The development, usability and acceptability of a cervical screening informed-choice tool for women with severe mental illness

THE DEVELOPMENT, USABILITY AND ACCEPTABILITY OF A CERVICAL SCREENING INFORMED-CHOICE TOOL FOR WOMEN WITH SEVERE MENTAL ILLNESS

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Abstract

People with severe mental illness (SMI) die on average 10–20 years younger than the general population, including those with morbidity relating to cancer. People with SMI face specific barriers to attending cancer screening, including for cervical cancer and, as a consequence, they are underrepresented in cancer screening generally and have poorer survival rates following a positive diagnosis. The aim of this PhD was to develop a cervical screening 'informed-choice tool' for women with SMI. The tool was designed to address barriers to cervical screening uptake in order to help women with SMI make an informed choice about participating in screening. This research focused on three questions: (1) What are, if any, the specific design(s) and theoretical underpinning(s) of informed-choice tools developed for people with SMI? (2) What are service users' and clinicians' experiences of using the tool? (3) Does the tool have any impact on service users' decisional conflict to attend screening?

The tool was informed by a realist review of physical health interventions for people with SMI and by a systematic review of informed-choice tools for this population, which have now been published. A mixed-methods research design was used to develop the tool. The usability and acceptability of the tool was tested by service users and clinicians in two NHS Trusts using semi-structured interviews and the 'think-aloud' method. A preliminary evaluation of the tool was conducted to assess the impact on service users' decisional conflict to attend cervical screening sessions. Results from the evaluation (n = 25) showed that the tool may have an impact on some

women who are either overdue for their screening or have never attended. This work has resulted in a tool which is usable and acceptable by women with SMI and may impact on their screening uptake and hence their mortality rates from cervical cancer. An animated video has also been developed to illustrate the key findings of the tool. The tool and video have since been disseminated widely across the NHS and third sector organisations. Future research may involve further assessments of the real-world impact of the tool and its adaptation to other health-related decisions.

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In terms of dedications, I myself lost an uncle, and three of my childhood friends lost a parent to cancer during the course of this research, so I would like to close by saying what an honour it has been to be able to play a small part in minimising the effects of an illness that devastates so many families and communities.

In relation to mental health and the substantial leaps currently being made in the awareness of its importance, may we continue to work diligently as a society to comprehend it as fully as we can and thereby manage its impact with even more efficacy than we currently are.

In memoriam, Professor Marcia Worrell (1966–2020) and

Louise Mary Cadman (1965-2020)

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List of Abbreviations

ANCI	American National Cancer Institute
BAME	Black, Asian and Minority Ethnic
BCT	Behaviour Change Technique
BMI	Body Mass Index
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CIN2+	Cervical Intraepithelial Neoplasia grade 2+
CMHT	Community Mental Health Team
CQUIN	Commissioning for Quality and Innovation
DCS	Decisional Conflict Scale
DCS-LL	'low literacy' Decisional Conflict Scale
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
EMIS	Egton Medical Information Systems
EUPD	Emotionally Unstable Personality Disorder
FGM/C	Female Genital Mutilation/Cutting
GAF	Global Assessment of Functioning scale
GUM	Genitourinary medicine
HbA1c	Glycated haemoglobin
HDL-C	High-density lipoprotein – cholesterol
HPV	Human papilloma virus
Hr-HPV	High-risk types of the human papillomavirus
ICD-10	International Statistical Classification of Diseases and Related Health Problems
ICHP	Imperial College Health Partners
ICROMS	Integrated quality Criteria for the Review Of Multiple Study designs
IPDAS	International Patient Decision Aids Standards
IQR	Interquartile range

MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NSUN	National Survivor User Network
PDSA	Plan, Do, Study, Act
PHE	Public Health England
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International prospective register of systematic reviews
PTSD	Post-Traumatic Stress Disorder
QOF	Quality and Outcomes Framework
RAMESES	Realist and Meta-narrative Evidence Syntheses: Evolving Standards
RCT	Randomised Controlled Trial
SHRINE	Sexual and Reproductive Health Rights, Inclusion and Empowerment (King's Health Partners)
SIR	Standardised Incidence Ratio
SMI	Severe and enduring mental illness
SPSS	Statistical Package for Social Sciences
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
SUGAR	Service User and carer Group Advising on Research
STD	Sexually transmitted disease
TDF	Theoretical Domains Framework
TIDieR	Template for Intervention Description and Replication
TPB	Theory of Planned Behaviour
WHO	World Health Organisation

Overview of thesis

In this thesis, a major health inequality is addressed, namely that people with SMI are less likely to engage in cancer screening than the general population. Lower uptake is partly due to a number of barriers experienced specifically by this group. Although cancer screening saves lives, it remains a choice. This research aims to empower women with SMI to be better able to make an informed choice.

This thesis covers the development, acceptability and usability of a **cervical screening informed-choice tool** for women with SMI. There is a clear need for an intervention to support the uptake of cervical screening for this group. First, there was no evidence in the existing literature of any individual-level intervention for women with SMI regarding cervical screening (Barley et al., 2016). Second, cervical screening covers more women than any other NHS cancer screening programmes and attendance rates in the UK are suboptimal; indeed, in 2018, they dropped to a 20-year low. Third and finally, women with SMI face barriers to attending cervical screening, which needs to be addressed in any intervention targeted at their specific needs.

The primary aim of this research project was, therefore, to design, develop and test an informed-choice tool which improves the ability of women with SMI to decide whether to attend cervical screening. This project includes women's own experiences of using this tool, as well as feedback from clinicians, to ensure that this study provides a robust understanding of what women with SMI require from an informed-choice tool

on cancer screening and, how, in practice, they use it. This tool has been theoretically underpinned to ensure its appropriateness and acceptability for any future trial evaluation. The tool is currently being disseminated in a range of clinical settings.

In **Chapter One,** the background to this research is introduced. A definition of 'SMI' is provided, followed by a description of the context for the work, namely the overall problem of excess morbidity and mortality in the SMI population. A discussion of the prevalence, incidence and impact of cancer in people with SMI is provided before highlighting the importance of cancer screening and discussing the lower uptake of screening by people with SMI than in the general population. Lastly, an overview of strategies to improve the uptake of cancer screening by women with SMI in the UK is presented. This section introduces the concept of making an 'informed choice', an essential condition for deciding whether to take up any health intervention, and the rationale for deciding, in this study, to develop an informed-choice tool as opposed to other decision-making tools.

In **Chapter Two,** the rationale and protocol for this research are outlined before moving to a discussion of the research paradigm and methods chosen. This research is underpinned by the Medical Research Council (MRC) guidance for developing complex interventions (Craig et al., 2013) and, as such, five linked studies were conducted, with each subsequent study building on the former. An outline of each study and how it maps onto the MRC is provided.

In **Chapter Three,** a realist review of interventions to increase access to or uptake of physical health screening in people with SMI is reported (study one), followed by a discussion of how the findings of the review informed the development of the informed-choice tool. A paper describing this work has been published in a peer-reviewed journal (Lamontagne-Godwin et al., 2018).

In **Chapter Four,** a systematic review of the design and evaluation of informed-choice tools for people with SMI is described (study two). The principal aim of this review was to determine the optimum design of an informed-choice tool for people with SMI, based on the available evidence. The findings from this review informed the development of the tool. This review is aligned with step one of the MRC guidance for complex interventions (Development phase). A paper describing this study has been published in a peer-reviewed journal (Lamontagne-Godwin et al., 2020).

In **Chapter Five,** a description of the tool's development and its theoretical underpinnings is provided; the tool was developed using the MRC guidance (Craig et al., 2013). The barriers and enablers to cancer screening uptake in people with SMI (Clifton et al., 2016), which were underpinned by the Theoretical Domains Framework (Cane et al., 2012), are also presented here, and a discussion of how the components of the tool were developed to address these identified barriers is included. Component behaviour change

techniques (Michie et al., 2015) were selected and/or refined to promote screening behaviour within the tool.

In **Chapter Six,** the research key stakeholders (service users and service user groups, clinicians and public health policymakers) are introduced. The importance of their input in the development of the tool is also discussed. Involving stakeholders at every stage of the development of the tool was important to ensure the acceptability and usability of the tool by women with SMI, and therefore, a description of the process of involving these women in refining the tool is provided. An overview of the clinicians' feedback on the first draft of the tool is also provided; this feedback was solicited to ensure that the content was clinically accurate and appropriate for testing with service users.

In **Chapter Seven,** study three, the objective of which was to test the acceptability of the tool with stakeholders, is presented. Service users and health professionals were recruited for this purpose from two NHS Trusts during the period from September to November 2018.

In **Chapter Eight,** study four, the objective of which was to test the usability of the tool with stakeholders, is presented. The 'think-aloud' method (van Someren et al., 1994) was used for this purpose. The readability of the tool was assessed, and final changes were incorporated to ensure that the tool was acceptable to the various organisations who supported its development and who will have a role in its dissemination. These organisations, including

Jo's Cervical Cancer Trust and the West London NHS Trust, supported this research by facilitating the recruitment of participants and ensuring the information contained in the tool conformed with NHS cervical screening guidelines (NHS, n.d.; PHE Screening, 2019). A description of how iterative changes were made to produce a version of the tool appropriate for preliminary evaluation is provided.

In **Chapter Nine,** study five**,** a preliminary evaluation of the tool's impact on cervical screening decision-making with women with SMI, is described. This evaluation aimed to establish proof of concept of the tool. Two validated scales were selected for this purpose: The Stage of Decision-Making scale, which measures 1) an individual's readiness to engage in decision-making, 2) progress in making a choice and 3) openness to considering or re-considering options (O'Connor, 2000 – updated 2003), and the Decisional Conflict Scale, which measures five dimensions of decision-making (ineffective decision-making, feeling uninformed, feeling uncertain, feeling unclear about values and feeling unsupported) (O'Connor, 1993 – updated 2010). Underpinned by the Theory of Planned Behaviour (Azjen, 1991) and using a mixed-method design, the data from this study were used to interpret qualitative data from stakeholders on the acceptability and usability of the tool in studies three and four.

In **Chapter Ten,** the findings from the five studies comprising this thesis are summarised, alongside a reflection on the unique contribution of this research to the field of cancer screening for people with SMI. The

methodological strengths and limitations of the methods chosen for developing the tool are also discussed. Lastly, the research implications for clinical practice and future research are considered.

Chapter One – Introduction to the research

This chapter establishes the background for this study. This thesis addresses a major health inequality – namely that people with SMI are less likely to take up cancer screening than the general population. This is important because cancer screening saves lives. In this chapter, a definition of what is meant by 'SMI' is provided and, to give context to the work, the overall problem of excess morbidity and mortality in the SMI population is described. A discussion about the prevalence, incidence and impact of cancer in people with SMI is then presented before highlighting why cancer screening is important and discussing the decreased uptake by people with SMI. Finally, an overview of the UK landscape in relation to improving the uptake of cancer screening in SMI is provided. This includes a discussion of 'informed choice', an essential factor in deciding whether to take up a health intervention.

1.1 Definition of SMI

There is no standard definition and little consistency in how 'SMI', the abbreviation for severe mental illness, serious mental illness, or severe and enduring/persistent mental illness, is defined in research or practice (Mauritz et al., 2013; National Institute for Health and Care Excellence (NICE), 2016; Center for Behavioral Health Statistics and Quality, 2017). The UK's National Institute for Health and Care Excellence (NICE) includes in its discussion of SMI a clinical diagnosis of schizophrenia, schizotypal and delusional disorders, bipolar affective disorder, or severe depressive episodes with or

without psychotic episodes (NICE, 2016). In the United States, Kessler et al. (2003) defined SMI as any DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition) disorder lasting for at least 12 months (American Psychiatric Organisation, 2000), other than a substance use disorder, with a Global Assessment of Functioning (GAF) score <60, suggesting moderate to severe mental health symptoms. In Europe, Ruggeri et al. (2000) have operationalised the National Institute of Mental Health criteria for SMI according to the degree of dysfunction (GAF score ≤50 or 70 depending on the primary diagnosis) and the duration of treatment (≥2 years) for any mental illness.

For this research, the definition of severe mental illness as operationalised by NICE (2016) was selected, using the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) (World Health Organization (WHO), 1992). ICD-10 uses specific codes to classify each disorder: schizophrenia spectrum disorders [F20.0-F20.9]; schizoaffective disorders [F25]; bipolar affective disorder [F31]; major depressive disorder, recurrent, severe without psychotic features [F33.2]; and major depressive disorder, recurrent, severe with psychotic symptoms [F33.3]. Schizophrenia occurs in approximately 1% of the population, with a similar percentage for bipolar affective disorder; schizoaffective disorder is estimated to occur in less than 1% of the population (Cosgroves and Suppes, 2013).

1.2 Excess morbidity and mortality in SMI

1.2.1 Excess morbidity in people with SMI

Comorbidity, defined as the presence of more than one distinct condition in an individual (Valderas et al., 2009), and multimorbidity, defined as two or more chronic conditions in the same individual (Smith et al., 2012), is frequently reported in this group (Reilly et al., 2015). Other than cardiovascular disease and certain cancers, physical health conditions found to be more prevalent in people with SMI include type 2 diabetes and metabolic syndrome (Holt and Mitchell, 2015; Mulligan et al., 2017; Osborn et al., 2008), tuberculosis, HIV, osteoporosis, poor dentition, impaired lung function, sexual dysfunction and obstetric complications (De Hert et al., 2011).

Metabolic syndrome is defined by the World Health Organization (WHO) (1999) as glucose intolerance, diabetes mellitus and/or insulin resistance, with two or more of the following: central obesity (waist-to-hip ratio: ≥0.90 in men and ≥0.85 in women and/or body mass index >30kg/m^2), raised arterial pressure (≥140/90 mm Hg), microalbuminuria (≥20 μg/min or albumin: creatinine ratio ≥30 μg/mg) and raised plasma triglyceride (≥ 150 mg/dl) and/or low HDL-C (High-density lipoprotein – cholesterol<35 mg/dl in men and <39 mg/dl in women)]. A systematic review (Mitchell et al., 2013) reported a significantly higher prevalence of metabolic syndrome in people with SMI than in the general population. Several factors contribute to these elevated rates of morbidity, including the metabolic effects of antipsychotic

medications, poor diet, the impact of symptoms on motivation and increased sedentary behaviour.

In addition to metabolic syndrome and the other conditions mentioned above, people living with SMI have five times the risk of dyslipidaemia (imbalance of lipids in the bloodstream), three times the risk of hypertension and metabolic syndrome, and double the risk of obesity and diabetes compared to the general population (Allison et al., 2009; Bradshaw and Mairs, 2014; Dickerson et al., 2006; Mangurian et al., 2016). People with SMI are also at greater risk of developing bowel cancer, as obesity is an important risk factor for this (Bhaskaran et al., 2014; Renehan et al., 2008).

The epidemiological evidence around cancer incidence for people with SMI is mixed (Osborn et al., 2013; Weinstein et al., 2016). Some studies have found the incidence for this group to be higher than for the general population (Lichtermann et al., 2001; McGinty et al., 2012; Pandiani et al., 2006). Other studies have found it to be lower (Barak et al., 2005, 2008; Chou et al., 2011; Grinshpoon et al., 2005; Ji et al., 2013; Lin et al., 2013) or equal (Goldacre et al., 2005; Levav et al., 2007, 2009). The potential for schizophrenia to serve as a protective factor for cancer has been explored, though the evidence is mixed (Catts et al., 2008; Hodgson et al., 2010; Tabares-Seisdedos et al., 2011). Biological factors have been brought forward to explain the reduced risk (Abel et al., 2006; Goldacre et al., 2005),

such as the p53 gene, which produces, through apoptosis,[1] the effect of both disrupting neurodevelopment and reducing the cancer risk (Park et al., 2004; Yang et al., 2004). Another gene, adenomatous polyposis coli, a key tumour suppressor gene, may confer susceptibility to schizophrenia and also be associated with reduced vulnerability to cancer in schizophrenia (Cui et al., 2005). Environmental and behavioural factors (such as reduced exposure to occupational carcinogens and sun rays and greater physical health screening in some environments) were also put forward as potential protective factors. Nonetheless, even if there is a decreased risk of cancer for people with SMI, many of the risk factors for metabolic and cardiovascular diseases, which this group is at increased risk of developing, overlap with those for cancer (Hodgson et al., 2010).

In addition, there is a high prevalence of smoking in people with SMI; between 30% and 70% of people with SMI smoke, compared with 20% of the general population (Peckham et al., 2016). Studies have shown that up to 70% of psychiatric inpatients are smokers, and of those, approximately 50% smoke heavily (20+ cigarettes/day) (Coulthard et al., 2002; Kelly and McCreadie 1999). Smoking rates are lower for people with SMI who live in the community and have less severe psychiatric symptoms; around 40% of this group smoke, almost 30% of whom do so heavily (Farrell et al., 2001; O'Brien et al 2002). People with SMI usually start smoking at a younger age than smokers with no mental illness (Weiser et al., 2004) and they usually

[1] Apoptosis is a type of cell death in which a series of molecular steps in a cell lead to its death; this is one way the body works to get rid of abnormal cells.

smoke more cigarettes a day than smokers without SMI; up to 50% of people with SMI smoke heavily compared with approximately 9% of the general population (Jochelson and Majrowski, 2006; Tsoi et al., 2010). People with SMI who smoke are less likely to get support to quit and are more likely to develop smoking-related illnesses than the general population of smokers (Gilbody et al., 2019; Szatkowski and McNeill, 2013). Smoking is the largest risk factor for cardiovascular disease and premature death for this group (Peckham et al., 2016).

The evidence presented in this section points to excess morbidity in this group; high rates of long-term conditions such as diabetes, cancer, cardiovascular disease, chronic obstructive pulmonary disease and obesity are reported. These can complicate treatment and contribute to poorer outcomes (Gilbody et al, 2019; Howard et al., 2010; Kisely et al., 2015; Weinstein et al., 2015). These compounding elements may have an impact on the excess mortality rate of people with SMI, which is discussed in the following section.

1.2.2 Excess mortality in people with SMI

Within the general population, people with SMI face one of the greatest health inequality gaps (Lawrence and Kisely, 2010). Reducing this gap is a key public health priority for the National Health Service in England (NHS England, 2016a). A reduced life expectancy of 10–20 years for individuals with SMI compared to the general population has been reported in the UK (Brown et al., 2010; Dutta et al., 2012; Hayes et al., 2017) and in other high-

income countries, such as the United States, the Nordic countries, Japan and Israel (Chesney et al., 2014; Laursen et al., 2007; Nielsen et al., 2013; Wahlbeck et al., 2011). A systematic review and meta-analysis, which included studies (*n* = 203) representing 29 countries, found that people with SMI have a twofold to threefold increased risk of premature mortality; people who have, at some point, been admitted to hospital had a significantly higher mortality rate compared to outpatients who have never been admitted (Walker et al., 2015). Higher inpatient mortality may be because this population tends to have more severe psychiatric symptoms and poorer overall health (Crump et al., 2013a). Findings from the review suggest a pattern of increased risk of premature mortality in Europe (*n* = 125), primarily Sweden (*n* = 30) and the UK (*n* = 18); North America: United States (*n* = 42) and Canada (*n* = 9); Asia (*n* = 16); Australia (*n* = 8); Africa (*n* = 2) and South America (*n* = 1). Of the 203 studies, the risk ratio on all-cause mortality in this group was reported for 148 studies. Of those, 135 studies reported mortality for people with SMI as significantly higher than the comparison group, while 14 studies reported no significant difference. No studies reported a lower mortality risk in this group (Walker et al., 2015).

The authors of an earlier systematic review (Saha et al., 2007) reported that people with schizophrenia have two-and-a-half times the risk of mortality compared with the general population. The data were identified in articles[2] (*n* = 37) from 25 countries, primarily in Europe (*n* = 24); North and South America (*n* = 11); Asia: (*n* = 9); Australia (*n* = 2) and the Middle East (*n* = 1)

[2] Some articles reported studies from more than one country.

(Saha et al., 2007). Therefore, internationally, there appears to be strong evidence of increased mortality. Additionally, the authors found that the mortality gap between individuals with schizophrenia and the general population increased over the period of the review, which took place between 1980 and 2006 (Saha et al., 2007).

In the UK, a nationally representative cohort study using primary care electronic health records between 2000 and 2014 found that the mortality gap between the general population and individuals with bipolar disorder and schizophrenia is widening (Hayes et al., 2017); this increasing mortality gap has been reported elsewhere (Hodgson et al., 2010; Lomholt et al., 2019; Nielsen et al., 2013). Authors highlight the fact that health improvements in people with SMI are increasing at a slower rate than in the general population, and that health inequalities for this group are growing despite significant public health efforts to address this issue. Other factors contributing to health inequalities, which can lead to premature mortality, include barriers to accessing preventive health services by people with SMI. There is also some evidence that addressing negative health behaviours, such as smoking, has been more effective in the general population than for people with SMI. For people with bipolar disorder, polypharmacy is increasingly common and could be contributing to the worsening cardiovascular disease mortality compared with the general population over the 2010–2014 period. Recent deinstitutionalisation in the UK may have also led to reduced support and care for people living with SMI in the community, which may be reflected in mortality rates. Finally, austerity measures

following the 2008 financial crash may have disproportionately hit people with SMI who may lack social safety-nets, which may further worsen their health.

Norman and Ryrie (2009) reported that while approximately 40% of premature deaths in people with SMI are linked to suicide and accidents, a significant cause of the mortality disparity is attributed to preventable and treatable long-term physical health conditions, with cardiovascular disease and cancer as the first and second leading cause of death, respectively, in individuals with SMI (De Hert et al., 2011; Tran et al., 2009). While the epidemiological evidence regarding cancer incidence in people with SMI is inconsistent, excess cancer mortality in people with SMI has been reported consistently. Cancer was, therefore, selected as the disease focus for this study.

1.3 Cancer in people with SMI

1.3.1 Excess cancer mortality rates in people with SMI

Several studies in the UK and other high-income countries have found that individuals with SMI have disproportionately higher cancer mortality rates than in the general population (Batty et al., 2012; Cook et al., 2014; Crump et al., 2013b; Ferron et al., 2011; Howard et al., 2010; Kisely et al., 2012; Weinstein et al., 2015). In comparison with the general population, mental health service users under the age of 75 in England have death rates that are two times higher for cancer (Public Health England, 2018). A prospective cohort study of patients with schizophrenia (*n* = 3470) was undertaken in

France (Tran et al., 2009), and during the 11-year follow-up, 14% of patients with schizophrenia had died. In this cohort, after suicide (*n* = 143), cancer was the second leading cause of death (*n* = 74), with a global standardised mortality rate of 1.5 (95% CI, 1.2-1.9). The cancer-related mortality rate was almost four times higher than in the general population; breast cancer was the most frequent neoplasm for women (*n* = 11), while for men, it was lung cancer (*n* = 23).

In Australia, Kisely et al. (2013) led a population-based record-linkage analysis, comparing mental health patients with the general population of Western Australia using an inception cohort. Mental health records were linked with cancer registrations and death records from 1988 to 2007. Cancer mortality was found to be 30% higher in people with SMI than in the general population (Kisely et al., 2013).

Findings from the UK Schizophrenia Commission (2012) indicated that people with schizophrenia who develop cancer are three times more likely to die than those in the general population. Also in the UK, a data-linkage study in South-East London (Chang et al., 2014) found that people with SMI and other mental disorders had significantly worse survival rates after a cancer diagnosis, independent of the cancer stage at diagnosis.

In Canada, authors reported a significantly higher risk of cancer mortality for people with SMI (Kisely et al., 2008). Results from a more recent Canadian study showed that among adults presenting with malignancies, use of mental

health services before a cancer diagnosis is independently associated with worse cancer-specific mortality and all-cause mortality (Klaassen et al., 2019).

1.3.2 Causes of excess cancer-related mortality

One key cause of excess cancer-related mortality to consider in this group is the inequity of access to specialist medical treatment and care (Kisely et al., 2013, 2015). A reduced likelihood of undertaking chemotherapy and radiotherapy has been reported for a range of cancers in people with SMI (Baillargeon et al., 2011; Chang et al., 2014; Irwin et al., 2014, Obuchi et al., 2014, Weinstein et al., 2016). Additionally, people with schizophrenia have a higher rate of complications and mortality following surgery (Cook et al., 2014); for example, findings have shown that women with SMI undergoing a mastectomy are more likely to have complications and longer stays in hospital settings (Loh et al., 2006).

Results from a US study led by Weinstein (2015, 2016) on cancer screening, prevention and treatment in people with SMI highlight three factors that may play a role in reduced rates of oncology treatment uptake. The first is fragmented health services, that is the lack of communication between primary, oncology and mental health professionals. The second is health professionals' stigmatising behaviour towards people with SMI, for instance, when a patient has poor hygiene due to self-neglect or where the symptoms of their mental illness make them behave aggressively (Ziedonis et al., 2007), and the last is 'diagnostic overshadowing'. Diagnostic overshadowing

is the attribution of an individual's symptoms to their mental condition when such symptoms suggest a comorbid condition, which may also delay appropriate diagnosis and treatment, especially for people with psychosis (Cook et al., 2014; Howard et al., 2010). In addition, people with SMI are more at risk of social isolation (Kilbourne et al., 2008), low income (Ferron et al., 2011; Sylvestre et al., 2018) and homelessness (Aubry et al., 2015), which all present challenges to the provision of cancer treatment and palliative care, as these factors contribute to whether people access healthcare services (Cook et al., 2014; Weinstein et al., 2015).

Another important factor which contributes to poorer survival rates of people with SMI after a cancer diagnosis is unequal access to cancer screening (Chang et al., 2014; Cunningham et al., 2015). A Western Australia data linkage study found that people with SMI are more likely to present with metastases at diagnosis (7.1%) than the general population (6.1%) (Kisely et al., 2013). A delayed cancer diagnosis, which may be due to postponements in help-seeking due to mental health symptoms (Cook et al., 2014*),* may not fully explain the mortality differential, but it is an important factor. Among women with SMI, delays in help-seeking are particularly problematic because women may be at an increased risk of invasive cervical cancer due to the prevalence of other risk factors for cervical cancer. These include a lifetime incidence of sexual abuse (69%), high rates of smoking and risky sexual behaviour associated with manic episodes (Anderson et al., 2016; De Hert et al., 2011; James et al., 2017).

This section has highlighted that cancer mortality in people with SMI is higher than in the general population, which has been evidenced in studies across several countries. One key factor which explains the excess mortality in this group is a delayed diagnosis, which may, in part, be due to the reduced uptake of cancer screening programmes. Lack of uptake is the risk factor for cancer addressed in this thesis; specifically, in relation to cervical screening. This is discussed in the following section.

