karen McKinnon is an international collaborator who will provide training and supervision on the use of the SERBAS interview schedule, with over twenty years of experience of administering the tool in an SMI population in both America and Brazil.

10. Dissemination

The findings from this study whilst not definitive, will inform how this population feel about discussing their sexual lifestyles and sexual behaviours. The findings will also provide feedback on the data collection methods and tools used and thereby inform future studies on sexual risk behaviour.

We will publish a report in a peer reviewed journal, produce a summary of the study for clinician and service user audiences, as well as informing the wider study (Samantha

Gascoyne PhD) and HTA RESPECT study development. We will present the findings at conferences as an effective way of disseminating findings to key audiences of mental health professionals.

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Feasibility and acceptability study of sexual risk behaviour in adults with severe mental illness in the UK: study protocol.

Miss Samantha Gascoyne[1], Professor Simon Gilbody[1], Professor Catherine Hewitt[1], Professor Elizabeth Hughes[2] and Professor Karen McKinnon[3].

Affiliations

[1] Department of Health Sciences, University of York, Heslington, York, YO10 5DD.

[2] Human and Health Sciences, University of Huddersfield, Queensgate, Huddersfield, HD1 3DH.

[3] Department of Psychiatry, Columbia University College of Physicians and Surgeons, New York, USA.

1.0 Background and Rationale

People with severe mental illness (SMI) experience significant inequalities in physical health and die on average 15-20 years earlier than the general population (BMA, 2014). In order to address this, physical health is higher on the health policy and practice agenda (DoH, 2010). However, sexual health is neglected from this. The World Health Organisation defines sexual health as “a state of physical, mental and social wellbeing in relation to sexuality. It requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free from coercion, discrimination and violence”, (WHO, 2006). Research evidence suggests that the sexual health of people with SMI is poor. There are a number of areas of concern:

- High levels of exploitation and violence in sexual relationships (intimate partner violence- IPV) (Howard et al., 2010a; Khalifeh et al., 2015)
- Stigma, leading to engagement in higher sexual risk behaviours (Elkington et al., 2010)
- People with SMI include key risk groups including men who have sex with men, and sex workers (and sex-trading) (Meade et al., 2009).
- An elevated risk of Blood Borne Viruses (BBVs), and other sexually transmitted infections (STI) (Hughes et al., 2015)
- Reduced use and access to contraceptives and higher levels of terminations of pregnancy (Coverdale et al., 1997; Matevosyan, 2009; Seeman and Ross, 2011)

Global prevalence rates of people with SMI have indicated a greater risk of HIV, Hepatitis B and C infections compared with expected rates found in the general population (Hughes et al., 2015). There is limited prevalence data from Europe. However, a recent meta-analysis found a pooled prevalence rate of HIV in the USA to be 6% in people with SMI compared with general population infection of around 0.6% in the USA (Hughes et al., 2015).

In addition, research has shown that people with SMI are sexually active, and some engage in ‘high risk’ sexual behaviours including unprotected sex, multiple partners, sex trading and sex work as well as risks associated with drug use itself (intoxication, impairing decision-making or leading to being exploited whilst under the influence) (Elkington et al., 2010; McKinnon et al., 2001; Meade et al., 2009). The link between

SMI and high risk sexual behaviour is complex and likely to be influenced by unstable psychiatric symptoms (such as hyper-sexuality), comorbid drug and alcohol problems, and sexual abuse and exploitation (McKinnon et al., 2001; Meade et al., 2008). Many of the studies have been undertaken in the USA with a very different set of cultural, organisational and socio-economic factors to the UK.

Sexual health issues are rarely discussed with service users in mental health settings (Hughes and Gray, 2009, McCann, 2010a, Quinn et al., 2011, Lagios and Deane, 2011). Hughes and Gray (2009) undertook a survey of mental health staff regarding their knowledge, attitudes and practice related to HIV and schizophrenia (the only UK survey related to this area). The main finding was that whilst staff reported feeling "comfortable" talking about sexual issues, they rarely did this in routine care. In addition, mental health staff also failed to perceive that people with schizophrenia may be at a higher risk of infection with BBVs.

Untreated sexually transmitted infections can lead to significant health problems (HPV can lead to cervical cancer; other STIs can result in infertility) and BBVs such as Hepatitis B and C can result in premature death. Co-morbidity of HIV and a serious mental illness such as schizophrenia poses particular challenges for both users and services even where efficacious HIV prevention strategies have been tested (McKinnon et al., 1999); in particular engagement with services and treatment adherence, as well as the psychiatric and neurological consequences compounding a pre-existing mental health problem (Angelino and Treisman, 2008). Early diagnosis and treatment has resulted in people living well with HIV and also has the potential to reduce onwards transmission. However many people are receiving late diagnosis for HIV and starting treatment after the point of maximum benefit (HPA, 2012). In addition, service users themselves value positive sexual relationships (McCann, 2010a) yet due to 'self-stigma' they feel limited in their choices of sexual partners and therefore end up being exposed to harmful relationships (Elkington et al., 2010; Wainberg et al., in press).

There is a need for us to be able to reliably assess those deemed to be at risk of contracting blood borne viruses and other STIs in this 'at risk' population in order for us to develop an intervention to promote positive sexual health and relationships. Much of the research in this field has be undertaken in the USA and Brazil (Cournos et al., 1994; Guimarães et al., 2014; McKinnon et al., 1993; Wainberg et al., 2008) and has demonstrated feasibility and acceptability with populations of people with SMI in those

countries and also the studies did not experience any adverse events or exacerbation of symptoms as a result of participation in these studies (McKinnon et al., 1993).

As part of the Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC YH) there is a programme of research led by Professor Liz Hughes on improving the sexual health of people SMI. As part of this there is a three year funded studentship (Sam Gascoyne) which aims to examine the intersection between mental health and sexual health in people with severe mental health problems. In addition, Professor Hughes is chief investigator of a feasibility trial of an intervention to promote sexual health in people with SMI. However, this research has never been done in the UK and we need to consult with service users on the most effective ways of recruitment to a study related to this topic, as well as optimising comfort in undertaking an assessment of sexual health. Hence a small pilot study will be undertaken to inform the CLAHRC YH sexual health research programme.

2. Research Objectives

The overall aim is to undertake a small pilot study to examine recruitment processes, and get participant feedback on the acceptability of a sexual health interview.

2.1 Main objectives

5. Assess the feasibility and acceptability of undertaking a study of sexual risk behaviours by: assessment of numbers eligible, number consenting to participate and number of completed questionnaire/interviews.
6. Explore acceptability of data collection measures used and data collection method.

2.2 Secondary Objectives

So, In addition to the main aims, the following secondary aim will also be met by this study:

4. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused).

3. Methods

Potentially eligible participants will be identified by clinical staff in inpatient settings or community mental health services in the South West Yorkshire Partnership Foundation NHS Trust. The researcher will discuss the project both in team meetings and with

individual staff and ask the teams to approach people on their caseloads who potentially meet inclusion criteria. The staff will have a pack to give out to people for initial information.

3.1 Inclusion and exclusion criteria

Inclusion criteria

- People over the age of 18
- Adults on the caseload of community mental health services with a diagnosis of schizophrenia, other psychotic/delusional disorders or bipolar disorder.

Exclusion criteria

- Adults with a primary diagnosis of substance use
- Adults with a primary diagnosis of cognitive impairment
- Those who lack capacity to consent as per the Mental Capacity Act
- Non-English speaking participants

Those on the sex offenders register
Adults with literacy difficulties will not be excluded; in these instances all study information and questionnaires will be read out to them.

We feel the option of providing translated versions of study questionnaires and interview schedule would not be feasible due to the scope of this small study.

3.2 Recruitment and consent

Recruitment will take place over a two month period in one study site, the South West Yorkshire Partnership Foundation NHS Trust. It is expected that a convenience sample of five men and five women with an eligible diagnosis will be recruited to take part in this study lasting approximately 60 minutes.

Potentially eligible participants will receive an information pack about the study via their case manager. This will contain a detailed participant information sheet (appendix 1) and a consent to contact form (appendix 2). The case manager who gives them the pack will be able to explain the study and obtain consent to contact. NHS trust communications networks will be utilised to raise awareness of the study and clinicians will receive (by email) information about recruitment and eligibility, as well as information at team meetings. On receipt of a faxed or scanned signed consent to contact form the researcher will contact the person directly by telephone to confirm eligibility, and arrange for an appointment to meet at a mutually convenient time and venue.

The participant information sheet will provide contact details of the research team should participants wish to request further information about the study or ask any questions before providing their written consent.

On meeting with the researcher, a full oral explanation of the participant information leaflet will be given, participants will have a further opportunity to clarify any points they did not understand, or gain more information. If written informed consent is given (appendix 3- consent form) and the time is convenient for the participant, the questionnaire/interview session will also be done at the same time. However, if this is not convenient, a later date will be booked.

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3.5 Primary outcomes

As this is a pilot feasibility study the primary outcome will be in line with the study objectives:

3. Recruitment rates: Quantitative assessment of the feasibility of the research will be assessed by numbers eligible, numbers consenting to participate and number of completed questionnaire/interviews.
4. Acceptability of the research will be assessed from outcomes of the experience/acceptability questionnaire.

3.6 Secondary outcomes

2. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused/missing data)

4. Data analysis

Due to the nature of this study all data will be presented descriptively with no formal statistical analyses undertaken as the study is not statistically powered to detect an association.

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Withdrawal can occur at any stage of the study following consent at the request of the participant. All personal information and data collected will be securely destroyed following the request to withdraw from the study.

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6.1 Anticipated risks and benefits

The well-being of our potential participants is of utmost importance, therefore, they will be approached about the study by a member of their care team in the first instance to confirm eligibility and to ensure they are able to provide informed written consent. A participant information leaflet will be provided with the contact details of the researcher should a potential participant wish to ask further questions about the study before deciding whether to take part or not. Only when a consent to contact form has been received by the researcher will they then make contact by telephone with the potential participant. The researcher will contact the participant to arrange to meet at a time and place convenient to the participant. At this meeting, the researcher will give a full oral explanation of the study before obtaining informed written consent. If no consent to contact form is received, no contact will be made.

The main ethical issue from participating is potential embarrassment regarding discussing sexual behaviour, sexual health and relationships. We will also be aware that some people who have experienced sexual abuse and exploitation may find this study distressing and may trigger difficult feelings. In order to minimise this, people will be informed of the specific nature and content of the study prior to consent. We have made this point clear in the participant information sheet that the content may trigger upsetting memories.

Further ethical issues may relate to the potential disclosure of suicidal thoughts, self-harm or other potential risks (e.g. domestic abuse, risk to others). The researcher is an experienced mental health researcher and in addition has the support of senior mental health clinicians Professor Elizabeth Hughes (registered mental health nurse) and Professor Simon Gilbody (consultant psychiatrist). Hughes or Gilbody will be available by telephone for every interview scheduled. Also, within community mental health teams, a duty worker is on call at all times and the researcher will have the contact details of the duty worker when undertaking interviews. A detailed risk protocol will be in place to deal with such instances.

The questionnaire/interview session will take place face to face at a time and location convenient to the participant. This will be held within the premises of the South West Yorkshire Partnership NHS Trust during office hours 9-5pm. The questionnaire/interview session will be administered face to face due to the nature of the questionnaire and interview. The researcher will be there in case of any literacy or comprehension issues. Also some terminology regarding human sexual activity may be

unfamiliar to some participants, therefore the researcher is there for clarification of terminology and to ensure they are as comfortable as possible.

6.2 Informing participants of anticipated risks and benefits

The participant information sheet will provide potential participants with information about the possible benefits and any known risks of taking part in the study. As the questionnaire/interview involves discussing some potentially sensitive topics, the participant information sheet will provide examples of areas that are covered in the questionnaire/interview. The participant information sheet suggests potential participants may wish to discuss their participation in this study with friends, family, GP or mental health professional.

6.3 Obtaining consent

Potential participants will receive an information pack about the study from their case manager. The pack will contain a participant information sheet and a consent to contact form. The participant information sheet provides contact details for a member of the research team in the event a potential participant requests further information about the study. Consent to contact will be received prior to the potential participant being contacted by the researcher. A full oral explanation of the study will be given by the researcher before obtaining written informed consent and prior to any questionnaire/interview session taking place.

6.4 Retention of study documentation

All data will be stored for a minimum of five years at the University of York after the end of the final analysis of the study. Study data will be stored in accordance with the Department of Health Sciences Data Security Policy at the University of York. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records and will be destroyed securely at the end of the study. All electronic records will be stored on a password protected server within the Department of Health Sciences at the University of York. All personal information will be destroyed securely at the end of the study.

7. Public and patient involvement

Patient and public involvement (PPI) have contributed to the design and conduct of the proposed study and were all individuals with lived experience of SMI. A focus group was held in April 2015 to get advice on recruitment strategies, study documentation and data collection tools. This has been instrumental in the design of the study and the development of the study protocol. This study is designed to facilitate direct

involvement in the recruitment and implementation of a sexual health interview to maximise recruitment and comfort in future studies.

8.0 Research governance

The study will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 Helsinki Declaration. Participants will not receive any financial incentive to participate in this study. The explicit wishes of the participant will be respected including the right to withdraw at any time. The interest of the participant will prevail over those of science and society. Provision will be made by the sponsor.

8.1 Suicide, self-harm and other potential risks

The participant's eligible for this study will have diagnoses consistent with severe mental illness (Bipolar disorder/Schizophrenia/Schizoaffective disorder or other psychotic disorder). There is a possible risk of suicide, self-harm or disclosures of other types of risk (e.g. domestic abuse, risk to other people). All participants will be subject to their usual GP care and community mental health services. However, we will follow good clinical practice in monitoring such risks during researcher encounters with study participants. Where any risks are disclosed, we will follow the study suicide/self-harm and other potential risk protocol (see appendix 6).

9.0 Study management

9.1 Study sponsorship

The University of York will act as the sponsor for this study

Sue Final
Intellectual Property Manager
University of York,
Research Innovation Centre,
York Science Park,
York,
YO10 5DG

9.2 Indemnity

Normal NHS indemnity procedures will apply. The University of York will also provide relevant cover.

9.3 Funding

This project is being funded as part of an NIHR CLAHRC PhD studentship.

9.4 Study management and responsibilities

The Chief Investigator (Miss Samantha Gascoyne) will have overall responsibility for the day to day running of the study. As this is part of a PhD project, Samantha will be supported by the academic supervisory team (Professor Liz Hughes, Professor Simon Gilbody and Professor Catherine Hewitt) who are all senior health researchers with significant experience of leadership. This supervisory team are also collaborating on the wider HTA funded RESPECT study as part of the CLAHRC YH programme of research. Professor Liz Hughes and Professor Simon Gilbody will be the clinical contacts where clinical advice is deemed necessary (as per risk protocol, see appendix 6). Professor Catherine Hewitt will provide statistical guidance where necessary. Professor Karen McKinnon is an international collaborator who will provide training and supervision on the use of the SERBAS interview schedule, with over twenty years of experience of administering the tool in an SMI population in both America and Brazil.

10. Dissemination

The findings from this study whilst not definitive, will inform how this population feel about discussing their sexual lifestyles and sexual behaviours. The findings will also provide feedback on the data collection methods and tools used and thereby inform future studies on sexual risk behaviour.

We will publish a report in a peer reviewed journal, produce a summary of the study for clinician and service user audiences, as well as informing the wider study (Samantha Gascoyne PhD) and HTA RESPECT study development. We will present the findings at conferences as an effective way of disseminating findings to key audiences of mental health professionals.

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Appendix 10- Service user participant information sheet

Sexual risk behaviour in adults with Severe Mental Illness (IRAS ID 202431)

Participant Information Sheet

Sexual health and safe intimate relationships are an important part of life and often an area we all tend to neglect. We know from previous studies and from talking with people themselves that there are a number of concerns that we would like to understand better. These include:

- Access to contraception and family planning
- Keeping safe from infections that are transmitted sexually (such as HIV)
- Understanding the risks that certain sexual behaviours pose
- How to promote positive sexual relationships free from abuse and bullying.

In the UK there appears to have been little research on this subject. So, we need your help in understanding sexual health issues from your perspective. This is so we can design studies in the future that will be comfortable and useful to people who use services, and the ultimate aim will be to improve the service responses.

What is the purpose of this study?

We want your opinion! We would like to invite you to take part in this. Before you decide, it's important to know what you are signing up to. So we have provided information below and the researcher will talk through all the detail. If you want, you can take some time to discuss with family, friends or a member of your care team before you decide. Our contact details are on the back page if you would like any more information.

Who is doing the study?

This study is being led by Sam Gascoyne who is a doctoral student at the University of York. She is supported by Professor Liz Hughes (University of Huddersfield), Professor Simon Gilbody and Professor Catherine Hewitt (University of York).

Why have I been asked to participate?

We are inviting anyone with a diagnosis of severe mental illness receiving care in the South West Yorkshire Partnership NHS Foundation trust.

Do I have to take part?

It is entirely your decision whether to take part or not. If you do decide to take part, you are free to withdraw from the study at any time without giving a reason. Your decision to take part or not has no impact on your care and treatment in the South West Yorkshire Trust.

What will be involved if I take part in this study?

You will be taking part in one interview session with a specially trained researcher (Sam Gascoyne). This will be at a time and location that is most suitable to you and within the premises of the South West Yorkshire Partnership NHS Trust. The session will last a maximum of 90 minutes but is likely to take much less time.

There are four sections to interview session.

1. A few questions about yourself
2. A questionnaire to complete about sexual lifestyle and attitudes (topics include: first sexual experience, contraception, sexual attraction, non-consensual sex, sex for money and sexually transmitted infections).
3. Questions about your recent sexual activity and sexual practises.
4. A short questionnaire about your experiences of taking part in a study about sexual health.

Your comfort is very important to us. Breaks may be taken at any point or the session can stop if you don't feel comfortable answering the questions.

What are the advantages/benefits and disadvantages/risks of taking part?

We want to ensure that future research takes into account the views and experience of people who live with mental illness. We want to understand from your perspective how this interview feels, and how to ensure that people feel as comfortable as possible with the process.

However, this is a topic related to private issues. We will be asking about personal and intimate things however, none of the questions are compulsory. Most people feel a bit embarrassed when asked these questions. However, we also know that these types of questions can trigger upsetting memories. This is something to consider before you

decide to take part. If any of the questions asked make you worried that you may have some sexual health concerns, we provide a list of local services and if you specifically request it, we can pass on your concerns to your key worker or GP who will help you access information, testing and treatment if needed.

You will be given a £10 voucher to thank you for your time.

Can I withdraw from the study at any time?

Taking part is completely up to you. It is voluntary and you are free to withdraw from the study at any time without giving any reason. There are no consequences to this and this will have no bearing on your treatment. If you decide to withdraw from the study, your personal information and any data collected will be securely destroyed.

Will the information I give be kept confidential?

Yes. Information collected about you during the study will be stored in accordance with the Data Protection Act. Any personal information which could identify you will be kept separately from your study information and will only be accessed by members of the research team.

We will destroy all personal information immediately after the end of the study. We will store your study information securely for 5 years and then destroy it.

Limitations to confidentiality

- **The safety of yourself and others is very important to us. If during any part of the study process you express current or future intention to harm yourself, someone else or you are at risk of harm from another person, there would be no grounds for maintaining confidentiality**. Your case manager or a duty worker will be informed of your thoughts/intentions. We will inform you that we need to breach confidentiality at the point of disclosure.

What will happen to the results of the study?

The study findings will be published in a research report and in articles for health professionals. We will also send you a summary of the study findings at the end of study. You will not be personally identified in any publications from this study.

Who has reviewed this study?

This study has been reviewed and approved by the Health Sciences Research Governance Committee at the University of York. The research has also been reviewed and approved by Liverpool Central NHS ethics committee.

Who do I contact in the event of a complaint?

In the first instance you can raise any queries or concerns with the educational supervisor (Professor Liz Hughes at the University of Huddersfield on 07714615199). If you're not happy with the care or treatment you've received as part of this study, you have the right to complain. Your local Patient Advice and Liaison Service (PALS) will be able to help you make a complaint. Phone NHS 111 for details of your nearest PALS.

What should I do now?

If you would like to take part in this study, please give the completed consent to contact form to your case manager. The researcher will then contact you to arrange to meet face to face. On meeting with the researcher, a full oral explanation of the study will be given and there will be an opportunity for you to ask questions. If you are then happy to provide written consent and the time is convenient, the questionnaire/interview session will also be done at the same time. However, if this is not convenient, we can arrange a later date.

If you decide that you do not wish to take part, no further action is required.

If you agree to take part, would like more information or have any questions or concerns about the study please contact:

For specific information about this study please contact:

Study coordinator: Samantha Gascoyne
Address: Mental Health and Addictions Research Group, ARRC building, Department of Health Sciences, University of York, Heslington, York, YO10 5DD
Telephone: mobile 07552285845
Email: samantha.gascoyne@york.ac.uk

This study is funded by the National Institute for Health Research: Collaboration for Leadership in Applied Health Research (PhD studentship).