1.4 Low cancer screening uptake in people with SMI

Screening, and the resulting early detection and treatment, has been shown to reduce mortality and morbidity from certain cancers (Kalager et al., 2010; Stang and Jöckel, 2018). As a public health intervention, cervical screening can achieve reductions in cancer incidence by up to 80% where practised effectively (Ogilvie et al., 2013). There is some indication that cervical screening contributes to reducing the presentation of malignant (cancerous) tumours, the two most common tumours of the cervix being squamous cell carcinomas (around 80-85% of cases) and adenocarcinoma (around 15-20% of cases) (Wang et al., 2004). Evidence shows that cervical screening is more effective for detecting the first tumour type (Sasieni et al., 2009). Delayed diagnoses can partly be addressed by attending health screening (Kalager et al., 2010), but only if people with SMI attend both screening and subsequent appointments at the same rate as the general population. Relative to the general population, some health services tend to be underused by people with SMI (Druss, 2007), including preventive and screening services, such as cancer screening programmes and dental

checks (Bardi and Moorley, 2016; Kisely et al., 2015; John et al., 2018; Lamontagne-Godwin et al., 2018). This reduced uptake in cancer screening can often be explained by the fact that these programmes do not address the underlying psychological variables that may influence a person's decision to attend the screening (Bish et al., 2000). As mentioned earlier (section 1.3.2), there is a high prevalence of trauma, including physical and sexual abuse, among people with SMI (Anderson et al., 2016); this may impact on their decision to attend cancer screening (Clifton et al., 2016). A literature review of the barriers to cancer screening in SMI is reported in Chapter Five (section 5.1).

In contrast to their uptake of screening programs, people with SMI access non-psychiatric medical care, such as acute and emergency care, at much higher rates than individuals without mental illness as a result of the increased prevalence of poor physical health (Dismuke and Egede, 2011; Jayatilleke et al., 2018). Authors from a UK study reported that in 2013/14, people with mental illness had 3.2 times more Accident and Emergencies attendance and 4.9 times more emergency inpatient admissions than people without mental illness (Dorning et al., 2015). This indicates that people with SMI may experience unique obstacles (or 'barriers') in their preventive care pathway that go beyond access to general healthcare (Xiang, 2015).

Evidence on cancer screening uptake indicates that for a range of cancers, screening attendance is significantly lower in people living with SMI compared to the general population. Solmi et al. (2019) led a prevalence and

comparative meta-analysis of 4.7 million people with mental illness to explore world-wide disparities in cancer screening uptake in people with SMI across the world in comparison with the general population. Attending cancer screening appointments was found to be significantly less frequent in people with any type of SMI compared with the general population for any cancer (k=37; OR 0·76 [95% CI 0·72–0·79]), breast cancer (k=27; 0·65 [0·60–0·71]), cervical cancer (k=23; 0·89 [0·84–0·95]) and prostate cancer (k=4; 0·78 [0·70–0·86], but not for colorectal cancer (k=8; 1·02 [0·90–1·15]) (Solmi et al., 2019). In a prior review conducted by Howard et al. (2010), evidence suggested (*n* = 12 studies: United States (*n* = 8), one each in Iceland, Canada, Australia and the UK) that adults with SMI were less likely than other groups to receive screening for a range of cancers (cervical, breast, colorectal and prostate cancer). Another review (*n* = 16 studies: United States (*n* = 10), Canada (*n* = 4), one in Taiwan and one study that included 10 European countries; Happell et al., 2012) showed that most studies demonstrated a 20–30% reduced likelihood of cervical screening attendance in the SMI population. Authors of a subsequent review (Aggarwal et al., 2013) of breast and cervical screening uptake in the SMI population (*n* = 19 studies: Australia (*n* =1), Canada (*n* = 2), UK (*n* = 1), US (*n* = 15)), which also included studies in people with depression and anxiety disorders, reported similar findings.

There was considerable overlap between the three reviews, which all showed a reduced uptake of cancer screening in people with SMI. Results from two Japanese studies (Fujiwara et al., 2017; Inagaki et al., 2018) have

also found rates of cancer screening to be 40% lower for people with schizophrenia. Authors from a recent cross-sectional study using the UK Biobank reported that more severe depressive symptoms were associated with reduced participation in cervical and breast screening programmes (Niedzwiedz et al., 2020). In the US, the severity of mental health diagnoses is strongly associated with lower initial and follow-up breast screening rates (Carney and Jones, 2006; Weinstein et al., 2019), while in Denmark, an observational study showed a strong association between psychiatric morbidity and an increased likelihood of non-participation in breast cancer screening (Jensen et al., 2016).

A scoping review of access to screening by people living with SMI from London's African Caribbean communities considered all types of cancer screening (MacAttram and Chinegwundoh, 2014). Key findings suggested that currently no strategies exist to ensure that people living with mental illness are included in cancer screening programmes; involvement in cancer screening by this population is unrecorded, the needs of psychiatric inpatient groups are not considered and mental health and cancer screening service providers do not collaborate. Lastly, the ethnicity of screening attenders is not recorded, so it is unclear whether people with SMI in some Black, Asian and Minority Ethnic (BAME) groups attend cancer screening to the same extent as White British people with SMI. General population studies have shown that women from BAME backgrounds are less likely to attend cervical and breast screening than White British women (Marlow et al., 2015; Moser et al., 2009), another significant health inequality.

With regards to bowel cancer screening, a cohort study (*n* = 80,670) in the US (Baillargeon et al., 2011) found that people diagnosed with a mental disorder up to two years before their cancer diagnosis were more likely to die of any cause (hazard ratio (HR) = 1.33, 95% CI (confidence interval) = 1.31–1.36) or colon cancer (HR = 1.23, 95% CI = 1.19–1.27). UK uptake of cancer screening is lower among the most socioeconomically deprived, women with disabilities, black and minority ethnic populations, and those with learning difficulties (Duffy et al., 2017).

This section has highlighted the reduced uptake of cancer screening programmes in people with SMI, as reported in the UK and internationally. The focus of this thesis is cervical screening uptake in women with SMI; the following section presents the current evidence specific to this type of screening.

1.4.1 Cervical screening uptake in women with SMI: the UK and international figures

Similar to other types of cancer, reduced uptake of cervical screening in women with SMI has been reported in several UK and international studies (e.g. Abrams et al., 2012; Aggarwal et al., 2013; Druss et al., 2010; Fang et al., 2011; Fujiwara et al., 2017; Howard et al., 2010; Inagaki et al., 2018; James et al., 2017; Martens et al., 2009; Mo et al., 2014; Tilbrook et al., 2010; Woodhead et al., 2016; Xiang, 2015).

In the UK, based on the primary care records of 1.7 million primary care patients, women with schizophrenia were less likely to have had a cervical sample taken in the preceding five years (63%) compared with the general population (73%) (NHS Employers, 2018). In Canada, Martens et al. (2009) reviewed records of women (*n* = 338 514) and found a 30% decrease in cervical screening rates among women with schizophrenia compared to the general population. Another Canadian study reported that women with psychosis were more than five times less likely to receive adequate cervical screening compared with the general population despite their higher rates of smoking and a higher number of primary care visits (Tilbrook et al., 2010). Given that the study took place in a setting that specifically aimed to provide primary care to people with SMI, it is possible that rates of uptake would be even lower in other clinical settings. Other studies (Druss et al., 2010; Fang et al., 2011) have found lower rates of cervical screening among women with SMI, particularly among older women and those living with schizophrenia or other psychotic disorders.

A US study (Xiang, 2015) found that serious psychological distress (*n* = 1340) was associated with 41% lower odds of being up to date with cervical screening among women eligible for screening. Another US study (James et al., 2017) found that only 20.2% of women in California with SMI received cervical screening during one year compared with 42.3% of Californian women in the general population. Women with bipolar disorder were also significantly more likely than those with schizophrenia to have been screened. In contrast, the authors of a study in Maryland, United States

(Abrams et al., 2012) reported higher cervical screening rates in women with mental illness compared with controls without a diagnosis of mental illness. The authors concluded that a higher rate of screening uptake by women with SMI may be because study participants were enrolled in Maryland's Medicaid programme; Maryland is a wealthy US state with a well-funded public mental health system.

Eligible SMI patients in a London data linkage study were almost 60% less likely to have received cervical screening than women without SMI (Woodhead et al., 2016). Having a diagnosis of schizophrenia and receiving depot medication (suggesting severe illness) were associated with the lowest odds of uptake of cervical screening among women with SMI. A depot antipsychotic prescription is a special preparation of the medication which is given by injection; it is slowly released into the body over several weeks (Royal College of Psychiatrists, 2015). Being prescribed depot injections may indicate a difficulty with self-management, which in turn might reduce the likelihood of attending cancer screening (Woodhead et al., 2016). Health systems vary between countries (even within countries, such as the United States), but reduced rates of screening for people with SMI have been found in all but the one study discussed above (Abrams et al., 2012).

This section has highlighted the reduced uptake of cervical screening by women with SMI in the UK and internationally. The following section summarises cervical cancer incidence and risk factors. The UK's cancer

screening programme is then briefly introduced to provide a background to the setting of this research.

1.5 Cervical cancer and UK's cancer screening programme

1.5.1 Cervical cancer: a brief overview

Cervical cancer is the second most common cancer in women, and the most common cancer in women aged 35 and under (Jo's Cervical Cancer Trust, n.d.). Cervical cancer is the fourth most commonly diagnosed cancer and the fourth leading cause of cancer-related death; an estimated 527,600 cases and 265,700 deaths worldwide were attributed to cervical cancer in 2012 (Ferlay et al., 2012). In high-income countries, it is the second most frequently diagnosed cancer after breast cancer and is the third leading cause of cancer-related death after breast and lung cancers (Ferlay et al., 2012).

Cervical cancer is now a preventable and curable illness following the introduction of cervical screening and HPV vaccination programmes (Banerjee, 2017) and 100,000 deaths from cervical cancer are estimated to have been prevented by the UK national screening programme since its initiation in 1988 (Peto et al., 2004). The main risk factor for cervical cancer is chronic and persistent infection with human papillomavirus (HPV) (Villain et al., 2015), and another risk factor is to never have been screened or being under-screened (Lofters et al., 2007). In a data linkage study comparing women with SMI to the general population in Western Australia, cancer-specific mortality for women with SMI was found to be high for

gynaecological cancer (risk ratio: 1.26) with a reduced likelihood of surgery, especially for resection (surgical removal of tissue) of cervical cancers (hazard ratio: 0.73). It is also the highest increased risk of mortality in people with schizophrenia (hazard ratio: 1.96) (Kisely et al., 2013).

In England, data suggest higher cervical cancer mortality in women living in the most deprived quintile of areas nationally compared with those living in the least deprived quintile. Relative survival increases over time: at one year there is a 6% gap in relative survival; this gap in relative survival increases to 11% at the five-year mark (Trent Cancer Registry, National Cancer Intelligence Network and the NHS Cervical Cancer Screening Programme, 2012). In the UK general population, incidence rates for cervical cancer are projected to rise between 2014 and 2035 by 43% (Cancer Research UK, 2014), which is a projected average annual percentage change of 1.65 for the same period (Smittenaar et al., 2016). Though the incidence rate is projected to fall for the over-75 age group, the overall projected increase in cervical cancer incidence is driven by changes in the 25–49 and 50–64 age groups (Smittenaar et al., 2016). The following section briefly introduces the UK's cancer screening programmes.

1.5.2 UK cancer screening programmes

Earlier research has shown that screening can reduce cervical cancer mortality and that a reduction in incidence and mortality seems to be proportional to the intensity of the screening efforts (Laara et al., 1987; Miller et al., 1976). It has been reported that the uptake of new cancer screening

programmes can be low, particularly in the target groups who are most at risk of developing cervical cancer (Makuc et al., 1989).

Three universal cancer screening programmes are offered in the UK once the required age is reached. These are for bowel, breast and cervical cancer. Risk-stratified screening is offered for a range of other cancers, such as lung cancer (NHS Choices, 2018). Cervical screening was selected as the focus of this research since women aged 25–64 are eligible for cervical screening, ensuring a suitably large and diverse sample set. When compared to breast screening, which counts women aged 50–70 in its eligibility, and bowel screening, where those aged 60–69 form the standard eligibility group and those aged 70–75 can be included on request, the decision to focus on cervical screening was made with a view that the potential impact of the work would be greater due to the larger numbers of people affected.

Attendance rates for cervical screening in the UK have been suboptimal for the past two decades, in 2018 dropping to a 21-year low: in England, 71.4% of eligible women attended cervical screening (NHS Digital, 2018). This is the lowest rate since 1997 and a decrease from 75.7% in 2011 (Jo's Cervical Cancer Trust, 2016).

1.6 Improving access and uptake of cancer screening in SMI

1.6.1 Policies to improve cancer screening uptake in SMI: current UK state of affairs

People living with SMI are not consistently being offered appropriate or timely physical health assessments – which include cancer screening – despite being at an increased risk of poor physical health (Lawrence and Kisely, 2010), and therefore, making screening more accessible for people with SMI is an important healthcare policy for the UK Department of Health (2011) and Public Health England (PHE) (Syson-Nibbs, 2018). PHE has been addressing this by undertaking a survey of cancer screening uptake among people with SMI using the 'Health Improvement Network' database of GP records. The results will form a baseline from which change can be measured (Public Health England, 2018). In the *Five Year Forward View for Mental Health* (NHS England, 2016b), NHS England has committed to leading work to ensure that by 2020/21, 280,000 people living with SMI will have had their physical health needs met by increasing early detection and expanding yearly access to evidence-based physical care assessment and intervention.

To address this reduced uptake of and access to health screening, incentive schemes in the NHS, such as the Quality and Outcomes Framework (QOF) and the Commissioning for Quality and Innovation (CQUIN) schemes, have been utilised (British Medical Association, 2003; NHS England, 2019). For instance, under QOF, GPs are incentivised to offer annual physical health reviews to people with diagnoses of schizophrenia or bipolar disorder, including, since 2006, the offer of age- and gender-appropriate cancer screening (British Medical Association, 2006). A QOF indicator [MH-008] established in 2010 incentivises GPs to ensure that women with

schizophrenia, bipolar affective disorder or other psychoses are given cervical screening according to national guidelines (NHS Employers, 2018). In the NHS, the care pathways that manage the physical health of people with SMI are organised in two ways, depending on whether the patient is registered in secondary (mental health services) or primary care only.

Primary care teams are responsible for carrying out annual physical health assessments and follow-up care for people with SMI who are not in contact with secondary mental health services, including both those whose care has always been solely in primary care and those who have been discharged from secondary care. This also includes patients with SMI who have been in contact with secondary care mental health teams (with shared care arrangements in place) for more than 12 months and/or whose condition has stabilised (NHS England, 2018). GPs can use an online physical health recording template (the 'Bradford Template'), which includes a review of their patient's blood tests to monitor their cardiovascular and type 2 diabetes risk/management, their smoking and alcohol intake habits, their sexual health and whether they are up to date on cancer screening (NHS England, 2016c). Secondary care teams are responsible for carrying out annual physical health assessments and follow-up care for patients with SMI under the care of a mental health team for less than 12 months and/or whose condition has not yet stabilised and for inpatients. A clinical resource (the 'Lester tool') is available for secondary care health professionals to assess patients' cardiovascular health (Shiers et al., 2014). The tool is in widespread use to support the implementation of the physical health (CQUIN – Commissioning

for Quality and Innovation) targets. These targets aim, through remuneration, to improve collaborative and effective physical health monitoring and management of common physical health conditions and risk factors in people with psychotic illnesses (e.g. smoking, lifestyle, obesity, hypertension, diabetes and hyperlipidaemia, though not specifically cancer screening). The Bradford physical healthcare template is aligned with the Lester 2014 tool (NHS England, 2016c).

It is not known whether these measures influence screening uptake by people living with SMI. A report (2013) by Rethink – a national mental health charity in the UK – found that in some areas, only 30% of people living with SMI had received their physical health review, suggesting that the incentivisation appears to have been relatively ineffective in some areas. The latest figures show little variation: in England, 32.3% of people on the GP mental health register on the 31st December 2019 had received their physical health review in the preceding 12 months (NHS England, 2020).

Like every adult eligible based on age in the UK general population, people living with SMI should receive invitations from the NHS to attend cervical, breast and bowel cancer screening. The mental health status of screening attendees is not recorded by the NHS cancer screening programmes, however, so rates of screening uptake in this population, which are lower than for people with SMI, are unknown on a national basis. UK studies have therefore relied on datasets created by linking local primary care databases (Woodhead et al., 2016) and hence only provide region-specific evidence.

1.6.2 Interventions to improve uptake of cancer screening at the patient level

Whether to take up cancer screening is a health decision faced by most people, and recently, more emphasis has been put on to enabling people who access health services (including cancer screening) to make an informed choice (Jepson et al., 2007; Michie et al., 2004). Deciding whether to attend screening involves making an informed choice that includes consideration of the advantages and risks of the screening process. In recent years, the focus has moved away from solely promoting the benefits of screening to providing comprehensive information which enables individuals to make an informed choice (Jepson et al., 2005). Consideration of pros and cons may be part of most people's decision-making; however, people with SMI may face additional barriers to cancer screening uptake that are specific to them and which may affect their decision-making (Clifton et al., 2016).

Systematic reviews on cancer screening in people living with SMI report many barriers that are also experienced by the general population and other disadvantaged groups (e.g. embarrassment, childcare responsibilities, fear of receiving an abnormal result). Evidence suggests that barriers to screening uptake in people with SMI vary for different types of screening, at different stages of the screening process and between individuals (Clifton et al., 2016). Several individual-level interventions exist that aim to facilitate decision-making in health care, including those targeted at patients and clinicians, namely tools to promote shared decision-making and decision support tools targeted to patients. The support tools aimed at supporting

patients include informed-choice tools and patient decision aids. Both have been used for screening decisions, though they have different goals. Informed-choice tools seek to support patient autonomy and ensure that individuals are neither deceived nor coerced (Jepson et al., 2005), while the goal of a patient decision aid is to help patients make a decision and be satisfied with it. Given that the intervention in this study is being developed for women with SMI, a group that tends to underuse cancer screening services, the goals of informed-choice tools were considered to be more appropriate than those of a patient decision aid for this population. Each type of decision support tool is presented below.

a. Shared decision-making tools

'Shared decision-making' interventions are available to support individuals' decisions (Elwyn et al., 2012; Légaré et al., 2018). These may be regarded as an intermediate model that falls between a paternalistic approach and the informed-choice model (Charles et al., 1997; Kon, 2010) as they facilitate a collaborative process through which a clinician supports a patient to decide on their treatment (Elwyn et al., 2010). Shared decision-making interventions share similarities with informed-choice tools in that they both seek to clarify values, but the decision-making process is different as the decision is shared with a health professional (Drake et al., 2009; Duncan et al., 2010; Elwyn et al., 2010).

b. Decision aids

The International Patient Decision Aids Standards (IPDAS) collaboration (Elwyn et al., 2006; IPDAS, 2005; Joseph-Williams et al., 2013) defines decision aids as evidence-based tools designed to help patients make specific and deliberate choices among healthcare options (Stacey et al., 2017). Decision aids describe the decision that must be made and the options available and help people to think about the options from a personal viewpoint (Stacey et al., 2017); they are used by the patient on their own to weigh the pros and cons of a decision, clarify the values underpinning that decision and determine what they need to support them to pursue a given option. In the general population, decision aids are effective in helping people make decisions about a range of health issues, including screening (Stacey et al., 2017). Patient decision aids have been developed to guide individuals through a cancer screening decision-making process (Martínez-Alonso et al., 2017; Trikalinos et al., 2014; Volk et al., 2016).

c. Informed-choice tools

Informed-choice tools aim to provide the individual with the required information to allow them to make an informed choice, while also including the patient's values in the decision-making process (Barratt, 2008). These tools are a variant on the decision aid idea, sometimes known as 'decision support tools', and come in various formats, including pamphlets, videos or web-based tools such as apps. Informed-choice tools, which are commonly delivered online, might include 'personal stories', namely testimonies or videos of people who have faced a similar decision. These tools often also

include exercises that allow participants to explore the advantages and disadvantages of a choice (Brunette et al., 2011).

Of the three tools described above, two are potential methods to support decision-making around cancer screening: shared decision-making and informed-choice tools. People living with SMI commonly report poor continuity of care (Biringer et al., 2017) and difficult relationships with health professionals, particularly in primary care (Clifton et al., 2016; Ross et al., 2015), so shared decision-making tools may not be appropriate for everyone within this population. In addition, primary care clinicians face time constraints to using a shared decision-making tool (Gravel et al., 2006), so an informed-choice tool, which could be used independently or with a supporter of choice, may be a more suitable format for assisting women with SMI in their decision to attend their screening appointment. An informed-choice tool was therefore the selected format for this research.

1.6.3 The evidence so far on initiatives to increase uptake

The World Health Organization (2013) has recognised the important role of mental disorders in contributing to the global burden of non-communicable diseases, such as cancer, and highlighted the need for equitable access to healthcare interventions for people with mental illness. Nevertheless, in England, there is a lack of support in practice. People with SMI are not currently supported to use available health information and advice or to take up medical tests and interventions that reduce the risk of preventable health conditions (NHS England, 2018). In addition, there is little research on ways

to increase cancer screening uptake in this group. A range of initiatives has been developed for the general public to address uptake to the NHS Cervical Screening Programme, including the Public Health England (PHE) Decision aid leaflet 'NHS Cervical Screening: Helping you Decide' and 'An Easy Guide to Cervical Screening', which were developed in collaboration with women who have learning disabilities (PHE, 2012, 2013a). Jo's Cervical Cancer Trust[3] has several information leaflets on their website for anyone who is thinking about attending the cervical screening or has a question about cervical cancer.

So far, in the existing literature, no individual-level intervention for women with SMI has been identified to increase uptake of or access to cancer screening (Barley et al., 2016). Only one published study has reported the testing of a shared decision-making intervention to assist formerly homeless women in Philadelphia (US) living with SMI to attend breast cancer screening (Weinstein et al., 2015, 2019). Authors of a comparative meta-analysis on the cancer screening disparities between people with mental illness and the general population report the urgent need for the development of tailored interventions to increase uptake of cancer screening for this group (Solmi et al., 2019). Researchers have also identified the need for interventions to support people with SMI to process information concerning cancer and cancer screening in order to enable them to recognise the importance and benefits associated with cancer screening (Clifton et al., 2016; Mo et al., 2014; Weinstein et al., 2015). Findings from research conducted by Mo et al.

[3] https://www.jostrust.org.uk/shop/information

(2014) suggest that tailor-made information about cancer and the benefits of screening should be provided in a way that is accessible and easy to understand; the intervention should address their beliefs, concerns and possible misconceptions about cancer.

An important consideration in screening for people with SMI is that of their capacity to decide whether to attend their appointment. The NHS Cancer Screening Programme (2009) posits that some people who lack mental capacity due to a mental health problem, learning disability or dementia may be unable to make an informed decision about whether to attend the screening. The Mental Capacity Act (2005) defines the lack of mental capacity as the inability to decide at a particular time. Informed consent in the medical context can be defined as the process in which a health professional educates an individual about the benefits, risks and alternatives of a given intervention or procedure (Berg et al., 2001). In contrast, informed choice is central to supporting patient autonomy by ensuring that people make choices in line with their interests, values and preferences and that these choices are based on all relevant information, as well as being free from coercion (Jepson et al., 2005; Smith et al., 2010).

The Informed Consent Guidelines on cancer screening (2009, updated 2018) under the provisions of the Mental Capacity Act (2005), state that individuals must be provided with all practicable help to make their own decisions before anyone assumes they are not able to do so. The Mental Capacity Act (2005) posits that before a decision is made on whether a person lacks capacity,

steps must be taken to allow the person to try to make the decision themselves. These steps are listed below:

1) providing the person with all the relevant information they require,
2) ensuring they have been given information on any alternatives,
3) checking the information has been presented in a way that is easier for them to understand (e.g. using simple language).

A higher proportion of people living with SMI has, relative to the general population, difficulty in processing information due to poor concentration, or may periodically face executive function issues, including drowsiness or cognitive blunting (Castillo et al., 2015; Le et al., 2017). Some people with SMI and lower functioning may struggle with understanding health information and may have limited numerical literacy, limited computing skills and lower literacy, which could impact on how informed-choice tools are used (Borzekowski et al., 2009; Clausen et al., 2016, Ferron et al., 2011). Every step outlined in the Mental Capacity Act above is therefore critical to consider with regards to the development of decision-making tools for people with SMI. It has been stated that having a range of information and choices is integral to the empowerment of people with SMI (Linhorst, 2006). For those with poor decision-making skills and/or unmanaged psychiatric symptoms, or those who lack decision-making experience, making even a small choice can be empowering (Carling, 1995; Hagner and Marrone, 1995; Linhorst, 2006). Research has shown better health outcomes for those with a mental health diagnosis as a result of active participation in decision-making (Martin et al., 2015; Weinstein et al., 2019).

Chapter summary

This chapter has highlighted that there is a higher mortality rate and reduced life expectancy of people with SMI compared to the general population. Cancer mortality is higher in this group than in the general population due to several factors, one of which is low uptake of cancer screening. Yet, cancer screening programmes have been shown to help with early detection and reduce the risk of premature mortality. Thus, an intervention that can support the uptake of cancer screening among this group is needed. Cervical screening was selected as the focus of this research as considerably more people are eligible for this, compared to other screening programmes; hence, the potential impact of the work is greater. In addition, attendance rates for cervical screening among the overall UK population have been falling year on year, suggesting that attention is needed in this area. Several interventions aimed at the individual were discussed in this chapter, with an informed-choice tool deemed the most appropriate for responding to the specific needs of people with SMI. This study was therefore designed to develop such a tool and to test its usability, readability and acceptability within this population.

Chapter Two – Rationale and outline of the research

This chapter outlines the rationale and protocol for the research. It describes the research paradigm that informs the chosen methods and introduces the Medical Research Council (MRC) guidance (Craig et al., 2013), which provides the overarching framework for the research. Based on this guidance, this research project comprises five linked studies, each of which is outlined in this chapter.

2.1 The current research

As reported in Chapter One, rates of uptake of cervical screening programmes are lower for people with SMI compared to the general population. This finding, along with research on barriers to screening that are specific to this population (Clifton et al., 2016) illustrates that it may be harder for people with SMI compared with the general population to access preventive care. To address this, a cervical screening informed-choice tool will be developed that is informed by known barriers to cancer screening uptake among people with SMI. These barriers have been identified through a literature review that is reported in Chapter Five (section 5.1). Moreover, as discussed in Chapter One (see section 1.7.2), the optimum design for an informed-choice tool for people with SMI is currently unknown. Informed by relevant identified barriers to cervical screening for women with SMI, a theoretically underpinned cervical screening informed-choice tool will therefore be developed to redress this population's unequal access to and uptake of cervical screening.

2.2 Aims and objectives of the research

The primary aim of this research is to develop and test an intervention to surmount or reduce the impact of barriers to cervical screening in women with SMI. Based on the literature, an informed-choice tool (thereafter tool) appears to be a suitable instrument for achieving this aim. This tool directly needs to target the decision to attend cervical screening, a particular health behaviour. The evidence shows that going for screening is the best way to avoid cervical cancer; nonetheless, it remains a choice whether to do so. The primary aim of the tool is therefore to support women to make an informed decision regarding cervical screening. The information needs to be provided in the tool in a way that is accessible, usable and acceptable to this group, and the tool should address barriers to screening and be theoretically underpinned to ensure its acceptability and appropriateness for future evaluation in a trial. Acceptability can be defined as the perception among stakeholders (in this case mental health service users and mental health professionals) that an intervention is agreeable to them (Peters et al., 2013). Usability testing involves evaluating the intervention through the analysis of typical end users interacting with the intervention; this allows for iterative modifications (Kushniruk, 2002). Testing the usability of an intervention can lead to increased user satisfaction and performance (Alhadreti and Mayhew, 2017). The objectives of this research are listed in the box below.

Objective one: To develop an informed-choice tool for women with SMI which addresses some of the barriers to screening attendance

Objective two: The informed-choice tool should be theoretically underpinned

Objective three: Acceptability and usability of the tool by stakeholders should be tested

2.3 Selection of research paradigm

2.3.1 Research paradigms in social research

Paradigms can be defined as ways to view the world; they summarise researchers' beliefs about their contribution to knowledge (Kuhn, 1996; Rallis and Rossman, 2003). Four main paradigms can be distinguished in social research: constructivist, positivist, participatory and pragmatist (Creswell, 2009). Constructivism is associated with qualitative research and is used to obtain an understanding of the world from an individual perspective. The assumption is that no objective truth exists and that everyone is shaped by their experience and environment (Creswell et al., 2011). Positivism is associated with quantitative research and aims to test hypotheses to obtain objective truth and generalise theories to other contexts (Willig, 2013). The main purpose of the participatory paradigm is to explore and interpret the views, concerns, and experiences of people from their own perspectives; this then allows them to undertake measures to improve their situations (Heron and Reason, 1997). The fundamental principle of participatory research is

that it is research ‘with’, rather than ‘on’ people (Heron and Reason, 1986). Lastly, the pragmatist approach is defined as a ‘third way’, moving away from the traditional opposition between constructivism and positivism.

Within social research, the pragmatist approach is not new (Gage, 1989; Patton, 1988); however, its link to the use of mixed methods is more recent (Pearce, 2012; Tashakkori and Teddlie, 2010). Constructivism and positivism were previously regarded in the literature as irreconcilable approaches (Creswell and Plano Clark, 2007; Howe, 1988); however, the pragmatist approach is integrally linked to both. Pragmatism has gained considerable traction in social research over the last 20 years (Johnson and Christensen, 2012), and the gradual use of mixed methods (Creswell et al., 2011; Johnson et al., 2007) has been interpreted as a ‘third methodological movement’, adding to quantitative and qualitative methodologies (Greene, 2008; Tashakkori and Teddlie, 2003). The pragmatist approach was selected for this research.

2.3.2 The pragmatic paradigm and the use of mixed methods in research

Pragmatism adopts a form of relativism and rejects the need to choose between paradigms that are either entirely context-specific or linked to a universal value (Coghlan and Brydon-Miller, 2014). Pragmatists emphasise the importance of the research question and use all appropriate approaches available to understand the problem. They favour the approach of using several methods in their inquiries and choosing the most appropriate method

for answering the research question (Johnson and Onwuegbuzie, 2004). They are not committed to any philosophical view or reality; their beliefs are more directly connected to actions (Dewey, 2008). Pragmatists seek a truth that is practically useful rather than absolute. They focus on what works at a specific time and why research should be conducted in a specific way (Creswell and Plano Clark, 2007). Critics posit that the philosophical foundations of pragmatism have not been sufficiently examined with consideration of the focus in the literature on the practical aspects of the pragmatic paradigm, which embraces a plurality of methods. In turn, this approach of using multiple methods has been criticised for the lack of epistemological consensus surrounding it (Creswell, 2011; Denzin and Lincoln, 2011). Pragmatism is often employed in health services research (O'Cathain et al., 2007) as it offers a sensitivity to the research context, a focus on applied research, and the valuing of different forms of knowledge (Long et al., 2018).

Because of its appropriateness for health services research, pragmatism was thus selected as the dominant paradigm in which to ground this research. For the research enquiry relating to the development of the tool and to service users' and clinicians' experiences of using the tool, qualitative methods were deemed the most appropriate. Quantitative methods were selected to investigate the impact the tool had on service users' decisional conflict to attend the screening. Decisional conflict, explained in more detail in section 2.5, can be defined as being uncertain about which choice to make

when the different options comprise regret, risk or challenge to personal life values.

2.4 Development of complex interventions

The tool developed through this work represents a ‘complex intervention’. An intervention can be described as complex (Craig et al., 2008; Hawe et al., 2004) if the conditions listed below are met; the chapter describing the tool in relation to these conditions are provided in parentheses:

- interacting behaviours or components are required by those receiving or delivering the intervention (Chapter Five),
- several groups or organisational levels are targeted by the intervention (Chapter Six),
- there is more than one outcome (this chapter) and
- a degree of flexibility or tailoring of the intervention is permitted (Chapter Ten).

Different frameworks, guidance, and theoretical models have been recommended to inform the development of a theory-driven complex intervention (de Silva et al., 2014; Hurley et al., 2016; O’Cathain et al., 2019). The ‘gold standard’ tool in health services research is the Medical Research Council (MRC) guidance, which provides a framework for developing and evaluating complex interventions (Craig et al., 2013; Moore et al., 2015). The MRC guidance for developing and evaluating interventions that contain

several interacting components was originally published in 2000 (Campbell et al., 2000) and updated in 2008 (Craig et al., 2008), and it has helped researchers develop and evaluate several theories and evidence-based health interventions (Bobrow et al., 2018; Dowding et al., 2017; Lakshman et al., 2014; Troughton et al., 2016). The updated 2008 MRC guidance provides a non-linear cyclical framework (Figure 2.1), advising health researchers to answer a range of sequential questions regarding the theory of the intervention, feasibility and acceptability, effectiveness and cost-effectiveness, and sustainability of the intervention (Craig et al., 2008; Fletcher et al., 2016). The MRC guidance has four phases (Development, Feasibility/Piloting, Evaluation and Implementation), and each phase includes three steps. Given its widespread use, the MRC guidance was selected as the most appropriate framework for this research, which addresses elements of the first three phases of the MRC. The fourth phase, 'Implementation', involves the dissemination, translation and monitoring of the intervention into routine practice. Dissemination of the tool has begun (see Chapter Ten, section 10.4.1) and other aspects of this phase of the MRC will be the subject of future research.

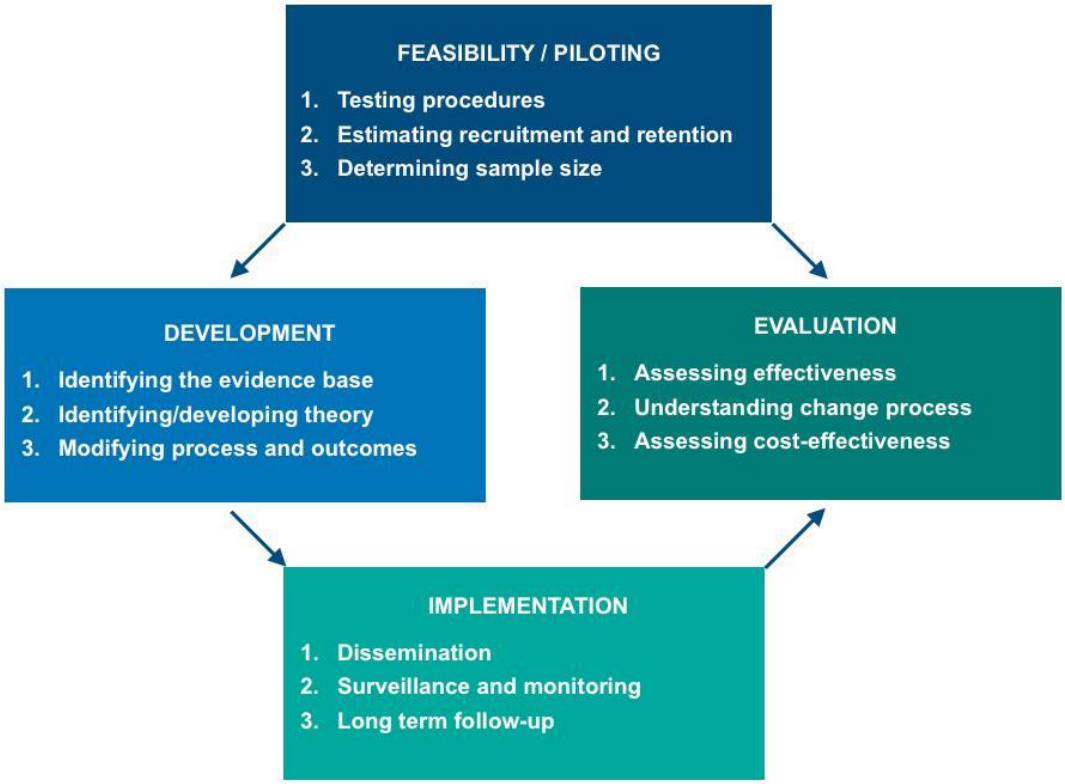


Figure 2.1 Key elements of the development, evaluation, and implementation process of complex interventions (Craig et al., 2008).

2.5 Overview of the research

This research comprises the conception and design of the tool and five related studies, all of which are in line with MRC guidance. An overview of each element of the MRC guided research is provided here; subsequent chapters detail each element concerning the tool developed.

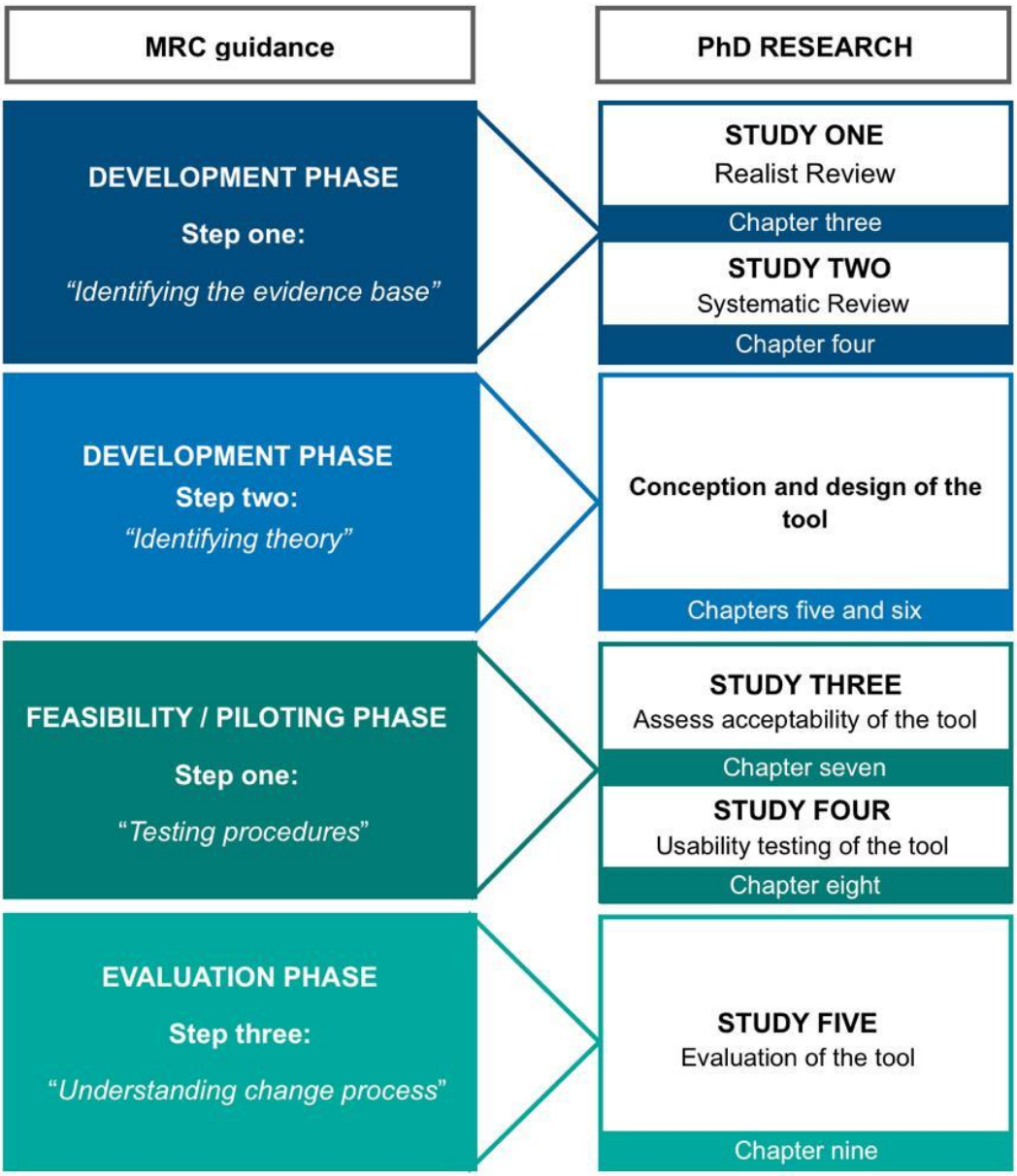


Figure 2.2 Mapping out of each study to the MRC guidance for the development and evaluation of complex interventions

1) Study one [Chapter Three]

Identifying the evidence base: Step one of the MRC *Development Phase*

This step aims to identify the existing evidence and what is already known about similar physical health interventions for people with SMI and the methods that have been used to evaluate them (Craig et al., 2013). The MRC guidance states that if there is no recent, high-quality recent systematic

review of the relevant evidence, one should be conducted (Craig et al., 2013). Therefore, a systematic realist review of studies was conducted to evaluate the effectiveness of interventions developed to increase uptake of or access to physical health screening in people diagnosed with an SMI. Recent research has described and exemplified how social scientists can integrate realist principles across all phases of the MRC guidance (Fletcher et al., 2016). Consideration of what part of an intervention works for whom, in what circumstances, in what setting and how is deemed useful to the development of this tool (Fletcher et al., 2016; Holland et al.,2013; Rycroft-Malone et al., 2012). Results from the review were published in a peer-reviewed journal (Lamontagne-Godwin et al., 2018).[4]

2) Study Two [Chapter Four]

Identifying the evidence base (2): Step one of the MRC *Development Phase*

In line with this step of the MRC guidance, a systematic review was also conducted to identify the specific design(s) and theoretical framework(s) used to develop informed-choice tools for people diagnosed with SMI, and whether there was any evidence of their effectiveness. The results from the review (*n* = 9 studies) informed the development of the tool. A manuscript of the systematic review (*n* = 10)[5] has been published in a peer-reviewed

[4] Lamontagne-Godwin, F., et al. (2018) 'Interventions to increase access to or uptake of physical health screening in people with severe mental illness: a realist review', *BMJ Open*, 8, e019412. http://dx.doi.org/10.1136/bmjopen-2017-019412.

[5] An additional study describing a fourth intervention was included following an update of the review in March 2020.

journal (Lamontagne-Godwin et al., 2020).[6]

3) Conception and design of the tool [Chapters Five and Six]

Identifying theory: Step two of the MRC *Development phase*

The MRC guidance recommends to first understand, from a theoretical perspective, the factors that can act as barriers or enablers to performing the behaviours that are to be targeted in the intervention. The Theoretical Domains Framework (TDF) can be defined as an integrative framework, which was developed from a synthesis of psychological theories to support the application of theoretical approaches to interventions targeting behaviour change (Cane et al., 2012; Phillips et al., 2015). The TDF has been used previously to explore the behaviours of people diagnosed with SMI behind the decision of whether to attend cancer screening (Clifton et al., 2016). Using the barriers and enablers identified in the Clifton et al. (2016) study ensured that the development of the tool's components was theoretically underpinned. In addition, a literature review of the barriers and enablers to cancer screening in people with SMI was conducted. The rationale for this review was to explore all possible barriers and enablers across different national health systems to ensure none were missed. This study also identified the underpinning 'active ingredients' of the

[6] Lamontagne-Godwin, F., Henderson, C., Lafarge, C., Stock, R. and Barley, E. (2020) 'The effectiveness and design of informed choice tools for people with severe mental illness: A systematic review', *Journal of Mental Health,* pp. 1-16. doi:10.1080/09638237.2020.1803232.

tool and how its components were expected to interact synergistically with one another to generate the expected outcomes (Bonell et al., 2015).

4) Study Three [Chapter Seven]

Testing procedures: Step one of the MRC *Feasibility/Piloting phase*

In line with this step of the MRC guidance, user testing was conducted with various stakeholders. NICE's Behaviour Change guidance [PH6] states that an intervention should be planned in collaboration with individuals, communities, organisations and populations (Holman et al., 2018) and should 'take account of the circumstances in which people live, especially the socio-economic and cultural context' (NICE, 2007). Before testing in clinics, a key informants' group was established that, together with service user groups, provided iterative feedback on the tool. Semi-structured interviews with women diagnosed with SMI and their health professionals working in mental health outpatient settings were then conducted across two NHS Trusts to assess acceptability and relevance of the tool and to ensure that no information was excluded. Feedback received on the content of the tool was transcribed, analysed and incorporated into the tool once the interviews were completed.

5) Study Four [Chapter Eight]

Testing procedures (2): Step one of the MRC *Feasibility/Piloting phase*

The updated version of the tool was then presented to a second group of women diagnosed with SMI and health professionals to test its usability

using the ‘think-aloud’ method (van Someren et al., 1994). This is a validated method for assessing user experience and the usability of interventions that allow for observation of the actual reactions of the participant using the tool. The method was used to test an intervention with participants who were diagnosed with SMI (Vilardaga et al., 2016). Feedback on the tool was transcribed, analysed and incorporated once the interviews were completed.

6) Study Five [Chapter Nine]

Understanding the change process: Step three of the *Evaluation phase*
This step of the MRC guidance aims to establish the proof of concept of intervention. The evaluation of the tool is reported in Chapter Nine. Women diagnosed with SMI were asked to complete the measures of their decisional conflict to attend cervical screening using two validated scales. Decisional conflict is generated by four factors: unclear values, the perception that an ineffective decision has been made and inadequate knowledge and support (Janis and Mann, 1977). In other words, it is a reflection of the level of comfort someone faces in making a decision (Thompson-Leduc et al., 2016). The data analysis of the preliminary evaluation of the tool is reported in this chapter. Analysis of the qualitative data helped with the interpretation of the results from the quantitative study.

Chapter summary

This chapter presents the rationale for this PhD research, which is the need

for the development of an intervention to reduce inequality in cervical screening uptake for women living with SMI. The research paradigm and the overarching framework for the research have been presented, with each element of the research briefly outlined. The next chapter outlines Study One, the realist review, in detail.

Chapter Three – Identifying the evidence base: A realist review of interventions to increase access to or uptake of physical health screening in people with SMI

This chapter describes a realist review that was conducted of interventions to increase access to or uptake of physical health screening in people with SMI. A discussion of how the results of the review informed the tool is also provided. This review is in line with step one of the MRC guidance for complex interventions (Development phase), and a paper describing this work has been published in a peer-reviewed journal (Lamontagne-Godwin et al., 2018).

3.1 Background

Several systematic reviews have identified effective interventions for increasing access to, or uptake of, screening for a range of physical health conditions in the general population (Bonfill et al., 2001; Brouwers et al., 2011; Camilloni et al., 2013; Everett et al., 2011; Jepson et al., 2000). One study (Segnan et al., 1998) included in the Camilloni et al. (2013) review explicitly excluded women with SMI. It is unclear whether people with SMI were excluded from the other studies and, as they are general population samples, the expected proportion of people with SMI would be very low; in England, 1–2% of the population will, at some point in their lives, receive a bipolar disorder diagnosis and 0.72% a diagnosis of schizophrenia (Pini et al., 2005; Saha et al., 2005). There is a lack of knowledge about whether the interventions are effective for people with SMI specifically. To address this

gap in the literature, a realist review of studies was conducted to evaluate the effectiveness of interventions developed to increase uptake of or access to physical health screening in people diagnosed with an SMI.

The realist review methodology is a relatively novel method of a systematic review that is used especially in health services research. It provides an explanatory analysis of complex interventions, aiming to discern what works, under what circumstances, for whom, in what respects and how (Pawson et al., 2005). It involves identifying underlying causal mechanisms and understanding how interventions work (or not) and under what conditions (Rycroft-Malone et al., 2012).

As mentioned in the previous chapter (section 2.5), the *Development phase* of the MRC guidance for the development of complex interventions involves identifying the existing evidence and what is already known about similar interventions and the methods that have been used to evaluate them (Craig et al., 2013). If no recent, high-quality systematic review of the relevant evidence has been undertaken, the MRC guidance recommends that one should be conducted (Craig et al., 2013). This provides the rationale for conducting this realist review.

Recent research has described and exemplified how social scientists can integrate realist principles across each phase of the MRC guidance (Fletcher et al., 2016). Intervention development and modelling, as well as feasibility and pilot studies that represent the different phases of the MRC guidance (Chapter Two, Figure 2.1) need to take into consideration which contexts are

necessary for intervention mechanisms to be activated. In cases where interventions are scaled up into routine practice (the *Implementation phase* of the MRC guidance), realist principles can facilitate knowledge about longer-term sustainability, as well as benefits and harms (Fletcher et al., 2016). The realist review methodology was selected over a standard systematic review in this research, to find out not only whether screening interventions for people with SMI produce the desired outcomes, but also to discern the contexts in which they are more likely to be successful.

Guidance on quality assurance and uniform reporting of the results is a key phase for any type of primary research that moves towards improving the quality and consistency of studies (Wong et al., 2014). Although there is a growing acknowledgement of the value of qualitative and mixed-method approaches to a systematic review as an alternative to quantitative reviews, the quality of such reviews can be hard to assess. The RAMESES project (Realist And Meta-narrative Evidence Syntheses: Evolving Standards) has produced methodological guidance, publication standards, and training resources for those choosing to use the realist approach to a systematic review (Wong et al., 2016). This realist review is described in accordance with RAMESES and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Appendix 1 contains the completed PRISMA checklist, which confirms how this review was completed according to best-practice guidance.

The review question was ‘what works, for whom and why to increase the uptake of or access to physical health screening programmes by people living with SMI’? The objectives were threefold: to identify and evaluate interventions to increase uptake of or access to physical health screening programmes by adults with SMI; to examine the use of behaviour change models within the identified interventions; and to identify the factors that predict screening attendance and attrition.

3.2 Methods

3.2.1 Study selection

The inclusion criteria used in this review were as follows:

- Intervention studies of any design
- Studies of any intervention to promote access to, or uptake of, screening for or monitoring of any physical health condition
- Participants were aged 18 years and over
- No date restriction was applied in the search
- Participants had a diagnosis of SMI (psychosis or bipolar disorder however diagnosed)
- For studies where some of the participants had mental health disorders other than SMI, a minimum of 50% of participants needed to have either a diagnosis of psychosis or bipolar disorder
- The full text was published in a peer-reviewed journal
- The study was reported in English

The exclusion criteria included:

- Intervention studies aiming to improve the physical health in people with SMI, which may involve screening, but where uptake or access to screening was not a primary outcome
- Service evaluations or audits which considered screening but did not test any intervention
- Studies where the mental illness diagnoses were not specified

3.2.2 Terminology

Any intervention described as promoting either screening or monitoring of physical health was included. The UK National Screening Committee defines screening as a 'public health service in which members of a defined population (…) are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications' (Public Health England, 2013b). 'Monitoring' was defined as per the Cochrane review by Tosh et al. (2014) as a means 'to obtain information which can then be acted on to treat or prevent a physical health problem'. For clarity, the term 'screening' is used throughout the review. Uptake of screening was the review's primary outcome.

3.2.3 Search strategy

The search strategy was informed by published, related systematic reviews (Barley et al., 2016; Holland et al., 2013; Holt and Mitchell, 2015) and was checked by a specialist health librarian at the University of West London. Searching was conducted in December 2016. An example of a full electronic

search strategy for one database (MEDLINE) is contained in Appendix 2. The review protocol is registered on the international prospective register of systematic reviews (PROSPERO Registration number: CRD42016047848).

3.2.4 Data sources

Medline, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsychINFO, Cochrane Database of Systematic Reviews and Database of Abstracts of Reviews of Effectiveness were searched independently of each other. Reference chaining of identified studies was also conducted. This is a research method that involves looking at the references or works cited in key publications on a particular topic, tracing a particular topic both forward and backward in time.

3.2.5 Selection of studies

Titles and abstracts were screened independently by two reviewers [a health psychologist and a chartered psychologist with expertise in health psychology]. Full texts were retrieved and screened by three reviewers [the candidate, a health psychologist and a chartered psychologist with expertise in health psychology]. Among the 33 full texts selected was a recent systematic review of studies of ‘Strategies to implement physical health monitoring in people affected by severe mental illness’ (Ferrara et al., 2015), which included 14 studies. Although the focus of the Ferrara et al. (2015) review was slightly different from the current one, it contained one study that was also included in this review (Hardy and Gray, 2012). It also included two studies that were excluded: one was not an intervention study (Hardy et al.,

2012) and the other tested the validity of a health-monitoring tool (Bressington et al. 2014).

It was decided by the reviewing team that health-monitoring (in addition to health-screening) tools were also relevant to the review question. The rationale for this was that although such studies aimed to improve the quality of screening (e.g. more health indicators measured) and ongoing monitoring, this often resulted in increased uptake. Identified studies and those included in the Ferrara et al. (2015) review were re-screened by two reviewers [a health psychologist and a chartered psychologist with expertise in health psychology] to select the final set of studies for inclusion.