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

Appendix 11- Simple information leaflet for potential service user participants

UNIVERSITY of York

NHS South West Yorkshire Partnership NHS Foundation Trust

Sexual health PhD study information for potential participants

- Sexual health is topic often ignored in mental health research and clinical services
- This subject has been researched in USA and Brazil for over 20 years- participant's have enjoyed talking about a 'normal' aspect of life.
- This study has been reviewed and approved by an NHS ethics committee.

Please contact study manager Samantha Gascoyne on 07552285845 or via email at Samantha.Gascoyne@york.ac.uk if you would like more information.

Simple participant leaflet V1.0 20/03/2017

- It's an opportunity for you to contribute to the development of a new tool to assess sexual health.
- We want the views of people with lived experience in order to design a more "user friendly tool".
- Information is completely confidential and not shared with clinical team (except disclosure of significant risk to self/others)
- You don't have to answer anything they don't feel comfortable about (this is part of what we are trying to find out).
- Interview up to 1.5hrs but likely to be much less.
- The researcher is trained to use the questionnaire and is experienced in mental health research
- Talking to the researcher doesn't commit you to the study.
- You will be given a £10 voucher for your time

Appendix 12- Service user consent to contact form

South West Yorkshire Partnership NHS
NHS Foundation Trust

UNIVERSITY of York
The Department of Health Sciences

University of HUDDERSFIELD

Sexual risk behaviour in adults with Severe Mental Illness (IRAS ID 202431)

CONSENT TO CONTACT FORM

Contact details for researcher: Samantha Gascoyne, Mental Health and Addictions Research Group, Department of Health Sciences, University of York, Heslington, York, YO10 5DD.

Email: *Samantha.gascoyne@york.ac.uk*

Mobile: 07552285845

I agree that my contact details as given below can be given (in person or by telephone or via post) to the researchers carrying out this study. This will enable them to contact me and arrange a time/place to explain the study in more detail so that I can then decide whether or not to take part.

BLOCK CAPITALS PLEASE:

Name: ……

Address: ……

Postcode: ……

Main contact number: ……

Alternative contact number: ……..

Email: ……

Preferred method of contact:……..

Signature: ……

Date: _____/_____/20____

PLEASE RETURN THIS COMPLETED FORM TO YOUR CASE MANAGER WHO WILL PASS IT TO THE RESEARCH TEAM.

Appendix 13- Covering letter for service users in Health and Wellbeing Cohort

With all of us in mind

South West Yorkshire Partnership NHS
NHS Foundation Trust

UNIVERSITY of York
The Department of Health Sciences

University of HUDDERSFIELD

Dear insert name,

We are writing to let you know that the South West Yorkshire Mental Health Community Mental Health Teams are supporting a research study exploring the sexual health of people with severe mental illness. Sexual health means not just being free of sexually transmitted infections, it's also about being able to express your sexuality and sexual identity, as well as feel safe and respected in intimate relationships.

This study is an opportunity for people with lived experience to contribute to the development of a new more "user friendly" tool to assess sexual health.

Please find enclosed some information which tells you a more about the study, what being involved would mean for you and the people who are organising it. The study is looking for people who are currently using mental health services. If you are interested in knowing more about the study please complete the 'consent to contact form' enclosed. Completing the 'consent to contact' form just allows a researcher from the study to get in touch with you, it does NOT mean you have agreed to take part. The form can be returned to me using the freepost envelope enclosed and someone will be in touch to tell you more about the study.

I would be grateful if you would take the time to read the leaflet to help you decide. Please get in touch if there is anything that is not clear to you or if you would like more information.

Yours sincerely,

Study coordinator

Appendix 14- Service user consent form

	Please confirm agreement to the statements by putting your initials in the boxes below
I have read and understood the participant information sheet [date 22/03/2016, version 2]	
I have had the opportunity to ask questions and discuss this study	
I have received satisfactory answers to all of my questions	
I have received enough information about the study	
I understand my participation in the study is voluntary, will not affect my future care, and that I am free to withdraw from the study:- 1 At any time 2 Without having to give a reason for withdrawing	
I agree to my GP/case manager being informed of my participation in the study.	
I understand that any information I provide, including personal details, will be kept confidential, stored securely and only accessed by those carrying out the study. 1. I understand that confidentiality may need to be breached in situations where I am at risk of harm from others or at risk of harming myself.	
I understand that any information I give may be included in published documents but all information will be anonymised.	
I would like to receive a written summary of the results of the study.	
I agree to take part in this study	
Participant Signature ……	Date
Name of Participant	
Researcher Signature ……..	Date
Name of Researcher	

Appendix 15- Letter informing GP/case manager of study participation

South West Yorkshire Partnership NHS
NHS Foundation Trust

UNIVERSITY of York
The Department of Health Sciences

University of HUDDERSFIELD

Mental Health and Addictions Research Group
Department of Health Sciences
University of York
Heslington,
York,
YO10 5DD

Email:Samantha.gascoyne@york.ac.uk
Telephone: (TBC)

Our ref: <*Study ID*>

<*Name of G/CMHT case manager*>
<*Name of Practice*>
<*Address 1*>
<*Address 2*>
<*Address 3*>
<*Address 4*>
<*Postcode*>

<*Insert Date*>

Dear <*Name of GP/Practice Manage/case managerr*>

Re: <Forename> <MiddleName> <Surname> <DOB>

I am writing to inform you that your patient, «Forename» «MiddleName» «Surname», has recently consented to take part in a research study at the University of York.

An information leaflet describing the study is enclosed for your information, in addition to a copy of the consent form signed by the patient.

Please do not hesitate to contact us if you have any queries or would like any more information about the study.

Yours sincerely,

S. Gascoyne

Samantha Gascoyne
Study Coordinator

Appendix 16- Service user demographic questionnaire

Thank you very much for taking the time to take part in this study. Before we begin the questionnaire/interview we would first like to gather some background information. Please circle the answers most relevant to you. If you have any questions at any time please do not hesitate to ask.

Section one- Background information

Age:

18-30

31-40

41-50

51-60

60+

Gender:

Male

Female

Other (please specify):

Sexuality:

Heterosexual

Homosexual

Bisexual

Other (please specify):

Relationship status:

Single

Married

Divorced/separated

In steady relationship

In casual relationship

Diagnosis (please specify):……..

Are you currently taking any antipsychotic medication?

Appendix 17- Adapted version of the NATSAL

Section two- NATSAL

Section 2.1- First sexual experience

1. How old were you when you first had sexual intercourse with someone of the opposite sex, or hasn't this happened?

2. How old were you when you first had any type of experience of a sexual kind - for example, kissing, petting, or feeling one another - with someone of the opposite sex (or hasn't this happened either)?

The next few questions are about the first time you had sexual intercourse with someone of the opposite sex (that is, the first person you had sex with after you turned 13).

3. How old was that partner at that time?

4. As far as you now know, was it (also) your partner's first time ever, or not? If don't know Do you think it was (her/his) first time, or not?

a) Yes, first time

b) Think it was first time

c) Think it was not first time

d) No, not first time

5. Would you say that you were both equally willing to have intercourse that first time, or was one of you more willing than the other? If one more willing: Who was more willing?

a) Both equally willing

b) Respondent more willing

c) Partner more willing

6. Would you say..?

a) that you were also willing, (go to 9)

b) or, that you had to be persuaded (go to 9)

c) or, that you were forced? (go to 7)

7. If forced… Was any form of contraception used on that occasion, or not?

a) Condom (Sheath/Durex)

b) The Pill

c) Emergency contraception

d) Other contraception

e) No contraception used

8. If forced… Which one of these descriptions best applies to you and this person at that time?

a) It was someone I didn't know

b) We had recently met

c) We had known each other for a while, but were not in a steady relationship

d) We used to be in a steady relationship, but were not at that time

e) We were in a steady relationship

f) We were living together as a couple / married at the time

g) Something else

(go to 11)

9. Did you or your partner use any form of contraception or take any precautions that first time, or not?

a) Condom (Sheath/Durex)

b) The Pill

c) Emergency contraception

d) Other contraception

e) (partner) withdrew

f) Made sure it was a safe period

g) No precautions by me, don't know about partner

h) No precautions by either of us

10. Which one of these descriptions applies best to you and your partner at the time you had you first had intercourse?

a) We had just met for the first time

b) We had recently met

c) We had known each other for a while, but were not in a steady relationship

d) We used to be in a steady relationship, but were not at that time

e) We were in a steady relationship at the time

f) We were living together as a couple/married at the time

11. How did you meet the person who you first had sexual intercourse with?

a) At school

b) At university or college

c) At work (or through work)

d) In a pub, bar, night club, dance, or disco

e) Introduced by friends or family

f) Through a sports club, faith group, or other organisation or society

g) Holiday or while travelling

h) Internet dating website

i) Other dating agency/personal ad

j) Online, but not through a dating website

k) Had always known each other (eg as family friends or neighbours)

l) Neighbour/lived locally/house or flatshare

m) Arranged marriage

n) In a public place (e.g. park, cafe, shop, public transport)

o) (MEN ONLY) She was a sex worker / prostitute

p) Other (Specify at next question)

12. Looking back now to the first time you had sexual intercourse, do you think...

a) ...you should have waited longer before having sex with anyone,

b) or, that you should not have waited so long,

c) or, was it about the right time?

13. Which of these things applied to you at the time? Can answer more than one.

a) I was curious about what it would be like

b) I was carried away by my feelings

c) Most people in my age group seemed to be doing it

d) It seemed like a natural 'follow on' in the relationship

e) I was a bit drunk at the time

f) I had smoked some cannabis

g) I had taken some other drugs

h) I wanted to lose my virginity

i) I was in love

j) Other particular factor (SPECIFY AT NEXT QUESTION)

k) Can't remember

14. If more than one please choose the main one that applied at the time…

a) I was curious about what it would be like

b) I was carried away by my feelings

c) Most people in my age group seemed to be doing it

d) It seemed like a natural 'follow on' in the relationship

e) I was a bit drunk at the time

f) I had smoked some cannabis

g) I had taken some other drugs

h) I wanted to lose my virginity

i) I was in love

j) Other particular factor (SPECIFY AT NEXT QUESTION)

k) Can't choose

l) Can't remember

Section 2.2- Contraception

15. Now a few more general questions about things affecting sex. First, from this list, could you tell me which you or any partner have ever used, together? More than one answer can be chosen.

a) No method used – ever

b) (Partner has been /I have been sterilized)

c) (I have been /partner has been sterilized (had vasectomy))

d) The Pill

e) Male condom

f) Female condom

g) Morning after pill

h) Emergency intra-uterine device (IUD)

i) Coil/intra-uterine device (IUD)

j) Hormonal IUD - MIRENA

k) Cap/diaphragm

l) Injections

m) Spermicides (foams/gels/sprays/pessaries)

n) Natural family planning (safe period/rhythm method/Persona)

o) Withdrawal

p) Implants

q) Other method of protection (please say what)

16. And which have you used at all with a partner in the last year?

a) No method used in the last year

b) (Partner has been /I am sterilized)

c) (I have been /partner has been sterilized (had vasectomy))

d) The Pill

e) Male condom

f) Female condom

g) Morning after pill

h) Emergency intra-uterine device (IUD)

i) Coil/intra-uterine device (IUD)

j) Hormonal IUD - MIRENA

k) Cap/diaphragm

l) Injections

m) Spermicides (foams/gels/sprays/pessaries)

n) Natural family planning (safe period/rhythm method/Persona)

o) Withdrawal

p) Implants

q) Other answer given

If you have used more than one method of contraception continue, if not go to question 19.

17. In the last year have you always used these methods on different occasions or have you sometimes used them in combination on the same occasion?

a) Always used on different occasions

b) Sometimes in combination on same occasion (including once only)

c) Always in combination on same occasion

18. Which would you say is your most usual method these days?

a) No method used at the moment

b) (Partner has been /I am sterilized)

c) (I have been /partner has been sterilized (had vasectomy))

d) The pill

e) Male condom

f) Female condom

g) Morning after pill

h) Emergency intra-uterine device (IUD)

i) Coil/intra-uterine device (IUD)

j) Hormonal IUS - MIRENA

k) Cap/diaphragm

l) Injections

m) Spermicides (foams/gels/sprays/pessaries)

n) Natural family planning (safe period/rhythm method/Persona)

o) Withdrawal

p) Implants

q) Other answer given

19. If condoms used… In the past year have you used condoms…

a) to prevent pregnancy;

b) or to protect against HIV; or

c) to protect against other sexually transmitted infection

20. Have you got contraception from any of these sources in the last year?

a) A doctor or nurse at your GP's surgery

b) Sexual health clinic (GUM clinic)

c) Family planning clinic / contraceptive clinic / reproductive health clinic

d) NHS antenatal clinic / midwife

e) Private doctor or clinic

f) Youth advisory clinic (e.g. Brook clinic)

g) Pharmacy / Chemist

h) Internet website

i) Supplies from school / college / university services

j) Over the counter at a petrol station/supermarket/other shop

k) Vending machine

l) Mail order

m) Hospital accident and emergency (A & E) department

n) Any other type of place (please say where)

o) I have not got contraception in the last year

21. If all of these different types of service were available in your area and easy to get to, which one you would you prefer to get contraception from?

a) A doctor or Nurse at your GP's surgery

b) Sexual health clinic (GUM clinic)

c) Family planning clinic / contraceptive clinic / reproductive health clinic

d) Youth advisory clinic (e.g. Brook clinic)

e) Pharmacy / Chemist

f) NHS or Department of Health website

g) None of these

h) Not needed

Section 2.3- Sexual attraction and experience

22. I have felt sexually attracted...

a) Only to (females/males), never to (males/females)

b) More often to (females/males), and at least once to a (male/female)

c) About equally often to (females/males) and to (males/females)

d) More often to (males/females), and at least once to a (female/male)

e) Only ever to (males/females), never to (females/males)

f) I have never felt sexually attracted to anyone at all

g) Refused

23. Sexual experience is any kind of contact with another person that you felt was sexual (it could be just kissing or touching, or intercourse or any other form of sex). I have had some sexual experience...

a) Only with (females/males) (or a (female/male)), never with a (male/female)

b) More often with (females/males), and at least once with a (male/female)

c) About equally often with (females/males) and with (males/females)

d) More often with (males/females), and at least once with a (female/male)

e) Only with (males/females) (or a (male/female)), never with a (female/male)

f) I have never had any sexual experience with anyone at all

g) Refused

Section 2.4- Heterosexual sex

24. Can we just check now that you have read these terms: since age 13, have you ever had sex with a (man/woman)? That is vaginal intercourse, oral sex, or anal sex.

a) Yes

b) No

The (first/next) questions are about different kinds of sex with (WOMEN/MEN).

25. When, if ever, was the last occasion you had vaginal sexual intercourse with a (woman/man)?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had vaginal intercourse

26. When, if ever, was the last occasion you had oral sex with a (woman/man) - by you to (her/him), that is your mouth on (her/his) genital area?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had oral sex - by me to a (woman/man)

27. When, if ever, was the last occasion you had oral sex with a (woman/man) - by (her/him) to you, that is (her/his) mouth on your genital area?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had oral sex - by a (woman/man) to me

28. When, if ever, was the last occasion you had anal sex with a (woman/man)? Anal sex (anal sexual intercourse) is a man's penis in a partner's anus (rectum or back passage).

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had anal sex

29. When, if ever, was the last occasion you had genital contact with a (woman/man) not involving intercourse?

Forms of contact with the genital area NOT leading to intercourse (vaginal, oral, or anal) but intended to achieve orgasm, for example, stimulating by hand.

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had genital contact (without intercourse as well)

30. On how many occasions in the last 4 weeks have you had sex with a (woman/man)? This means vaginal intercourse, oral sex, anal sex. Please give an estimate if you can't say exactly.

31. Was this a new partner with whom you had not had sex before?

a) Yes

b) No

32. How many of these were new partners with whom you had not had sex before?

33. (Did you use a condom (sheath)/ Was a condom (sheath) used) when having vaginal (or anal) sex with a (woman/man) in the last 4 weeks?

a) Yes, used every time

b) Yes, used sometimes

c) No, not used in the last 4 weeks

34. On how many occasions in the last 7 days have you had sex with a (woman/man)?

35. In the last YEAR have you ever had vaginal (or anal) intercourse with a (woman/man) without using a condom?

a) Yes (have had intercourse without a condom in the past year)

b) No (have used a condom on all occasions of vaginal (or anal) intercourse in the past year)

36. How many (women/men) have you had vaginal (or anal) intercourse with in the past year without using a condom?

37. When, if ever, was the last occasion you masturbated? That is aroused yourself sexually.

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 year and 5 years ago

f) Longer than 5 years ago

g) Never masturbated or aroused myself sexually

38. In the last 7 days, how many times have you masturbated? That is aroused yourself sexually.

Section 2.5- Homosexual sex

The next questions are about sex with (men/women)

Have you ever had any kind of sexual experience or sexual contact with a (male/female)?

39. Please say 'yes' here, even if it was a long time ago or did not involve contact with the (genital area/penis/vagina).

a) Yes

b) No (if never please go to section 2.6)

40. How old were you the first time that happened?

41. Have you had sex with a (man/woman) involving (genital area/penis/vaginal) contact? (That is oral (or anal) sex or any other contact involving the genital area).

a) Yes

b) No

42. And how old were you the first time you had sex with a (man/woman) involving (genital area/penis/vaginal) contact? This could be the same age you just gave, or older.

43. Have you had sex with any other (men/women) involving (genital area/penis/vaginal) contact since you turned 13?

a) Yes

b) Not with anybody else since age 13

44. How old were you then? Please estimate how old you were if you can't say exactly.

This is about different kinds of sex with (male/female) partners, involving contact with the (genital area/penis/vagina).

45. When, if ever, was the last occasion you had oral sex with a (man/woman) - by you to a (him/her), that is your mouth on (his/her) genital area?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had oral sex - by me to a (man/woman)

46. When, if ever, was the last occasion you had oral sex with a (man/woman) - by (her/him) to you, that is (his/her) mouth on your genital area?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had oral sex – by a (man/woman) to me

47. When, if ever, was the last occasion you had anal sex with a man - by you to him? That is your penis in a man's anus (rectum or back passage).

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had anal sex - by me to a man

48. When, if ever, was the last occasion you had anal sex with a man - by him to you? That is a partner's penis in your anus (rectum or back passage).

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had anal sex - by him to me

49. When was the last occasion you had any other form of sex with a (man/woman) that involved genital contact but not also oral (or anal) sex? Genital contact not involving intercourse is forms of contact with the genital area not leading to oral (or anal) intercourse, but intending to achieve orgasm, for example, by stimulating by hand.

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 6 months ago

d) Between 6 months and 1 year ago

e) Between 1 and 5 years ago

f) Longer than 5 years ago

g) Never had genital contact without oral and/or anal sex as well

50. On how many occasions in the last 4 weeks have you had sex with a (man/woman)? Please give an estimate if you can't say exactly.

51. With how many (men/women) have you had sex in the last 4 weeks?

52. Was this a new partner with whom you had not had sex before?

a) Yes

b) No

53. How many of these were new partners with whom you had not had sex before? Please record the number, '0' if none.

54. Was a condom (sheath) used on any occasions of having anal sex with a man in the last 4 weeks?

a) Yes, used on every occasion

b) Yes, used on some occasions

c) No, not used in the last 4 weeks

55. On how many occasions in the last 7 days have you had sex with a (man/woman)? Please record the number, '0' if none.

56. In the last year, when you've had anal sex, how often have you, or your partner, used a condom?

a) Every time

b) Most of the time

c) Occasonally

d) Not at all in the last year

57. In the last year, how many men have you had anal intercourse with without using a condom? Please record the number, '0' if none.

58. How often, if at all, do you usually go to gay pubs, bars, or clubs?

a) At least once a week

b) Less often but at least once a month

c) Less often but at least twice a year

d) Less often but at least once a year

e) Less often than once a year

f) Never

Section 2.7- Number of partners

The next questions are about the number of people you have had sex with at different times in your life. When answering these questions please include everyone you have ever had sex with, whether it was just once, a few times, a regular partner or (wife/husband).

Be as accurate as you can: give your best estimate if you can't remember exactly.

59. Altogether, in your life so far, how many (women/men) have you had sexual intercourse with (vaginal, oral or anal)? Please record the number, '0' if none.

60. Which of these best describes how you worked out that answer?

a) I just knew the number

b) I remembered each partner, and counted them up

c) I estimated or guessed the number

d) I remembered some partners and then added on an estimated number for others

e) Other

61. Altogether, in the last 5 years, how many (women/men) have you had sexual intercourse with? Please record the number in the last 5 years, '0' if none.

62. And altogether, in the last year, how many (women/men) have you had sexual intercourse with? Please record the number in the last year, '0' if none.

63. How many of these (women/men) were new partners who you had sex with for the first time during the last year? Please record the number, '0' if none.

64. Was this (woman/man) a new partner who you had sex with for the first time during the last year?

a) Yes

b) No

65. In the last year, were there any (women/men) you had only oral sex with, and never vaginal (or anal) sex?

a) Yes

b) No

66. How many different (women/men) in the last year did you have only oral sex with, and never vaginal (or anal sex)? Please record the number.