3.2.6 Study quality assessment

The quality of randomised controlled trials (RCT) (Druss et al., 2010; Osborn et al., 2010) was assessed using the Cochrane tool, the only evidence-based tool for measuring the risk of bias of RCT (Higgins et al., 2011). It covers seven principles, including a recommendation not to use quality scales, that the focus should be on internal validity and that it is necessary to report outcome-specific evaluations of risk of bias (Higgins et al., 2011). No similar 'gold standard' tool exists that could be used across the other study designs, so each of the non-RCT studies was assessed using a simple checklist based on the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) (von Elm et al., 2007) statement and a recent review of tools to assess bias in observational studies (Sanderson et al.,

2007). Each study was rated independently by two reviewers, with discrepancies resolved by discussion.

3.2.7 Data extraction

Each reviewer independently extracted information from up to five articles, with one reviewer [health psychologist] reviewing all studies. Data were extracted regarding study authors, year of publication, geographical location, and setting, participant characteristics, features of the intervention, screening (targeted screening or with multiple parameters; when, how and wherein the care pathway screening was offered; screening health professional(s) and type of service), outcome measures, study design and limitations. Though not an inclusion criterion, patient-related outcomes – such as a significant reduction in cardiovascular disease risk at follow-up – were included when available. They provided important additional information and gave an accurate reflection of the effectiveness of the interventions.

3.2.8 Approach to synthesis

The main task of a realist synthesis is to understand the mechanisms by which an intervention works (or not). The basic focus of the synthesis process is to refine the programme theory, i.e., to determine what works, why, in what circumstances, for whom and in what respects. The aim of a realist synthesis is not to determine ‘best’ practice, but to describe the relationships between interventions and the contexts in which those interventions occur. Similarities and differences in the intervention approach were identified and summarised across studies into separate clusters.

Barriers and enablers to the implementation of each intervention cluster were identified and these were then synthesised by theme. Exploration of how and why different approaches might have worked was undertaken by searching for themes across studies, paying particular attention to disconfirming evidence. As there was considerable between-study variation in outcome measures, a meta-analysis was not possible.

3.3 Results

3.3.1 Search results

The initial electronic search identified 1872 potentially relevant publications; six others were identified through reference chaining. Forty-four studies were identified as being potentially relevant and were screened by two reviewers. Twenty-two of these did not meet the inclusion criteria, and a total of 22 studies were included. The screening and study selection processes are detailed in Figure 3.1.

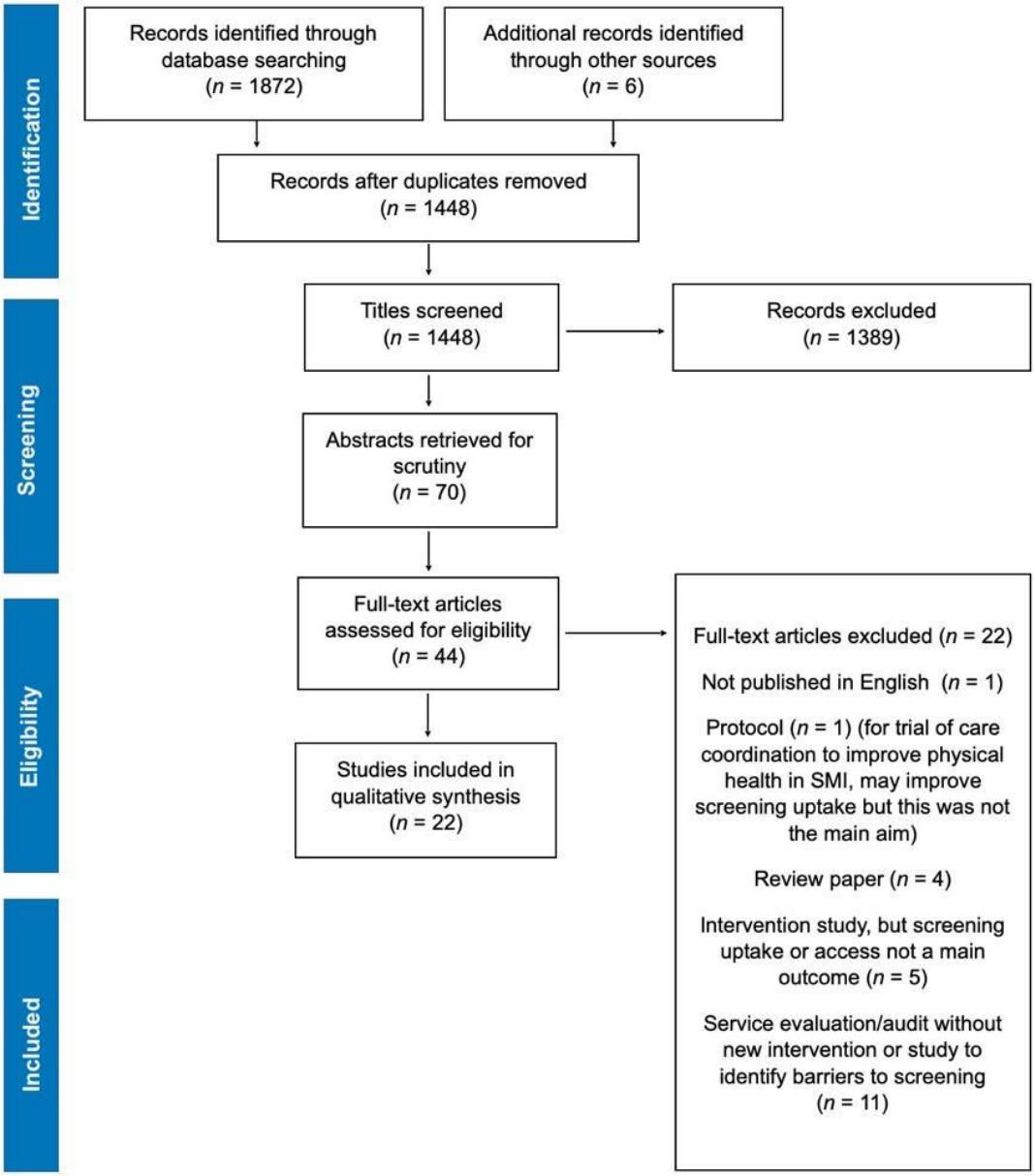


Figure 3.1 PRISMA Flow Diagram (Moher et al., 2009)

3.3.2 Study quality assessment

While there is no universal definition for study ‘quality’, it involves the extent to which the study design, conduct, analysis and presentation are appropriate for answering the research question (Higgins et al., 2011). The aim of the quality assessment is not to exclude any study from the synthesis, but to determine the reliability of the overall body of evidence. A description

of the main study weaknesses is presented in Tables 3.1 and 3.2. The most common ones were small sample size and lack of generalisability.

3.3.3 Study characteristics

A range of study designs was employed (pre-post audit *n* = 9, consecutive prospective case series design *n* = 1, repeat audit *n* = 1, cross-sectional study *n* = 1, quality improvement *n* = 4, retrospective audit *n* = 4, RCT *n* = 1, cluster-randomised feasibility trial *n* = 1). Study characteristics are detailed in Tables 3.1 and 3.2; each study has been given a number in column 1 of the tables. The numbering system was used in this chapter and subsequent chapters to reference the studies for ease of reading. Studies either described the testing of a new tool (e.g. computer programme to support clinicians to monitor and screen physical health indicators) to facilitate screening for health professionals (1-10) (Table 3.1) or complex health services delivery changes (11-22) (e.g. invitation letter from primary care to encourage patients to attend screening as part of their physical health check-up) (Table 3.2). Mental health staff performed 'in-house' screening (1,7,8,16,18,19,21), ordered screening tests (2-4,6,9,15-17,19,20,22) or acted as a broker between the patient and screening service (2,12,14,15).

3.3.4 Study settings

Studies pertaining to health service delivery changes were conducted in multiple settings: community mental health clinics (12,16-17), early intervention in psychosis services (15,19-20), primary care (13,22), a community drop-in centre (14) and a clozapine clinic (21). Two tools to facilitate screening (5,10) and two health service delivery change (11,13)

interventions were delivered in primary care. The remainder took place in inpatient and outpatient mental health services.

3.3.5 Types of conditions screened

Two studies (14,22) considered breast cancer screening and one included infection preventive services (22). Other than one study (14), which was designed to increase rates of mammography uptake, all remaining studies (*n* = 21) considered metabolic syndrome screening by targeting metabolic syndrome-related risk factors: blood pressure (1,2,4,5,7-13,15-20,22), cholesterol/sugar (1-13,15-17,19,20,22) and BMI (1-13,15-20,22). Two studies described national screening programmes (14,22) and 20 studies reported the development of 'in-house' screening pathways (1-13,15-20). Interventions focused on metabolic/cardiovascular screening for all studies. One study monitored the uptake of both national cancer screening services and metabolic screening (22). The data collection tools (Table 3.2) were designed to gather information required to improve metabolic syndrome screening (2,3,6,9) or physical health screening (1,4,5,7,8,10). Metabolic syndrome screening was evaluated using the following measurements: blood pressure, smoking status, waist circumference, fasting blood glucose, BMI triglycerides and high-density lipoprotein cholesterol. These measures were based on the following clinical guidelines:

1) National Institute for Health and Care Excellence [NICE] (5,7,8,10,11,13,15,16)
2) Maudsley prescribing guidelines (4,8,11,15,20)

3) American Diabetes Association (2,3,4,6,9)
4) U.S. Preventive Services Task Force (12,22)
5) American Psychiatric Association Practice (1,9)
6) National Heart, Lung and Blood Institute (2)
7) de Hert (2009) guidelines (5).
8) Early Psychosis Prevention and Intervention Centre (19)
9) Psychotropic Therapeutic Guidelines (21)

3.3.6 Study participants

All studies targeted adults, though in one study (20) eligible participants were 14–35 years old. Study populations included participants with schizophrenia (1-5,8,9,11,12,14,16-18,22), bipolar disorder (1-3,5,9,12,14,16-18,22), schizoaffective disorder (1-3,5,12,14,16-18), other psychotic disorders (1,4,5,9,17,18,22) and other mental health disorders (2,9,12,14,16,17,18,22). Some studies did not specify the SMI (10,13,19,20) diagnosis, while other studies included patients with SMI who were on antipsychotics (3,6,7,15) with no breakdown by condition.

Table 3.1 Studies on tools to facilitate screening.

Study and allocated number (n)	Country	Population studied	Intervention	Screening	Method(s) applied	Findings	Main study weaknesses
Bressington et al. 2014 (1)	Hong Kong	148 community based psychiatric SU[7]	Training for community psychiatric nurses on how to use the HIP[8] and conduct required physical examinations	HIP contains 27 gender-specific items highlighting indicators of physical health risk in SU Items are divided into four categories: measurements, blood tests, screening and lifestyle indicators. HIP used at baseline and at twelve-month FU[9] during routine clinical practice. Community psychiatric nurses trained to use the HIP in a community mental health clinic	Consecutive prospective case series design Pre-post evaluation	Significant improvement in self-reported exercise & reduced prescription mean WC[10] increased at FU Absence of deterioration in most areas of cardiovascular risk (BMI mean: 25.79 to 25.66, weight mean: 66.76 to 66.49) At FU, prescriptions reduced for diabetes (10.8% to 5.4%) and hypertension (21% to 14%) medication General improvements in health behaviours over the 12-month period: 7% increase in the number of SU eating sufficient fruit and vegetables, but only exercise improved to a statistically significant level (p = 0.02)	No randomisation, no control group Selection bias Possible measurement error

[7] Service user (patient with SMI) = SU
[8] Health Improvement Profile = HIP
[9] Follow-up = FU
[10] Waist circumference = WC

Castillo et al. 2015 (2)	United States	141 community-based assertive outreach SU	Systematic screening protocol for MS[11] and educational sessions for staff and SU	MS screening (WC, BP[12], fasting blood glucose, triglycerides and high-density lipoprotein cholesterol) Blood tests ordered for metabolic monitoring when clinicians prescribed scheduled second-generation antipsychotics to their inpatients During routine clinical practice, WC and BP measured using standard size adult BP cuff available at each site. Measurements typically conducted in patients' homes by nurses and psychiatrists working in three Assertive Community Treatment teams	QI[13] project	75 (53%) participants met the criteria for MS Five of these diagnoses came from the use of adapted diagnostic criteria using random glucose measurements Of the 66 participants who did not have MS, only 9 had no metabolic risk factors 34 met 2 criteria and the remaining 23 met 1 criterion for MS	No randomisation, no control group

[11] Metabolic syndrome = MS
[12] Blood pressure = BP
[13] Quality improvement = QI

Delmonte et al. 2012 (3)	United States (Michigan)	SU on second-generation antipsychotics on a general psychiatric inpatient unit – 171 at pre-alert and 157 post-alert. SU receiving second-generation antipsychotics on an as-needed basis only were excluded	Use of computerised electronic patient alerts to enhance metabolic monitoring	Metabolic monitoring (fasting blood glucose and lipid). SU weight, BP, information regarding family history and WC not collected as part of this study Prescribers entering order of second-generation antipsychotics assess the need for metabolic monitoring and facilitate ordering of appropriate blood tests directly via electronic pop-up alert	Retrospective chart review of notes and tests ordered to assess for metabolic syndrome Pre-post study design	Significant difference in the availability of metabolic monitoring data post-intervention: 12.9% to 47.8% in the number of service users with both fasting glucose level & fasting lipid panel	No randomisation, no control group Open to time bias
Gonzalez et al. 2010 (4)	UK	Male and female community-based SU taking regular antipsychotic medication Inner-city London population First audit *n* = 126 Second audit *n* = 106 No significant difference in demographic details of both samples	Local adaptation of clinical guidelines Implementation of monitoring tool: A4 page filed in the patients' records, both as a prompt to doctors regarding their patients' need for the physical monitoring and as an instrument to facilitate later data collection	Blood tests for SU taking first-generation antipsychotics (full blood count, urea and electrolytes, liver function test, thyroid function test, glycosylated haemoglobin, prolactin, glucose and lipids) Routine blood testing ordered by psychiatrists every six months for SU on first-generation antipsychotics	A retrospective audit of patients' clinical records for physical health monitoring Systematic randomisation by selecting every 4th file in alphabetical order until 25% of caseload was selected	Post-intervention: significant improvement in all tests (glucose: 24.6% to 72.6%, lipids: 7.1% to 52.8%, liver function: 38.9% to 79.2%) except HbA1c (3.2 to 5.7%) and Prolactin (0.8% to 0) Implementation of the monitoring tool achieved in 48% of the re-audit sample	No randomisation, no control group Did not include other measure for detection of MS and did not include electrocardiogram Limited time between audits to allow embedding of the intervention Other factors may have resulted in improvements seen due to increased awareness within the service due to local policy and national guidelines or other potential factors

Hardy et al. 2014 (5)	UK	400 community-based SU	Two-hour training for practice nurses to increase level of screening for cardiovascular disease risk factors with lifestyle counselling (health check includes seven elements)	Screening for cardiovascular disease risk factors (BMI or WC, blood glucose, serum cholesterol, diet advice, BP, exercise recommendations and smoking cessation guidance) carried out by practice nurses as part of their routine clinical role	Repeat audit to monitor how well primary care practitioners are screening SU for cardiovascular disease following training	Training practice nurses on cardiovascular disease prevention increased number of SU receiving wide-ranging health check Pre-training: *n* = 33, 8% Post-training: *n* = 60, 15%, *p* = .01 Increase in number of service users receiving lifestyle interventions	No randomisation, no control group Unclear why other 26 primary care centres did not participate Did not look at any other factor (e.g. other training, professional development, targets by the organisation) which could have influenced staff Possible Hawthorne effect and no exploration of whether increased screening improves patient outcomes
Kioko et al. 2016 (6)	United States	100 notes of community mental health SU aged 19 years and above on second-generation antipsychotics	Recommended MS monitoring and screening tool to improve identification of patients at risk of metabolic syndrome	MS screening (BP, weight, height, lipid panel, fasting glucose and/or glycated haemoglobin parameters) during routine consultation at clinic with SU on second generation antipsychotics Blood tests ordered and vital signs obtained and results recorded in the patient electronic health system. Screening undertaken by mental health clinicians in a local community mental health clinic	Pre-post intervention design to evaluate the effectiveness of using a recommended MS monitoring and screening tool to improve identification of metabolic syndrome risk for SU	Percentage of blood tests ordered were 62% post-intervention compared to 22% pre-intervention	No randomisation, no control group Difficulty obtaining WC – parameter frequently omitted Lack of agreement over who is responsible for ordering blood tests and following-up results Small sample size – difficult to generalise results

Shuel et al. 2010 (7)	UK	31 community-based SU 9 Mental Health Nurses 4 Psychiatrists 12 GPs	Paper sheet screening instrument	HIP filled out during consultation with SU on antipsychotics who were invited to attend outpatient medication management clinic at the hospital Mental health nurses were trained to use the HIP in a nurse-led outpatient medication management clinic	Retrospective audit of patient and clinician views using semi-structured interviews	Thirty-one patients participated in audit Mean number of parameters per patient requiring intervention was 6.1 and a total of 189 physical health issues were identified At least one physical health issue was identified per patient High prevalence of obesity, poor diet (41% of patients) and lack of exercise 14 referrals for potentially serious conditions including raised glucose and lipids, hypertension and cardiac problems	No randomisation, no control group
Vasudev et al. 2012 (8)	UK	15 male inpatients on a medium secure forensic psychiatric rehab unit diagnosed with SMI and on antipsychotics	Introduction of a physical health monitoring sheet by the Trust to prompt staff to do the checks	Six-monthly physical health monitoring (weight, BMI, WC, BP, results of blood tests and electrocardiogram, diabetic status if suffering from cardiovascular disease, smoking status, calculated cardiovascular risk over the next ten years, and use of alcohol in units per week) of all SU in a male medium secure forensic psychiatric rehabilitation unit Nurse took responsibility for completing the section on weight, BMI, WC, BP and smoking status while the rest	Pre-post audit of physical health monitoring (12 months apart)	At re-audit 100% of service users had up to date records on the physical health monitoring sheet At FU increased number of service users prescribed hypolipidaemic agents Significant reduction in cardiovascular disease risk at FU	No randomisation, no control group Small male-only sample Type of ward and environment could influence patient engagement and motivation

				of the information was completed by the junior doctor			
Wiechers et al. 2012 (9)	United States	206 adult SU of a psychiatric resident outpatient clinic who were prescribed any antipsychotics	Metabolic Screening Bundle template Three one-hour education sessions conducted to review antipsychotic medication-associated metabolic abnormalities	Documentation in the last 12 months of any individual element of the Metabolic Screening Bundle (BP, BMI, glucose and lipid panel) for patients on antipsychotic medication Screening performed by psychiatry residents in an academic medical centre outpatient psychiatry clinic	Audits of the Electronic Medical Record completed at baseline and each quarter for the following year QI intervention	Rates component parts of the Metabolic Screening Bundle in the preceding 12 months increased from baseline audit through the Quarter 4 audit: BMI 5% to 44%; BP 4% to 39%; Fasting glucose 15% to 55%; Fasting lipid panel 14% to 55%	No randomisation, no control group Chart audit unable to capture undocumented results/results documented other than psychiatry notes that may have been reviewed by the resident but not remarked on in the progress-note Unclear whether gains made with intervention and cohort of residents can be sustained without a dedicated group of residents championing change
Yeomans et al. 2014 (10)	UK	335 SU on the primary care SMI register	GP practices received 30-minute staff training on how to use a computerised physical screening template designed for annual health checks	Annual physical health review (systolic BP, BMI, high-density lipoprotein: cholesterol ratio, smoking status) performed in primary care during annual check-up by GPs	Retrospective evaluation of computerised template designed for annual physical health check	23% SU with a computerised template review had data rich QRisk2 compared QRisk2 scores above 20% seen in 3.9% of template-based reviews Use of template increased detection risk for cardiovascular disease	No randomisation, no control group Method dependent on accurate record keeping and clinician behaviour No record of unrecorded activity taking place which would contribute to annual patient review

							GPs selected patients for review: possible bias acknowledged but considered unlikely Quality and Outcomes Framework incentive for annual health checks removed and replaced by CQUIN[14]

[14] Commissioning for Quality and Innovation = CQUIN

Table 3.2 Studies describing health service delivery changes.

Study and allocated number (n)	Country	Population studied	Intervention	Screening	Method(s) applied	Results	Main study weaknesses
Abdallah et al. 2016 (11)	UK	95 SU with schizophrenia living in care homes	Patient education and education of care home staff	Physical health monitoring (blood workup, liver function test, urea and electrolytes, full blood count, fasting blood glucose, blood lipid, glycated haemoglobin (HbA1c),[15] prolactin, BP/pulse/weight measurement, BMI, WC) offered during Care Programme Approach review (held every six months to one year) Screening done by GPs	QI - PDSA[16] cycle	Improvement in culture within care home where staff and SU actively participated in physical health monitoring BP and weight measured in 68% of patients compared to 10% and 0 at baseline 55% of SU had pulse measured compared to 0 at baseline 68% had bloods done compared to 0 at baseline	No randomisation, no control group Small sample, difficult to determine results as in later PDSA cycles the interventions did not target only the patient group included in the results
Druss et al. 2010 (12)	United States	407 SU under care of community teams	SU at an urban community mental health centre randomly assigned to either the medical care management intervention or usual care Intervention group: care managers provided communication	23 screening indicators from the U.S. Preventive Services Task Force guidelines included across four domains: 1) physical examination (BP, eye, height/weight, oral, breast, mammogram and pelvic) 2) screening tests (cholesterol, faecal blood, HIV, sigmoid and tuberculosis) 3) vaccinations (influenza, hepatitis B, measles, mumps,	RCT	12-month FU evaluation: intervention group received average 58.7% of recommended preventive services compared with 21.8% in usual care Significantly higher proportion of evidence-based services for cardio-metabolic conditions (34.9% versus 27.7%)	Low risk of bias (Performance bias as control group – treatment as usual – not blinded) Broad entry criteria limited the statistical power to examine outcomes for individual medical conditions Study was conducted in a single site so

[15] Average blood glucose (sugar) levels for the last two to three months
[16] PDSA = Plan, Do, Study, Act

			and advocacy with medical providers, health education and support in overcoming system-level fragmentation and barriers to primary medical care	and rubella, pneumococcal bacterial infection, tetanus-diphtheria and varicella) 4) education (exercise, self-examination, smoking, nutrition and weight) Care managers (registered nurses) supported SU to get screened by providing communication and advocacy with medical providers, health education and support in overcoming system-level fragmentation and barriers to primary medical care		Higher likelihood to have primary care provider (71.2% versus 51.9%) Intervention group showed significant improvement on SF-36 mental component summary (8.0% [versus a 1.1% decline in the usual care group]) Scores on Framingham Cardiovascular Risk Index significantly better in intervention group (6.9%) than usual care group (9.8%)	replication would be needed to fully assess generalisability to different types of community mental health settings
Hardy and Gray 2012 (13)	UK	92 community SU 338 patients with diabetes	Retrospective comparison of response rate of SU and diabetes patients to an invitation appointment letter to attend a primary care health check Patients with SMI sent an appointment at a predetermined time and date. Annual health check for SU followed the HIP guidance	SU were sent an appointment letter 10 days before the appointment inviting them to attend a primary care health check (HIP) with a predetermined date and time. Screening carried out by the practice nurse	Retrospective audit	66% service users with SMI attended appointment 81% service users with diabetes attended appointment Service users with diabetes 2.2 more likely to attend health check	No randomisation, no control group Unclear if sample reflects whole population of SMI (or diabetes)

Heyding et al. 2005 (14)	Canada	Disadvantaged women aged 50–70 who attended inner-city drop-in centre (*n* = 158 in 1995–2001 and *n* = 89 in 2002)	Drop-in centre and nearby hospital in Toronto initiated collaborative breast cancer screening project in which staff of drop-in centre accompanied small groups of women for mammography visits at weekly pre-arranged time	A staff member of the drop-in centre accompanied small groups of women aged 50–70 for mammography visits at a pre-arranged time. A family physician working at the drop-in centre served as the referring physician requesting the mammogram	Pre-post audit comparison between screening before and after intervention year	Increase from average of 4.7% women receiving a mammography to 29.2%	No randomisation, no control group Observational rather than experimental design Limited control over extraneous variables Audited documentation may have been inaccurate or incomplete
Latoo et al. 2015 (15)	UK	52–55 SU receiving antipsychotics in Early intervention in Psychosis service	Advancing Quality Alliance design to examine six physical health parameters: weight, height, BMI, BP, blood glucose and serum lipids	Comprehensive physical assessment (serum lipid profile, blood glucose, body weight, height, BMI and BP) Other information was collected such as smoking, diet, exercise, sexual health, sleep, dental and optical health, electrocardiograms and other routine blood checks. Notification list alerted on the computer when screening was due Screening took place in primary care and physical health clinics Access to blood tests was established to help facilitate prompt access to blood results	Retrospective review of clinical records following improvement in physical health monitoring	Screening and monitoring of six parameters: At 4 weeks 29 patients recorded screening, 19 (66%) of which had six types of screening At 24 months, out of 16 patients who had their screening recorded, 15 (95%) had 6 types of screening	No control group No randomised design to test new screening and assessment method
Millar 2010 (16)	UK	152 community-based SU	Dundee Health Screening Clinic developed to address needs of	MS audit of 152 community-based SU to quantify their physical health problems. Database set up to record	Mixed Methods: pilot study, audit and satisfaction survey	Heavy burden of physical health problems identified in Phase One (66%	No randomisation, no control group Generalisability may be limited due

		100 inpatient and community SU all prescribed antipsychotic medication	this population by monitoring physical health and providing FU to ensure that patients received necessary care	measurements completed within the clinic Results collected and appropriate FU was organised through primary care or specialist services Health Screening Clinic included three main types of clinical investigations: 1) physical examination, electrocardiogram, and blood screening 2) rating scales with medical/ drug histories and 3) diet and lifestyle advice Nursing staff were trained in bloodletting, measuring BP and WC and completing electrocardiograms		obesity, 60% elevated cholesterol, 32% hypertension) Of the first 100 patients audited: 33% had metabolic syndrome 99% agreed health screening important 65% reported lifestyle change	to differences in availability of resources in different areas, though no additional resources were used to develop the intervention
Osborn et al. 2010 (17)	UK	121 SU under the care of a community mental health team	Nurse-led screening programme and education pack regarding appropriate screening for cardiovascular disease-related risk factors	Cardiovascular disease screening (including smoking, BP, random blood glucose and lipids) Intervention established system to monitor whether cardiovascular disease screening had occurred for community-based SU and sent prompts to primary and secondary care staff if screening had not occurred The nurse offered screening to cover SU who still had not received the complete battery of cardiovascular disease screening Within intervention arm, approximately half the screening was performed in	Cluster Randomised Feasibility trial	After the trial cardiovascular disease screening increased in both arms but participants from intervention arm were significantly more likely to have received screening for BP (96% vs 68%), cholesterol (66.7% vs 26.9%), glucose (66.7% vs 36.5%), BMI (92.5% vs 65.2%), smoking status (88.2% vs 57.8%) and have 10-year cardiovascular disease risk score calculated (38.2% vs 10.9%)	Low risk of bias Response rate in the recruitment for outcome data was main limitation Recruitment was time-limited because of funding Participants who provided outcome data may have been a biased sample of community mental health team patients; therefore, generalisation of results is difficult

				general practice and half by the trial registered general nurse with previous experience of providing cardiovascular screening			
Rosenbaum et al. 2014 (18)	Australia	60 SU on inpatient psychiatric ward in Sydney 25 mental health nurses	Educational training including WC measurement Change in assessment-form design	Over a nine-month period, file-based reminder for nurse-assessed WC measurement of mental health inpatients within a private psychiatric facility Screening performed by mental health nurses	Pre-post audit of the frequency of WC Documentation before/after intervention	Improved measurement by nurses of WC from 0–58% WC was higher in these patients than general population 19% had BMI within a healthy range, 37% smoked, 31% were hypertensive	No randomisation, no control group Not all staff were able to receive intervention
Thompson et al. 2011 (19)	Australia	118 files of SU on antipsychotics under the care of Early Psychosis and Prevention Centre service in Melbourne	Educational intervention for staff Development of local guidelines, provision of monitoring equipment, prompts in patients' records and regular reviews	Weight and metabolic monitoring (height and weight to estimate BMI, systolic and diastolic BP, WC and hip circumference (to obtain waist-hip ratio), fasting blood glucose, full fasting blood lipid profile (including total cholesterol, low- and high-density lipoprotein and triglycerides), number of cigarettes smoked daily and level of daily exercise Equipment required to undertake monitoring (e.g. scales, tape measures, BP cuffs) located in each psychiatrists' room Stamps indicating necessary blood tests for monitoring placed in psychiatrists' rooms to aid ordering and completion of the correct blood investigations	Pre-post audit of completion of metabolic screens	Improvements in screening and monitoring of four metabolic indices at the post-intervention time point Individual rates were higher for screening (74.4% to 84.9%) than monitoring outcomes (24.4% to 41.6%) Rates ranged between 17.4% for blood lipids and 34.9% for obesity measures	No randomisation, no control group Naturalistic setting

				Metabolic screening within six months of being prescribed an antipsychotic and metabolic monitoring one-six months following initiation of antipsychotic medication Regular review of an SU's metabolic status was built into the clinical review process which occurs on a three-month basis for all SU			
Vasudev and Martindale 2010 (20)	UK	66–72 SU aged 14 to 35 under care of Early Intervention service for more than a month	In-house training for members of the Early Intervention Service Interventions between audit – in-house training, physical health mandatory component on care plan review, joint responsibility for communicating with GP, referral information updated to include physical health, liaison with wider multi-disciplinary teams	Annual physical health check (weight, BP, blood sugar, lipids, electrocardiogram (only done if patient at high risk due to young patient age), full blood count, urea and serum electrolytes, liver function tests and prolactin) Mental health clinicians address physical health with SU during clinical practice and letters] sent annually to GPs to remind them to conduct the physical health checks (study audited this process) Screening took place in primary care	Pre-post audit	Number of SU having at least one annual physical health check increased from 20% to 58% Patients who had undergone physical health check at re-audit, a record of some/all of the checks was available in the notes for 75% of patients	No randomisation, no control group Focuses on Early Intervention so many people do not have a formal diagnosis of SMI e.g. schizophrenia Only 7 months between audits; therefore, a very short time to measure long-term impact
Wilson et al. 2014 (21)	Australia	107 to 232 SU attending clozapine clinic	Six education sessions covering test interpretation, MS, diabetes management,	Metabolic monitoring (including fasting blood glucose, lipids, BMI, girth) occurs in May and November	QI Mixed Methods	Completion rates of metabolic monitoring: 69.2% at first month and 65.1% at second month	No randomisation, no control group Limited possibility of generalisation due to single site

			obesity, smoking cessation and lifestyle interventions 'Let's Get Physical' initiative – designation of two months annually as physical health months during which time revised service protocol required metabolic monitoring for all eligible patients Service protocols were revised to require metabolic monitoring of all eligible patients during 'physical health months'	(designed as 'physical health months') In the months preceding May and November, investigation order forms were attached to charts for provision by administrators, written information about investigations was provided to SU during consultations, and necessary equipment was placed in consulting rooms In May and November, a proforma for recording test results and lifestyle assessments (smoking, exercise, alcohol intake) were attached to charts, and clinic appointments were extended from 20 to 30 minutes		Limited evidence of actions post-results	and very specific population
Xiong et al. 2008 (22)	United States	Patients were receiving outpatient mental health treatment at four mental health clinics in California	Comparison of preventive services used in an integrated behavioural health primary care clinic with two existing community mental health programmes	Cancer services included the following tests/procedures: mammogram, cervical screening, prostate specific antigen test, digital rectal exam, faecal occult blood test and flexible sigmoidoscopy or colonoscopy Metabolic profile included BP, height and weight, cholesterol and blood sugar for diabetes Infection preventive services included influenza	Cross-sectional study comparing use of preventive services 350 surveys	Patients on antipsychotic medication less likely to use preventive non-cancer services than their comparison group Integrated Behavioural Health Primary Care unit associated with higher overall service utilisation than a community mental health team	No randomisation, no control group Unable to adjust for confounding factors such as severity of illness

				immunisation, Hepatitis C Virus and HIV tests Psychiatrists made referrals to primary care doctors for screening in routine clinical practice Screening was undertaken by various clinical staff and took place in primary care			

3.3.7 Intervention type

Based on the type of intervention tested, three clusters of interventions to facilitate screening were identified: screening template, staff education and training and computer/paper prompt for staff. Five clusters of interventions for health service delivery changes were also identified, namely: staff education and training, invitation letter to physical health screening, improving access to monitoring resources, integrating care across health settings and staff accompaniment to appointments. Most interventions were multi-faceted, so they appeared in more than one cluster. Barriers and enablers to the successful implementation of the interventions were identified; these are presented in the tables below (Tables 3.3–3.5). Identified barriers to the successful implementation of interventions to facilitate screening can be clustered into categories of resource constraints, environmental barriers, unclear boundaries around the professional role and a perceived lack of professional skills and training.

Authors of several studies (2-4,8-10) noted a number of logistical and resource constraints to the successful collection of measurements that were related to limited staff time (2,5,6,9) and difficulty accessing monitoring equipment (such as specific waist circumference tool for obese patients and access to blood pressure monitors in community mental health clinics). Staff also reported difficulties capturing monitoring results onto the tool (1,6,9,10) (e.g. complicated guidelines to follow). Other barriers included transportation, cultural and language barriers to access phlebotomy clinics, arranging an appointment and patient resistance to exploring sensitive topics, such as

sexual health. Some of these barriers are also reported in the literature review of barriers to the uptake of and/or access to cancer screening specifically (section 5.1). An example of a specific barrier that overlaps screening for any physical condition and screening for cancer is feeling stigmatised by health professionals.

Identified enablers to the successful implementation of interventions to facilitate screening relate to staff feeling invested and having a sense of ‘responsibility’ in physical health monitoring (2,7,8,10), as well as staff flexibility around taking measures by using alternative (e.g. less invasive) equipment and tests (2,10). From an organisational perspective, having a clinical psychiatric pharmacist on the ward (3,8) to support mental health professionals (e.g. by providing the relevant guidelines and precautions to follow when lipid-lowering drugs are prescribed) was also an enabler.

Table 3.3 Barriers and enablers to using data collection tools (by cluster).

Cluster 1: Screening template[1,2,4,6,7-10]		**Cluster 2: Staff education and training**[1,2,5,9,10]		**Cluster 3: Computer or paper prompt for staff**[3,4,8,10]	
Evaluation of the effectiveness of using a tool to increase screening uptake and raise staff awareness of physical health screening		Staff training as a component of the intervention[17]		Testing of a computer- or paper-based prompts to support clinicians to monitor and screen physical health indicators	
Barriers	**Enablers**	**Barriers**	**Enablers**	**Barriers**	**Enablers**
Difficulty entering monitoring results onto the tool[1,6,9,10]	Staff flexibility by using alternative equipment and tests[2,10]	Workload issues[2,5,9]	'Booster' education and team meetings[2]	Technical constraints in terms of collecting measurement results[3,10]	Having a clinical psychiatric pharmacist on the ward to remind clinicians to request investigations such as blood tests when appropriate and to provide the relevant guidelines and precautions when initiating hypolipidemic (lipid-lowering) medication[3,8]
'Social desirability bias'[1,7] (patients self-report their health behaviour in an overly positive picture in an effort to please their keyworkers)	Investment of staff in physical health monitoring[2,7,8,10]	Lack of objective verification that waist circumference measurements taken by health professionals adhered to the intervention protocol[1]	Investment of staff in physical health monitoring[2,10]	Limited access to equipment and resources[4,8]	
Low uptake of data collection on sensitive topics[7]		Lack of training in mean waist circumference measurement[1]		Low uptake of test measurements e.g. waist circumference[8] and fasting blood glucose[3,8]	
Staff reluctant to see metabolic syndrome screening as their responsibility[2,4,6]				Lack of expertise from mental health professionals to interpret physical health results[4,8]	

Difficulty in obtaining equipment[8,9] and accessing laboratory services[2]				Unclear communication channel between primary and secondary care[4,8]	
Lack of integration with primary care for treatment or referral[2,8,9]				Low uptake of test measurements e.g. waist circumference[8] and fasting blood glucose[3,8]	
Inability to attend appointment[2,6] leading to data missing in the template (e.g. missing data on waist circumference[2] and fasting blood glucose[2,6])					
Lack of expertise in mental health professionals to interpret physical health results[4,8]					
Workload issues[2,6,9]					
Refusal by some patients to undergo physical measurements (e.g. waist circumference and blood tests)[8]					
Reluctance by some staff to have physical contact with patients[9]					

[17] No author described the content or format of education interventions in detail.

Barriers to the successful implementation of health service delivery changes are clustered into three areas: environmental barriers, unclear boundaries around the professional role and patient resistance. Environmental barriers include resource constraints (3,12,15), lack of coordination across the primary and secondary care interface (15,17,19,22) and difficulty for patients and staff to obtain a screening appointment (2,14). In relation to staff, authors note staff turnover (18,19), resistance to change (2,11,17,18), lack of time (2,3,11), limited clarity over who is responsible for screening (15,21), and not perceiving physical health screening as a priority (15,18). In relation to patients, areas of concern were reluctance to engage with screening due to lack of motivation/scepticism in the screening process (15,18), inability to attend appointments (2,14,20) and particular resistance to invasive tests (18,20).

Staff enablers include having team ‘champions’ or a key worker to encourage screening, staff who feel invested with regard to physical health screening (2,3,11,14,15,20) and established trust between patients and staff (2,12,14). Organisational enablers include stakeholder involvement (11,14,16,20) and having strong links to primary care and specialist services (2,14,17,20-22), including at-home phlebotomy services.

Table 3.4 Barriers and enablers to using interventions for health service delivery change (clusters 1–2)

Cluster 1: Staff education and training[11,17-21]: Patient and staff (working in primary and secondary care) education		**Cluster 2: Staff accompaniment to appointments**[2,11,12,14]: Accompaniment of service users to appointments as part of each intervention to address potential difficulties in locating and visiting unfamiliar places	
Barriers	**Enablers**	**Barriers**	**Enablers**
Staff time constraints[11,21]	Team's ownership of training[11,20]	Staff workload issues[2,11]	Staff feeling invested/having a sense of ownership regarding physical health screening[2,11,14]
Poor communication across primary and secondary care clinical teams[17,19]	Team 'champions' to encourage screening[11,20]	Difficulty engaging staff[2,11]	Having access to primary care/in-home phlebotomy services[2,12,14]
Lack of clarity over scope of practice[21]	High visibility/structure around monitoring and better liaison with primary care[20,21]	Patient reluctance to undergo screening[2,14]	Trust between patients and staff[2,14]
Patient resistance to invasive tests[18,20]		Difficulty obtaining an appointment/appointment non-adherence[2,14]	
Staff resistance to change[11,17,18]			
Staff turnover[18,19]			

Table 3.5 Barriers and enablers to using interventions for health service delivery change (clusters 3-5)

Cluster 3: Invitation letter to physical health screening[11,13,20]: Using an invitation letter from primary care to encourage patients to attend screening as part of a physical health check-up		**Cluster 4: Improving access to monitoring resources**[15,18,19,21]: Testing interventions developed to improve the collection of physical health data to increase screening		**Cluster 5: Integrating care across health settings**[11,12,14,16,17,20,22]: Evaluation and reduction of the fragmentation of care between different care providers. New clinics to improve physical healthcare were set up and evaluated[14,16,22], two trials[12,17] evaluated nurse-led care management and two studies audited improvement in awareness[20] and communication[11] within the multidisciplinary care coordination team	
Barriers	**Enablers**	**Barriers**	**Enablers**	**Barriers**	**Enablers**
Patient resistance to invasive tests[20]	Team's ownership of screening[11,20]	Patient resistance and lack of motivation in the screening process[15,18]	High visibility and structure around monitoring[21]	Lack of coordination across the primary and secondary care interface[17,22]	Team's investment in screening procedure and stakeholder involvement[11,14,16,20]
Staff resistance to change[11]	Team 'champions' to encourage screening[11,20]	Patient resistance and lack of motivation in the screening process[15,18]	Having a key worker system with key workers' duties involving screening[15]	Patient reluctance to attend appointment/undergo screening[14,20]	Psychosocial support and trust between patients and staff to help them obtain screening[12,14]
	Getting stakeholders involved[11,20]	Inadequate links with primary care[15,19]		Staff resistance to change[11,17]	Availability of primary and specialist care[14,17,20,22]
	Living in a suburban (rather than urban) area[13]				
		No clarity about who takes responsibility for screening[15,21]		Lack of a prescribing provider[12]	
		Staff turnover[18,19]			
		Staff not perceiving physical health screening as a priority[15,18]			
		Time and resource (screening equipment) constraints[15,21]			
		Poor recording and knowledge of screening guidelines and tests[15,21]			

3.3.8 Outcome measures

In this review, interventions to increase *uptake* of screening (or change patient behaviour with respect to uptake of screening) are defined as interventions that support health professionals with screening for physical health conditions (1-12,17-21). Interventions to increase *access* to screening are defined as interventions that are targeted at health professionals or health service delivery which facilitate the availability of screening (13-14,16,22).

3.3.9 Intervention effects

All studies reported sub-optimal screening and monitoring at baseline, with improved levels of screening and monitoring post-intervention (Tables 3.1–3.2). This appeared to be independent of screening type or study design. However, limited evidence of actions occurring as a result of these improvements was reported. As most studies were rated as being of low or moderate quality, it was difficult to assess whether findings of improvements in rates of screening are valid. The effect size was not reported for any study, so it is difficult to determine the impact of the interventions.

3.4 Discussion

3.4.1 Summary of findings

The review sought to explore what works, in what setting, for whom and why to increase the uptake of or access to physical health screening interventions by adults with SMI. However, this overall objective was not achieved since no studies tested every parameter. Several potentially useful intervention approaches were identified, however, such as staff accompanying service users to appointments or having a ‘team champion’ or key worker to encourage screening. In addition, the review identified specific barriers and enablers to screening uptake or access in people with SMI. These findings could be used to target components of future screening interventions, as each intervention may target different aspects of screening and different barriers and enablers may apply.

All but one study considered metabolic monitoring. Cancer screening uptake/access was included in two studies (14,22), while three studies (1,7,13) referred to the health improvement profile, which has a section on cancer screening uptake. No cancer screening intervention was developed in collaboration with service users to ensure that it was acceptable and usable to them, nor was any intervention underpinned by behaviour change theory.

As part of this review, a large international body of work was identified, with diversity in the number of physical health conditions and clinical settings studied. The challenges involved in increasing uptake of physical health

screening and monitoring in people with SMI were not unique to a single country, setting or health service configuration. This review illustrates that people with SMI receive care from a variety of clinicians from different health services and that systems are not always in place to allow different teams to communicate effectively, leading to gaps in patients' care pathway, including treatment and referral post-diagnosis (2,4,8,9).

Flaws relating to the reliability of findings or the generalisability of results were highlighted in all studies (Tables 3.1–3.2); these data suggest that findings concerning the size of effect should be considered with caution because the quality of data has been identified as being generally low. Overall, there is no strong evidence to ascertain whether an intervention to increase uptake of screening would be more effective in primary or secondary care. Two of the key barriers were that mental health staff were reluctant to see metabolic syndrome screening as their responsibility (2,6), leading to resistance to engagement in this activity, and a perceived lack of expertise on the part of mental health professionals to interpret physical health results (4,8). The low uptake (2,3,6,7,8,9) and lack of training to collect waist circumference data in a uniform way was reported, as was unawareness of a potential 'social desirability bias' (1,7), factors that contribute to the risk of unreliable results. Lastly, mechanisms to establish and maintain strong links between primary care/screening clinics and mental health services to ensure that patients attend screening appointments appear to be central to monitoring patients' physical health. One US study[2] illustrates this barrier: the aim of the intervention was to make annual

metabolic syndrome screening a ‘routine responsibility’ for the mental health team; however, it also acknowledged that the team cannot refer patients to primary care for follow-up.

3.4.2 Limitations of the review

There is inconsistency within the published literature around how terms such as ‘screening’ and ‘monitoring’ are used, which makes comparisons across studies difficult. The candidate’s use of these terms may differ to that of others who may use different terms and include different studies. To compensate for this, and in line with the realist review methodology, a broad and inclusive study identification process was used, which was adapted iteratively through the study selection process, as described above (section 3.2.1). The quality of data was identified as being generally low; therefore, it is not possible to determine the size of effect any intervention may have. Given the high level of heterogeneity and the limited quality of evidence included in this review, it is not possible to draw firm conclusions. Nonetheless, this review has highlighted the variety of physical health screening interventions for people with SMI across several countries. A wide range of studies was identified with varied participants, settings, interventions and outcomes. A narrower review may provide answers which are more applicable to specific situations; however, the lack of good-quality evidence identified suggests that this is unlikely to be the case.

3.5 Conclusions

3.5.1 Implications for policy and practice

Improving uptake of and access to screening in people with SMI requires changes both at the system and individual levels. Strategies to improve coordination between primary and secondary care are needed, as are guidelines to clarify professional role boundaries of who holds responsibility for screening. Resource constraints, such as workload issues and lack of monitoring equipment in mental health settings, need to be addressed.

3.5.2 Implications for research

There were no studies that reported a follow-up at any time other than at the immediate post-intervention time point. Therefore, this review is unable to clarify whether screening was maintained post-intervention and whether the increase in uptake is sustainable or if it is a consequence of the Hawthorne effect, whereby health professional behaviour changes as a result of being observed. Longer follow-up is needed after interventions are funded, and published evaluations of routine care are needed after research studies to see whether effects are sustained. The description of interventions in publications is often extremely vague, which limits the implementation and replicability of interventions, and the studies included in this review are no exception. With the aim of improving intervention reporting and ultimately their replicability, the Template for Intervention Description and Replication (TIDieR) checklist and guide was developed by an international expert group (Armstrong et al, 2015). Future studies should report interventions using the 12-item TiDieR checklist (brief name, why, what (materials), what

(procedure), who provided, how, where, when and how much, tailoring, modifications, how well (planned), how well (actual)) (Armstrong et al, 2015; Hoffmann et al, 2014). Future studies should also refer to the MRC guidance (Anderson, 2008), to make explicit how the components of complex interventions may work. The use of behaviour change theory was considered in only one intervention design (19). Some studies acknowledged that it was not considered – which provides no insight into what might have impacted on staff and service user behaviour to increase uptake. Few interventions were designed in collaboration with service users, and the users' preferences were not explored.

Performing 'in-house' screening in mental health services rather than in a primary care context warrants further research, including what training and equipment this would require. Interventions to reduce patient and health professionals' reluctance to screening which are informed by behaviour change theory should be developed and tested. Involving service users in the intervention design and testing would ensure that it is both acceptable and usable to them, for example by identifying their preferences for location, frequency and type of support.

3.5.3 Implications for tool development

Results from this realist review have shown that clinicians' workload, as well as lack of integrated care between primary and secondary settings are significant barriers to implementation. The tool developed for this study will be aimed at the individual – service user – level, rather than as a shared

decision-making tool (though it may be discussed with their health professional and/or relative). This review has highlighted that behaviour change theory should be used in the development phase of any intervention. Chapter Five addresses how the tool is theoretically informed and its testing with service users and mental health clinicians to ensure its acceptability (Chapter Six) and usability (Chapter Seven).

Chapter summary

As discussed in Chapter One, screening attendance requires an individual to make an informed choice. This realist review found no informed-choice tool available that aims to increase uptake of or access to physical health screening, including cancer screening, for people with SMI. The review identified a knowledge gap regarding the evidence on the effectiveness of informed-choice tools for people with SMI, and the methods used for their design. A review that explores the development and effectiveness of informed-choice tools for people with SMI was therefore needed. This (Study Two) is reported in the following chapter.

Chapter Four – Identifying the evidence base: A systematic review of the design and evaluation of informed-choice tools for people with SMI

This chapter reports on a systematic review of the design and evaluation of informed-choice tools for people with SMI, which was conducted to inform the development of the tool. It completes the realist review (Study One) which identified a knowledge gap regarding interventions to increase the uptake of or access to cancer screening among individuals living with an SMI. The principal aim of this systematic review is to determine the optimum design of an informed-choice tool for people with SMI, based on the available evidence. This review is in line with step one of the MRC guidance for complex interventions (Development phase). A modified version of this chapter was published in a peer-reviewed journal (Lamontagne-Godwin et al., 2020).

4.1 Background

In healthcare, there has been a gradual shift from a paternalistic model, whereby the clinician holds the power, towards a model that involves greater patient autonomy and control (Barry and Edgman-Levitan, 2012; Kaba and Sooriakumaran, 2007). In several countries, including Australia, Canada, New Zealand, the US and UK, promoting choice has been regarded as a significant factor for modernising health and social care services and has formed part of governments' delivery plans (Coulter, 2010), such as *Creating a Patient Led NHS* in the UK (Department of Health/NHS, 2005) and the

evolution of *Standard Two – Partnering with Consumers within the National Safety and Quality Health Services Standards* in Australia (Trevena et al., 2017). In mental health services in the UK, this includes providing informed choice of service or treatment and care pathway (Samele et al., 2007). There is a shift towards providing information to the individual in a way that helps them make an informed 'choice', rather than simply obtaining informed 'consent', which is more passive (Coulter et al., 2011; King and Moulton, 2006; Liu et al., 2018; Woolf et al., 2005).

In recent years, there has been increasing emphasis on empowering those offered healthcare to make informed choices (Michie et al., 2004). To make an informed choice, information must be understood and presented in a balanced way so as not to suggest a right or wrong option (Hope, 2002; Jepson et al, 2005). In addition to having the relevant information, clarification of one's personal preferences and values is needed to make a good choice. Uncertainty about which course of action to take when choice among competing options involves risk, regret, loss, or challenge to personal life values is termed 'decisional conflict' (Leblanc et al., 2009). Decisional conflict was defined in Chapter Two (section 2.5) as an individual's uncertainty about which course of action to take when faced with a choice among competing options (Janis and Mann, 1977). It is generated by inadequate knowledge and support, unclear values and the perception that an ineffective decision has been made (LeBlanc et al., 2009).

The need for further research on the use of decision-making tools in populations with lower literacy was identified in a systematic review of decision aids (Stacey et al, 2017). Many individuals with SMI have limited literacy rates (Lincoln et al., 2017), which may impede their ability to use an informed-choice tool. In addition, this group may face additional barriers to using such a tool, such as difficulty with concentration; these were discussed earlier in Chapter One (see section 1.5). A systematic review of interventions that aimed to enhance informed choice to undergo health screening (including cancer screening) reported that for most interventions, the acceptability of the information needs to be systematically reviewed by experts but, equally importantly, also by the target population (Biesecker et al., 2013). In addition, the usability of the intervention, namely the literacy level, format and presentation of the information, needs to be taken into account to ensure that the intended participants can understand the information (Biesecker et al., 2013). The optimal design and steps to follow when developing an informed-choice tool for people with SMI is currently unknown. The literature was therefore systematically reviewed to answer the following questions: (1) how effective are informed-choice tools for people with SMI in reducing their decisional conflict and (2) what methods and processes contribute to the effectiveness of informed-choice tools for people with SMI?

4.2 Methods

4.2.1 Study selection

The inclusion criteria used in this review were as follows:

- Studies concerning any informed-choice tool specifically for use by adults with an SMI, whose method of design and/or evaluation is described, and where the aim of the tool was to improve decision-making
- No restrictions on study design
- Studies with populations involving people with mental disorders other than those defined as severe above (e.g. obsessive compulsive or anxiety disorders) only if more than 50% of participants had a diagnosis of SMI, or if data limited to those with SMI were available
- Study participants were adults (18 years or over) of any gender with an SMI, however diagnosed and being treated in any setting. The definition of SMI used throughout this research was applied here (see Chapter One, section 1.1)
- Studies where participants were defined by authors as having an SMI, even when specific diagnoses were not provided
- The study was reported in English
- The full text was published in a peer-reviewed journal

The exclusion criteria included:

- Shared decision-making tools that could not be used by people with SMI independently of a healthcare professional
- Studies of participants with severe depression without psychotic symptoms – there is evidence that their behaviour around screening decision-making differs from that of people with psychosis (Howard et al., 2010)

- Articles published before 1996, since this coincides with the introduction of the evidence-based medicine movement, which highlights the importance of understanding research evidence when making health decisions (Sackett et al., 1996)

Studies involving participants with substance abuse disorders co-morbid with SMI were eligible, as were those with participants with SMI who reported a physical illness

4.2.2 Search strategy

This systematic review is reported in accordance with the 2009 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Moher et al., 2009). The review protocol (Lamontagne-Godwin et al., 2017) is registered on the international prospective register of systematic reviews (PROSPERO Registration number: CRD42017083507). The completed PRISMA checklist is contained in Appendix 3.

4.2.3 Data sources

A search of Cochrane Central Register of Controlled Trials, EBSCOhost, Web of Science, Academic Search Elite, MEDLINE, Embase, CINAHL and PsycINFO was conducted for studies published between 1996 and January 2018. An update was conducted in March 2020. The grey literature was also systematically searched, including conference abstracts through Open Grey and the Grey Literature Report, and the reference lists of included studies and relevant review articles were reviewed. No geographical limits were imposed. The literature search was restricted to English-language

publications. The first author of the included studies was contacted to find relevant unpublished work. To identify relevant studies, the search strategy used a combination of subject headings. The final strategy included relevant synonyms and incorporated appropriate search tools to ensure maximum sensitivity. A list of key search terms is published in the protocol (Lamontagne-Godwin et al., 2017).