67. Previously, you said you had sex with (woman/women/man/men) in the last year. Does this number include (all/both of) the (woman/women/man/men) you had only oral sex with?

a) Yes, (all/both) included

b) No, did not include (all of them/both of them)

68. In total, how many different (women/men) did you have sex with in the last year, including those you had only oral sex with? Please record the number.

69. In the last year, have you and a (female / male) partner, as a couple, engaged in sex with other couples?

a) Yes

b) No

70. Altogether, in the last 3 months, how many (women/men) have you had sexual intercourse (vaginal, oral or anal) with? Please record the number in the last 3 months, '0' if none.

Section 2.8- Same sex partners

71. Altogether, in your life so far, how many (men/women – same sex) have you had sex with (that is oral (or anal) sex or other forms of genital contact)? Please record in the number in your life (so far), '0' if none.

72. Which of these best describes how you worked out that answer?

a) I just knew the number

b) I remembered each partner, and counted them up

c) I estimated or guessed the number

d) I remembered some partners and then added on an estimated number for others

e) Other

73. Altogether, in the last 5 YEARS, how many (men/women) have you had sex with? Please record the number in the last 5 years, '0' if none.

74. And - altogether, in the last YEAR, how many (men/women) have you had sex with? Please record the number in the last year, '0' if none.

75. How many of these (men/women) were new partners who you had sex with for the first time during the last year? Please record the number, '0' if none.

76. Was this (man/woman) a new partner who you had sex with for the first time during the last year?

a) Yes

b) No

77. AND - Altogether, in the last 3 MONTHS, how many (men/women) have you had sex with? Please record the number, '0' if none.

78. Thinking about all of the people you have had sex with in the last five years, did any of them overlap in time? In other words did you have sex with someone (person A) then have sex with someone else (person B) then have sex with the first person (person A) again?

a) Yes

b) No

79. Have you used the internet to find a sexual partner in the last 12 months?

a) Yes

b) No

Section 2.9- Nonconsensual sex

The next question is about your experience of sex when you might not have been willing.

80. Since the age of 13, has anyone tried to make you have sex with them, against your will?

a) Yes

b) No

c) Don't know

81. If yes…And since the age of 13, has anyone actually made you have sex with them, against your will?

a) Yes

b) No

c) Don't know

82. How old were you when this last happened?

83. Was this person:

a) Someone you were, or had been, in a relationship with

b) Someone known to you as a family member or friend

c) Someone known to you but not as a family member or friend

d) Someone you didn't know

e) Other

84. Did you talk to anyone about this?

a) Yes

b) No

85. Did you speak to the police about this?

a) Yes

b) No

Section 2.10- Paying for sex

The next questions are about paying for sex.

86. Have you ever paid money for sex with a (man/woman – opposite sex)?

a) Yes

b) No (if, no got to section 2.11)

87. If yes…When was the last time you paid money for sex with a (man/woman – opposite sex)?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 1 year ago

d) Between 1 year and 5 years ago

e) Longer than 5 years ago

88. In your lifetime, how many different (men/women – opposite sex) have you paid money for sex?

89. Previously, you said you had sex with a number of (men/women – opposite sex) in your life. Does this include the (man/woman – opposite sex) you paid money for sex?

a) Yes, included

b) No, not included

90. If male, Have you ever paid money for sex with a man?

a) Yes

b) No

91. If yes, When was the last time you paid money for sex with a man?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 1 year ago

d) Between 1 year and 5 years ago

e) Longer than 5 years ago

92. In your lifetime, how many men have you paid money for sex?

93. Previously, you said you had sex with a number of men in your life. Does this include the man you paid money for sex?

a) Yes, included

b) No, not included

94. Have you ever paid anyone for sex in a country outside the UK? By outside the UK we mean any country other than England, Wales, Scotland or Northern Ireland.

a) Yes

b) No

95. If yes… Where did you pay for sex? You can choose more than one.

a) Other European countries (including Ireland, Eastern Europe, Russia)

b) Australia, New Zealand

c) North America (USA and Canada)

d) South America, Central America (including Mexico)

e) Caribbean countries

f) Asian countries (including China, India, Pakistan, Bangladesh, Thailand, Malaysia, etc)

g) Middle East, North Africa

h) African countries (other than North Africa)

i) Other region or country

j) Don’t know which country or region

Section 2.11- Sexually transmitted infections and HPV vaccinations

The next questions are about infections that can be transmitted by sex. Please answer even if you have never had an infection that was transmitted by sex.

96. If you thought that you might have an infection that is transmitted by sex, where would you first go to seek diagnosis and/or treatment?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) NHS Antenatal clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Hospital accident and emergency (A&E) department

j) Somewhere else

97. Have you ever attended a sexual health clinic (GUM clinic)?

a) Yes

b) No

98. When was that? (The last time if more than once.)

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

99. Have you ever been told by a doctor or other healthcare professional that you had any of the following?

Please type in the numbers for any that you have had, even if not transmitted by sex (women only: e.g. Thrush). You can choose more than one.

a) Chlamydia

b) Gonorrhoea

c) Genital Warts (venereal warts)

d) Syphilis

e) Trichomonas vaginalis (Trich, TV)

f) Herpes (genital herpes)

g) Pubic lice / crabs

h) Hepatitis B

i) (Men only:) NSU (Non Specific Urethritis), NGU (Non Gonococcal Urethritis)

j) (Men only:) Epididymitis

k) (Women only:) Pelvic Inflammatory Disease (PID, salpingitis)

l) (Women only:) Vaginal thrush (Candida, Yeast infection)

m) (Women only:) Bacterial vaginosis

n) Yes, but can't remember which

o) None of these

100. If yes to Chlamydia…when were you last told by a doctor or healthcare professional that you had Chlamydia?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

101. When you were last tested for Chlamydia, where were you offered the test?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Ante-natal Clinic / midwife

e) Private non-NHS clinics or doctor

f) Youth advisory clinic (e.g. Brook Clinic)

g) School / college / university

h) Termination of pregnancy (abortion) clinic

i) Hospital accident and emergency (A&E) department

j) Pharmacy / chemist

k) Internet

l) Other non-health care place, e.g. youth club, festival, bar

m) Somewhere else

102. Why were you last tested for Chlamydia?

a) I had symptoms

b) My partner had symptoms

c) I was notified because a partner was diagnosed with Chlamydia

d) I wanted a general sexual health check-up

e) Check up after previous positive test

f) I had no symptoms but I was worried about the risk of Chlamydia

g) I was offered a routine test

h) Other

103. Where were you last treated for chlamydia?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

104. In the last year, have you been offered and refused a test for Chlamydia?

a) Yes

b) No

105. If yes to Gonorrhea…when were you last told by a doctor or healthcare professional that you had Gonorrhea?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

106. Where were you last treated for Gonorrhea?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

107. If yes to genital warts…When were you last told by a doctor or healthcare professional that you had Genital Warts (venereal warts)?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

108. Where were you last treated for Genital Warts (venereal warts)?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

109. If yes to Syphilis… When were you last told by a doctor or healthcare professional that you had Syphilis?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

110. Where were you last treated for Syphilis?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

111. If yes to Trichomonas…When were you last told by a doctor or healthcare professional that you had Trichomonas vaginalis (trich, TV)?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

112. Where were you last treated for Trichomonas vaginalis (trich, TV)?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

113. If yes to Herpes…When were you last told by a doctor or healthcare professional that you had Herpes (genital herpes)?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

114. Where were you last treated for Herpes (genital herpes)?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

115. If NSU…When were you last told by a doctor or healthcare professional that you NSU (Non Specific Urethritis), NGU (Non Gonococcal Urethritis)?

a) Less than 1 year ago

b) Between 1 and 5 years ago

c) Between 5 and 10 years ago

d) More than 10 years ago

116. Where were you last treated for NSU (Non Specific Urethritis), NGU (Non Gonococcal Urethritis)?

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Antenatal Clinic / midwife

e) Private non-NHS clinic or doctor

f) Pharmacy / chemist

g) Internet site offering treatment

h) Youth advisory clinic (e.g. Brook clinic)

i) Termination of pregnancy (abortion) clinic

j) Hospital accident and emergency (A&E) department

k) Somewhere else

117. If female and over 25…When did you last have a cervical smear test?

a) I have never had one

b) Less than 3 years ago

c) Between 3 and 5 years ago

d) Between 5 and 10 years ago

e) More than 10 years ago

118. Have you ever been vaccinated against cervical cancer (received HPV vaccine)?

a) Yes – I have completed three doses of the vaccine

b) Yes - I have had one or two doses of the vaccine, but not all three doses

c) No

119. Do you intend to receive the other doses and complete the vaccination course?

a) Yes

b) No

120. Were you ever offered the vaccination?

a) Yes, I was offered but refused it

b) No, I was never offered it

121. Where (were you offered/ did you receive) the HPV vaccination?

a) General practice (GP) surgery

b) NHS Sexual health clinic (GUM clinic)

c) Private (Non-NHS) clinic or doctor, including a chemist / pharmacy

d) Somewhere else

122. If male (between 16&44)…In the last month, that is since (date one month ago), have you had any of the following symptoms. More than one can be selected.

a) Pain, burning or stinging when passing urine

b) Passing urine more often than usual

c) Genital wart / lump

d) Genital ulcer /sore

e) Discharge from the end of the penis

f) Painful testicles

g) None of these

123. I female (between 16&44)…In the last month, that is since (date one month ago), have you had any of the following symptoms. More than one can be selected.

a) Pain, burning or stinging when passing urine

b) Passing urine more often than usual

c) Genital wart / lump

d) Genital ulcer / sore

e) Abnormal vaginal discharge

f) Unpleasant odour associated with vaginal discharge

g) Vaginal pain during sex

h) Abnormal bleeding between periods

i) Bleeding after sex (not during a period)

j) Lower abdominal or pelvic pain (not related to periods)

k) None of these

Section 2.12- HIV Testing

124. Have you ever donated blood, that is, been a blood donor?

a) Yes

b) No, never

125. When was the last time you donated blood?

a) In the last year

b) Between 1 and 2 years ago

c) Between 2 and 5 years ago

d) Between 5 years and 10 years ago

e) Longer than 10 years ago but since the beginning of 1986

f) Longer ago than the beginning of 1986

126. Apart from when you were donating blood, have you ever had a test for HIV, the virus that causes AIDS?

a) Yes

b) No

c) Maybe/Not sure

127. Have you ever had a test for HIV (the virus that causes AIDS)?

a) Yes

b) No

c) Maybe/Not sure

128. Why were you tested? You can choose more than one answer.

a) I/ my partner was pregnant

b) for insurance or mortgage purposes or to travel to another country

c) as part of a sexual health check up

d) as part of a general health check up

e) I wanted to stop using condoms in a relationship

f) I was concerned about personal risks to myself or a partner

g) A doctor advised me to have an HIV test

h) Or, other reason

129. When was that test? (the last HIV test if more than one)

a) In the last year

b) Between 1 and 2 years ago

c) Between 2 and 5 years ago

d) Longer than 5 years ago

130. Where were you tested? (the last HIV test if more than one) Please choose one answer from this list.

a) General practice (GP) surgery

b) Sexual health clinic (GUM clinic)

c) NHS Family planning clinic / contraceptive clinic / reproductive health clinic

d) Ante-natal clinic / midwife

e) Private non-NHS clinic or doctor

f) Internet site offering postal kit

g) Youth advisory clinic (e.g. Brook clinic)

h) Termination of pregnancy (abortion) clinic

i) Hospital accident and emergency (A&E) department

j) Somewhere else

131. Were you given the result of the test? (We do not want to know what the result was.)

a) Yes, I was given the result

b) No, I was not given the result

Section 2.13- Drugs

132. Have you ever taken any of the drugs listed below? (Please do not count any drugs you have injected). Please select the numbers of all the drugs you have taken, but did not inject.

a) Cannabis (marijuana, grass, hash, ganja, draw, skunk, weed, spliff)

b) Amphetamines (speed, whizz, uppers, billy)

c) Cocaine or coke (charlie)

d) Crack (rock, stones, white)

e) Ecstasy (E)

f) Heroin that was not injected (smack, skag, H, brown, gear, horse)

g) Acid or LSD (tabs, trips) or magic mushrooms

h) Crystal Meth

i) Amyl Nitrates (poppers, liquid gold, rush)

j) Other non-prescribed drugs

k) None of these

133. If yes…You mentioned that you had taken (name of drug/s). Have you taken (this drug/ any of these drugs) in the last 12 months?

a) Yes

b) No

134. Have you taken (this drug/any of these drugs) in the last 4 weeks?

a) Yes

b) No

135. Have you ever injected yourself with any non-prescribed drugs or other substances?

a) Yes

b) No

136. When was the last time you injected yourself with non-prescribed drugs or other substances?

a) In the last 7 days

b) Between 7 days and 4 weeks ago

c) Between 4 weeks and 1 year ago

d) Over 1 year ago

137. How old were you the last time you injected yourself with non-prescribed drugs or other substances?

138. How old were you the first time you injected non-prescribed drugs or other substances?

139. Have you ever shared a needle, or other equipment used for injecting, with someone else?

a) Yes

b) No

Section 2.14- Attitudinal questions

Now I would like to ask you some questions on your views about different types of relationships.

140. A married person having sexual relations with someone other than his or her partner?

a) Always wrong

b) Mostly wrong

c) Sometimes wrong

d) Rarely wrong

e) Not wrong at all

f) Depends/Don't know

141. What is your opinion about a person having one night stands?

142. What is your general opinion about sexual relations between two adult men?

143. And sexual relations between two adult women?

Social Norms

144. It's OK to have sex with someone without being in love with them

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don't know

145. People are under a lot of pressure to have sex nowadays.

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don't know

146. It is natural for people to want sex less as they get older

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don't know

147. Men have a naturally higher sex drive than women

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don’t know

148. There’s too much sex in the media these days

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don’t know

149. Young people today start having sex too early

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don’t know

150. Gay men should be able to adopt children

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don’t know

151. Lesbians should be able to adopt children

1. Agree strongly

2. Agree

3. Neither agree nor disagree

4. Disagree

5. Disagree strongly

6. Don't know

152. Teaching young people about sexual matters encourages them to have sex

a) Agree strongly

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Disagree strongly

f) Don't know

153. Do you have any children who are aged 16 to 25, who you had contact with while they were growing up? (This could include step and adopted children).

If respondent does have children in this age range, but did not have contact with them when they were growing up, please code this as 'no'.

1. Yes

2. No

154. How easy or difficult did you find it to talk to your children about sexual matters when they were growing up?

a) Easy

b) Difficult

c) Easy with some children but difficult with others

d) It depended on the topic

e) I did not discuss sexual matters with my children

155. Nowadays, how many young people in the UK do you think have had sexual intercourse before their 16th birthday?

a) Less than a quarter

b) About a quarter

c) About a half

d) About three-quarters; or

e) More than three-quarters?

f) Don't know/ Refused

156. There are different opinions about how many people are at risk of becoming infected with HIV, the virus that causes AIDS, but we would like to know what you think about the risks to you, personally, with your present sexual lifestyle?

a) Greatly at risk

b) Quite a lot

c) Not very much

d) Not at all at risk

e) Don't know

157. People are also at risk of getting other sexually transmitted infections. What do you think about the risks to you, personally, with your present lifestyle of getting a sexually transmitted infection that is not HIV?

a) Greatly at risk

b) Quite a lot

c) Not very much

d) Not at all at risk

e) Don’t know

Section 2.15- Unplanned pregnancy

158. Can we just ask, have you been pregnant in the last 12 months?

a) Yes

b) No

Below are some questions that ask about your circumstances and feelings around the time you became pregnant. Please think of your current (or most recent) pregnancy when answering the questions below.

159. Just before I became pregnant.....

(Please tick the statement 1) In the month that I became pregnant.....

(Please tick the statement which most applies to you):

a) I/we were not using contraception

b) I/we were using contraception, but not on every occasion

c) I/we always used contraception, but knew that the method had failed (i.e. broke, moved, came off, came out, not worked etc) at least once

d) I/we always used contraception

160. In terms of becoming a mother (first time or again), I feel that my pregnancy happened at the.....

(Please tick the statement which most applies to you):

a) right time

b) ok, but not quite right time

c) wrong time

which most applies to you):

a) I intended to get pregnant

b) my intentions kept changing

c) I did not intend to get pregnant

161. Just before I became pregnant....

(Please tick the statement which most applies to you)

a) I wanted to have a baby

b) I had mixed feelings about having a baby

c) I did not want to have a baby

In the next question, we ask about your partner - this might be (or have been) your husband, a partner you live with, a boyfriend, or someone you've had sex with once or twice.

162. Before I became pregnant....

(Please tick the statement which most applies to you)

a) My partner and I had agreed that we would like me to be pregnant

b) My partner and I had discussed having children together, but hadn't agreed for me to get pregnant

c) We never discussed having children together

163. Before you became pregnant, did you do anything to improve your health in preparation for pregnancy? (Please tick all that apply)

a) took folic acid

b) stopped or cut down smoking

c) stopped or cut down drinking alcohol

d) ate more healthily

e) sought medical/health advice

f) took some other action, please describe _____

or

g) I did not do any of the above before my pregnancy

Appendix 18- Full version of the SERBAS

SERBAS

INTERVIEWER: IF PARTICIPANT HAS JUST FINISHED ANOTHER INTERVIEW, ASK,

Would you like a break before we continue?

INTERVIEWER: IF YOU HAVE NOT CONDUCTED ANOTHER INTERVIEW SCHEDULE WITH PARTICIPANT BEFORE THIS ONE, INTRODUCE YOURSELF: I am the interviewer on the research team who will be asking some questions about your sexual behaviour. Please keep in mind that the hospital staff will not have access to any of the answers you give me.

INTERVIEWER: EXPLAIN THAT THIS IS SEPARATE FROM PARTICIPANT'S TREATMENT AND TREATING STAFF WILL NOT HAVE ACCESS TO THE ANSWERS. BUILD INITIAL RAPPORT BY HAVING A BRIEF GENERAL CONVERSATION.

INSTRUCTIONS

This part of the interview asks specific questions about sexual behaviours and relationships. I will ask questions about your sexual partners and sexual activity. If you find that any of these questions make you feel uncomfortable, please tell me. We are trying to understand more about how people are reacting to the AIDS epidemic and your answers to these questions will help us to do that.

Let me also remind you that all your answers to these questions will be kept confidential and will not be shared with anyone.

SECTION A- INTRODUCTION

Let's begin with your current relationships.

A001. Do you currently have a spouse or lover?

No	0	(A011)	/39
Yes	1		

A002. Is this person a…?

Man	1	
Woman	2	/40

How long have you been in this relationship, that is, been married or with this lover?

A003. … Weeks **OR** /41-42

A004. … Months **OR** /43-44

A005. … Years /45-46

A006. Do you live together?

No	0	(A009)	/47
Yes	1		

How long have you lived together? (INTERVIEWER: "LIVING TOGERTHER"

IS DEFINED AS SHARING THE SAME RESIDENCE)

A007. … Months **OR** /48-49

A008. … Years /50-51

A009. Do you and your partner have sex together, or is your relationship a non-sexual one?

Non-sexual	0	/52
Sexual	1	

EVEN IF RELATIONSHIP IS NON-SEXUAL, ASK A010.

A010. How satisfied are you with your sexual life together? Would you say?

	Very satisfied	1	
	Satisfied	2	
SHOW HANDCARD	Fairly satisfied	3	/53
1	Fairly unsatisfied	4	
	Unsatisfied	5	
	Very unsatisfied	6	

A011. In general, during the last 6 months, how have you been thinking of yourself privately: as gay, bi-sexual, or straight?

Straight	1	
Bisexual	2	/54
Gay	3	
Other (specify)	8	

SECTION B-S CURRENT PARTNERS, BY TYPE- MALE

Now let's talk about sex with men over the past 6 months. So that would be from (TODAY'S DATE, 6 MONTHS AGO) to (TODAY'S DATE).

IF SUBJECT SPONTANEOUSLY DENIES SEX WITH ANY MAN IN THE LAST 6 MONTHS, GO TO INTRO ABOVE B001 AND ASK PERTINENT SCREENS; OTHERWISE GO TO INTRO, NEXT PAGE. IF SUBJECT DENIES SEX AFTER YOU'VE STARTED WITH B003, GO TO INTRO ABOVE B001 AND ASK PERTINENT SCREENS.

In doing many of these interviews we have found that, sometimes, when people think about sex with their partners, they don't include people they had sex with for money, or drugs, or cigarettes. And sometimes they don't think about all the different types of sex people might have. Because this can be confusing, I need to ask you a few more questions.

B001. From what you've told me, you never had any hand jobs, oral sex, anal sex, vaginal sex, or any other form of sex with ANY man in the last 6 months?

Denies any sex with men	0	/57
Has had sex with men	1	(INTRO ABOVE B003)

B002. And you did not have any sex with men for money, drugs, rent, food or cigarettes?

Denies any sex with men	0	/58
Had had sex with men	1	(INTRO ABOVE B003)

B002a. When was the last time you had a male partner?

Month……. Day……..Year

Can you tell me why you haven't had sex with a male partner since (above date)? (INTERVIEWER: AFTER PROBE, SKIP TO SECTION E).

(E)

In the next part of the interview, we'll be talking about your sex life during the last 6 months. Before we start, let's take a minute to talk about the types of sex people may get into.