4.2.4 Selection of studies

Titles and abstracts were independently screened by one reviewer [the candidate] to identify studies that potentially met the eligibility criteria. A second reviewer [a chartered psychologist] screened 10% of the titles and abstracts. Agreement on screening results was 80%; differences were reconciled with a third reviewer [a chartered psychologist with expertise in health psychology]. The full text of potentially eligible studies was assessed by three reviewers [the candidate, a chartered psychologist and a chartered psychologist with expertise in health psychology]. Disagreements were resolved through discussion with a fourth [a health psychologist] and fifth reviewer [a psychiatrist and health services researcher].

4.2.5 Study quality assessment

The Integrated quality Criteria for the Review Of Multiple Study designs (ICROMS) was used to assess the quality of the included studies (Zingg et al., 2016). ICROMS allows reviewers to attribute points to a study when it successfully meets a quality criterion. The quality criteria for each study are assessed using seven dimensions (e.g. managing bias in outcome

measurements and blinding, managing bias in sampling or between groups), with criteria allocated to each dimension. Scores are applicable to each criterion: Yes (criterion met): 2 points; Unclear: 1 point; No (criterion not met): 0 points. The sum of points attributed to each criterion represents the global quality score for that study. A minimum global score threshold is attributed for each study design. Studies were not excluded based on quality, but assessments of quality informed the data synthesis and interpretation of results. The study quality assessment was shared with the third and fourth reviewers; each reviewer scored two-thirds of the studies. Any discrepancies in scoring were resolved by discussion.

4.2.6 Data extraction

Data extraction forms were piloted to develop a framework, which was then reviewed by two reviewers [a chartered psychologist with expertise in health psychology and a chartered research psychologist]. Papers were divided into two categories: 1) those describing the development of a tool (Table 4.1) and 2) those describing the evaluation of a tool (Table 4.2). Some papers described both. The following data were extracted and synthesised for each category of studies: 1) participants (response rate, sample size, demographics, setting), intervention development (tool development, description of tool, use of behaviour change theory) and study weaknesses (Table 4.1); 2) participants (demographics setting), intervention evaluation (design, outcomes, results) and main study weaknesses (Table 4.2). All the data were extracted by one reviewer [the candidate]; one reviewer [a chartered psychologist with expertise in health psychology] verified half the

extracted data, while another reviewer [a chartered psychologist] verified the other half.

4.2.7 Approach to synthesis

A narrative synthesis of the findings was produced from the included studies, structured according to intervention type and method of development (Popay et al., 2006). Methods of intervention development were described. Data concerning all reported outcomes were included in the synthesis. Changes in scores for decisional conflict and knowledge are key indicators of improvement in decision-making. Both indicators were selected to assess the effectiveness of the intervention (Stacey et al., 2017). Changes in decisional conflict were compared with and, where possible, related to process variables and modifiers, such as the theory used to guide development or participant characteristics. Meta-analysis was not possible due to insufficient data and heterogeneity in study design and outcome measures.

Table 4.1 Data extraction for studies describing the development and design of an informed-choice tool

Study and allocated number	Population studied		Intervention	Setting	Method			Global quality score (ICROMS)	Study design	Main study weaknesses
	Response rate	Demographics			Tool Development	Description of tool	Use of behaviour change theory			
Brohan et al., 2014a (1)	N/A	*n* = 15 (8 female) **Ethnicity**: White British: *n* = 8 Black African: *n* = 3 Black Caribbean: *n* = 2 Black British: *n* = 1 Other white: *n* = 1 **Diagnosis**: Bipolar: *n* = 7 Schizophrenia: *n* = 1 Do not know: *n* = 2	Decision aid for disclosure of mental illness to employers	Secondary care (England)	Systematic review (Brohan et al., 2012) highlighted barriers to employment and qualitative study explored beliefs and experiences (Brohan et al., 2014b) Participants with mental illness read and completed the draft tool and rated it for brevity, simplicity and relevance Semi-structured interview data provided feedback – which led to tool amendments and readability of the tool being tested and adapted following feedback from participants	Six sections: (a) 'Pros and cons' of disclosure, (b) my disclosure needs, (c) my disclosure values, (d) when to tell, (e) who to tell, (f) making a decision Quotes from interviews supported sections The tool was designed to be used independently from, or as an adjunct to, a clinical encounter	Theory of Planned Behaviour (Ajzen, 1991)	21 (minimum score required: 22)	Mixed-methods pilot study using convenience sampling	Small sample – lack of generalisability
Brunette et al., 2017 (2)	*n* = 89 participants referred to	*n* = 71 (26 female) **Ethnicity**:	Decision support system to	Secondary care	Literature review (Ferron et al., 2009) informed	Stage 1 – psycho-education	Health behaviour change	15.5 (minimum score	Mixed-methods (three	Small sample – lack of generalisability

Ferron et al., 2011 (3) Ferron et al., 2012 (4)	the study by their clinicians; *n* = 71 (80%) agreed to participate	Caucasian: *n* = 49 African American: *n* = 22	motivate people with SMI to quit smoking [Let's Talk About Smoking]	(United States)	website development Think-aloud method used to evaluate the design and layout of the website in two phases: 1) each section of website was evaluated, then modified following feedback, whole site evaluated, then modified according to feedback and 2) participants used improved version of the website to provide feedback	regarding personal impact of smoking Stage 2 – video including consumer testimonials and text about quitting through use of evidence-based smoking cessation treatments	theory informed the content (not specified)	required: 22) (Ferron et al., 2011) 20.5 (minimum score required: 22) (Ferron et al., 2012) 25.5 (minimum score required: 22) (Brunette et al., 2017)	phases of semi-structured interviews and t-tests to compare the difference between uses of first computer programme version and later version	Other groups of people living with SMI may have higher or lower capacity for use of computerised treatments and websites
Liebherz et al., 2015 (5)	*n* = 930 participants with a range of mental disorders started the online survey. Of these, *n* = 493 gave informed consent	*n* = 210 (146 female) **Country of birth**: Born in Germany: *n* = 193 **Diagnosis**: Bipolar: *n* = 210	Patient decision aid for affective disorders	Web-based (Germany)	Treatment decisions identified through systematic review and evidence-based treatment options in the German national disease management guidelines Patients with bipolar disorder involved in development of tool Their information and decision-making needs were explored using an online cross-	Three information needs categories were identified in the survey: general information on bipolar disorder, information about treatment options and tips on dealing with the condition	None recorded	18 (minimum score required: 16)	Online cross-sectional survey using a self-administered questionnaire	Higher percentage of participants in survey reported lifetime mental health service compared with German adult population High number of women in sample (2.3:1 versus 1.2:1 in European epidemiological studies) Validity of diagnoses

					sectional survey – data were used to tailor the various components of the tool					restricted due to self-reported diagnoses

Table 4.2 Characteristics and findings of studies evaluating informed-choice tools

Study and allocated number	Demographics	Setting	Design	Intervention evaluation		Global quality score (ICROMS)	Main study weaknesses
				Outcomes	Results		
Brohan et al., 2014a (1) [disclosure tool]	*n* = 15 (8 female) **Ethnicity:** White British: *n* = 8 Black African: *n* = 3 Black Caribbean: *n* = 1 Black British: *n* = 1 Other white background: *n* = 1 **Diagnosis:** Bipolar disorder: *n* = 7 Schizophrenia: *n* = 1 Do not know: *n* = 2	Secondary care	Before and after study	**Primary outcomes:** (a) stage of decision-making (b) decisional conflict (c) employment-related outcomes Feasibility was tested using measures of: brevity, ease of use, relevance to self and others Semi-structured interviews were administered to obtain further feedback on the informed-choice tool	Mean Decisional Conflict Scale scores improved (-16.5, SD: 17.5) after completing the tool Mean Stage of Decision-making Scale scores reduced from 4.6 to 4.3 (indicating improvement) Participants found the tool quick to use (60%), relevant (60%) and would recommend it to others (80%) 80% reported that they would definitely or probably use the tool in making disclosure decisions An equal number of participants were neutral and positive on the ease of use of the tool (40%) Interviews revealed a demand for more information on the legal implications of disclosure	21 (minimum score required: 22)	Lack of power to detect statistically significant change in outcome scores Small unrepresentative sample – limited generalisability No follow-up

Henderson et al., 2013 (6) [disclosure tool]	*n* = 79 (control group = 39, intervention group = 40) Control group (20 female) **Ethnicity:** White: *n* = 16 Black/Black British: *n* = 17 Asian/Asian British: *n* = 2 Other: *n* = 4 **Diagnosis:** Schizophrenia spectrum: *n* = 13 Bipolar disorder: *n* = 6 Mixed: *n* = 2 Don't know: *n* = 6 Intervention group (18 female): **Ethnicity:** White: *n* = 14 Black/Black British: *n* = 20 Asian/Asian British: *n* = 1 Other: *n* = 5 **Diagnosis:** Schizophrenia spectrum: *n* = 11 Bipolar disorder: *n* = 7 Mixed: *n* = 3 Don't know: *n* = 5	Vocational services for clients with mental health problems	Exploratory randomised controlled trial	Participants were randomly assigned to use the tool plus usual care or usual care alone Follow-up was at 3 months **Primary outcomes:** (a) stage of decision-making (b) decisional conflict (c) employment-related outcomes **Secondary outcomes:** (a) eight-item self-assessment of work performance (short version of the Work Limitations Questionnaire) (b) self-esteem–self-efficacy and power–powerlessness subscales (17 items) of the original Boston University Empowerment Scale	No substantial difference between trial arms for any variable Median time taken to complete the tool = 30 minutes No outcome measures were associated with loss to follow-up Decisional conflict at 3-month follow-up had fallen in both groups, but the reduction in the intervention group was significantly greater than that in the control (-22.7 versus -11.2) Little evidence of improvement in stage of decision-making, with no significant change between groups and no significant differences between groups at follow-up, although the changes in direction favour the intervention group	29 (minimum score required: 22)	Small sample and skewed distributions of employment-related activity
Brunette et al., 2011 (7)	*n* = 41 (control group = 20, intervention group = 21) Control group (7 female): **Ethnicity:** African American: *n* = 17	Psychosocial rehabilitation centre (provides supported housing and	Quasi-experimental design to test the decision support	Participants were interviewed at baseline and follow-up was two months later to	Two-month follow-up: participants who had used the smoking cessation tool were more likely	24 (minimum score required: 18)	Small sample Non-equivalent clinical characteristics of the groups

[smoking cessation tool]	Other: *n* = 3 **Diagnosis**: Schizophrenia: *n* = 19 Other: *n* = 1 Intervention group (7 female): **Ethnicity:** African American: *n* = 20 Other: *n* = 1 **Diagnosis**: Schizophrenia: *n* = 9 Other: *n* = 12	comprehensive psychiatric services)	system among smokers with SMI	assess for behaviours indicative of motivation to quit smoking **Primary outcome:** whether participants became motivated to quit smoking	to have engaged in at least one smoking cessation motivation behaviour (67%) than those in the control group (35%)		Differing levels of intensity of the experimental and control interventions Authors did not correct for the number of statistical tests
Ferron et al., 2012 (4) [smoking cessation tool]	*n* = 135 (38 female) **Ethnicity**: Black: *n* = 64 White: *n* = 49 Other: *n* = 22 **Diagnosis:** Schizophrenia/schizoaffective disorder: *n* = 95 Mood disorder: *n* = 34 Other : *n* = 6	Psychiatric rehabilitation centre	Secondary analysis of data from parent study that evaluated an RCT of whether use of feedback from a carbon monoxide monitor was a necessary ingredient in decision support system	**Primary outcomes:** 1) process variables, including length of time spent on two tool subsections and choice of video host and 2) behavioural outcome variables, including number of behaviours indicative of motivation to quit smoking (e.g. evidence-based treatment initiation)	55% of participants chose a young African-American woman to be programme 'host' Participants spent, on average, 92 minutes on website, split evenly between motivation and treatment sections About a third of the group initiated cessation treatment Almost a third met with smoking cessation specialist to discuss treatment and almost 40% of participants discussed using a quit smoking medication with their doctor More than 50% of participants engaged in one or	20.5 (minimum score required: 22)	Positive evaluation of tool may have been contributed to by the monetary compensation ($15) provided to participants The study does not allow the host choice aspect to be evaluated (i.e. whether it improves efficacy of the website)

					more behavioural indicator of motivation		
Brunette et al., 2013 (8) [smoking cessation tool]	*n* = 124 (control group = 66, intervention group = 58) Control group (21 female): **Ethnicity:** African American: *n* = 30 White: *n* = 16 Hispanic: *n* = 12 Other/multiple races: *n* = 4 Did not disclose: *n* = 4 **Diagnosis:** Schizophrenia/schizoaffective disorders: *n* = 46 Bipolar/depressive disorders: *n* = 18 Other: *n* = 2 Intervention group (14 female): **Ethnicity:** African American: *n* = 30 White: *n* = 26 Hispanic: *n* = 6 Other/multiple races: *n* = 4 **Diagnosis:** Schizophrenia/schizoaffective disorders: *n* = 38 Bipolar/depressive disorders: *n* = 16 Other: *n* = 4	Mental health treatment organisation	RCT	**Primary outcome**: initiating cessation treatment over two months **Secondary outcomes:** amount and frequency of smoking over two months, satisfaction with website, stage of change (four-point scale, from 'now' to not thinking of quitting smoking), basic knowledge about health effects of smoking and knowledge about carbon monoxide	At two-month follow-up participants in carbon monoxide group increased their knowledge about carbon monoxide ($\chi 2$ = 6.97, df = 1, p = .008) Basic knowledge about health effects of smoking was fairly high and did not increase differentially between groups Main and secondary outcomes did not differ significantly between groups (rate difference =15%, SE = 0.08, CI = − 0.31 to 0.01) Overall, 32% of participants initiated treatment. Main outcome, initiating cessation medication or counselling, did not differ between groups (rate difference =15%, SE = 0.08, CI = − 0.31 to 0.01)	29 (minimum score required: 22)	Study did not evaluate whether smokers with particular diagnoses were more or less likely to respond to intervention Study did not include placebo or attention control condition Purpose of study to demonstrate impact of tool on treatment use, so no comparison group to document the rate of treatment initiation and abstinence in people who did not receive tool Self-reported rate of abstinence could be inflated

Ferron et al., 2016 (9) [smoking cessation tool]	*n* = 124 (35 female) **Ethnicity:** African American: *n* = 57 White (non-Hispanic): *n* = 37 Hispanic: *n* = 18 **Diagnosis:** Diagnosed with psychotic disorder (schizophrenia/schizoaffective disorder): *n* = 86 Other: *n* = 38	Psychiatric rehabilitation centre	Six-month follow-up of an RCT	At two and six months post-intervention, participants were assessed for use of cessation treatment, quit behaviours and days of abstinence Regression analyses tested whether participant characteristics and treatment use predicted 7 days or more of continuous abstinence **Outcomes:** Self-reported abstinence outcomes over 6 months after the intervention: number who tried to quit, number of quit attempts, attained >1-day abstinence, days of abstinence and attained >7 days' abstinence	*n* = 74 reported quitting smoking for at least one day over six-month follow-up period Average length of self-reported abstinence among quitters was 18 days *n* = 36 sustained abstinence for at least 7 days *n* = 9 persisted in their abstinence and provided a breath CO<10ppm at six-month follow-up Participants' scores for the Stage of Change after intervention significantly predicted abstinence Participants' treatment use significantly predicted abstinence (strongest predictor) When both treatment use and stage of change after the intervention were included in the model, only treatment use significantly predicted abstinence	22 (minimum score required: 22)	Purpose of the study was to demonstrate the impact of the website on treatment use, so there was no comparison group to document the rate of treatment initiation and abstinence in people who did not receive the website The self-reported rate of abstinence could be inflated

Brunette et al., 2017 (2) [smoking cessation tool]	*n* = 81 **Control group** (n = 23; 11 female) Ethnicity: White: *n* = 20 Black: *n* = 2 Other: *n* = 1 Diagnosis: Schizophrenia/affective disorders: *n* = 9 Mood/anxiety disorders: *n* = 14 **Intervention group** (*n* = 30, 10 female) Ethnicity: White: *n* = 17 Black: *n* = 9 Other: *n* = 4 Diagnosis: Schizophrenia/affective: *n* = 12 Diagnosis mood/anxiety: *n* = 18 **Intervention group - Computerised National Cancer Institute Education** – (n = 28, 9 female) Ethnicity: White: *n* = 16 Black: *n* = 10 Other: *n* = 2 Diagnosis: Schizophrenia/affective: *n* = 14 Diagnosis mood/anxiety: *n* = 14	Mental health treatment programme	Randomised, controlled pilot study	**Primary outcome:** past three-month use of verifiable cessation treatment and quit attempts **Secondary outcomes**: smoking characteristics, self-reported quit attempts with days of abstinence, and biologically verified abstinence at study follow-up visits	6% of participants who received intervention utilised verifiable cessation treatment over three-month follow-up period Smokers with verified abstinence at 14-week assessment point had not used any verifiable cessation treatment After using assigned interventions, participants rated importance of quitting highly, but intentions to use cessation treatments were moderately low Secondary outcome: Those who received website more likely to have biologically verified abstinence from smoking and other tobacco product use at the 14-week assessment than those who received the computerised National Cancer Institute education	25.5 (minimum score required: 22)	Small sample - not possible to evaluate moderators and mechanisms of change with use of the tool

4.3 Results

4.3.1 Search results

The search results are summarised in the PRISMA Flow Diagram (Moher et al., 2009) (Figure 4.1). Papers were identified from the database search (*n* = 883) and using the other methods, as described in section 4.2.3 (*n* = 48). Duplicate articles were removed (*n* = 164) and the inclusion and exclusion criteria applied. The full text of 13 potentially eligible papers was assessed. Four papers were excluded: one described a shared decision-making tool designed to be used with a health professional, one did not specify the target audience and two did not include participants with an SMI diagnosis. Nine papers were included in the synthesis (two from England, one from Germany and six from the United States).

The included studies described three tools; detailed information on these is presented in Tables 4.1 and 4.2.

Tool 1 – disclosure tool
Paper-based decision aid (A4/12 pages)
Entitled CORAL [Conceal Or ReveAL]
Developed and trialled in England to assist people with SMI with reaching decisions regarding disclosure of their mental health status in the employment context (Brohan et al., 2014a: Henderson et al., 2013).

Tool 2 – smoking cessation tool
Web-based decision support system
Entitled *Let's Talk About Smoking*
Developed and trialled in the United States to stimulate motivation in people with SMI to quit smoking (Brunette et al., 2011, 2013, 2017; Ferron et al., 2011, 2012, 2016).

Tool 3 – treatment choice tool
Web-based patient decision aid
Available on: www.psychenet.de
Developed in Germany to encourage patients to participate in decision-making about treatment by providing information about the pros and cons of treatment options for bipolar disorder; it has not been evaluated (Liebherz et al., 2015).

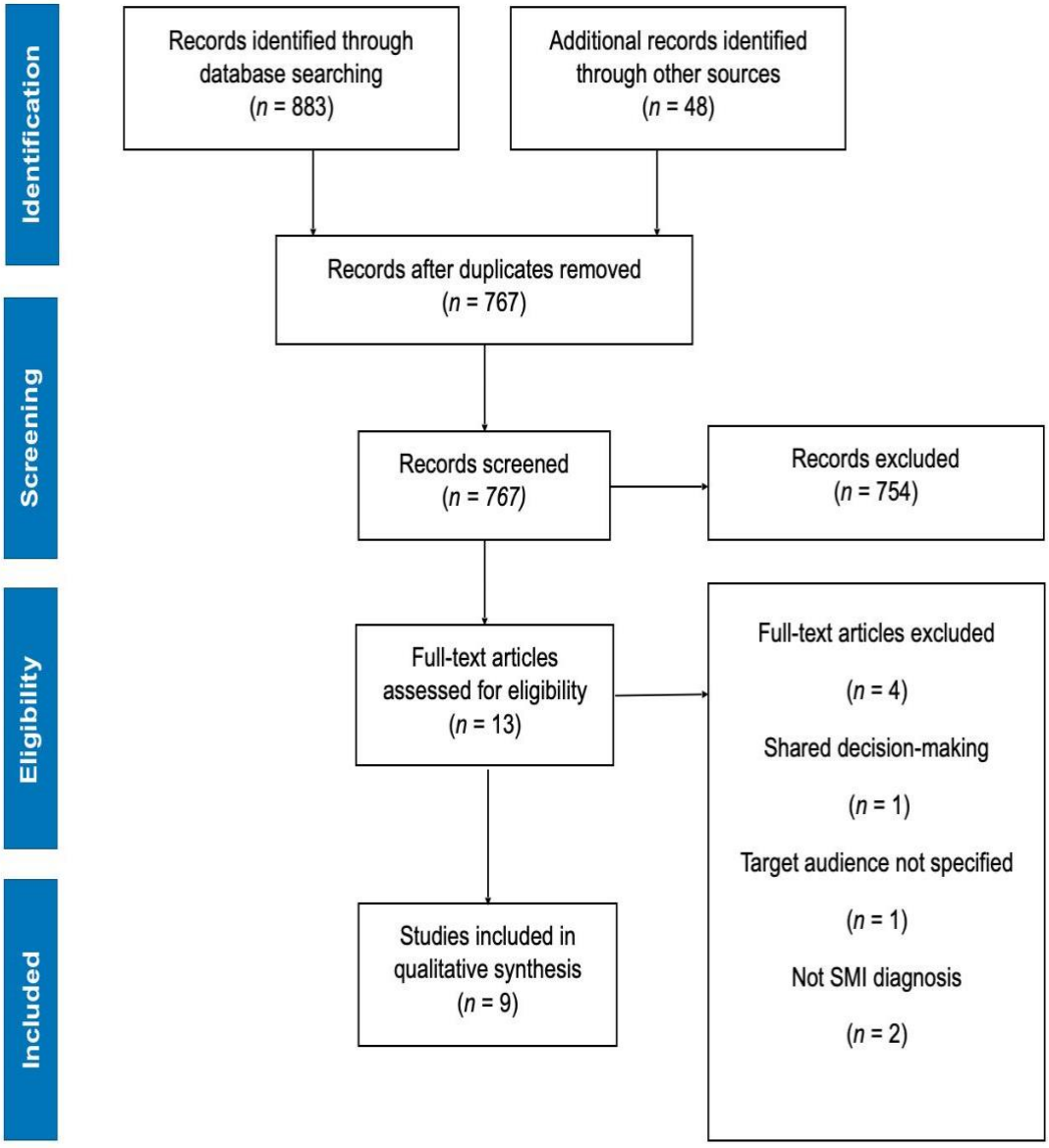


Figure 4.1 PRISMA Flow Diagram (Moher et al., 2009)

4.3.2 Assessment of study quality

A main aim of the review was to analyse the methods used to develop informed-choice tools for people with SMI. The ICROMS framework was

used to assess the study quality of development and evaluation studies, but quality per se was not an eligibility criterion. Using the matrix to calculate a 'global quality score' for each study, three of the four studies describing the development of the informed-choice tools produced a score below the threshold used to define 'adequate quality': 21/22[1], 15.5/22[3] and 20.5/22[4]. These low scores are not a reflection of their quality; the design and sample size selected by the authors for the development studies was appropriate for initial testing with cognitive debriefing. Rather, these low scores reflect that ICROMS is more appropriate for certain types of studies, while other design categories were not recognised by the framework. One study[9] met the minimum quality score and the remaining five scored above it[2,5-8]. The main study weaknesses are described in Tables 4.1 and 4.2. The most common weaknesses involve a small sample size and lack of generalisability. On balance, notwithstanding these limitations, the overall body of evidence was considered to be sufficiently reliable for conclusions to be drawn, since the quality of evidence for developmental studies was rated moderate overall and the evidence for the evaluation studies was rated good overall.

4.3.3 Evidence of effectiveness

The disclosure tool was evaluated in a pilot and in an exploratory randomised controlled trial (RCT)[1,6]. The smoking cessation tool was evaluated in a pilot study using a quasi-experimental design[7], an RCT[8], using secondary analysis of data[4] from the RCT[8]. The tool was also evaluated after a six-month follow-up of the RCT[9] and in a pilot trial comparing the smoking cessation tool to the computerised smoking education tool from the American

National Cancer Institute (ANCI)[2]. No effectiveness data are available for the treatment choice tool[5]. Reported outcomes are included in Table 4.2 and summarised in sections 4.3.5 and 4.3.6.

4.3.4 Development and design of informed-choice tools

Three studies (smoking cessation: *n* = 71, disclosure: *n* = 15, treatment choice: *n* = 210) described the informed-choice tools' development[1,5,7] and data on these are summarised in Table 4.1. Based on the current synthesised evidence from several studies[1-5,7], a preliminary list of steps that interventionists may wish to follow when developing informed-choice tools for people with SMI is listed in the box below.

Step one: Identify barriers to decision-making
Step two: Theoretically underpin the intervention
Step three: Involve service users in the development of the tool
Step four: Test usability of the intervention
Step five: Assess readability levels

The following section details each step.

1) Step one: Identify barriers to decision-making

Method: Conduct a (systematic) review of the literature

Barriers to decision-making were identified by study authors who conducted a literature search prior to the development of their respective tools[1,3,5].

Authors of the disclosure (Brohan et al., 2012) and treatment choice (Liebherz et al., 2015; Tlach et al., 2014) tools conducted a systematic review, while authors developing the smoking cessation tool reviewed the research on smoking cessation interventions for adults with SMI[3]. Authors of the disclosure tool also conducted a qualitative study to explore disclosure of decision-making (Brohan et al., 2014b).

2) Step two: Theoretically underpin the intervention

Method: Identify a theory of behaviour change and refer to the Ottawa decision support framework.

The Ottawa decision support framework is a three-step process used by interventionists developing decision aids to guide users through making health or social decisions (O'Connor et al., 1999). The first step involves the assessment of client and practitioner determinants of decisions to identify decision support needs; the second is to offer decision support tailored to client needs using counselling, decision tools/coaching; the last one is to evaluate the decision-making process and outcomes.

The development of the disclosure and treatment choice tools was based on this framework. Authors of the disclosure tool[1] included an integrated disclosure framework developed from their systematic review and earlier qualitative work as the theoretical basis for the disclosure tool (Brohan et al., 2012, Brohan et al., 2014b). The disclosure and smoking cessation tools used the Theory of Planned Behaviour (Ajzen, 1991) to inform content

development[1,3]. This ensured that the tools were theoretically underpinned and enabled evaluation of the process of change (Moore et al., 2015).

3) Step three: Involve service users in the development of the tool

Method: Collect feedback from service users on the content of the tool using semi-structured interviews/online survey. Use the think-aloud method to collect feedback on usability and acceptability of the tool.

People with an SMI were involved in the development phase of every tool in order to explore their needs when faced with making a particular decision[5] and to test the usability and acceptability of the tool[1,3]. Ease of use was tested for both the smoking cessation[2-4] and disclosure[1] tools (see below). Feedback from people with SMI was collected using semi-structured interviews[1,3]. Questions focused on their general opinions on the tool, other information/experiences which they felt should be included and any amendments to existing information[1]. Feedback was also collected using an online cross-sectional survey[5] and the think-aloud method[3]. This method was used to test an intervention that was used in a similar study for people with SMI (Vilardaga et al., 2016) and is described in more detail in section 8.1.

4) Step four: Test usability of the intervention

Method: Use the Perceived Usefulness and Ease of Use Scale (Davis, 1989) and refer to the usability guidelines for people with schizophrenia (Rotondi et al., 2007) and people with cognitive deficits (United States Department of Health and Human Services, 2010).

Ease of use was tested in four studies, three relating to the smoking cessation tool[2,3,8] and one to the disclosure tool[1]. Changes implemented following service user feedback on the smoking cessation and disclosure tools showed positive effects on ease of use for both tools. Most participants testing the smoking cessation tool (*n* = 124) reported high levels of satisfaction with the first and second (revised) versions of the tool: 75% were very satisfied and 98% agreed that the way the information was presented was good (28.2%), very good (28.2%) or excellent (41.6%)[8]. Participants (*n* = 15) testing the disclosure tool found the tool to be quick to use (60%) and relevant (60%) and they were neutral (40%) or positive (40%) on the ease of use of the tool[1].

The Perceived Usefulness and Ease of Use Scale (Davis, 1989) was adapted and used in one evaluation of the smoking cessation tool to assess participants' perceptions of the usefulness and ease of operating the tool. Items included the statement 'the smoking program gave me too much information'[3]. Results showed an increased ease of use from the first to the last version of the online tool, which was reflected in participants' reduction in unproductive clicking and fewer questions being asked about how to use the tool[3].

An evaluation study of the smoking cessation tool compared it with the computerised ANCI tool[2]. Users described that although they felt that both the tool and the ANCI tool were 'easy to use', 10.7% of ANCI education users versus 3.3% of users of the smoking cessation tool felt it was 'hard to understand'. In terms of satisfaction, 71.4% of the ANCI education users and

83.4% of users of the tool described the intervention as ‘good’ or ‘very good’. About 95% of both groups said they would recommend the intervention to their peers[2].

For the smoking cessation intervention, suggested improvements included integrating a mouse tutorial, using a flat interface, increasing font and button sizes, using a blank background with a simple border graphic and using text-to-speech software. To ensure usability of the smoking cessation tool, authors consulted previous research on usability for people with schizophrenia (Rotondi et al., 2007) and applied usability guidelines for people with cognitive deficits (United States Department of Health and Human Services, 2010). Changes implemented following service user feedback on the smoking cessation and disclosure tools showed positive effects on ease of use for both tools.

5) Step five: Assess readability levels

Method: Use the Flesch-Kincaid readability tests (Flesch Reading Ease and the Flesch–Kincaid Grade Level (Flesch, 1948; Kincaid et al., 1975).

The readability level of participants with SMI were checked during the development phase of the disclosure and smoking cessation tools[1,3]. Authors of the disclosure tool refer to the Flesch-Kincaid readability tests (Flesch Reading Ease and the Flesch–Kincaid Grade Level). Following feedback from participants, the interventionists developing the tools revised the readability of their tools to a revised Flesch-Kincaid grade level of 8.4 i.e. to be understandable by the average US 8th – 9th grader (aged 13–15 years)

and from an 8th grade to below a 5th grade reading level, respectively[1,3]. Further feedback concerning the format and design layout of tools suggested that providing definitions, simplifying language, 'breaking down' the information and including *ad verbatim* quotes or videos from peers are all helpful.

4.3.5 Evaluation of impact of the tools on primary outcomes

Disclosure tool: The impact on decisional conflict was measured using the validated Decisional Conflict Scale (O'Connor, 1993 – updated 2010)[1,6]. A before and after study (*n* = 15) found a reduction in decisional conflict, indicating improvement (mean difference -16.5 (SD: 17.5)[1]. Statistical significance was not tested, as the sample size was too small for significance to be meaningfully interpreted. This result was supported by an RCT (*n* = 79) that compared the tool users' group to a control group receiving usual care (mean improvement at three months: intervention group -22.7 (SD: 15.2); control group -11.2 (SD: 18.1), $p = 0.005$)[6].

Smoking cessation tool: The impact of the tool on knowledge was measured as an outcome in one study, which tested the effect of carbon monoxide feedback as an additional component to the smoking cessation tool[8]. At a two-month follow-up, participants testing the smoking cessation tool in the carbon monoxide intervention group (n = 58) reported increased knowledge about the risks of carbon monoxide compared to the control group. However, rudimentary knowledge about the health consequences of smoking was quite high and did not increase differentially between groups.

4.3.6 Evaluation of the Impact of the tools on other outcomes

Other outcomes tested in the evaluation studies included:

A) Stage of Change

Disclosure tool: The stage of change (Donovan et al., 1998), which is the participant's perceived degree of readiness to change their behaviour, was measured in two studies (*n* = 15 and *n* = 79). The Stage of Decision-Making scale (1-5) (O'Connor, 2000 – updated 2003) was used, which measures an individual's readiness to engage in decision-making[1,6]. In one study, the mean stage of decision-making scores increased (indicating improvement) pre- and post-use of the tool from 4.3 to 4.6, though the sample size was not powered to detect statistically significant change[1]. In the other study (i.e. feasibility trial), there was much less evidence of movement in stage of decision-making, with no significant change between groups and no significant differences between groups at follow-up, although the change between immediate and three-month follow-up was in a positive direction; the median increased from 4 (IQR 3–5) to 5 (IQR 3–6)[6].

Smoking cessation tool: the stage of change scale was also used to assess the impact of the smoking cessation tool. The stage of change (i.e. readiness to quit smoking) was used in three studies (*n* = 124, *n* = 135 and *n* = 124)[4,8,9] and was measured by one question – *Are you seriously thinking about quitting?* – at baseline and after using the smoking cessation tool using a four-point scale (DiClemente et al., 1991; Donovan et al., 1998). Measures of stage of change at baseline and after using the tool were tested and not

reported for two studies[4,8]. Authors of the third study reported an increase in the stage of change score (indicating improvement) pre- and post-use of the tool from 1.82 to 2.75[9].

The impact of the tools on behaviour was also measured with the following instruments.

B) Self-efficacy outcome

Disclosure tool: One study tested whether the tool led to a significant improvement on the power–powerlessness and the self-esteem–self-efficacy subscales of the Empowerment Scale (Rogers et al., 2010). This scale is a product of the Center for Psychiatric Rehabilitation at Boston University. Unadjusted and adjusted comparisons of the mean changes in the power–powerlessness subscale showed a significant reduction in scores, indicating improvement. No significant improvement was recorded in the mean (adjusted and non-adjusted) self-esteem–self-efficacy subscale score (unadjusted: mean difference 0.13 (SD: 0.40) compared with 0.04 (SD: 0.28)).

Change in attitudes and beliefs was tested in the following ways:

C) Behavioural withdrawal

Disclosure tool: One study tested whether the tool led to a lower rate of behavioural withdrawal in response to stigma using five items (e.g. secrecy) from the withdrawal scale (Link et al., 1989). The latter is based on the original nine-item subscale of the Stigma Coping Orientation scales (Link et

al., 2001) that measures social withdrawal[6]. There was no significant improvement in behavioural withdrawal and no significant differences between groups at follow-up.

D) Behavioural motivation

Smoking cessation tool: Four studies assessed whether the smoking cessation tool had any impact on behaviours indicative of motivation to quit smoking[4,7-9], however, one study[9] is a secondary analysis of data from a parent study[8] so these data were reported twice. Behaviours indicative of motivation were measured using the Behavioural Motivation Index[7]. Participants who used the tool were significantly more likely than the control group (67% versus 35%) to show any behavioural motivation to quit smoking (e.g. meet with a health professional to discuss cessation)[7]. The effect of the tool remained significant in an analysis that controlled for baseline group differences. In a separate evaluation, authors of the trial assessed participants' smoking behaviours and other quitting behaviours two months after use of the tool, finding that more than half (52.9%) of the participants engaged in at least one cessation behaviour[8]. During the six-month follow-up of the trial, 55.6% of participants engaged in a cessation behaviour and nearly 40% (*n* = 49) initiated at least one type of evidence-based cessation treatment[9].

E) Self-reported smoking cessation

Smoking cessation tool: Initiation of verifiable smoking cessation treatment was tested in three out of six evaluations of the smoking cessation tool, and rates of cessation varied across the studies. In their evaluation, authors from

two studies[4,8] reported that about 30% of the group had initiated cessation treatment by discussing treatment options with a smoking cessation specialist. In another evaluation, treatment was initiated by 32% of participants[8]. In the final evaluation, about 6% of participants who received the smoking cessation tool accessed a verifiable cessation treatment over the three-month follow-up period[2].

F) Self-reported abstinence

Smoking cessation tool: Self-reported abstinence was tested in two studies. Authors[9] reported in their study (*n* = 74) that almost 60% of participants abstained from smoking for at least one day over the six-month follow-up period. The mean length of self-reported abstinence among quitters was 18 days. Sustained abstinence was recorded for 29% of participants for at least seven days, while 7% persisted in their abstinence and provided a breath CO<10ppm[18] at six-month follow-up[9]. Another evaluation assessed whether the rate of treatment initiation and cessation behaviours would be higher among users of the tool in comparison to users of the computerised American National Cancer Institute (ANCI) education tool on smoking cessation. Almost 15% of participants who used the smoking cessation tool met the study's definition of biologically verified abstinence at the 14-week follow-up, whereas none of the smokers in the ANCI education group or comparison condition achieved smoking abstinence[2].

[18] The British National Institute for Health and Care Excellence (NICE) stipulates that a non-smoker is identified by a reading of less than 10ppm CO [carbon monoxide]

G) Importance of quitting smoking

Smoking cessation tool: This was tested in one study. Following use of the smoking cessation tool, participants rated the importance of quitting highly (mean 5.7 ± 1.4 on a 1–7 scale); however, intentions to use cessation treatments were relatively low (mean 3.6 ± 1.9 on a 1–7 scale)[2].

4.4 Discussion

4.4.1 Summary of key findings

This systematic review has identified that there are few available informed-choice tools that people with SMI can use to make decisions about their health without requiring support from a professional. Nevertheless, the available data suggest that such tools may facilitate a reduction in decisional conflict, improved knowledge and movement in stage of change towards decision-making. As stated in the protocol (Lamontagne-Godwin et al., 2017), the MRC guidance for developing and evaluating complex interventions provides a broad description on how to achieve this in four phases: development, feasibility/piloting, evaluation and implementation (Craig et al., 2008). This review has identified a clear list of key methodological considerations for the development of future informed-choice tools for people with SMI.

The findings suggest that such tools are effective, as was reported in an earlier systematic review of decision aids for people facing difficult treatment or screening decisions (Stacey et al., 2017). The findings of the review by Stacey (2017) indicate that in the general population, in comparison to usual

care, decision aids increase knowledge (MD 13.27/100; 95% CI = 11.32-15.23; 52 studies; *n* = 13,316; high-quality evidence) and reduce decisional conflict (MD −9.28/100; 95% CI = −12.20 to −6.36; 27 studies; *n* = 5707; high-quality evidence). Congruency between informed values and care choices was also found to increase (RR 2.06; 95% CI 1.46 to 2.91; 10 studies; *n* = 4626; low-quality evidence). However, these outcomes have not been tested in people with SMI. The review by Stacey (2017) therefore provided a strong rationale for testing these outcomes in people with SMI.

Although the present review has identified methods that can improve the acceptability and ease of use of the tools by people with SMI, challenges remain. For instance, feedback from people with SMI, collected using a range of methods, indicates difficulties with readability. Authors of the disclosure and smoking cessation tools[1,3] sought to increase readability by providing definitions, simplifying the language and breaking down the information. Further simplification of the disclosure tool may have been required for some users, but it was thought that this could risk diluting the complexity of the disclosure decision-making, thus lowering the effectiveness of the tool[1]. Authors of the treatment choice tool acknowledged that adaptations may be needed for people with low literacy levels[5]. Adaptations might include adding a button for audio for each section of text.

Data from semi-structured interviews with study participants identified a desire for specific information to be included. Participants who responded to the survey for the treatment choice tool specified general information

searches as their most relevant information need[5]. When asked what could be improved about the smoking cessation tool, 23% of participants wanted more detailed information about health effects of smoking and 3%–9% wanted more knowledge about electronic cigarettes and the social impact of smoking[2]. Participants of the study evaluating the disclosure tool wanted more information on the legal implications of disclosure[1]; however, this aspect was beyond the scope of the tool.

As recommended by the MRC guidance for developing complex interventions, deciding on which information to include can be partly addressed through an *a priori* review of the literature describing the barriers to performing the behaviour. This was addressed by the developers of every tool explored in this review. However, the feedback and interview data indicated that this may be insufficient on its own and that tools should be developed and tested in stages and informed by the target audience. This may be a drawback of the methodology used to develop the three tools, which advocates for service user involvement rather than a co-production model. Research is needed to evaluate whether a co-production methodology (Slay and Stephens, 2013) would be more effective for developing such interventions.

As reported in section 1.7.3, informed-choice tools aimed at the general public have been published by healthcare organisations e.g. the cervical and breast screening decision aid [‘Helping you Decide’] leaflets from Public Health England or the smoking education tool from the ANCI. Authors of one

study included in this review[2] randomised participants with SMI to compare the smoking cessation tool with the computerised standard education from the ANCI for the general population. Findings were in favour of the smoking cessation (i.e. SMI-specific) tool: those who received it were more likely to have biologically verified abstinence from smoking and other tobacco product use at the 14-week assessment than those who received the ANCI tool (14.8% vs. 0%)[2]. This finding supports the need for tools that are tailored to people with SMI, who may face specific barriers associated with their mental illness diagnosis (Clifton et al., 2016). While the review found no studies of routine use, it is worth noting that the smoking cessation and disclosure tools were felt to be easily deployed and implemented without significant resource implications in their respective settings (routine vocational services[1] and mental health treatment settings[2]).

This review has also highlighted gaps in the evidence base for the development and utilisation of informed-choice tools for people with SMI. For instance, there was little evidence of the use of theoretical frameworks in tool development. Use of theoretical frameworks, such as the Behaviour Change Wheel Framework, has been reported during the developmental phase of decision support interventions for the general population (Elwyn et al., 2011; Michie et al., 2011) and for interventions for people with SMI (Mangurian et al., 2017; Osborn et al., 2018). These may therefore be useful to consider in future tool development.

This review identified one paper-based[1] and two web-based tools[3,5], though no study directly compared the two formats. For the purposes of this research, before investing in the expense of a digital version, a paper informed-choice tool was developed as a first step. Leaflets are commonly used in health care and can be uploaded by different stakeholders. Alternative formats to this intervention are discussed in Chapter Ten (section 10.5). It is nonetheless worth noting that there is some evidence that changing the format (e.g. a video, computer programme or leaflet with a decision tree) of an informed-choice intervention from a well-prepared leaflet does not increase test uptake, knowledge or satisfaction with the decision (Biesecker, et al., 2013). Further research is needed to establish whether access to and acceptability of internet and digital technology is widespread among this group, although there has been a recent systematic review that investigated the acceptability of mobile phone- and online- delivered interventions for people with SMI (Berry et al., 2016). Authors of the review (Berry et al., 2016) advise researchers to use qualitative methods to assess acceptability at each phase of intervention development and testing. Other authors of a systematic review (Batra et al., 2017) that explored the use of digital health technology for patients with SMI concluded that short-term use of digital technologies seems to be feasible.

One included study noted that 61% (*n* = 82) of participants reported having used a computer more than five times in their life, while 22% (*n* = 30) had no computer experience (Ferron et al., 2012). Other studies have pointed to increased adoption and value of digital technology interventions by people

with SMI (Biagianti et al., 2017; Robotham et al., 2016). A survey was conducted in London in 2011 (*n* = 121, including *n* = 49 with psychosis) and 2016 (*n* = 241, including *n* = 121 with psychosis) to explore rates of digital exclusion for people with SMI and found that digital exclusion rates declined over time. In 2016, fewer than 1 in 10 participants were considered 'digitally excluded' (*n* = 24), although within that subsample, more than 80% (*n* = 20) had psychosis. In comparison to participants who were 'digitally included', those who were 'digitally excluded' were significantly older (included: mean 36.8, SD: 12.7 years and excluded: mean 45.7, SD: 9.7 years). Participants from the 'digitally excluded' group had accessed mental health services for longer (included: mean 8.7, SD: 8.3 years and excluded: mean 14.1, SD: 9.2 years). Factors associated with exclusion were psychosis, being older, having used mental health services for longer and being part of a BAME group (Robotham et al., 2016). More research is needed to collect long-term effectiveness data to demonstrate digital technologies' usefulness and acceptability for people with SMI (Batra et al., 2017).

In March 2020, the original search was updated, and an additional intervention was identified: a decision aid (booklet) for patients with bipolar II disorder and their families making decisions about treatment options to prevent relapse (Fisher et al., 2018a). The intervention was developed in Australia and the feasibility study protocol for a Phase II RCT of the decision aid was published (Fisher et al., 2018b).

4.4.2 Strengths and limitations of this review

This is the first systematic review to explore the development and evaluation of informed-choice tools for people with SMI. It includes heterogeneous interventions from different settings and mental health systems, though sample sizes were often small with no effect size available, so findings should be interpreted cautiously. The generalisability of the findings may be reduced, as a narrow definition of severe mental illness (psychosis) was applied, which excluded studies focusing on other mental health conditions such as anxiety disorders or PTSD. Despite overlap in terms of barriers, people with other mental health disorders may face different challenges that may not be relevant to those diagnosed with psychosis. It is unlikely that any one tool would be suitable for a diverse population.

A strength of this review is that ICROMS, a robust framework, was used to assess study quality; however, a limitation is that it was not fully able to capture the design of the descriptive studies.

4.4.3 Chapter summary and implications for the development of the tool

Few informed-choice tools exist for people with SMI. Though the review did not identify a definite method, the findings provide useful guidance for the development of informed-choice tools for people with SMI, using a clear list of key methodological considerations. For instance, the development of such tools should proceed in stages and include the views of people with SMI at each phase. Attention should be paid to readability and use of a theoretical framework could assist in determining how interventions may work best to inform adjustments. In terms of the format, although a digital version may be

acceptable to this group, for this research, a paper version of the tool was developed as a first step. The work to develop the tool in this thesis is informed by these steps and is described in Chapter Five.

Chapter Five – Conception and design of the tool

This chapter provides a description of how the tool was developed. The first step was to collect the evidence regarding barriers and enablers to cancer screening, followed by selecting the appropriate theoretical framework to develop the tool, and finally, completing the steps identified in the systematic review reported in Chapter Four. The contents of the initial draft of the tool are also presented here. This chapter addresses the first two objectives of the overall thesis. An illustration of how these objectives map onto the MRC phases and the development steps for informed-choice tools identified in the systematic review (Chapter Four) is displayed in Box 1 below.

Box 1: Development of the tool

Objectives of the research that this chapter addresses (in bold):

Objective one: To develop an informed-choice tool for women with SMI which addresses some of the barriers to screening attendance

Objective two: The tool should be theoretically underpinned

Objective three: Acceptability and usability of the tool by stakeholders should be tested

Phases of the MRC guidance

Development: Identifying the evidence base

Development: Identifying/developing theory

Feasibility/Piloting: Testing procedures

Evaluation: Understanding change process

Steps to follow when developing an informed-choice tool for people with SMI

Step one: Identify barriers to decision-making

Step two: Theoretically underpin the intervention

Step three: Involve service users in the development of the tool

Step four: Test usability of the intervention

Step five: Assess readability levels

5.1 Understanding the barriers and enablers to cancer screening uptake in people with SMI.

In line with the MRC guidance (Craig et al., 2013), the antecedents of behaviour and the causal determinants of change (i.e. barriers to screening) first need to be appropriately identified and targeted by the intervention (Hardeman et al., 2005; Michie and Abraham, 2004; Michie et al., 2008). A literature review of the barriers and enablers to cancer screening uptake by people with SMI was therefore conducted (Abrams et al., 2012; Aggarwal et al., 2013; Clifton et al., 2016; Howard et al., 2010; Kahn et al., 2005; MacAttram and Chinegwundoh, 2014; Martens et al., 2009; Miller et al., 2007; Owen et al., 2002; Werneke et al., 2006; Xiang, 2015). The eligibility criteria used in this review were as follows:

- No restrictions on study design
- Studies reporting on the barriers and/or enablers to cancer screening in people with SMI
- No date restriction was applied in the search
- Studies where participants were defined by authors as having an SMI (even when specific diagnoses were not provided)
- The full text was published in a peer-reviewed journal
- The study was reported in English.

The following search terms were used: barriers, enablers, facilitators, levers; cancer screening, cervical screening, smear test, pap test, bowel screening, colorectal screening, breast screening, mammography, prostate cancer

screening; severe mental illness, SMI, serious mental illness, schizophrenia, bipolar disorder, psychotic depression and psychosis.

Studies were identified from a number of high-income countries (*n* = 1 Australia (Sydney); *n* = 2 Canada (Manitoba region and Toronto); *n* = 3 England (including *n* = 2 London); *n* = 1 Hong Kong; *n* = 2 Japan; *n* = 2 United States (including *n* = 1 in Boston); *n* = 1 multiple high-income countries). A systematic review explored the disparities in breast and cervical screening uptake in women with SMI and other mental health disorders (Aggarwal et al., 2013). Some studies identified in the Aggarwal (2013) review overlapped with studies identified in this literature review (Martens et al., 2009; Miller et al., 2007; Owen et al., 2002; Tilbrook et al., 2010). The literature review found that some studies focused solely on cervical screening (Martens et al., 2009; Tilbrook et al., 2010), while others included barriers to breast and cervical screening (Miller et al., 2007; Owen et al., 2002; Woodhead et al., 2016; Xiang, 2015). Other studies explored barriers to bowel, breast and cervical screening (Clifton et al., 2016; Fujiwara et al., 2017; Inagaki et al., 2018; MacAttram et al., 2014; Mo et al., 2014); in addition to these screening programmes, some studies also incorporated prostate examination (Mo et al., 2014) and lung and gastric cancer screening (Fujiwara et al., 2017; Inagaki et al., 2018).

The barriers and enablers to cervical screening that were identified in the literature review are reported in Tables 5.1 and 5.2. The barriers and enablers were extracted from the review studies (*n* = 11) and then the

barriers were grouped into three clusters. The first encompasses environmental and systemic factors, such as not receiving invitations to screening or cancer testing kits if admitted to hospital or forensic services. The second category comprises the individual's belief system, e.g. fear that the test could trigger flashbacks of sexual violence/trauma. The third group relates to symptoms of the individual's mental illness; e.g. noisy screening environments can aggravate mental health symptoms. The enablers were categorised into two clusters: environmental and systemic factors, e.g. open-ended appointments system in sexual health clinics, and the individual's belief system, e.g. being anxious to avoid further health problems.

Table 5.1 Barriers to cervical screening uptake by people with SMI.

Environmental and systemic factors:	The individual's belief system:	Symptoms of the individual's mental illness:
Not being registered with a GP *(in the UK, lack of primary care registration implies being effectively 'excluded' from health screening)*	Fear of pain associated with the procedure	Fear of entering noisy or crowded places *(e.g. getting on the bus to attend a screening appointment or a busy GP surgery waiting room)*
Lacking access to transport to attend screening	Fear of receiving a cancer diagnosis	Neglect or poor level of self-care
Lacking reminders/having too many reminders to attend a screening appointment	Fear that the test could trigger flashbacks of a traumatic event *(e.g. Sexual violence or female genital mutilation/cutting (FGM/C))*	Underreporting of physical symptoms
Lacking familiar care providers	Adverse prior experiences of screening/physical health monitoring	Denial of physical symptoms
Low income *(this barrier is relevant in health systems where there is a cost to attending a screening appointment)*	Embarrassment	Poor insight into the importance of preventive care
Not receiving invitations to screening or cancer testing kits if admitted to hospital or forensic services *(forensic services are for people who may pose a risk to others and who may have been involved in the criminal justice system)*	Feeling like a burden on health services	Poor insight into the potential significance of symptoms
Health professionals deciding not to screen due to diagnostic overshadowing	Cancer fatalism	Inability to follow through with appointments
Health professionals feeling they lack training in mental health *(clinicians who are not mental health professionals e.g. sonographer, practice nurse)*		Difficulties with booking an appointment *(e.g., having a difficult relationship with receptionist staff at the GP practice)*
Health professionals fearing they will be misunderstood regarding an invasive procedure		Mistrust of the health system
Health professionals being uncomfortable to screen people with poor levels of hygiene		Feeling stigmatised/judged by health professionals
Health professionals deciding not to screen due to high time demand for treating acute mental illness		Delusions and paranoia *(e.g. sitting in waiting rooms for long periods of time can aggravate mental health symptoms)*

Health professionals having a negative attitude towards people with mental illness, which may discourage people from getting screened.		Having an impaired ability to communicate needs and symptoms *(additional support may be available, but this places the onus on the service user to make a request for help, which may be difficult for some without formal systems for reasonable adjustments in place).*

Table 5.2 Enablers to cervical screening uptake by people with SMI.

Environmental and systemic factors:	Individual's belief system:
Familiar location	Wanting to be informed
Reminder letters and texts	Past positive experience
Open-ended appointments system in sexual health clinics	Being anxious to avoid further health problems
Staff knowledge of mental illness	Feeling 'health conscious'
Staff being understanding	Understanding of benefits of screening
Encouragement from friends, family or health professionals	
Good relationship with GP	
Good relationship with the practice nurse	
Continuity of care *(e.g. being accompanied by a mental health worker to the appointment)*	

These barriers and enablers inform the development of the components of the tool. Each component of the tool with its corresponding barrier(s) and enabler(s) is described in section 5.2.3 (Tables 5.5 and 5.6).