(INTERVIEWER: IF PARTICIPANT DOES NOT VOLUNTEER VERNACULAR EXPRESSION, REVIEW EXAMPLESTHAT ARE PROVIDED IN BRACKETS FOLLOWING PRACTICE DESCRIPTION. WRITE IN 'NONE' IF PARTICIPANT DOESN'T PROVIDE ANOTHER TERM).

SHOW HANDCARD 2

- Manual sex, when you touch his penis with your hand or he touches your vagina with his hand; (PARTICPANTS TERM) (for example, some people call this jerking each other off)……
- Sexual intercourse, when he puts his penis inside your vagina; (PARTICIPANTS TERM) (for example, some people call this fucking)……

- Oral sex, when you put your mouth or tongue on his penis; (PARTICIPANTS TERM) (for example, some people call this going down; sucking off)…….

- Oral sex, when he puts his moth or tongue on your vagina; (PARTICIPANTS TERM) (for example, some people call this going down; sucking off)…….

- Anal intercourse, when he puts his penis inside your (rectum/butt); (PARTICIPANTS term) (for example, some people call this butt fucking).

- Rimming, when you put your mouth or tongue on his rectum or he does it to you; (PARTICIPANTS TERM)……..

- Anything else which includes genital contact or genital stimulation with a partner that I haven't mentioned (PARTICPANTS TERM)…….

(INTERVIEWER: CONFIRM S'S PREFERENCE REGARDING SEXUAL TERMINOLOGY. SUBSTITUTE S'S TERMS IF APPROPRIATE).

Do you have any questions?

As we continue, if there are any words or questions that aren't clear, please let me know. People have different words they use, and I want to make sure I use words that work for you.

I'm going to ask you some questions about your men partners. I'll want to know HOW MANY MEN you had sex with in the last 6 months and HOW MANY TIMES you had sex with each of them in the last 6 months.

B003. Has there been one man you've had sex with MORE THAN ANYONE ELSE in the past 6 months? (Interviewer note that type 1 partner is strictly defined by FREQUENCY OF SEXUAL CONTACT. A type 1 partner is ALWAYS the partner with whom participant most frequently had sex).

No	0	(B006)	/59
Yes	1		

B004. Do you think of this person as a…

Husband	1	/60
SHOW HANDACARD	Lover	2
3	Steady or regular partner	3
	Partner you know well who wasn't steady	4
	Someone you know just a little bit but not very much	5

(INTERVIEWER: FOR B005, B008, B010, B012: IF THERE HAVE BEEN MANY SEXUAL OCCASIONS, HAVE THE SUBJECT ESTABLISH FIRST

THE NUMBER OF OCCASIONS PER MONTH OR WEEK AND THEN DERIVE THE TOTAL NUMBER FOR THE PAST 6 MONTHS)

B005. About how many times would you say you've had sex with him during the past 6 months?

#TIMES/6MONTHS /61-63

B006. Now let's think about men you've had sex with two or more times. Are there any men you've had sex with TWO OR MORE TIMES in the past 6 months?

(MAKE CLEAR TO EXCLUDE TYPE 1 PARTNER; THAT IS SOMEONE PARTICIPANT HAD SEX WITH MORE THAN ANYONE ELSE).

No	0	(B009)	/64
Yes	1		

B007. How many different men did you have sex with TWO TIMES OR MORE over the past 6 months?

#/ 6 MONTHS /65-67

B008. About how many times altogether would you say you've had sex with (these men/this man) during the last 6 months?

#TIMES/ 6 MONTHS /68-70

B009. Now let's think about the men you had sex with ONLY ONCE. In the past 6 months, have you had sex with any man ONLY ONCE?

No	0	(B012)	/71
Yes	1		

B010. How many different partners have you had sex with only ONE TIME during the past 6 months?

#/6 MONTHS /72-74

(INTERVIEWER: IF S'S ONLY PARTNER IS TYPE 3, TREAT THAT PARTNER AS A TYPE 1 PARTNER AND CODE 0 FOR B003, B004 AND B005. B009 IN THIS CASE IS CODED NO (0), AND B010 AND B011 ARE LEFT BLANK).

B011. So there have been……. (B010) Partners you've had sex with only once in the past 6 months. That makes ……(B010) times (NOTE: B011 should equal B010).

TIMES/6 MONTHS /75-77

B012 In the past 6 months, about how many times have you had sex with two or more men at the same, for example a 3-way?

TIMES/ 6 MONTHS

B012a. In the past 6 months, about how many times have you had sex with two or more people, for example, a 3-way with one man and one woman?

TIMES/ 6 MONTHS /78-80

CARD:	0	2	/1-2	
		INSTRUMENT CODE	3	0	/3-4
		SUBJECT ID #:	0	1	/6-11

INTERVIEWER SUMMARY CHART OF TOTAL NUMBER OF MALE SEX PARTNERS AND MALE SEX EPISODES IN THE PAST 6 MONTHS

FILL IN SUMMARY CHART FROM ITEMS LISTED. CHECK TOTALS WITH SUBJECT AND RECONCILE DISREPANCIES, INCLUDING ADJUSTEMENTS FOR B012 AND B012a WHERE APPROPRIATE.

PARTNER TYPE	TOTAL NUMBER OF PARTNERS	TOTAL NUMBER OF EPISODES
TYPE 1	B003:	B005:
TYPE 2	B007:	B008:
TYPE 3	B010:	B011:
INITIAL TOTAL	B013: /15-17	B014: /18-20

So if we sum up all the times you had sex with men in the past 6 months, then you've had sex with…….. (B013) partners about…….. (B014) Is that about right?

RECONCILLED TOTAL	B015: /21-23	B016: /24-26

B017. In the last 6 months, how many partners did you have sex with that you never had sex with before?

NONE..000 (SEC C)

SHOW HANDCARD 4
How many of these partners would you describe as…

B017a. A one-night stand (you had sex once and don't plan to again)

PARTNERS

B017b. Someone you know slightly but you don't plan to become steady partners

PARTNERS

B017c. Someone you know well but don't plan to become steady partners

PARTNERS

BO17d. Someone you're starting or planning to start a steady relationship with

PARTNERS

B017e. Someone you've established a steady relationship with (a new lover)

PARTNERS

SECTION C- CURRENT PARTNERS BY SITUATION- MALE

Let me ask you about your men partner(s) of the past 6 months in more detail.

During the past 6 months, how many different men did you have sex with…

C001. …In exchange for giving them money?

MEN /41-44

C002. How many TIMES altogether?

TIMES /45-48

C003. … In exchange for receiving money from them?

MEN /49-52

C004. How many TIMES altogether?

#TIMES /53-56

C005. …In exchange for giving them drugs?

#MEN /57-60

C006. How many TIMES altogether?

TIMES /61-64

C007. … In exchange for receiving drugs from them?

MEN /65-68

C008. How many TIMES altogether?

#TIMES /69-72

C009. … because you were forced to by them?

#MEN /73-76

C010 How many TIMES altogether?

#TIIMES /77-80

C011. … In exchange for rent?

#MEN

C012. How many TIMES altogether?

#TIMES

C013. … In exchange for receiving food from them?

#MEN

C014 How many TIMES altogether?

#TIMES

C015… In exchange for receiving cigarettes from them?

#MEN

C016. How many TIMES altogether?

#TIMES

SECTION D- CURRENT PARTNER CHARACTERISTICS- MALE

CARD:	0	3	/1-2
INSTRUMENT CODE	3	0	/3-4
SUBJECT ID #:	0	1	/6-11

CHECK B003. IF S REPORTED TYPE 1 PARTNER, CONTINUE. OTHERWISE, SKIP TO INSTRUCTION D007.

Here are some additional questions about the men you have had sex with in the past 6 months. First the man you had sex with more than any other man. As far as you know…

D001. Was he HIV positive or diagnosed with ARC or AIDS?

No, tested negative	0	/15
Don't know, or not tested	1	
I suspect he was	2	
Yes	3	

D002. Was he an IV drug user either during the past 6 months or before? That it, has he ever shot drugs, including skin popping?

No or don't know	0	/16
Yes	1	

D003. Did he ever receive a transfusion of blood or blood products (for hemophilia) between 1977 and 1985?

No or don't know	0	/17
Yes	1	

D004. DELETED /18

D005. During the past 6 months, did he have symptoms of a sexually transmitted infection or venereal disease such as gonorrhea (clap), herpes, syphilis, crabs, or warts?

No	0	/19
I suspect he did	1	
Yes	2	

D006. Does he have sex with men?

No or don't know	0	/20
Yes	1	

(IF S REPORTED OTHER MALE PARTNERS, CONTINUE. OTHERWISE SKIP TO SECTION E).

Now, to the other men you had sex with in the past 6 month. As far as you know, how many of them…

D007. were HIV positive or diagnosed with ARC or AIDS?

#/6 MONTHS /21-23

D008. were IV drug users either during the past 6 months or before?

#/6 MONTHS /24-26

D009. Ever received a transfusion of blood or blood products (for hemophilia) between 1977 and 1985)

#/6 MONTHS /27-29

D010. DELETED /30-32

D011. had symptoms of a sexually transmitted disease during the past 6 months?

#/6 MONTHS /33-35

D012. have sex with men?

#/6 MONTHS /36-38

SECTION E- CURRENT PARTNERS BY TYPE- FEMALE

Now let's talk about sex with women over the past 6 months. Again, that would be from (TODAY'S DATE, 6 MONTHS AGO) to (TODAY'S DATE).

IF SUBJECT SPONTANEOUSLY DENIES SEX WITH ANY MAN IN THE LAST 6 MONTHS, GO TO INTRO ABOVE B001 AND ASK PERTINENT SCREENS; OTHERWISE GO TO INTRO, NEXT PAGE. IF SUBJECT DENIES SEX AFTER YOU'VE STARTED WITH E004, GO TO INTRO ABOVE B001 AND ASK PERTINENT SCREENS.

In doing many of these interviews we have found that, sometimes, when people think about sex with their partners, they don't include people they had sex with for money, or drugs, or cigarettes. And sometimes they don't think about all the different types of sex people might have. Because this can be confusing, I need to ask you a few more questions.

E001. So you're saying that you never had any hand jobs, oral sex, anal sex, vaginal sex, or any other form of sex with ANY woman in the last 6 months?

Denies any sex with women	0	/41
Has had sex with women	1	(INTRO BELOW E003)

E002. And you did not have any sex with women for money, drugs, rent, food or cigarettes?

Denies any sex with women	0	/42
Had had sex with women	1	(INTRO BELOW E003)

E003 Before we go on, how long ago was the most recent time you had sex of any kind with a woman? By having sex I mean touching your partner's vagina with your hand or mouth or your partner touching your vagina with her hand or mouth, or anything else involving your genitals or your partner's genitals?

19		(SEC I)	/43-44
NEVER	00	(SEC I)	

E004. Let's talk about the women you've had sex with. I'll want to know HOW MANY women you had sex with in the last 6 months, and HOW MANY times you had sex with each of them.

Before we start, let's take a minute to talk about the types of sex people may get into.

(INTERVIEWER: IF PARTICIPANT DOES NOT VOLUNTEER VERNACULAR EXPRESSION, REVIEW EXAMPLESTHAT ARE PROVIDED IN BRACKETS FOLLOWING PRACTICE DESCRIPTION. WRITE IN 'NONE' IF PARTICIPANT DOESN'T PROVIDE ANOTHER TERM).

SHOW HANDCARD 5

- Manual sex, when you touch her vagina with your hand or she touches your vagina with her hand; (PARTICPANTS TERM) (for example, some people call this jerking each other off)…….

- Oral sex, when she puts her mouth or tongue on your vagina or you put your mouth or tongue on her vagina; (PARTICIPANTS TERM) (for example, some people call this going down; sucking off)…….

- Rimming, when you put your mouth or tongue on her rectum or she does it to you; (PARTICIPANTS TERM)……..

- Anything else which includes genital contact or genital stimulation with a partner that I haven't mentioned (PARTICPANTS TERM)…….

(INTERVIEWER: CONFIRM S'S PREFERENCE REGARDING SEXUAL TERMINOLOGY. SUBSTITUTE S'S TERMS IF APPROPRIATE).

Do you have any questions?

E004. Let's begin with the woman you had sex with more than anyone else. Has there been one woman you've had sex with MORE THAN ANYONE ELSE in the past 6 months?

No 0 (E007) /45

Yes 1

E005. Do you think of this person as a… (Hand card 6)

SHOW HAND CARD 6

Lover 1
Steady or regular partner 2
Partner you know well who wasn't steady 3 /46
Someone you know just a little bit but not very much 4

(INTERVIEWER: FOR E006, E009, E011, E013: IF THERE HAVE BEEN MANY SEXUAL OCCASIONS, HAVE THE SUBJECT ESTABLISH FIRST THE NUMBER OF OCCASIONS PER MONTH OR WEEK AND THEN DERIVE THE TOTAL NUMBER FOR THE PAST 6 MONTHS).

E006. About how many times would you say you've had sex with her during the past 6 months?

#TIMES/6 MONTHS /47-49

E007. Now let's think about women you've had sex with two or more times. Are there any men you've had sex with TWO OR MORE TIMES in the past 6 months?

(MAKE CLEAR TO EXCLUDE TYPE 1 PARTNER; THAT IS, SOMEONE S HAD SEX WITH MORE THAN ANYONE ELSE).

No 0 (E010) /50

Yes 1

E008. How many different women did you have sex with TWO TIMES OR MORE over the past 6 months?

#/6 MONTHS /51-53

E009. About how many times altogether would you say you've had sex with (these women/this woman) during the last 6 months?

#/6 MONTHS /54-56

E010. Now let's think about the women you had sex with ONLY ONCE. In the past 6 months, have you had sex with someone ONLY ONCE?

No 0 (E013) /57

Yes 1

E011. How many different partners have you had sex with only ONE TIME during the past 6 months?

#/6 MONTHS /58-60

(INTERVIEWER: IF S'S ONLY PARTNER IS TYPE 3. TREAT THAT PARTNER AS A TYPE 1 PARTNER AND CODE FOR E004, E005 AND E006. E011 IN THIS INSTANCE IS CODED NO (0), AND E012 AND E013 ARE LEFT BLANK).

E012. So there have been……. (E011) partners you've had sex with only once in the past 6 months. That makes …… (E011) times (NOTE: E012 should equal E011).

#TIMES/6 MONTHS /61-63

E013. In the past 6 months, about how many times have you had sex with two or more women at the same, for example a 3-way?

#TIMES/6 MONTHS /64-66

E013a. In the past 6 months, about how many times have you had sex with two or more people, for example, a 3-way with one man and one woman?

#TIMES/6 MONTHS

CARD:	0 4	/1-2	
INSTRUMENT CODE	3 0	/3-4	
SUBJECT ID #:	0 1	/6-11	

INTERVIEWER SUMMARY CHART OF TOTAL NUMBER OF MALE SEX PARTNERS AND MALE SEX EPISODES IN THE PAST 6 MONTHS

FILL IN SUMMARY CHART FROM ITEMS LISTED. CHECK TOTALS WITH SUBJECT AND RECONCILE DISREPANCIES, INCLUDING ADJUSTEMENTS FOR E013, E013a AND B012a WHERE APPROPRIATE.

PARTNER TYPE	TOTAL NUMBER OF PARTNERS	TOTAL NUMBER OF EPISODES
TYPE 1	E004:	E006:
TYPE 2	E008:	E009:
TYPE 3	E011:	E012:
INITIAL TOTAL	E014: /67-69	E015: /70-72

So if we sum up all the times you had sex with women in the past 6 months, then you've had sex with…….. (E014) women about…….. (E015) times. Is that about right?

RECONCILLED TOTAL	E016: /73-75	E017: /76-78

E018. In the past 6 months, how many partners did you have sex with that you never had sex with before?

NONE.. 000 (SEC F)

SHOW HAND CARD 7

How many of these partners would you describe as…

E018a. A one-night stand (you had sex once and don't plan to again)

PARTNERS

E018b. Someone you know slightly but you don't plan to become steady partners

PARTNERS

E018c. Someone you know well but don't plan to become steady partners

PARTNERS

E018d. Someone you're starting or planning to start a steady relationship with

PARTNERS

E018e. Someone you've established a steady relationship with (a new lover)

PARTNERS

SECTION F- CURRENT PARTNERS BY SITUATION- FEMALE

Let me ask you about your women you've had sex with in the past 6 months in some more detail.

During the past 6 months, how many DIFFERENT women did you have sex with…

F001 …In exchange for giving them money?

WOMEN /24-27

F002. How many TIMES altogether?

TIMES /28-31

F003 … In exchange for receiving money from them?

#WOMEN /32-35

F004. How many TIMES altogether?

TIMES /36-39

F005 …In exchange for giving them drugs?

#WOMEN /40-43

F006. How many TIMES altogether?

#TIMES /44-47

F007 … In exchange for receiving drugs from them?

#WOMEN /48-51

F008. How many TIMES altogether?

TIMES /52-55

F009 … because you were forced to by them?

#WOMEN /56-59

F010. How many TIMES altogether?

#TIMES /60-63

F011 … In exchange for rent?

#WOMEN

F012. How many TIMES altogether?

#TIMES

F013… In exchange for receiving food from them?

WOMEN

F014. How many TIMES altogether?

#TIMES

F015… In exchange for receiving cigarettes from them?

#WOMEN

F016 How many TIMES altogether?

TIMES

SECTION G- CURRENT PARTNER CHARACTERISTICS- FEMALE

CHECK E004. IF S REPORTED TYPE 1 PARTNER, CONTINUE. OTHERWISE, SKIP TO INSTRUCTION ABOVE G006.

Here are some additional questions about the women you have had sex with in the past 6 months. First the woman you had sex with more than any other woman. As far as you know…

G001. Was she HIV positive or diagnosed with ARC or AIDS?

No, tested negative	0	/69
Don't know, or not tested	1	
I suspect she was	2	
Yes	3	

G002. Was she an IV drug user either during the past 6 months or before? That it, has he ever shot drugs, including skin popping?

No or don't know	0	/70
Yes	1	

G003. Did she ever receive a transfusion of blood or blood products (for hemophilia) between 1977 and 1985?

No or don't know	0	/71
Yes	1	

G004. DELETED /72

G005. During the past 6 months, did she have symptoms of a sexually transmitted infection or venereal disease such as gonorrhea (clap), herpes, syphilis, crabs, or warts?

No	0	/73
I suspect she did	1	
Yes	2	

(IF S REPORTED OTHER FEMALE PARTNERS, CONTINUE. OTHERWISE, SKIP TO SECTION I).

Now, to the other women you had sex with in the past 6 month. As far as you know, how many of them…

G006. …were HIV positive or diagnosed with ARC or AIDS?

#/6 MONTHS /74-76

G007 were IV drug users either during the past 6 months or before?

#/6 MONTHS /77-79

CARD:	0	4	/1-2		
		INSTRUMENT CODE	3	0	/3-4
		SUBJECT ID #:	0	1	/6-11

G008. Ever received a transfusion of blood or blood products (for hemophilia) between 1977 and 1985)

#/6 MONTHS /15-17

G009. DELETED /18-20

G010. had symptoms of a sexually transmitted disease during the past 6 months?

#/6 MONTHS

SECTION I- SEXUAL PRACTICES

(IF SUBJECT HAS BEEN TOTALLY CELIBATE DURING THE PAST 6 MONTHS (B002 AND E002 ARE ZERO), SKIP TO I105).

As you know, some sexual activities put people more at risk of AIDS infection than others. So, we need to find out in detail from everybody what kind of sex they are having. Remember, this will be kept private.

(INTERVIEWER: PERSONALISE THERMOMETER FOR PARTICIPANT BY ANCHORING DESCRIPTIONS WITH NUMBER OF REPORTED SEX OCCASIONS- E.G., IF PARTICIPANT HAD A TOTAL OF 40 SEX OCCASIONS WITH MALE PARTNERS, WRITE '40' BESIDE 'ALL OF THE TIME', '20' BESIDE 'HALF OF THE TIME', '0' BESIDE 'NEVER', ETC. IF PARTICIPANT HAD SEX WITH BOTH MALE AND FEMALE PARTNERS, GROUND A SEPARATE THERMOMETER FOR EACH).

(IF NO MALE PARTNERS (B002 IS ZERO), SKIP TO BOX I057C, OTHERWISE, CONTINUE).

Now we're going to review your sexual activities with all your men partners during the past 6 months. Please tell me HOW OFTEN you had the following sexual experiences with a man in the last 6 months. What PERCENT of the times in the last 6months when you had sex with a man did you…

MALE PARTNERS

With a male…	Percent of the time you had sex with male partner	In the past 6 months:	Percent of the time protection was used during this activity
Kissing I001. you and your partner kiss mouth to mouth	/51-53		
Caressing and fondling I002. You and your partner cuddle, touch, hug, massage each other	/54-56		
Masturbating I003. You masturbate or jerk him off I004. Your partner masturbate you	/57-59 /60-62		
Ejaculate into vagina I005. Your partner come in your vagina	/63-65	I006. Your partner use a condom when he came in your vagina	/66-68
Peno-vaginal I007. Your partner put his penis in your vagina	/69-71	I008. Your partner used a condom when he put his penis in your vagina	/72-74
Swallow semen			

I009. You swallow your partners semen	/75-77		
Oral-genital I010. You put your mouth/tongue on your partners penis/ he get a blow job I012 Your partner put his mouth/tongue on your vagina	/15-17 /21-23	I011. Your partner use a condom when you put your mouth/tongue on his penis I013. Your partner use plastic wrap (e.g. Saran Wrap) when he puts his mouth/tongue on or in your vagina	/18-20 /24-26
Ejaculate into rectum I014. Your partner come in your rectum	/27-29	I015. Your partner come in your rectum while wearing a condom	/30-32
Genital-rectal I016. Your partner put his penis in your rectum/have anal intercourse with him	/33-35	I017. Your partner use a condom when he put his penis in your rectum	/36-38
I018. Deleted	/39-41		
Oral-rectal I019. You put your tongue in your partners rectum/you rim him I021. Your partner put his tongue in your rectum/ he rim you	/42-44 /48-50	I020. you use plastic wrap (e.g. Saran wrap) when you rimmed him I22. Your partner use a plastic wrap (e.g. Saran wrap) when he rim you	/45-47 /51-53
Manual insertion I023. You put your fingers in your partner's rectum I025. Your partner puts his fingers in your rectum I027. You put your hand in your partner's rectum/you fist him I028. Your partner puts his hand in your rectum/he fist you	/54-56 /60-62 /66-68	I024. You use a condom or latex (rubber) gloves when you put your fingers in his rectum I026. Your partner use a condom or latex (rubber) gloves when he put his finger in your rectum I028. You use latex or rubber	/57-59 /63-65

	/72-74	gloves for fisting I030. Your partner use latex or rubber gloves for fisting	/69-71 /75-77
I031-I041. Deleted.	/15-47		
Sexual activity that might draw blood I042. Deleted I043. You get your partner's blood on your skin (which acts: indicate below) (includes acts such as piercing/puncturing the skin, using clamps, using weights, using whips, being tied up, or other (specify)).	/48-50 /51-53		
I044.- I050.- Deleted	/57-74		
Other sexual activity I051……. I052……..	/75-77 /78-80		
Orgasm I053. You come when having sex with a man	/15-17		

I054. During the past 6 months, how many times did you have unprotected vaginal intercourse (that is, he put his penis into your vagina without using a condom), WHILE YOU WERE HAVING YOUR PERIOD?

TIMES/6 MONTHS /18-20

(IF 0, SKIP TO I056)

I055. With how many different men did you do this with during the past 6 months?

#/6 MONTHS /21-23

I056. During the past 6 months, with how many different male partners did you have unprotected vaginal sex, that is, he put his penis into your vagina without a condom?

#/6 MONTHS /24-26

I057. How many different male partners did you RIM, that is, you put your mouth or tongue on or into their rectum?

#/6 MONTHS /27-29

In the next questions, we want to know how likely you are to use condoms (rubbers) with different kinds of partners. In the past 6 months, how often did you use condoms when you had vaginal and/or anal sex with…

I057a. Someone you had sex with more than anybody else

	All of the time	1
SHOW HAND CARD	Most of the time	2
8	Some of the time	3
	None of the time	4
	N/A	8

I057b. Someone you had sex with two or more times

All of the time	1	
SHOW HAND CARD	Most of the time	2
8	Some of the time	3
	None of the time	4
	N/A	8

I057c. Someone you only had sex with once?

All of the time	1	
SHOW HAND CARD	Most of the time	2
8	Some of the time	3
	None of the time	4
	N/A	8

(IF NO FEMALE PARTNERS (E002 IS ZERO), SKIP TO I105, OTHERWISW, CONTINUE).

FEMALE PARTNERS

Now I'd like to go over the types of Sex you had with all your women partners during the past 6 months. Please tell me HOW OFTEN you had the following sexual experiences with a woman in the last 6 months. What PERCENT of the times that you had sex with a woman did you:

With a female…	Percent of the time you had sex with male partner	In the past 6 months:	Percent of the time protection was used during this activity
Kissing I058. you and your partner kiss mouth to mouth	/30-32		
Caressing and fondling I059. You and your partner cuddle, touch, hug, massage each other	/33-35		
Masturbating I060. You masturbate your partner I061. Your partner masturbate you	/36-38 /39-41		
Oral-genital I062. You go down on your partner/You put your mouth/tongue on her vagina I064 Your partner put her mouth/tongue on your vagina	/42-44 /48-50	I063. Your partner use a condom when you went down on your partner I065. Your partner use plastic wrap (e.g. Saran Wrap) when she went down on you	/45-47 /51-53
Oral-rectal I066. You put your tongue in your partners rectum/you rim her I068. Your partner put her tongue in your rectum/ she rim you	/54-56 /60-62	1067. You use plastic wrap (e.g. Saran wrap) when you rimmed her I069. Your partner use a plastic wrap (e.g. Saran wrap) when she rimmed you	/57-59 /63-65
Manual insertion I070. You put your		I071. You use a	

fingers in your partner's rectum I072. Your partner puts her fingers in your rectum I074. You put your hand in your partner's rectum/you fist her I076. Your partner puts her hand in your rectum/she fist you	/15-17 /21-23 /27-29 /33-35	condom or latex (rubber) gloves when you put your fingers in her rectum I073. Your partner use a condom or latex (rubber) gloves when she put her finger in your rectum I075. You use latex or rubber gloves for fisting I077. Your partner use latex or rubber gloves for fisting	/18-20 /24-26 /30-32 /36-38
I078-I089. Deleted.	/39-74		
Sexual activity that might draw blood I090. Deleted I091. You get your partner's blood on your skin (which acts: indicate below) I092. Your partner get blood one her skin (which acts: () bracket below) (includes acts such as piercing/puncturing the skin, using clamps, using weights, using whips, being tied up, or other (specify)).	/15-17 /18-20 /21-23		
I093.- I098.- Deleted	/24-47		
Other sexual activity I099……. I100……..	/42-44 /45-47		
Orgasm			

I101. You come when having sex with a man	/48-50		

I102-I103- deleted

/51-56

I103a. In the past 6 months, have you gotten menstrual blood on any parts of your body during sex? For example, on your hands, fingers or mouth?

No 0 (I104)

Yes 1

I103b. How many times did this happen in the past 6 months?

#TIMES/6 MONTHS

I103c. With how many different women did this happen in the past 6 months?

#WOMEN/6 MONTHS

I104 How many different female partners did you RIM, that is, you put your mouth or tongue on or into their rectum?

#WOMEN/ 6 MONTHS /57-59

……..

As you know, most women masturbate, that is, stimulate themselves to come, at some point in their life. About how often in the past 6 months did you masturbate alone, per day, per week, or per month?

I105. …….. times a day OR

#TIMES/ DAY /60-61

I106…….. times a week OR

#TIMES/ WEEK /62-63

I107…….. times a month

#TIMES/ MONTHS /64-65

I108 ……..Total in 6 months

#TIMES/6 MONTHS /66-67

SECTION J- DRUG USE DURING SEX- PAST 6 MONTHS

Now, please think again about all the times you had sex with a partner during the past 6 months. Please look at this card and tell me how often you used (DRUG) when you've had sex with a man or woman in the last 6 months.

J001- If subject is abstaining from partner sex code…9

Show hand card 9	In the past 6 months: percent of the time you had partner sex using…
J002. Alcohol such as beer, wine or spirits	/16-18
J003. Marijuana, hashish (pot, grass)	/19-21
J004. Amphetamines (stimulants, uppers, speed, crystal meth, ICE)	/22-24
J005. Barbiturates (sedatives, downers, sleeping pills, seconal, Quaaludes, Lotus 8)	/25-27
J006. Tranquilizers (Valium, Librium, Ativan, Xanax	/28-30
J007. Crack	/31-33
J008. All other forms of cocaine (coke)	/34-36
J009.Heroin	/37-39
J010. Speedballing (heroin and coke together)	/40-42
J011. Methadone	/43-45
J012. Opiates (other than heroin: codeine, Darvon, opium)	/46-48
J013. Psychedelics (LSD, mescaline, peyote, psilocybin, DMT, PCP)	/49-51
J014. Ethyl chloride, amyl or butyl nitrate (poppers)	/52-54
J015. Combinations: (Ecstasy, MDA, MDM, special k)	/55-57
J016. Other (e.g. glue, white-out, gasoline) (specify)…	

SECTION K- PAST PARTNERS- MALE, FEMALE

I'd like to switch now to the past.

K001. Were you ever married to a man?

No	0	(INTRO ABOVE K008)	/15
Yes	1		

How old were you…

K002. When you first got married?

#AGE-YEARS /16-17

K003. When this marriage ended?

#AGE-YEARS /18-19

K004. When you got married for a second time?

#AGE-YEARS /20-21

K005. When your second marriage ended?

#AGE-YEARS /22-23

K006. When you got married for a third time?

#AGE-YEARS /24-25

K007. When your third marriage ended?

#AGE-YEARS /26-27

LIFETIME- Men

Let's figure out how many different men you have had sex with in your lifetime before the past 6 months. We can't be totally exact, of course, but let's try to make it a bit easier by doing it by decades in your life. (INTERVIEWER: IF SUBJECT WAS ABSTINENT WITH MALES IN PAST 6 MONTHS, REVIEW SEXUAL PRACTICES VERNACULAR BEFORE ADMINISTERING K008).

If subject denies sex with males lifetime skip to females intro-females

K008. Let's start with your teen years. Between age 10 and 19, how many different steady men partners did you have? (Enter in table- type 1) (Note that lovers may overlap decades so count such partners ONLY ONCE).

How many other men partners did you have sex with more than once? (Enter in table- type 2)

And how many men did you have sex with only once? (Enter in table- type 3)

So that makes altogether…. (SUM UP AND ENTER)

Continue for subsequent decades.

(If subject volunteers that she has had none, skip to intro, above K15. If subject volunteers a very low number, try to fill out summary table immediately).

SUMMARY OF MALE PARTNERS-LIFETIME (MINUS PAST 6 MONTHS)

	Age 10-19	20's	30's	40's	50's	60's
T-1 steady partners						
T-2 other partners you had sex with more than once						
T-3 partners you only had sex with once						
Totals	Men	Men	Men	Men	Men	Men

K009. So the total number of different STEADY PARTNERS you had sex with up until 6 months ago is…. (Note that a simple summing up may be misleading since lovers may overlap several decades so count such lovers ONLY ONCE).

SUM UP AND ENTER HERE……..#MEN /28-31

K010. Up until 6 months ago, the total number of men you had sex with MORE THAN ONCE, BUT NOT COUNTING YOUR STEADY PARTNER(S) is…….

SUM UP AND ENTER HERE……..#MEN /32-35

K011. And the total number of men you had sex with ONLY ONCE before (6months ago date) is…….

SUM UP AND ENTER HERE……..#MEN /36-390

K012. So the total number of men you had sex with in your life until (6months ago date) comes up to……..

Sum K009+K010+K011 #MEN /40-43

(PRELIMINARY)

K013. Does this sound about right?
(If not, reconcile with subject) #MEN /44-47

(RECONCILED)

K014. Now give me an estimate of how many times you have had any kind of sex with a man in your lifetime (This DOES NOT include the past 6 months).

#TIMES/LIFE /48-52

LIFETIME-WOMEN

Let's figure out how many different women you have had sex with in your lifetime before the past 6 months. We can't be totally exact, of course, but let's try to make it a bit easier by doing it by decades in your life. (INTERVIEWER: IF SUBJECT WAS ABSTINENT WITH FEMALES IN THE PAST 6 MONTHS, REVIEW SEXUAL PRACTICES VERNACULAR, BEFORE ADMINISTERING K015).

If subject denies sex with females lifetime skip to section L

K015. Let's start with your teen years. Between age 10 and 19, how many different steady sex partners did you have? (Enter in table- type 1) (Note that lovers may overlap decades so count such partners ONLY ONCE).

How many other women partners did you have sex with more than once? (Enter in table- type 2)

And how many women did you have sex with only once? (Enter in table- type 3)

So that makes altogether….

Continue for subsequent decades.

(If subject volunteers that she has had none, skip to intro, above K15. If subject volunteers a very low number, try to fill out summary table immediately).

SUMMARY OF FEMALE PARTNERS- LIFETIME (MINUS PAST 6 MONTHS)

	Age 10-19	20's	30's	40's	50's	60's
T-1 steady partners						
T-2 other partners you had sex with more than once						
T-3 partners you only had sex with once						
Totals	Women	Women	Women	Women	Women	Women

K016. So the total number of different STEADY WOMEN PARTNERS you had sex with up until 6 months ago is…. (Note that a simple summing up may be misleading since lovers may overlap several decades so count such lovers ONLY ONCE).

SUM UP AND ENTER HERE…….#FEMALES /53-56

K017. Up until 6 months ago, the total number of women you had sex with MORE THAN ONCE, BUT NOT COUNTING YOUR STEADY PARTNER(S) is…….

#FEMALES /57-60

K018. And the total number of women you had sex with ONLY ONCE before (6months ago date) is…….

#FEMALES /61-64

K019. So the total number of women you had sex with in your life until (6months ago date) comes up to……..

Sum K016+K017+K018 #FEMALES /65-68

(PRELIMINARY)

K020. Does this sound about right?

(If not, reconcile with subject) #FEMALES /69-72

(RECONCILED)

K021. Now give me an estimate of how many times you have had any kind of sex with a woman in your lifetime (This DOES NOT include the past 6 months).

#TIMES/LIFE /73-77

SECTION L- AVOIDANCE

L118. In the past 6 months, did you deliberately AVOID SEXUAL CONTACT with any man or woman because of fears or concerns about AIDS, or because you or your partner have the AIDS virus?

No	0	(END)	/47
Yes	1		

(INTERVIEWER: READ QUESTIONS FROM HAND CARD 10. (DO NOT SHOW CARD TO SUBJECT)).

L119. A……. /48
L120. B……. /49
L121. C…….. /50
L122. D…….. /51
L123. E……. /52
L124. F…….. /53

L125. G…….. /54

L126. F (some other reason)……. /55

L127. In the past 6 months, how much did you avoid sex because of fears or concerns about AIDS? Did you… **(show hand card 11)**

Have no sex (abstinence)	1		/56
Just have sex with one person	2	(END)	
Just have sex with fewer people than you used too	3	(END)	
Other	4		

(If subject reported avoiding all sexual contact because of AIDS-related reasons, ask L128).

L128. When did you stop having sex with men? (even if more than 6 months ago)

MONTH……. DAY…… YEAR…… /57-62

(If applicable…)

L129. When did you stop having sex with women? (even if more than 6 months ago).

MONTH……. DAY…… YEAR…… /63-68

SECTION M- INTERVIEWER REMARKS

M001. Subject's cooperation was: /20

Very good	1
Good	2
Fair	3
Poor	4

The quality of the interview is: (COMPLETE FOR EACH SECTION)

High quality	1
Generally reliable	2
Questionable	3
Unsatisfactory	4

SECTION

M002. Introduction	1	2	3	4	/21
M003. Current partners, by type- male	1	2	3	4	/22
M004. Current partners by situation- male	1	2	3	4	/23
M005. Current partner characteristics- male	1	2	3	4	/24
M006. Current partners, by type- female	1	2	3	4	/25
M007. Current partners by situation- female	1	2	3	4	/26
M008. Current partner characteristics- female	1	2	3	4	/27
M009. DELETED	1	2	3	4	/28
M010. Sexual practices- past 6 months	1	2	3	4	/29
M011. Drug use during sex	1	2	3	4	/30

M012. Past partners- male, female 1 2 3 4 /31

M013. Avoidance- past 6 months 1 2 3 4 /32

M014. The overall quality of the interview is:

High quality	1	(N001) /33
Generally reliable	2	(N001)
Questionable	3	
Unsatisfactory	4	

The reasons for unsatisfactory or questionable quality of information were because the subject:

	No	Yes	
M015. Did not feel comfortable with the topic	00	01	/34-35
M016. Did not want to be more specific	00	01	/36-37
M017. Did not understand or speak English well	00	01	/38-39
M018. Was bored or uninterested	00	01	/40-41
M019. Seemed upset or depressed	00	01	/42-43
M020. Seemed to have poor hearing or speech	00	01	/44-45
M021. Was confused by frequent interruptions	00	01	/46-47
M022. Seemed emotionally unstable	00	01	/48-49
M023. Was physically ill	00	01	/50-51
M024. Seemed to have trouble remembering	00	01	/52-53

M025. Refused to give information for certain sections 00 01 /54-55

(Which sections, specifically?

M026. Other (specify) 00 01 /56-57

Comments:

Appendix 19- Acceptability questionnaire

1. **Why did this study interest you, why did you agree to take part**

2. **How did you find out about the study?**

3. **How did you find the overall experience?**

4. **What could have improved the experience**

   a. **Time/timing?**

☐	☐	☐	☐
Far too long	Somewhat too long	Just the right timing	Not enough time

   b. **Comfort?**

☐	☐	☐	☐
Very comfortable	Comfortable	Somewhat Uncomfortable	Not at all comfortable

   c. **Supportive and safe environment?**

☐	☐	☐
Very safe and	Safe and supportive	Somewhat unsafe

supportive environment environment and unsupportive environment

☐

Not at all safe or supportive

environment

d. Nature of questions relevant?

☐ ☐ ☐ ☐

Very relevant Relevant Somewhat Not at all

relevant relevant

e. Convenience of location?

☐ ☐ ☐ ☐

Very convenient Convenient Somewhat Not at all

convenient convenient

f. Privacy?

☐ ☐ ☐ ☐

Very private Private Somewhat Not at all

private private

5. How did you feel about completing the questionnaire/interview?

a. Any particular aspects or topics you want to mention in terms of comfort?

b. Any suggestions for issues not included?

c. How can we improve how we collect this important data in the future?

6. Have you thought about or talked about any of these issues with…

a. Partner
b. Friend
c. Key worker
d. GP
e. Psychiatrist
f. other

Appendix 20- Risk protocol

The following principles and procedures govern the assessment, reporting and monitoring of risk of self-harm/suicide or other potential risks for the sexual health and severe mental illness study:

- All researchers should follow this protocol when conducting all participant assessments.
- All researchers will be given risk training specific to this study.
- When clinical leads are away they should ensure appropriate cover is arranged for any risk issues that may arise.

This study specific procedure includes the following:

1. **Preparation for sessions**
2. **Exploring risk questions & level of risk**
3. **Reporting risk to clinical lead**
4. **Documenting the procedure and storage**
5. **Exploring other risk issues**

Appendix 1: Clinical contact details

Appendix 2: Self-harm/suicide risk disclosed during questionnaire/interview session: flow chart 1

Appendix 3: Exploring risk questions (3a) & Guidance (3b)

Appendix 4: Self-harm/suicide risk form

Appendix 5: Non-suicide risk form

1. Preparation for assessments

The researcher **must** ensure that they have the following documents with them when conducting questionnaire/interview sessions with participants to ensure risk protocols can be implemented as quickly and as accurately as possible:

- A copy of the 'researcher protocol: Disclosure of self-harm/suicide risk and other potential risks'
- Contact details for clinical lead(s)

- Copies of the risk of self-harm/suicide flowchart
- A blank copy of the 'exploring risk questions'
- A copy of the 'exploring risk questions' Guidance
- A copy of the 'self-harm/suicide risk form'
- A copy of the 'non-suicide risk form'
- Access to a mobile phone
- Contact details for: participant's care co-ordinator/duty worker, out of hours/crisis team/local taxi number- in case of risk emergencies.

Disclosure of risk during questionnaire/interview session:

- This protocol must be enacted if the participant discloses risk of suicidal thoughts/intent/plans, or expresses risk of self-harm to the researcher during a questionnaire/interview session.
- This protocol must also be enacted if the participant discloses other potential risks (see section 5).

2. Exploring Risk Questions & Level of Risk

- If risk of self-harm/suicide is disclosed during the questionnaire/interview session, the six 'exploring risk questions' should be asked.

Actions to take following disclosure of risk of self-harm/suicide:

- Explain to the participant that you need to ask them some further questions, using the following phrase:

  "You have mentioned <repeat participant's words used in interview>. I'm sorry that you're feeling this way right now. I would like to ask you a few more questions that will explore these thoughts and feelings further. Some of the questions are sensitive but they are very important in making sure you receive the right kind of support"

- Ask the participant the six 'exploring risk questions' (see Appendix 3a) – make sure you document **verbatim** the participant's responses to the probing question **and** each of the six exploring risk questions to aid in establishing level of risk.
- Use the 'exploring risk questions guidance' (Appendix 3b) to determine the possible level of risk & advise the participant of the outcome:

- **Level A:** advise the participant to make an appointment to see a member of their care tea, to talk about their thoughts and feelings. **Contact the clinical lead by telephone immediately following the session.**

- **Level B:** advise the participant that you will be writing to their care coordinator/duty worker to tell them they have been experiencing these thoughts and feelings, and advise them to make appointment to see a member of their care team to talk about their thoughts and feelings. **Contact the clinical lead by telephone immediately following the assessment.**

- **Level C:** advise the participant that you are going to contact your clinical lead and their care coordinator/duty worker/the emergency services to let them know they have been experiencing these thoughts and feelings and to arrange for them to receive immediate help. **Contact the clinical lead by telephone IMMEDIATELY.** If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… Level C risk'. The clinical lead will then respond when available. The researcher should then **follow the 'Actions to take in the case of immediate risk' below.**

- The researcher should then contact the clinical lead by telephone to advise them of the risk of self-harm/suicide, the participant's responses to the exploring risk questions and your response following the exploring risk questions guidance.

- If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… risk'. The clinical lead will then respond when available.

- If the clinical lead advises/confirms that a letter needs to be sent to the participant's care co-ordinator/duty worker, a brief narrative summary of the participant's response to the exploring risk questions should be completed. The letter should be signed by the researcher and countersigned by the clinical lead, and then sent to the participant's care team.

- The researcher should sign and date the exploring risk questions form.

- The researcher should then complete the 'self-harm/suicide risk form' (Appendix 4). This needs to be signed and dated by the researcher and countersigned and dated by the clinical lead.

Actions to take in the case of immediate risk:

- If the level of risk has been identified as **Level C** then the participant requires immediate help – **do not leave the participant alone.**
- Contact the clinical lead by telephone **IMMEDIATELY** in order to involve a supervisory clinician right away. The clinician will discuss with the researcher the necessary actions to take, which are likely to include one or more of those listed below.
- If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… IMMEDIATE risk'. If the clinical lead does not respond immediately, the researcher should take one of the actions listed below.
- Contact care coordinator/duty worker.
- Accompany the participant to A&E if the participant is on hospital premises – do not leave the participant until a clinician has taken responsibility for their care.
- Call a taxi to take the participant to A&E if participant is not on hospital premises. The researcher should accompany the participant to A&E and should not leave the participant until a clinician has taken responsibility for their care.
- Call an ambulance.

Telephone Numbers for care co-ordinator/ duty worker: <insert relevant number>

3. Reporting risk to clinical lead

- If a participant has been disclosed being at risk of self-harm/suicide, the researcher must contact the clinical lead by telephone via the contact details list.
- If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… risk'. The clinical lead will then respond when available.
- The researcher will need to report how the risk was identified/disclosed and the participant's verbatim responses to the exploring risk questions.
- The clinical lead and researcher will decide whether or not the participant's care coordinator/duty worker should be contacted, and if so whether to contact them by letter or by telephone, depending on the level of risk:
- The clinical lead may advise the researcher not to call or send a letter to the participant's care team (i.e. Level A risk).

- The clinical lead may advise the researcher to send a letter to the participant's care team ('Letter: Notification of Risk') detailing a brief narrative summary of the participant's response to the exploring risk questions. The letter must be signed by the researcher and countersigned by the clinical lead.
- The clinical lead may advise the researcher to contact the participant's care coordinator/duty worker by telephone to advise them of the participant's risk of self-harm/suicide.
  - The researcher is to inform the clinical lead when the participant's care coordinator/duty worker has been informed (by telephone or by letter) of the risk of self-harm/suicide.
  - The researcher should sign and date the exploring risk questions form.
  - The clinical lead should countersign and date the 'self-harm/suicide risk form' once completed and signed and dated by the researcher.

4. Documenting the procedure and storage

- The researcher must ensure they have signed and dated the exploring risk questions form.
- Researcher must ensure the self-harm/suicide risk form (Appendix 4) has been completed accurately, signed and dated, and has been countersigned and dated by the clinical lead.
- Researcher to clearly document all contacts, decisions, actions/lack of actions and rationales on the self-harm/suicide risk form. The form should be signed and dated by the researcher, and countersigned and dated by the clinical lead.
- Researcher to document on the study spreadsheet that the risk protocol has been enacted and that letter has been sent to participants care coordinator/duty worker
- Researcher must ensure the completed self-harm/suicide risk form and exploring risk questions form have been filed away in the participant's personal non-data file.
- Researcher must ensure that a copy of the 'Letter: Notification of Risk' letter is stored in the participant's personal non-data file.

There may be instances where a different course of action needs to be implemented from those detailed here, where this is deemed clinically appropriate following consultation with a clinician. Any such instances will be documented appropriately on the self-harm/suicide form.

5. Exploring other risk issues

Instances may arise when other non-suicide risk issues need to be explored. Such instances may include, but are not restricted to:

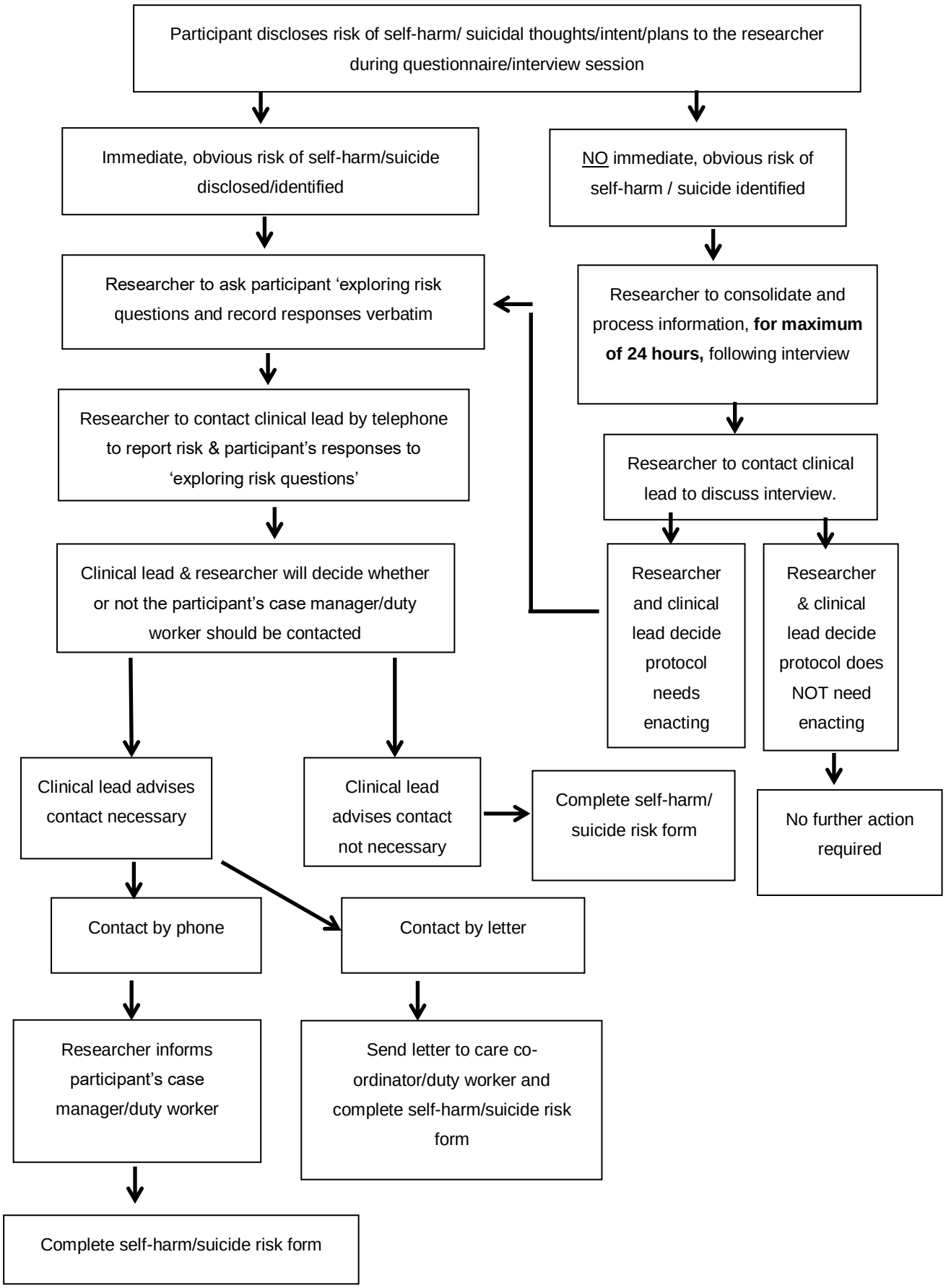
- Risk to others
- Risk from others - this includes events such as domestic violence

- The researcher should contact the clinical lead by telephone to discuss their concerns.
- Researcher must ensure the non-suicide risk form (Appendix 5) has been completed accurately, signed and dated, and has been countersigned and dated by the clinical lead.
- Researcher to clearly document all contacts, decisions, actions/lack of actions and rationales on the non-suicide risk form. The form should be signed and dated by the researcher, and countersigned and dated by the clinical lead.
- Researcher to document on the study spreadsheet that a non-suicide risk form has been completed.
- Researcher must ensure the completed non-suicide risk form has been filed away in the participant's personal non-data file.
- If any letters are sent regarding a non-suicide risk, the researcher must ensure that a copy of the letter is stored in the participant's personal non-data file.

Clinical lead contact details

	Contact 1: **Professor Elizabeth Hughes**	**Contact 2:** **Professor Simon Gilbody**
Role	Clinical Lead/supervisor	Clinician/Psychiatrist/supervisor
Mobile		
Email	E.C. Hughes@hud.ac.uk	Simon.gilbody@york.ac.uk

Self-harm/suicide risk flowchart 1: Disclosed via questionnaire/interview session



Exploring risk questions

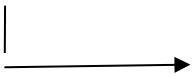
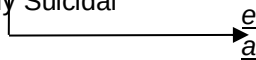
Probing question: "Can you tell me more about why you expressed suicidal thoughts/intent/plans? Details of disclosed thoughts (please record verbatim as far as possible)	
Plans	
7. Do you know how you would kill yourself? If **Yes** – details	Yes / No
8. Have you made any actual plans to end your life? If **Yes** – details	Yes / No
Actions	
9. Have you made any actual preparations to kill yourself? If **Yes** – details	Yes / No
10. Have you ever attempted suicide in the past? If **Yes** – details	Yes / No
Prevention	
11. Is there anything stopping you killing or harming yourself at the moment? If **Yes** – details	Yes / No
12. Do you feel that there is any immediate danger that you will harm or kill yourself? If **Yes** – details	Yes / No

Researcher name:

Researcher signature: **Date:**

Exploring risk questions guidance

This guidance is to be used to determine the level of risk, A B or C, based on the participant's responses to the six Exploring Risk Questions.

Participant's responses to Exploring Risk Questions	**Advise the participant**
All answers 'no' apart from Q5 'yes':  **A** 	*I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see a member of your mental health team to talk about these feelings.*
'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6  **B1** 	*Things seem to be very hard for you right now and I think it would help if you were to speak to a member of your mental health team about these feelings. I will be writing to your care co-ordinator to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see a member of your mental health team to talk about these feelings.*
Scoring 'no' to Q5 or 'yes' to Q6  **C** Actively Suicidal 	*I am very concerned about your safety at this moment, I am going to make some telephone calls to your GP/ the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.*

Self-harm/suicide risk form

The participant below has disclosed/identified as having thoughts of suicidal intent/self-harm during the questionnaire/interview session.

Participant ID Code: ☐☐☐

Date of questionnaire/interview session:

Has the participant been advised to contact their care co-ordinator/ duty worker?: Yes ☐ No ☐

Has the care team been sent the notification of risk letter? Yes ☐ No ☐

Summary of how suicide risk protocol was implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact care co-ordinator/duty worker within mental health team, name of person spoken to, date of contact)

Researcher name: …….....

Research signature: …… Date: ……...

Name of clinical contact: …….....

Clinical contact signature: ……. Date: ……..

Non-suicide risk form

The participant below has disclosed/identified as being at risk other than self-harm/suicide during a questionnaire/interview session.

Participant ID Code: ☐☐☐

Assessment date:

Risk identified and how:

Summary of how risk protocol implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact care co-ordinator/duty worker within mental health team- name of person spoken to, date of contact)

Researcher name: ……..

Research signature: …… Date: ……...

Name of clinical contact: ……..

Clinical contact signature: …… Date: ……..

Appendix 21- Lone worker policy

Lone Worker Policy

This Lone Worker Policy applies to participant assessments which are to be conducted either in a **community location** or in a **participant's home**. It is essential that the researcher follow this policy.

1. The 'buddy' system:

- A 'buddy' system needs to be in place for all participant questionnaire/interview sessions conducted in a community location or in a participant's home.

- The 'buddy' will need to be a member of the supervisory team who works on study and has the necessary approvals to access participant information.

- The 'buddy' will need to be contactable **by telephone** (landline and/or mobile) for the time period of the planned participant questionnaire/interview sessions.

2. Before the Assessment:

- Once the researcher has arranged to conduct the participant assessment, they will need to arrange a buddy who will be contactable **by telephone** (landline or mobile) for the time period of the questionnaire/interview session

- The researcher will need to provide their buddy with details of the participant's ID, and the date, time and location of the scheduled participant questionnaire/interview session.

- The researcher should ensure that:
  - Their buddy has their (the researcher's) correct contact details
  - Their buddy has their (the researcher's) 'designated contact' contact details
  - They have their buddy's correct contact details
  - Their mobile phone is fully charged

- The day before the participant questionnaire/interview session is due, the researcher should confirm that their buddy is still available for the required time period

3. After the assessment:

- Immediately after the participant questionnaire/interview session has finished, the researcher should contact their buddy **by telephone** to confirm that the participant questionnaire/interview session has finished and that they are safe and are on their way back to the research site
- If the researcher is unable to get through to their buddy, they are to leave a **voice message** advising their buddy that they have finished the questionnaire/interview session and that they are safe and are on their way back to the research site
- If the buddy has not contacted the researcher back after 10 minutes, the researcher is to try contacting the buddy again.

4. Buddy's responsibilities:

- The buddy needs to be available for the entire time period of the scheduled participant assessment
- The buddy needs to have the researcher's contact details to hand, and all the information relevant to the participant's assessment (i.e. participant's ID, date, time and location of assessment)
- The questionnaire/interview session should last a maximum of 90 minutes.
    - The buddy should remain available until the researcher has contacted them **by telephone** to confirm that the participant assessment has finished, and that they are safe and are on their way back to the research site
    - If the buddy misses the call from the researcher, the buddy is to contact the researcher **by telephone** as soon as the message is received.

If no contact has been made by the researcher:

- If the researcher has not been in contact with their buddy by telephone **20 minutes** after the participant questionnaire/interview session was due to end, then the buddy should contact the researcher on their mobile phone.

- If the researcher does not answer their phone or does not contact the researcher back within a further **10 minutes**, then the buddy should contact another member of the supervisory team, in case the researcher has been in touch with them.
- If the other members of the supervisory team confirm that the researcher has not been in contact with them, the buddy should then attempt to contact the participant using their home and/or mobile contact numbers.

- If the buddy is not able to make contact with the participant, they should attempt to contact the researcher's 'designated contact' by telephone to see if the researcher has been in contact with them.

- If the buddy has still not made contact with the researcher, then the buddy should contact the local police and give them the location of the participant assessment and explain the situation.

5. Researcher's responsibilities:

If the researcher has been delayed:

- If the researcher is delayed – either during the participant questionnaire/interview session or arriving at the questionnaire interview session – the researcher should contact their buddy **by telephone** to inform them of this delay and to advise of an approximate time that the session is now due to finish.

If the researcher is being held against their will:

- If the researcher is being held against their will during the participant questionnaire/interview session and is able to contact their buddy (either by telephone or text) but is unable to explain their situation, they should say "Can you cancel my meeting with Steve please?"
- The buddy should then contact the local police **immediately**, providing them with the location of the participant assessment and explaining the situation.

Appendix 22- Initial response from HSRGC

UNIVERSITY of York

Department of
Health Sciences

c/o Department of Philosophy
Heslington
York YO10 5DD

Telephone (01904) 433253
Fax (01904) 321383
E-mail
smh12@york.ac.uk

Dr Stephen Holland

www.york.ac.uk/healthsciences

16th March 2016

Samantha J Gascoyne

Department of Health Sciences

Mental Health and Addictons Research Group

University of York

YO10 5DD

Dear Samantha

An acceptability and feasibility study of sexual risk behaviour in adults with severe mental illness in the UK: A pilot study

Thank you for submitting your project to the Health Sciences Research Governance Committee for approval. The study was considered by the committee at its meeting on 14 March 2016. The committee decided not to approve the IRAS form, and require a resubmission. As I explained in my subsequent email, I am very aware how disappointing this is, especially given the time pressure you are under to complete

your thesis. So, I will give you all the support I can to help you revise the submission. In this respect, thank you for agreeing to meet with me next Tuesday to discuss the study. Also, I am writing some specific feedback points which will help us to structure that discussion; in addition, I will convene a subcommittee of the HSRGC to consider your resubmission, so you do not have to wait for the next full HSRGC meeting.

First, here are some specific feedback points:

1. Section A13 of the REC form is not filled in. This is a very important section, so the form could not go forward without this being completed.
2. A17-2: 'Adults with a primary diagnosis of substance use (unless they also have an SMI)' are excluded. (i) It would be clearer to exclude all adults with a primary diagnosis of substance use, (ii) substance use can compromise the capacity to consent and (iii) substance users are an unpredictable participant group, increasing worries about researcher safety.
3. A.18: The committee thought it unrealistic that the questionnaire/interview contained in Appendix 5 would only take 60 minutes.
4. A35: under *Further details* it would be worth explaining that the research timeframe is short so loss of capacity is unlikely.
5. A.43: less than 3 months is a very short time for data to be stored.
6. A53. 'The participants will be asked during the consent process …': there does not seem to be a relevant tick box on the consent form.
7. Patient information sheet: under 'Who has reviewed this study?' the name of the committee is the Health Sciences Research Governance Committee.

In addition, the committee had more general concerns with the project, and I think this is where we should focus our discussion on Tuesday. The main issues are the research objective and study design, and the relationship between these. The committee are unclear on quite what the aim of the study is: e.g., is it to elicit substantive data on the sexual history and attitudes of adults with an SMI; or is it a methodological question, focusing on how best to design studies intended to acquire such data? Large parts of the Data Collection Tool (Appendix 5) are basically surveys; why would these need to

be administered 1-1 and face-to-face, especially given that this will increase discomfort on the part of a very vulnerable participant group, and create worries about researcher safety? The various parts of the Data Collection Tool don't seem entirely coherent (e.g., repetition of questions) or appropriate (e.g., 'Please keep in mind that the hospital staff will not have access to any of the answers you give me').

In sum, the committee felt that the study needs looking at again before going out to the REC. Your supervisors and I will help you in this. But I would like to reiterate some points. The committee fully recognises that this is an important area of research. Large parts of the submission are perfectly approvable, and there is clear evidence of sensitivity to ethical issues arising from the research, such as embarrassment, and sensible ways of dealing with them. Finally, and without in any way prejudging the outcome, in my experience, resubmissions of worthwhile research by good students with experienced supervisors have invariably been successful.

I look forward to meeting you on Tuesday, when we will work together to develop the resubmission, in the light of this feedback

Yours sincerely

Stephen Holland

Chair: HSRGC

Appendix 23- Response letter to HSRGC

An acceptability and feasibility study of sexual risk behaviour in adults with severe mental illness in the UK: A pilot study

S, Gascoyne, Professor E Hughes, Professor S Gilbody, Professor C. Hewitt, Professor K McKinnon.

Please find below actions and responses to recommendations made by the HSRGC on 16th March 2016 and following a meeting with Dr Stephen Holland on 22nd March 2016.

Recommendations from HSRGC	**Response and actions from research team**
Section A13 of the REC form is not filled in. This is a very important section, so the form could not go forward without this being completed.	This was a system error and has now been completed.
A17-2: 'Adults with a primary diagnosis of substance use (unless they also have an SMI)' are excluded. (i) It would be clearer to exclude all adults with a primary diagnosis of substance use, (ii) substance use can compromise the capacity to consent and (iii) substance users are an unpredictable participant group, increasing worries about researcher safety.	All adults with a primary diagnosis of substance use are excluded
A.18: The committee thought it unrealistic that the questionnaire/interview contained in Appendix 5 would only take 60 minutes.	This has now been increased to approximately 90minutes, to take account of differing levels of sexual activity. This has also been updated on the participant information sheet.
A35: under *Further details* it would be worth explaining that the research timeframe is short so loss of capacity is unlikely.	This has been added into relevant section.
A.43: less than 3 months is a very short time for data to be stored.	This section specifically refers to 'personal data' therefore has remained at 'less than 3 months' as personally identifiable information will be destroyed securely within this 3 month period.

A53. 'The participants will be asked during the consent process …': there does not seem to be a relevant tick box on the consent form.	This relates to the dissemination of study findings. This has now been added to the consent form.
Patient information sheet: under 'Who has reviewed this study?' the name of the committee is the Health Sciences Research Governance Committee.	This has been added to the participant information sheet.
The committee are unclear on quite what the aim of the study is: e.g., is it to elicit substantive data on the sexual history and attitudes of adults with an SMI; or is it a methodological question, focusing on how best to design studies intended to acquire such data?	The overall aim is to undertake a small pilot study to examine recruitment processes, and get participant feedback on the acceptability of a sexual health interview. **Main objectives** 1. Assess the feasibility and acceptability of undertaking a study of sexual risk behaviours by: assessment of numbers eligible, number consenting to participate and number of completed questionnaire/interviews. 2. Explore acceptability of data collection measures used and data collection method. **Secondary Objectives** In addition to the main aims, the following secondary aim will also be met by this study: 3. Evaluate the completeness of the sexual health questionnaire and interview (which questions were completed/refused) (pg 4 protocol)
Large parts of the Data Collection Tool (Appendix 5) are basically surveys; why would these need to be administered 1-1 and face-to-face	Section 3 of the questionnaire/interview session is a gold standard interview validated to be administered face to face, this is led by the researcher trained to undertake the interview. Sections 1, 2 and 4 will be self-completed by the participant. Due to the nature of questions, the researcher will be present to ensure the participant is comfortable at all times, to support or seek support (from duty worker or study clinicians) on behalf of the participant if the questions trigger

	difficult memories, or to clarify any of the terminology within the self-report questionnaires.
The various parts of the Data Collection Tool don't seem entirely coherent (e.g., repetition of questions) or appropriate (e.g., 'Please keep in mind that the hospital staff will not have access to any of the answers you give me').	Section 3 of the interview is a validated gold standard interview and so the script and questions have to remain exactly as presented by the author (from whom we have written permission to use the interview). This example is part of the gold-standard interview '(e.g., 'Please keep in mind that the hospital staff will not have access to any of the answers you give me').' Some of the questions are a little repetitive but are asked in different ways and cover a number of different 'high risk' sexual behaviours identified within the literature.

If any further clarification is required, please do not hesitate to contact me.

Kind regards,

Samantha Gascoyne on behalf of the study team

Appendix 24- HSRGC approval letter

Department of
Health Sciences

c/o Department of Philosophy
Heslington
York YO10 5DD

Telephone (01904) 433253
Fax (01904) 321383
E-mail smh12@york.ac.uk

Dr Stephen Holland

www.york.ac.uk/healthsciences

11th April 2016

Samantha J Gascoyne

Department of Health Sciences

Mental Health and Addictions Research Group

University of York

YO10 5DD

Dear Samantha

An acceptability and feasibility study of sexual risk behaviour in adults with severe mental illness in the UK: A pilot study

Thank you for resubmitting your project for review by a subcommittee of the Health Sciences Research Governance Committee (HSRGC), and for our very helpful meeting on 22nd March to discuss the feedback from the HSRGC on your original application.

The subcommittee has now reviewed the NHS REC form and supporting documents, and I am very pleased to confirm that the study now has HSRGC approval, and can be forwarded to the REC.

I was asked to feedback one comment:

Section A26: 'This is likely to be a low risk study for the researcher'. This might be misinterpreted by the REC as taking potential risks to researchers too lightly – which we know is not the case – and it is at odds with the sensible and very thorough precautions being proposed, so could be reworded.

Thank you, again, for engaging so positively with our ethics and governance review process. If you have any further queries, or make substantial amendments to the project, please contact me.

Yours sincerely

Stephen Holland

Chair: HSRGC

Appendix 25- Initial opinion letter from NHS REC

North West - Liverpool Central Research Ethics Committee

3rd Floor

Barlow House

4 Minshull Street

Manchester

M1 3DZ

Teleph

one: 020 71048008 06 June 2016

Miss Samantha J Gascoyne

University of York

Department of Health Sciences, Mental Health and Addictions Research Group University of York, Heslington

York

YO10 5DD

Dear Miss Gascoyne

Study Title:	**A pilot study to establish the acceptability and feasibility of recruiting and administering sexual risk behaviour assessment tools in adults with severe mental illness in the UK.**
REC reference:	**16/NW/0404**
Protocol number:	**N/A**
IRAS project ID:	**202431**

The Research Ethics Committee reviewed the above application at the meeting held on 01 June 2016. Thank you for attending to discuss the application.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

The Committee would like to see the revised questionnaire as it will be used in the study

a. The Committee would like to see the Participant Information Sheet revised to change the sentence beginning "in the UK, this topic has been neglected…." To " In the UK there appears to have been little research on this subject"
b. The Committee would like to see the Consent Form revised to include a further clause "I understand that relevant sections of my medical notes and data collected from the study may be looked at by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information"

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Carol Ebenezer whose contact details are on this letter.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisionalhttp://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 06 July 2016.

Summary of the discussion at the meeting

The Chair welcomed you to the REC and thanked you for attending to discuss the study. The Committee told you that this was a really good study on an area that needs to be researched.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee asked whether you had any experience of asking these very explicit sexual questions and what you would do if the participant became aroused while being asked them.

You stated that you were undergoing extensive training at the moment to address this. If the participant became aroused, you would have to terminate in safety. The questionnaire had been in use for 20 years.

The Committee asked why there was no check as to whether the participant was on the sex offenders list.

You said that this would be checked by the clinicians and said it would be an exclusion criterion.

The Committee was happy with this.

Informed consent process and the adequacy and completeness of participant information The Committee commented that the Participant Information Sheet was very clear but requested a minor change to the Participant Information Sheet and Consent Form as described in the decision below.

Suitability of supporting information

The Committee asked why there was no mention in the questionnaires of the side effects of antipsychotic drugs in terms of sexual dysfunction.

You said that these questions had been omitted as you were not looking at this aspect.

The Committee told her that the questions should be asked in order to get a fuller picture. One of the reasons patients stop taking their drugs is due to the effect on sexual function.

You accepted this and agreed to send the revised questionnaire to the Committee.

The Committee was pleased to note that you had recognised that the main questionnaire used American English and would therefore be present when it was being completed.

You had no questions for the Committee.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity letter]		04 May 2016
GP/consultant information sheets or letters [GP/CMHT letter informing consent to study]	1	01 March 2016
Interview schedules or topic guides for participants [Appendix 6 SERBAS]	1	29 February 2016
IRAS Application Form [IRAS_Form_06052016]		06 May 2016
IRAS Application Form XML file [IRAS_Form_06052016]		06 May 2016
Non-validated questionnaire [Appendix 7 acceptability questionnaire]	1	29 February 2016
Non-validated questionnaire [Appendix 5 NATSAL AMENDED]	1	29 February 2016
Other [Appendix 8 Risk protocol]	1	02 March 2016
Other [Insurance brokers liability letter]		31 July 2015
Participant consent form [Participant consent to contact form]	1	25 February 2015
Participant consent form [Participant Consent Form]	2	22 March 2016
Participant information sheet (PIS) [Appendix 1 Sexual health Participant Information Sheet]	1	27 February 2016
Referee's report or other scientific critique report [Health Sciences Research Governance Committee University of York Decision Letter]		11 April 2016
Referee's report or other scientific critique report [Scientific critique initial letter]		16 March 2016
Research protocol or project proposal [Sexual health and SMI research protocol]	2	22 March 2016
Summary CV for Chief Investigator (CI) [Samantha Gascoyne Academic CV]	2	26 February 2016
Summary CV for supervisor (student research) [Professor Elizabeth Hughes CV]		

Summary CV for supervisor (student research) [Professor Simmon Gilbody CV]		
Summary CV for supervisor (student research) [Professor Catherine Hewitt CV]		

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

Statement of compliance

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

16/NW/0404	**Please quote this number on all correspondence**

Yours sincerely

Mrs Julie Brake Chair

Email: nrescommittee.northwest-liverpoolcentral@nhs.net

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

Copy to: *Professor Simon Gilbody*

Dr Rachel Moser, South West Yorkshire Partnership NHS Foundation Trust

Appendix 26- REC approval letter

NHS
Health Research Authority

North West - Liverpool Central Research Ethics Committee
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 020 71048008

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

16 June 2016

Miss Samantha J Gascoyne
PhD student
University of York
Department of Health Sciences, Mental Health and Addictions Research Group University of York, Heslington
York
YO10 5DD

Dear Miss Gascoyne

Study title:	**A pilot study to establish the acceptability and feasibility of recruiting and administering sexual risk behaviour assessment tools in adults with severe mental illness in the UK.**
REC reference:	**16/NW/0404**
Protocol number:	**N/A**
IRAS project ID:	**202431**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make

a request to postpone publication, please contact the REC Manager, Mrs Carol Ebenezer, nrescommittee.northwest-liverpoolcentral@nhs.net.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

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

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

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

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

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

Registration of Clinical Trials

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

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

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

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

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

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

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

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity letter]		04 May 2016
GP/consultant information sheets or letters [GP/CMHT letter informing consent to study]	1	01 March 2016
Interview schedules or topic guides for participants [Appendix 6 SERBAS]	1	29 February 2016
IRAS Application Form [IRAS_Form_06052016]		06 May 2016
IRAS Application Form XML file [IRAS_Form_06052016]		06 May 2016
Non-validated questionnaire [Appendix 7 acceptability questionnaire]	1	29 February 2016
Non-validated questionnaire [Amended NATSAL]	1.1	06 June 2016
Other [Appendix 8 Risk protocol]	1	02 March 2016
Other [Insurance brokers liability letter]		31 July 2015
Participant consent form [Participant consent to contact form]	1	25 February 2015
Participant consent form [Participant Consent Form]	2.1	06 June 2016
Participant information sheet (PIS) [Appendix 1 Sexual health Participant Information Sheet]	2.1	06 June 2016

Referee's report or other scientific critique report [Health Sciences Research Governance Committee University of York Decision Letter]		11 April 2016
Referee's report or other scientific critique report [Scientific critique initial letter]		16 March 2016
Research protocol or project proposal [Sexual health and SMI research protocol]	2.1	06 June 2016
Summary CV for Chief Investigator (CI) [Samantha Gascoyne Academic CV]	2	26 February 2016
Summary CV for supervisor (student research) [Professor Elizabeth Hughes CV]		
Summary CV for supervisor (student research) [Professor Simmon Gilbody CV]		
Summary CV for supervisor (student research) [Professor Catherine Hewitt CV]		

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make

your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/qualityhttp://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/assurance/

HRA Training

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

16/NW/0404	**Please quote this number on all correspondence**

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

Yours sincerely

Mrs Julie Brake Chair

Email:nrescommittee.northwest-liverpoolcentral@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Professor Simon Gilbody*

Dr Rachel Moser, South West Yorkshire Partnership NHS Foundation Trust

Appendix 27- HRA approval letter

NHS
Health Research Authority

Miss Samantha J Gascoyne
PhD student
Email: hra.approval@nhs.net
University of York
Department of Health Sciences, Mental Health and
Addictions Research Group
Heslington
York YO10 5DD

18 November 2016

Dear Miss Gascoyne,

Letter of HRA Approval

Study title:	**A pilot study to establish the acceptability and feasibility of recruiting and administering sexual risk behaviour assessment tools in adults with severe mental illness in the UK.**
IRAS project ID:	**202431**
REC reference:	**16/NW/0404**
Sponsor:	**University of York**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities *Confirmation of capacity and capability* -

this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **202431**. Please quote this on all correspondence.

Yours sincerely,

Emma Stoica
Senior Assessor

Email: hra.approval@nhs.net

Copy to:

Professor Simon Gilbody, sponsor contact: simon.gilbody@york.ac.uk
Dr Rachel Moser, lead NHS R&D contact: research@swyt.nhs.uk

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity letter]		04 May 2016
GP/consultant information sheets or letters [GP/CMHT letter informing consent to study]	1	01 March 2016
IRAS Application Form [IRAS_Form_06052016]		06 May 2016
Non-validated questionnaire [Male]		
Non-validated questionnaire [Female]		
Non-validated questionnaire [Appendix 7 acceptability questionnaire]	1	29 February 2016
Non-validated questionnaire [Amended NATSAL]	1.1	06 June 2016
Notice of Minor Amendment		19 September 2016
Other [Appendix 8 Risk protocol]	1	02 March 2016
Other [Insurance brokers liability letter]		31 July 2015
Other [Statement of Activities]	2	15 November 2016
Other [Schedule of Events]	2	15 November 2016
Participant consent form [Participant consent to contact form]	1	25 February 2015
Participant consent form	2.2	14 November 2016
Participant information sheet (PIS)	2.2	14 November 2016
Referee's report or other scientific critique report [Health Sciences Research Governance Committee University of York Decision Letter]		11 April 2016
Referee's report or other scientific critique report [Scientific critique initial letter]		16 March 2016
Research protocol or project proposal [Sexual health and SMI research protocol]	2.1	06 June 2016
Summary CV for Chief Investigator (CI) [Samantha Gascoyne Academic CV]	2	26 February 2016
Summary CV for student [Samantha Gascoyne Academic CV]	2	26 February 2016
Summary CV for supervisor (student research) [Professor Elizabeth Hughes CV]		
Summary CV for supervisor (student research) [Professor Simmon Gilbody CV]		
Summary CV for supervisor (student research) [Professor Catherine Hewitt CV]		

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in

England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Professor Simon Gilbody, simon.gilbody@york.ac.uk; Telephone 01904321370

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and process	Yes	Minor changes were made to the Information sheet and consent form in order to bring them in line with the HRA standards.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of Activities will form the agreement of the NHS organisation to participate.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study.
4.3	Financial arrangements assessed	Yes	The sponsor will not provide any funding to the participating NHS organisation.

Section	HRA Assessment Criteria	Compliant with Standards	Comments
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	A minor amendment has been submitted to replace one of the questionnaires. This amendment did not require REC review.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one type of NHS organisations participating in the study, and one participating NHS organisation, carrying out research activities as described in the Statement of Activities and Schedule of Events. The activities at the participating site are limited to identifying potential participants, handing our information packs, obtain permission to be contacted where possible and hosting interviews.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

The participating NHS organisation in England **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

The Chief Investigator will be taking responsibility for all research activities. As members of the central research team will be present at the participating NHS organisation to undertake some research activities, a Local Collaborator should be in place to facilitate identification of potential participants and support practical arrangements e.g. access for researcher on site, secure an interview room. The Local Collaborator has been identified.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Where arrangements are not already in place, staff undertaking research activities would be expected to obtain Letters of Access on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). Standard DBS checks and occupational health clearance would be appropriate. The applicant confirmed that the Local Collaborator has appropriate contractual arrangements with the participating NHS organisation.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
• The project is being funded as part of an NIHR CLAHRC PhD studentship. • It will be expected that a private room will be available at the participating NHS site for the interviews.

Appendix 28- Simplified PIS for staff use

Sexual health PhD study information for staff

NOT TO BE GIVEN TO POTENTIAL PARTICPANTS

- Sexual health is topic often ignored in mental health research and clinical services
- This subject has been researched in USA and Brazil for over 20 years- participant's have enjoyed talking about a 'normal' aspect of life.
- This study has been reviewed and approved by an NHS ethics committee.

- It's an opportunity for service user's to contribute to development of a new tool to assess sexual health.
- We want the views of people with lived experience in order to design a more "user friendly tool".
- Information is completely confidential and not shared with clinical team (except disclosure of significant risk to self/others).
- Participant's don't have to answer anything they don't feel comfortable about (this is part of what we are trying to find out).
- Interview up to 1.5hrs but likely to be much less (depending on complexity).
- The researcher is trained to use the questionnaire and is experienced in mental health research.
- Taking to the researcher doesn't commit the person to the study.

Appendix 29- REC approval letter for substantial amendment 1

NHS
Health Research Authority

North West - Liverpool Central Research Ethics Committee

3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

03 April 2017

Miss Samantha J Gascoyne
PhD student
University of York
Department of Health Sciences, Mental Health and Addictions
Research Group University of York, Heslington
York
YO10 5DD

Dear Miss Gascoyne

Study title:	**A pilot study to establish the acceptability and feasibility of recruiting and administering sexual risk behaviour assessment tools in adults with severe mental illness in the UK.**
REC reference:	**16/NW/0404**
Protocol number:	**N/A**
Amendment number:	**1**
Amendment date:	**07 March 2017**
IRAS project ID:	**202431**

Additional recruitment methods, offer of £10 voucher, simplified information sheet

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

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

The committee found no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	07 March 2017
Other [Simple information leaflet]	1	20 March 2017
Participant consent form	3	07 March 2017
Participant information sheet (PIS)	3	07 March 2017
Research protocol or project proposal	3	07 March 2017

Membership of the Committee

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

Working with NHS Care Organisations

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

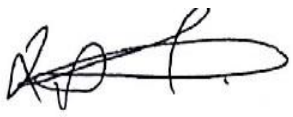
Statement of compliance

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

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

16/NW/0404:	**Please quote this number on all correspondence**

Yours sincerely



Mrs Julie Brake Chair

E-mail: nrescommittee.northwest-liverpoolcentral@nhs.net

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

Copy to: *Dr Rachel Moser, South West Yorkshire Partnership NHS Foundation Trust*
Professor Simon Gilbody

North West - Liverpool Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 03 April 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Yes	
Dr Lyvonne Tume	Senior Nursing Research Fellow Paediatric ICU	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Zainab Ahmed	REC Assistant

Appendix 30- HRA approval for substantial amendment 1

From: nrescommittee.northwest-liverpoolcentral@nhs.net
[mailto:nrescommittee.northwestliverpoolcentral@nhs.net]
Sent: 20 March 2017 14:25
To: samantha.gascoyne@york.ac.uk; simon.gilbody@york.ac.uk
Cc: research@swyt.nhs.uk
Subject: IRAS 202431. Confirma on of REC Valida on and Categorisa on of Amendment

Dear Miss Gascoyne,

IRAS Project ID:	**202431**
REC Reference:	**16/NW/0404**
Short Study Title:	**Sexual risk behaviour in adults with Severe Mentall Illness**
Date complete amendment submission received:	**20 March 2017**
Amendment No./ Sponsor Ref:	**1**
Amendment Date:	**07 March 2017**
Amendment Type:	**Substantial**

Thank you for submitting the above referenced amendment. I am pleased to confirm that this amendment has been submitted to the REC for ethical review. Please find attached a copy of the validation letter.

Categorisation of Amendment

In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

- **Category A -** An amendment that has implications for, or affects, ALL participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England.

Subject to the three conditions below, you will be able to implement the amendment at your participating NHS organisations in England **35 days after you notify them of the amendment.** A template email to notify participating NHS organisations in England is provided here.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion, (for participating organisations in England, this includes receiving confirmation of HRA Approval for the amendment). You should provide regulatory approvals to the research management support offices and local research teams at

 your participating NHS organisations in England, plus to local research teams at any participating NHS organisations in Northern Ireland, Scotland or Wales*.

- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.

Note: you may only implement changes described in the amendment notice or letter.

If you receive required regulatory approvals (for participating organisations in England, this includes confirmation that the amendment has been granted HRA Approval) after the 35 days have passed, you may then immediately implement this amendment at all participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study.

There is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

* Where the study involves NHS organisations in Northern Ireland, Scotland or Wales, the HRA will forward regulatory approvals to the relevant national coordinating function to distribute to their research management support offices.

Please do not hesitate to contact me if you require further information.

BW Carol


cid:image002.jpg@01D0C9DC.CF40C160

Carol Ebenezer | REC Manager
Health Research Authority

3rd Floor

Barlow House

4 Minshull St

Manchester

M1 3HY

E: carol.ebenezer@nhs.net | T: 02071048008 | www.hra.nhs.uk

The HRA is keen to know your views on the service you received – our short feedback form is available **here**

IMPORTANT – **Click here** for the latest details of the roll-out of HRA Approval in England

The HRA is keen to know your views on the service you received – our short feedback form is available **here**

Appendix 31- REC approval letter for substantial amendment 2

Health Research Authority

North West - Liverpool Central Research Ethics Committee
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 020 71048008

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

10 May 2017

Miss Samantha J Gascoyne
University of York
Department of Health Sciences, Mental Health and Addictions Research Group University of York, Heslington
York
YO10 5DD

Dear Miss Gascoyne

Study title:	**A pilot study to establish the acceptability and feasibility of recruiting and administering sexual risk behaviour assessment tools in adults with severe mental illness in the UK.**
REC reference:	**16/NW/0404**
Protocol number:	**N/A**
Amendment number:	**2**
Amendment date:	**27 April 2017**
IRAS project ID:	**202431**

Change to protocol, inclusion of cover letter in recruitment, inclusion of staff single interviews

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

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

The members had no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [mail out cover letter]	1	24 April 2017
Notice of Substantial Amendment (non-CTIMP)	2	27 April 2017
Other [Staff topic guide]	1	27 April 2017
Participant consent form [Staff interview Consent Form]	1	24 April 2017
Participant information sheet (PIS) [Staff interview PIS]	1	24 April 2017
Research protocol or project proposal	4	27 April 2017

Membership of the Committee

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

Working with NHS Care Organisations

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

Statement of compliance

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

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

Yours sincerely

Mrs Julie Brake Chair

E-mail: nrescommittee.northwest-liverpoolcentral@nhs.net

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

Copy to: *Dr Rachel Moser, South West Yorkshire Partnership NHS Foundation Trust*
Professor Simon Gilbody

North West - Liverpool Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 10 May 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Yes	
Mr Paul Mooney	Senior Clinical Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Carol Ebenezer	REC Manager

Appendix 32- HRA approval for substantial amendment 2

IRAS 202431. Amendment 2. Assessment of Amendment Complete

2 messages

AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net> 10 May 2017 at 15:05
To: "samantha.gascoyne@york.ac.uk" <samantha.gascoyne@york.ac.uk>
Cc: "AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)" <hra.amendments@nhs.net>, "research@swyt.nhs.uk" <research@swyt.nhs.uk>, "simon.gilbody@york.ac.uk" <simon.gilbody@york.ac.uk>

Dear Miss Gascoyne,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Joanna Ho

Assessor

Health Research Authority

HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH
E:

hra.amendments@nhs.net

www.hra.nhs.uk

The HRA is keen to know your views on the service you received – our short feedback form is available **here**

From: nrescommittee.northwest-liverpoolcentral@nhs.net [mailto:nrescommittee.northwest-liverpoolcentral@ nhs.net]
Sent: 04 May 2017 10:52
To: samantha.gascoyne@york.ac.uk; simon.gilbody@york.ac.uk
Cc: research@swyt.nhs.uk
Subject: IRAS 202431. Confirmation of REC Validation and Categorisation of Amendment

Dear Miss Gascoyne,

IRAS Project ID:	**202431**
REC Reference:	**16/NW/0404**
Short Study Title:	**Sexual risk behaviour in adults with Severe Mentall Illness**
Date complete amendment submission received:	**03 May 2017**
Amendment No./ Sponsor Ref:	**2**
Amendment Date:	**27 April 2017**
Amendment Type:	**Substantial**

Thank you for submitting the above referenced amendment. I am pleased to confirm that this amendment has been submitted to the REC for ethical review. Please find attached a copy of the validation letter.

Categorisation of Amendment

In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

- **Category A -** An amendment that has implications for, or affects, ALL participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England.

If you have participating NHS organisations in Northern Ireland, Scotland and/or Wales, you should communicate directly with the relevant research teams to prepare them for implementing the amendment, as per the instructions below. You do not need to provide this email or your amended documentation to their research management support offices, as we will pass these to the relevant national coordinating functions who will do this on your behalf.

Subject to the three conditions below, you will be able to implement the amendment at your participating NHS organisations in England **35 days after you notify them of the amendment.** A template email to notify participating NHS organisations in England is provided here.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion, (for participating organisations in England, this includes receiving confirmation of HRA Approval for the amendment). You should provide regulatory approvals to the research management support offices and local research teams at your participating NHS organisations in England, plus to local research teams at any participating NHS organisations in Northern Ireland, Scotland or Wales*.
- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.

Note: you may only implement changes described in the amendment notice or letter.

If you receive required regulatory approvals (for participating organisations in England, this includes confirmation that the amendment has been granted HRA Approval) after the 35 days have passed, you may then immediately implement this amendment at all participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study.

There is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

* Where the study involves NHS organisations in Northern Ireland, Scotland or Wales, the HRA will forward regulatory approvals to the relevant national coordinating function to distribute to their research management support offices.

Please do not hesitate to contact me if you require further information.

Kind regards

Zainab Tauqeer

REC Assistant

HRA Logo

Health Research Authority

HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH

E: hra.amendments@nhs.net

www.hra.nhs.uk

Appendix 33- HRA approval email for minor amendment 1

IRAS 202431. Confirmation of Amendment Categorisation as Category C

1 message

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amendments hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net> 29 September 2016 at 14:54 To: Samantha Gascoyne <samantha.gascoyne@york.ac.uk>, "Simon Gilbody (simon.gilbody@york.ac.uk)" <simon.gilbody@york.ac.uk>

Dear Samantha Gascoyne,

IRAS Project ID:	202431
Short Study Title:	Sexual risk behaviour in adults with Severe Mentall Illness
Date complete amendment submission received:	**28/09/2016**
Amendment No./ Sponsor Ref:	Minor Amendment 1
Amendment Date:	19/09/2016
Amendment Type:	**Non-substantial**

Thank you for submitting the above referenced amendment. In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

Category C - An amendment that has no implications that require management or oversight by the participating NHS organisations

As such, the sponsor may implement this amendment **as soon as any relevant regulatory approvals are in place** (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below).

As Chief Investigator/Sponsor, it remains your responsibility to ensure that the research management offices and local research teams (if applicable) at each of your participating organisations are informed of this amendment.

Note: you may only implement changes described in the amendment notice or letter.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

Please do not hesitate to contact me if you require further information.

Kind regards

Laura Greenfield

Laura Greenfield | Amendments Coordinator

Health Research Authority Research Ethics Service (RES)

HRA, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS

E: hra.amendments@nhs.net

www.hra.nhs.uk

Appendix 34- HRA approval email for minor amendment 2

IRAS 202431. Amendment acknowledgement and implementation information

6 messages

AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net> 28 April 2017 at 09:14

To: Samantha Gascoyne <samantha.gascoyne@york.ac.uk>

Cc: "research@swyt.nhs.uk" <research@swyt.nhs.uk>, "simon.gilbody@york.ac.uk" <simon.gilbody@york.ac.uk>

Dear Samantha Gascoyne,

Thank you for submitting an amendment to add one or more new sites to your project

If you have listed new sites in any other UK nations we will forward the information to the national coordinating function(s) for nations where the new site(s) are being added. In Northern Ireland, Scotland and Wales, NHS/HSC R&D offices will be informed.

What Happens Next?

Please set up the new site(s) as per the guidance found within IRAS. **Please note** that processes change from time to time so please use the most up to date guidance about site set up.

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

IRAS Project ID:	202431
Short Study Title:	Sexual risk behaviour in adults with Severe Mentall Illness
Date complete amendment submission received:	24/04/2017
Sponsor Amendment Reference Number:	Minor Amendment 2
Sponsor Amendment Date:	24/04/2017
Amendment Type	Non-substantial
For new sites in Northern Ireland, Scotland and/or Wales only:	Please start to set up your new sites. Sites may not open until NHS management permission is in place.
For new sites in England only:	~~For studies which already~~ have HRA Approval: **This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA.** Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable). For studies which do not yet have HRA Approval: HRA Approval is pending and you will receive confirmation of HRA Approval. You can start the process of setting up the new site but cannot open the study at the site until HRA Approval is in place and the site has confirmed capacity and capability (where applicable).

If you have any questions relating to setting up sites in England, please direct these to hra.approval@nhs.net .

If you have any questions relating to setting up sites in Northern Ireland, Scotland or Wales, please direct these to the relevant national coordinating function.

Note: you may only implement changes described in the amendment notice.

Please do not hesitate to contact me if you require further information.

Kind regards

Laura

Laura Greenfield | Amendments Coordinator

Health Research Authority

HRA, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS

E: hra.amendments@nhs.net

Appendix 35- HRA approval email for minor amendment 3

IRAS 202431. Confirmation of Amendment Categorisation as Category C

3 messages

AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>
26 May 2017 at 11:41 To: Samantha Gascoyne <samantha.gascoyne@york.ac.uk>
Cc: "simon.gilbody@york.ac.uk" <simon.gilbody@york.ac.uk>, "research@swyt.nhs.uk" <research@swyt.nhs.uk>

Dear Samantha Gascoyne,

IRAS Project ID:	202431
Short Study Title:	Sexual risk behaviour in adults with Severe Mentall Illness
Date complete amendment submission received:	23/05/2017
Amendment No./ Sponsor Ref:	Minor Amendment 3
Amendment Date:	22/05/2017
Amendment Type:	**Non-substantial**

Thank you for submitting the above referenced amendment. In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

Category C - An amendment that has no implications that require management or oversight by the participating NHS organisations

As such, the sponsor may implement this amendment **as soon as any relevant regulatory approvals are in place** (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below).

As Chief Investigator/Sponsor, it remains your responsibility to ensure that the research management offices and local research teams (if applicable) at each of your participating organisations are informed of this amendment.

Note: you may only implement changes described in the amendment notice or letter.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

Please do not hesitate to contact me if you require further information.

Kind regards

Laura Greenfield

Laura Greenfield | Amendments Coordinator
Health Research Authority

HRA, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS
E: hra.amendments@nhs.net

T: 020 7104 8096
www.hra.nhs.uk

Appendix 36- Staff qualitative interviews PIS

UNIVERSITY of York
The Department of Health Sciences

University of HUDDERSFIELD

Sexual risk behaviour in adults with Severe Mental Illness (IRAS ID 202431)
Staff interview participant information sheet

Invitation: You are invited to take part in a semi-structured which aims to explore your views on the sexual health of people with severe mental illness as part of a PhD project. Before you decide whether you want to be involved it is important for you to understand why the research is being done and what it will involve. I would be grateful if you would take the time to read this information sheet. Please ask if there is anything that is not clear to you or if you would like more information.

What is the purpose of the interview?
The purpose of the interview is to explore a number of themes, including the importance of the subject area, any perceptions of risk in this population with regards to sexual health, potential barriers to supporting patients in this area and provisions for training.

Why have I been approached to take part in the study? You have been approached for this study as you are a mental health professional working within the South West Yorkshire Foundation Partnership NHS Trust who have been supporting a PhD study at the University of York.

What will happen to me if I take part? It is anticipated that the interview will last up to a maximum of one hour. With your permission, we I would like to audio-record the session, which will then be transcribed verbatim with any identifying information removed. You may have a copy of the transcript if you wish by contacting Samantha Gascoyne (details at the end). The audio recording of the interview will be destroyed as soon as analysis of the interview is completed. The transcript of the interview will be securely stored at the University of York and only the people directly involved in the research will have access to it. At the end of the study, data will be securely archived for a period of 10 years. Your name will not be used in any published material; you will be identified with a code to ensure that you have confidentiality. If you wish to take part but are not able to meet for a face to face interview, I can organise a telephone interview with you.

Do I have to take part? Participation is entirely voluntary. You may refuse to take part and you do not have to tell the researchers why you do not want to take part. If you decide to take part you can choose to drop out at any time up to the end of the interview session

Are there any risks involved? There are no risks to taking part in the interview. You will not be asked to provide any information about individual patients, and participants will be asked to agree to keep the content of the discussions private.

What will happen to the data collected? The interview data will be analysed and will contribute to a PhD thesis. Your confidentiality will be preserved in all published articles and when disseminating the findings at conferences. We would be happy to supply you with a copy of the results on request.

Who is organising and funding the study? This study is being led by Sam Gascoyne who is a doctoral student at the University of York. She is supported by Professor Liz Hughes (University of Huddersfield), Professor Simon Gilbody and Professor Catherine

Hewitt (University of York). This study is funded by the National Institute for Health Research: Collaboration for Leadership in Applied Health Research (PhD studentship).

If you agree to take part, would like more information or have any questions or concerns about the study please contact:

For specific information about this study please contact:

Study coordinator: Samantha Gascoyne
Address: Mental Health and Addictions Research Group, ARRC building, Department of Health Sciences, University of York, Heslington, York, YO10 5DD
Telephone: mobile 07552285845
Email: samantha.gascoyne@york.ac.uk

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

Appendix 37- Staff qualitative interviews consent form

South West Yorkshire Partnership NHS
NHS Foundation Trust

UNIVERSITY of York
The Department of Health Sciences

University of HUDDERSFIELD

Sexual risk behaviour in adults with Severe Mental Illness (IRAS ID 202431)
Staff Consent Form

	Please confirm agreement to the statements by putting your initials in the boxes below
I have read and understood the participant information sheet [date **27/04/2017**, version **1.0**]	
I have had the opportunity to ask questions and discuss this study	
I understand that I am free to withdraw from the study up to the end of the interview without having to give a reason.	
I give permission for the interview to be audio-recorded and transcribed using a transcription service.	
I understand that any information I provide, including personal details, will be kept confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give (including direct quotes) may be included in published documents and reports but it will not be possible to identify me.	
I would like to receive a written summary of the results of the study.	
I agree to take part in this study	
Participant Signature …… Date	
Name of Participant	
Researcher Signature …….. Date	
Name of Researcher	

Appendix 38- Qualitative interview topic guide

With all of us in mind

South West Yorkshire Partnership NHS
NHS Foundation Trust

University of York
The Department of Health Sciences

University of Huddersfield

Sexual risk behaviour in adults with Severe Mental Illness (IRAS ID 202431)

Staff topic guide

1. Perceived importance of the topic area

2. Perception of risk in this population as a clinician- is this something you consider as part of your practice?

3. Talking to patients about sexual health- current practice (is this a topic you discuss with patients/do patients bring this topic up themselves? How often? What are the problems they face?).

4. Comfort in discussing sexual health? Are the patients comfortable discussing this? Do you feel there are any perceived barriers to supporting patients around this topic? Who is the best person to provide this support- would it be another practitioner or would they refer to another service (internally and/or externally)?

5. Barriers to research- are there any? Is this because of organisational pressures/workload, unsure of appropriate referrals, safeguarding vulnerable patients, do not perceive sexual health within their remit (already covered on the schedule). What support do you give? Where do you sign post them too?

6. Training? Have they ever received training? If not, what sort of training would be suitable? Should it be mandatory? Organisational support for research/supporting patients with sexual health issues

Appendix 39- RESPECT baseline feedback questionnaire (version 1.2)

Baseline Feedback Questionnaire

You have been asked if you would be interested in taking part in the RESPECT research study which is looking at promoting sexual health. One of the aims of this study is to find out if people are willing to take part in this kind of research. You may have agreed to join the study OR you may have decided not to take part. Either way, we would value your feedback, however this questionnaire is optional and you do not have to complete it if you do not want to.

If you have decided not to take part, we fully respect that decision and your feedback is valuable to us regardless of the choice you made. **We are NOT asking you again to take part in the study.**

If you choose to complete it please place the completed questionnaire in the small envelope addressed to University of Huddersfield. This can then be posted directly to the RESPECT researchers who are conducting the study (the envelope is freepost), or handed back to a member of staff who will post it on your behalf.

Please answer a few questions about your experience. You can circle your answer from the options given, or write an answer in the space provided:

1. **Who explained most of the RESPECT study to you?**

Researcher	Mental Health Worker	Other (please state) ……

2. **Are you taking part in the RESPECT study?**

Yes	No

3. **The statements below are about your decision to take part or to not take part in the RESPECT study. Please circle the number that best shows how you feel about the following statements:**

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
I understand what the RESPECT study is about	**1**	**2**	**3**	**4**	**5**
I understand the differences between the two groups in the study (sexual health sessions plus care as usual OR care as usual)	**1**	**2**	**3**	**4**	**5**
I was satisfied that either group could be suitable for me	**1**	**2**	**3**	**4**	**5**
I wanted to have care as usual rather than the sexual health sessions	**1**	**2**	**3**	**4**	**5**
I was encouraged by some family / friends to take part	**1**	**2**	**3**	**4**	**5**
I understood how my care would be chosen (by chance, at random) as part of the study	**1**	**2**	**3**	**4**	**5**
The idea of 'randomisation' worried me	**1**	**2**	**3**	**4**	**5**
I trusted the person explaining the study to me	**1**	**2**	**3**	**4**	**5**
I wanted to help with the research	**1**	**2**	**3**	**4**	**5**
I feel that others with the same difficulties as me will benefit from the study results	**1**	**2**	**3**	**4**	**5**
I found it difficult to participate in the study due to practical reasons (childcare, travel, time out of my day)	**1**	**2**	**3**	**4**	**5**

4. Did you read the Participant Information Sheet? Yes No

If yes: Was it helpful? Yes No

Was the amount of information in it: Too little Just right Too much

Do you have any comments on the Participant Information Sheet?

.....

.....

5. If you have any other reasons for deciding to take part or not please write below:

.....

.....

6. Did any other information help you make your decision?

.....

.....

7. If you are not taking part we would appreciate if you could tell us the main reason why:

.....

.....

8. Do you have any other comments about the study?

Please return this form in the small freepost envelope addressed to University of Huddersfield (provided)

Appendix 40- RESPECT baseline feedback questionnaire (version 1.3)

Baseline Feedback Questionnaire (V1.3 29 03 17)

You have been asked if you would be interested in taking part in the RESPECT research study which is looking at promoting sexual health. One of the aims of this study is to find out if people are willing to take part in this kind of research. You may have agreed to join the study OR you may have decided not to take part. Either way, we would value your feedback.

Please answer a few questions about your experience

I understand what the RESPECT study is about	Agree	Disagree
The idea of 'randomisation' worried me	Agree	Disagree
I feel that others with similar needs as me will benefit from the study results	Agree	Disagree
I found it difficult to participate in the study due to practical reasons (childcare, travel, time out of my day)	Agree	Disagree

Did any other information help you make your decision?

If you are NOT taking part it would be really helpful if you could tell us the main reason why

Do you have any other comments about the study?

Appendix 41- RESPECT exit feedback questionnaire

[insert Trust/site logo]

Exit Feedback Questionnaire

Thank you for taking part in the RESPECT study. This questionnaire is to find out about your experience of taking part in the study. You may have participated fully in the study **OR** you may have decided to withdraw, your feedback is valuable to us regardless of the choice you made. However, this questionnaire is optional and you do not have to complete it if you do not want to.

Did you stay in the study to the end?	**Yes**	**No**
Do you think it was a good thing to participate in the RESPECT study?	**Yes**	**No**
Did you have any negative experiences?	**Yes**	**No**
If you had negative experiences, what could have been done (or has been done) to help you? …… …… ……		
Is there anything that you wish you had known about the RESPECT study before you agreed to take part?	**Yes**	**No**
Would you recommend taking part in this study to others?	**Yes**	**No**

Please explain your answer:

……

……..

If you choose to complete it please place the completed questionnaire in the attached envelope. This can then be posted directly to the RESPECT researchers who are conducting the study (the envelope is freepost) or handed back to a member of staff who will post it on your behalf.

Please answer a few questions about your experience. Circle the chosen answer or fill in the space provided:

Can you please let us know how much you agree or disagree with the following statements. Please circle the number that best shows how you feel about the following statements:

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
Taking part in RESPECT was helpful to me	1	2	3	4	5
The questionnaires were easy to complete	1	2	3	4	5
I found the questionnaires took too long to complete	1	2	3	4	5

During the study I felt it was OK to ask the researcher questions about the study (if I wanted to)	1	2	3	4	5
The researcher set up appointments to complete the questionnaires at a time convenient to me	1	2	3	4	5
I understood what the RESPECT study was about	1	2	3	4	5
Looking back, I understood what it meant to be randomized to receive sexual health sessions plus care as usual OR care as usual	1	2	3	4	5

Thank you for completing this questionnaire, please return using the freepost envelope provided

Abbreviations

A&E- Accident and Emergency

AIDS- Acquired Immunodeficiency Syndrome

AMSTAR- Assessing the Methodological quality of Systematic Reviews

APMS- Adult Psychiatric Morbidity Survey

ARBAQ- AIDS risk behaviour assessment questionnaire

BBV- Blood Borne Virus

BFQ- Baseline Feedback Questionnaire

CI- Confidence Interval

CIDI- Composite International Diagnostic Interview

CIS-R- Clinical Interview Schedule Revised

CLAHRC- YH- Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber

CMHT- Community Mental Health Team

CONSORT- Consolidated Standards of Reporting Trials

CPD- Continuing professional development

CRD- Centre for Reviews and Dissemination

CRN- Clinical Research Network

CTC- Consent to Contact

CVD- Cardiovascular Disease

Df- degrees of freedom

DIAMONDS- Diabetes and Mental Illness: Improving Outcomes and Services

DIGS- Diagnostic Interview for Genetic Studies

DoH- Department of Health

DSM- Diagnostic and Statistical Manual of Mental Disorders

EFQ- Exit Feedback Questionnaire

EIT- Early Intervention Team

GBL- Gamma-Butyrolactone

GHB- Gamma-hydroxybutyrate

GP- General practitioner

HIV- Human Immunodeficiency Virus

HIV-RBT- HIV Risk Behaviour Test

HRA- Health Research Authority

HSR- Health Services Research

HSRGC- Health Sciences Research Governance Committee

ICD-10- International Classification of Diseases (version 10)

IPV- Inter partner violence

M- Mean

MDD- Major Depressive Disorder

MeSH- Medical Subject Headings

MINI- Mini-International Neuropsychiatric Interview

MOOSE- Meta-analyses of Observational Studies in Epidemiology

MSM- Men who have sex with men

N- Number

NATSAL- National Survey of Sexual Attitudes and Lifestyles

NICE- National Institute for Health and Care Excellence

NIHR- National Institute for Health Research

NOS- Newcastle Ottawa Scale

OR- Odds Ratios

OT- Occupational Therapist

PIS- Participant Information Sheet

PPI- Patient and Public Involvement

PRISMA- Preferred Reporting Items for Systematic Reviews and Meta-analyses

PROSPERO- International Prospective Register of Systematic Reviews

RDC- Research Diagnostic Criteria

REC- Research Ethics Committee

RCTs- Randomised Controlled Trials

RESPECT- Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment

RR- Risk Ratio

SADS-L- Schedule for Affective Disorders and Schizophrenia- Lifetime version

SCID- Structured Clinical Interview for DSM

SD- Standard Deviation

SERBAS- Sexual Risk Behaviour Assessment Schedule

SMI- Severe Mental Illness

STD- Sexually Transmitted Disease

STI- Sexually Transmitted Infection

STROBE- Strengthening the Reporting of Observational Studies in Epidemiological Statement

SUD- Substance use disorders

WHO- World Health Organisation

WSW- Women who have sex with women

YLDs- Years Lived With Disability

YTU- York Trials Unit

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