5.1.1 Gathering service user feedback on the barriers and enablers to cancer screening

A workshop was led by the candidate in spring 2018 at City, University of London with a service user group of people who have lived experience of mental illness (SUGAR, Service User and carer Group Advising on Research). Participants (*n* = 10) were presented with the full list of barriers and enablers to cancer screening that were identified in the literature review reported in section 5.1. Participants were asked to score each barrier and enabler in terms of importance to them in their cervical screening behaviour (1 = most important, 5 = least important). Male members of the group (*n* = 2) were asked to complete the exercise as if it related to prostate cancer screening. Results are reported in Tables 5.3 and 5.4 below.

Table 5.3 Ranking of barriers to cancer screening uptake by members of a service user group (May 2018) (*n* = 10).

Barrier	Very important	Fairly important	Important	Slightly important	Not at all important
Fear of receiving a cancer diagnosis	6	1	2	1	0
Unfriendly/negative attitude of staff	6	1	2	1	0
Having experienced trauma (including sexual/domestic violence)	6	0	3	1	0
Having experienced FGM/C (female genital mutilation/cutting)[19]	6	0	2	0	0
Long waiting times in waiting areas are problematic (e.g. when suffering from paranoia)	5	2	3	0	0
Mental health staff prioritise mental health over physical health	5	2	2	1	0
Difficult relationship with staff at GP practice (e.g. receptionist unwilling to rebook an appointment)	5	2	2	1	0
Mental health stigma of staff at GP practice/sexual health clinic	5	1	3	1	0
Not acting on physical symptoms [e.g. irregular bleeding]	5	1	3	0	0
Adverse prior experience(s) of screening/physical health check	4	3	3	0	0
Embarrassed by the procedure	4	4	2	0	0
Fear of pain associated with the procedure	3	4	2	1	0
Lack of reminders [you would not be invited for screening if you are in hospital/not registered with a GP/admitted to forensic services]	3	1	5	1	0
Mistrust of the health system	3	3	2	0	0
Does not believe smear test applies to them	2	4	1	2	0
Feeling overwhelmed with existing health and social care appointments	2	3	3	2	0
Feeling like a burden on health services	2	1	2	3	2
Lack of transport/transportation cost	0	3	5	2	0
Received too many reminders (letters, texting)	0	2	3	4	1

[19] Not ranked by male members of the group

Table 5.4 Ranking of enablers to cancer screening uptake by members of a service user group (May 2018) (*n* = 10).

Enablers	Very important	Fairly important	Important	Slightly important	Not at all important
Ask the nurse to explain procedure and ask to touch and feel the instruments	6	0	1	0	1
Bring a carer with you to the appointment for support	4	2	1	1	1
Request a smaller speculum (tool used to perform smear test)[20]	4	1	2	1	0
Request a practice nurse you feel comfortable with	3	2	3	0	1
Ask GP for Diazepam prescription (medication to reduce anxiety) before the procedure	2	5	1	0	1
If you do not want to discuss history of abuse/trauma, write it on a piece of paper and pass it to the nurse	2	3	3	0	0
Request a 'double' (i.e. longer) appointment at your GP practice	2	2	3	0	1
Request a reminder from your GP practice	2	1	3	2	1
Request the last appointment of the day at your GP practice	1	2	3	1	1
Bring earphones and music device (to help you relax)	0	1	2	6	0

Barriers to screening which scored highest were fear of receiving a cancer diagnosis, negative attitude of staff and having experienced trauma (sexual/domestic violence or FGM/C). Enablers with the highest ranking were asking the nurse to explain the procedure and being able to touch/feel the instruments, requesting a smaller speculum (tool used to perform the test) and bringing a carer to the appointment for support.

Following this exercise, a discussion among the SUGAR members on cervical screening uptake for people with SMI was facilitated by the candidate. The idea of a cervical screening informed-choice tool for women

[20] Not ranked by male members of the group

with SMI was well-received by the group. The group asked whether the tool could be sent out prior to the appointment and whether translations of the tool were planned (e.g. in Arabic), as English may be a barrier for some women. The enabler ‘Ask GP for Diazepam prescription (medication to reduce anxiety) before the procedure’ triggered a debate within the group. Some felt it was important to reduce anxiety before the test, while others felt it could be risky, given some people’s history of substance misuse with prescribed medication. The group discussed suggestions to include in the tool, such as requesting the first appointment of the day to avoid long waiting times in a crowded GP surgery. The full list of suggestions is contained in Appendix 4; these were incorporated into the draft tool, which was then checked for clinical accuracy (Chapter Six) and tested with service users and health professionals for acceptability and usability (Chapters Seven and Eight).

Additional barriers were discussed by participants; several of these overlapped with those identified in the literature review (section 5.1):

- Hygiene problems can make you feel embarrassed
- Not wanting to share health problems with people that hardly know them
- ‘If I am, say, psychotic, I may believe that an invasive procedure is tantamount to assault’
- Anxiety about travel and going to new places

- Focus on weight/speaking about weight whenever someone goes to the GP (e.g. if someone has a history of an eating disorder) can put people off *any* appointment to the GP practice
- Some women may have a different anatomy and be embarrassed
- Unfair that inpatients/people without a GP miss out on screening
- Getting the leaflet to the people who need it the most may be challenging
- Paranoia is an issue (waiting room can cause anxiety, also fear that you might get infected with something during your smear or someone inserts a chip to keep track of you).

Some of the above barriers relate to systemic or societal barriers to screening, which cannot be addressed by this tool (e.g. 'unfair that inpatients/people without a GP miss out on screening'). Suggestions from the service user group were incorporated into the draft tool, which was then revised to ensure clinical accuracy (see Chapter Six) and acceptability with service users (see Chapter Seven). The next section covers the theoretical frameworks used to develop the tool.

5.2 Identifying theoretical framework(s) to underpin the development of tool

Cancer screening uptake is described as a behaviour to protect health (Michie et al., 2017). Screening itself is not considered a homogeneous behaviour (Marteau, 1993); cervical screening attendance can be described as a complex protective behaviour, since it requires several steps to achieve the behaviour (Sheeran and Orbell, 2000). It is therefore important to

understand the theoretical construct of this behaviour, namely cervical screening uptake and the determinants of behaviour change in this context. There are several relevant theories, concepts and techniques to be considered when developing a theoretically underpinned tool. The tool was developed using several theoretical frameworks; the rationale for their use will be discussed in the following section.

5.2.1 The Theory of Planned Behaviour

First, the theoretical construct of an individual's behaviour in the context of cervical screening was explored using the Theory of Planned Behaviour (TPB) (Godin and Kok, 1996; Schifter and Ajzen, 1985). The TPB is based on the premise that an individual's 'cognitive determinants', namely attitude, subject norms and perceived behavioural control, together determine their behavioural intentions and behaviour (Michie et al., 2004). Within this model, attitude is defined as an individual's positive or negative evaluation of performing the behaviour. Subjective norms reflect an individual's perceptions of social approval for performing the behaviour, while perceived behavioural control suggests being able to perform the behaviour in the face of 'internal' and 'external' barriers. The TPB posits that people form an intention in advance of behaviour (Ajzen, 1985, 1991). Each cognitive determinant makes an independent contribution to the intention to perform a behaviour, the latter then makes an independent contribution to performing the behaviour (Michie et al., 2004). These constructs of the TPB in the context of cervical screening for women with SMI are depicted in Figure 5.1.

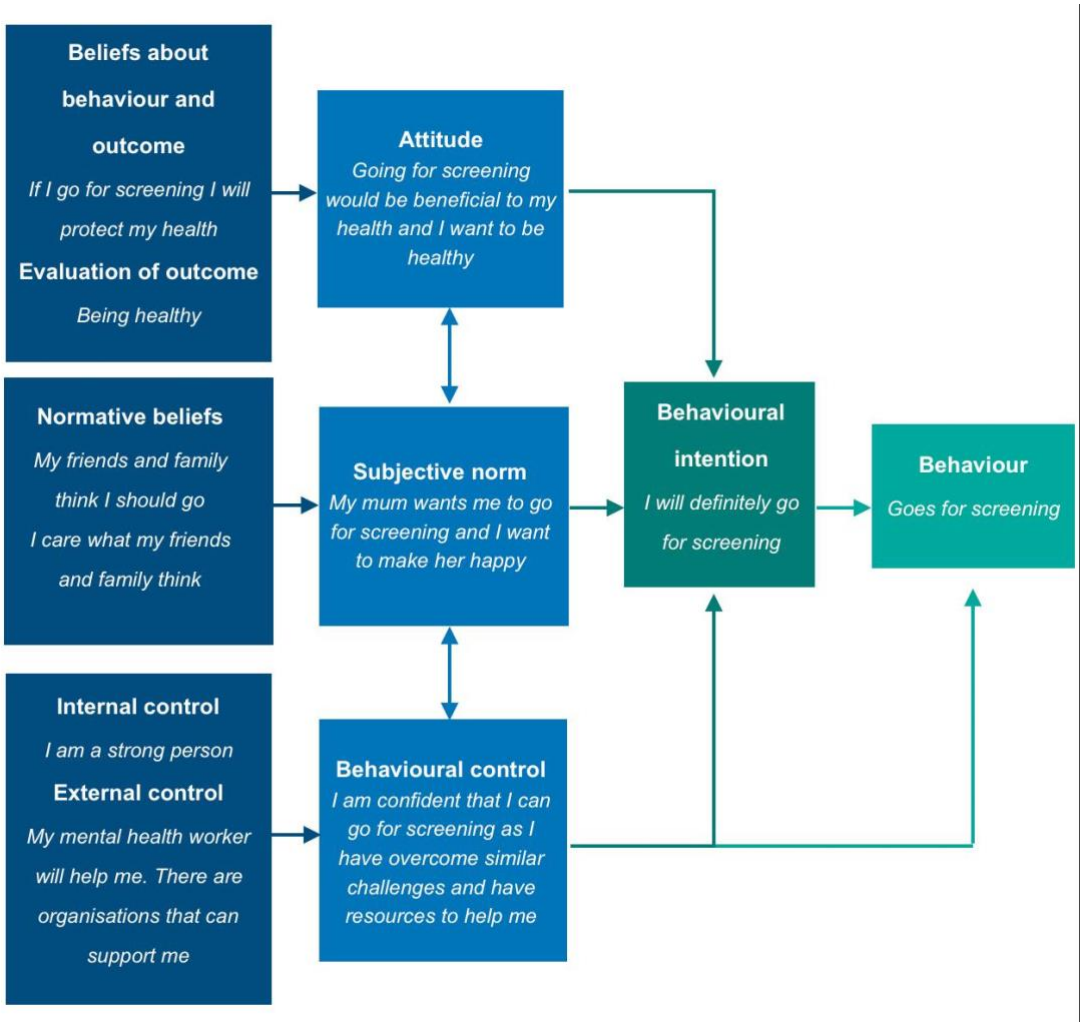


Figure 5.1 Theory of Planned Behaviour as applied to cervical screening attendance for women with SMI (Azjen, 1991).

The TPB has been applied to decision-making scenarios and been used as a theoretical framework for decision-making tools (Kasper et al., 2012; Krones et al., 2010; Sivell et al.,2013), and it has been shown to predict a range of health-related behaviours (Armitage and Conner, 2001; Johnston et al., 2004), including uptake of cancer screening tests (Ogilvie et al. 2013; Roncancio et al., 2013; Rutter, 2000; Sheeran and Orbell, 2000; Sieverding et al., 2010; Tolma et al., 2006). In addition, the TPB was identified in Study Two, the systematic review of informed-choice tools for people with SMI (Chapter Four) as a relevant model for informing content development,

thereby ensuring that the informed-choice tools were theoretically underpinned. For the reasons stated above, the TPB was selected for this research, and a critical appraisal of this theory is discussed in Chapter Ten (see section 10.3). The TPB links a person's beliefs and behaviour (Godin and Kok, 1996; Schifter and Ajzen, 1985). Research has shown that an individual's belief system is a variable that could affect their intention to attend screening (Roncancio et al., 2013). For women with SMI, the range of beliefs that can act as barriers or enablers to uptake of cervical screening were listed in the previous section (Tables 5.1 and 5.2). The preliminary data analysis (see Chapter Nine, section 9.4) will borrow some of the constructs of the TPB (see Figure 5.1) to categorise the impact of the tool on participants' decision-making.

5.2.2 The Theoretical Domains Framework

The Theoretical Domains Framework (TDF) was the selected framework to underpin the tool (Cane et al., 2012). Informed by 128 explanatory constructs from 33 theories of behaviour, the TDF has been used in several contexts to understand health behaviour and design theoretically informed interventions (Cane et al., 2012; Francis et al., 2012; French et al., 2012; Michie et al., 2005). The TDF covers 14 domains, comprising the main evidence-based factors influencing behaviour change, such as knowledge about the behaviour, beliefs about the consequences of the target behaviour, social influences such as the attitudes of relatives, and the environmental context. The TDF was selected in a qualitative study to explore the cancer screening behaviours of people with SMI (Clifton et al., 2016); the chosen domains are

listed in Tables 5.5 and 5.6. As part of the Clifton et al. (2016) study, health and screening professionals were also interviewed to explore their experience of offering and providing cancer screening to people with SMI. Through triangulation of data from service users and health and screening professionals, authors were able to identify five overarching themes or factors influencing cancer screening behaviour for which there was at least partial agreement:

1) Knowledge of screening programmes and processes,
2) Knowledge of and attitudes regarding mental illness,
3) Health service delivery factors,
4) Beliefs and concerns of people with SMI regarding screening and
5) Practicalities for people with SMI.

The barriers and enablers, which could be associated with the different stages of screening, were identified. Authors of the Clifton et al. (2016) study coded each barrier and enabler to a TDF domain; based on those findings, each component of the tool was mapped out using the identified barriers and enablers, underpinned by the TDF (Cane et al., 2012). A critical appraisal of the TDF in relation to the development of the tool is presented in Chapter Ten (see section 10.4).

Some of the identified barriers could not be targeted by the tool, as they required change at the provider or societal level (e.g. service users who are barred from GP practices) (Clifton et al., 2016), while this research focused

on individual determinants of health behaviour. The following section describes how the components of the tool were developed to overcome the barriers and enhance the enablers to screening uptake by women with SMI (French et al., 2012).

5.2.3 Component behaviour change techniques

To develop the components of the tool, the taxonomy of behaviour change techniques (Michie et al., 2015) was used. A behaviour change technique (BCT) can be defined as one of the 'active ingredients' (or components) of an intervention that is 'an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour'' (Michie et al., 2013: 23). The MRC guidance for developing and evaluating complex interventions recommends specifying the 'active ingredients' as a required step to establish how an intervention can be effective across its target population group and setting (Craig et al., 2008). Behaviour change techniques (BCTs) are classified in a taxonomy of 93 hierarchically-clustered techniques and grouped into 19 categories (Michie et al., 2015). Every BCT is numbered and given a title (e.g. *4.1 Information on how to perform the behaviour*). The taxonomy maps the BCTs to the 14 domains of the TDF (Cane et al., 2014; French et al., 2012; Michie et al., 2008). Each TDF domain has BCTs allocated to it, for example 'Behavioural Regulation' (TDF domain 14) had 68 BCTs assigned to it.

To develop the components of the tool, behaviour change techniques (Michie et al., 2015) were selected in conjunction with the domains of the TDF that

had been identified in earlier research (Clifton et al., 2016); these are listed in Tables 5.5 and 5.6. Each BCT was selected and tailored to be used in the tool and to promote change (Michie and Prestwich, 2010; Michie et al., 2008; Rothman, 2004). Using BCTs to develop the tool facilitates further exploration of the links between the components of the intervention and its desired effects (Michie et al., 2009). The BCTs were coded by two researchers [the candidate and a chartered psychologist with expertise in health psychology], who independently linked each BCT to the barrier(s) or enabler(s) components of the tool (themselves underpinned by the TDF), and this coding exercise was verified by a third researcher [a health psychologist]. A summary is presented for the barriers and enablers to cancer screening in Tables 5.5 and 5.6, respectively. Some BCTs were originally coded and subsequently removed following a discussion within the coding team. These are displayed in Appendix 5 to demonstrate the thought process that underpinned the final selection of BCTs.

Table 5.5 Coding of component behaviour change techniques to identified barriers underpinned by the TDF.

Barrier to cancer screening (Clifton et al., 2016)	TDF Domain (Cane et al., 2012)	Component behaviour change technique(s) (Michie et al., 2015)
Not knowing what to expect or what to do	Knowledge [of condition]	4.1 Information on how to perform the behaviour
Unsure of need for screening	[Procedural] Knowledge	13.2 Framing/reframing
Difficult to process information	Memory, attention and decision processes [Cognitive overload, tiredness, attention control]	11.3 Conserving mental resources
Additional burden	Goals [goal priority]	1.3 Goal setting (outcome) 1.4 Action planning 9.3 Comparative imagining of future outcomes
Mental health symptoms reduce motivation for self-care	Goals	1.3 Goal setting (outcome) 1.4 Action planning 3.3 Social support (emotional)
Stigma of mental illness	Emotion	3.3 Social support (emotional) 11.3 Conserving mental resources
Past negative experience	Emotion	3.3 Social support (emotional)
Embarrassment	Emotion	12.6 Body changes 3.3 Social support (emotional)
Traumatising	Emotion	3.3 Social support (emotional) 5.4 Monitoring of emotional consequences 11.2 Reduce negative emotions
Fear of bad news	Emotion	3.3 Social support (emotional) 11.2 Reducing negative emotions 13.2 Framing/reframing
Lack of understanding of mental illness in screening professionals	Behavioural regulation	No BCT was identified

Screening environment aggravates mental health symptoms	Behavioural regulation	3.3 Social support (emotional) 5.4 Monitoring of emotional consequences 6.1 Demonstration of the behaviour 12.2 Restructuring the social environment
Staff can be rushed	Behavioural regulation	3.3 Social support (emotional) 12.2 Restructuring the social environment
Staff can be rough	Behavioural regulation	3.3 Social support (emotional)
Exclusion from GP registers	Behavioural regulation	No BCT was identified
Appointment booking	Environmental context and resources	4.1 Instruction on how to perform behaviour 11.3 Conserving mental resources
Transport difficulties	Environmental context and resources	4.1 Instruction on how to perform behaviour 11.3 Conserving mental resources
Difficulty remembering appointments	Environmental context and resources	6.1 Demonstration of the behaviour 11.3 Conserving mental resources
Difficulty leaving the house due to mental health problems	Environmental context and resources	3.3 Social support (emotional) 11.2 Reduce negative emotions
Taking time off	Environmental context and resources	No BCT was identified
Made to feel like a burden on health service	Emotion	3.3 Social support (emotional)
Poor relationship with GP	Emotion	12.2 Restructuring the social environment
Diagnostic overshadowing	Emotion	No BCT was identified

Table 5.6 Coding of component behaviour change techniques to identified enablers underpinned by the TDF.

Enabler to cancer screening (Clifton et al., 2016)	TDF Domain (Cane et al., 2012)	Component behaviour change technique(s) (Michie et al., 2015)
Wanting to be informed	Knowledge	4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences
Understanding of benefits of screening	Knowledge	5.1 Information about health consequences
Encouragement	Social influences	3.2 Social support (practical) 3.3 Social support (emotional) 6.1 Demonstration of the behaviour 11.3 Conserving mental resources 15.1 Verbal persuasion about capability
Feeling 'health conscious'	Goals	1.3 Goal setting (outcome) 5.1 Information about health consequences
Being anxious to avoid further health problems	Goals	1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 2.3 Self-monitoring of behaviour
Physical symptoms	Goals	1.3 Goal setting (outcome) 1.4 Action planning 5.1 Information about health consequences 7.1 Prompt/cues
Past positive experience	Emotion	15.3 Focus on past success
Staff being understanding	Behavioural regulation	3.3 Social support (emotional)
Staff knowledge of mental illness	Behavioural regulation	No BCT was identified
Familiar location	Environmental context and resources	12.1 Restructuring the physical environment
Reminders	Environmental context and resources	6.1 Demonstration of the behaviour 7.1 Prompt/cues
Good relationship with GP	Emotion	3.3 Social support (emotional)
Good relationship with Practice Nurse	Emotion	3.3 Social support (emotional)
Continuity of care	Emotion	3.2 Social support (practical) 3.3 Social support (emotional)

These component behaviour change techniques were used to develop the draft components of the tool; an example of how a behaviour change technique facilitated the development of each component of the tool is described below.

5.2.4 Draft components of the tool

The tool was formatted as an A5 paper colour leaflet. The table of contents of the initial draft of the tool (Version 0.1, Appendix 6) is provided in the box below. The following section details how the draft content of each component was developed and lists which barriers and enablers it addresses. An example of how a BCT was used to develop the content of the draft tool for each component is provided below.

Version 0.1

Title: Thinking about cervical screening (smear test)
Why this leaflet was developed
Why am I invited for cervical screening?
What happens on the day?
Common questions and anxieties
Tips for booking your appointment
Getting ready for your appointment
Your appointment day
What happens next?
Additional information

‘*Why this leaflet was developed’*

This page provides a brief context as to why the tool was developed and who it is intended for. This first section also outlines that the purpose of the tool is to help women make a decision whether to attend screening and can be used to plan their appointment.

Component one: *‘Why am I invited for cervical screening?’*

Description of content

This component outlines:

- who is eligible for screening,
- what cervical screening is for and
- the benefits of attending and what happens if you test positive for HPV

This page was later revised to include more information on the risks of non-attendance (see Chapter Seven, section 7.3.2).

Rationale for content

This component addressed the following barriers: unsure of need for screening, fear of bad news (see Table 5.1).

This component incorporated the following enablers: understanding of benefits of screening, feeling ‘health conscious’, being anxious to avoid further health problems, familiar location.

Theory used

The selected BCTs included: 1.1 Goal setting (behaviour), 1.3 Goal setting (outcome), 3.3 Social support (emotional), 5.1 Information about health consequences, 11.2 Reducing negative emotions, 13.2 Framing/reframing.

Application of a BCT to the development of this component

Behaviour change technique *5.1 Information about health consequences* is defined as 'Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour' (Michie et al., 2015). This section highlighted the positive health consequences of attending the screening appointment (e.g. 'Having a smear test lowers your chances of getting cervical cancer' and 'If you have cancer, getting it diagnosed and treated early can save your life').

Component two: *'What happens on the day'*

Description of content

This component lists each step of a cervical screen test (e.g. 'The nurse or doctor will ask you to undress from your waist down and lie on a bed with your knees bent and apart' and 'A small brush (like a long cotton bud) will be used to take a sample from the surface of your cervix').

Rationale for content

This component addressed the following barriers: not knowing what to expect or what to do, traumatising.

This component incorporated the following enablers: wanting to be informed.

Theory used

Selected BCTs: 4.1 Instruction on how to perform the behaviour and 5.1 Information about health consequences.

Application of a BCT to the development of this component

Behaviour change technique *4.1 Instruction on how to perform the behaviour* is defined as 'Advise or agree on how to perform the behaviour' (Michie et al., 2015). This section of the tool describes the steps that a woman needs to take in order to be screened.

Component three: *'Common questions and anxieties'*

Description of content

This component includes quotes from service users from the Clifton et al. (2016) qualitative study (e.g. 'It's hard for me to leave the house' and 'I have a poor relationship with my GP/nurse'). It also includes an action planning text box where users can write down what would help them attend their appointment and suggests thinking of reasons why they might want to go and why they think it is important.

Rationale for content

This component addressed the following barriers: Going for screening is an additional burden.

This component incorporated the following enablers: Past positive experience, Being anxious to avoid further health problems, Feeling 'health conscious', Encouragement.

Theory used

Selected BCTs: 1.3 Goal setting (outcome), 1.4 Action planning, 9.3 Comparative imagining of future outcomes, 15.3 Focus on past success.

Application of a BCT to the development of this component

Behaviour change technique *1.4 Action Planning* is defined as 'Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive) and includes 'implementation intentions'' (Michie et al., 2015).

Currently in England, women receive an open invitation for cervical screening, which requires them to think not only *if*, but also *when*, *how,* and *where* they will attend their appointment and possibly *whom/what* to bring to the appointment. It is necessary for them to make an appointment to successfully enact the cancer screening behaviour. One way to reduce this 'gap' between intentions and performing the behaviour (i.e. screening attendance) is to form implementation intentions (Gollwitzer, 1993). This would involve a woman outlining the various steps required to perform the behaviour. The tool is structured around the five steps required to perform

the screening behaviour. For each step, a list of tips/support available is provided as an action plan to form an implementation intention to perform the behaviour.

Step one: Make an informed decision whether to attend, which may include getting informed on what support is available.
Relevant components: *What is cervical screening, Booking your appointment, Tick-box page* and *Getting Support.*

Step two: Book the appointment.
Relevant component: *Booking your appointment.*

Step three: (Possibly) plan a set of actions to prepare for the appointment.
Relevant components: *Before your appointment, 'Action plan' boxes* and *Tick-box page.*

Step four: travel to your appointment.
Relevant component: *Before your appointment.*

Step five: attend the appointment.
Relevant component: *During your appointment.*

Component four: *'Tick box page'*

Description of content

This component is presented as an optional list of statements to tick. Each box represents a service user's barrier to cancer screening. It was developed as a 'disclosure aid' to support women who may find it hard to discuss their issue(s) with the nurse. This component is designed to be shown to the nurse before the test, so he/she becomes aware of the barrier/issue(s) without having to discuss them. This '*tick box page*' may also help elicit understanding and empathy from the screening professional by providing context for the patient's personal circumstances. It may also help emotional regulation by removing the necessity for the person being screened to disclose a painful episode or something she finds embarrassing.
Below are some examples of 'tick box options':

- ☑ I am a voices hearer and get distressed during a physical exam
- ☑ My medication makes me shake
- ☑ I have visible cutting scars
- ☑ I survived a traumatic experience

<u>Rationale for content</u>

This component addressed the following barriers: difficult to process information, mental health symptoms reduce motivation for self-care, stigma of mental illness, past negative experience, embarrassment, traumatising, lack of understanding of mental illness in screening professionals, screening environment aggravates mental health symptoms, staff can be rushed, staff can be rough, difficulty leaving the house due to mental health problems, made to feel like a burden on the health service.

This component incorporated the following enablers: staff being understanding, good relationship with GP, good relationship with practice nurse.

Theory used

Selected BCT: 3.3 Social support (emotional), 5.4 Monitoring of emotional consequences, 6.1 Demonstration of the behaviour, 11.2 Reduce negative emotions, 11.3 Conserving mental resources, 12.2 Restructuring the social environment, 12.6 Body changes.

Application of a BCT to the development of this component

Behaviour change technique *6.1 Demonstration of the behaviour* is defined as trying 'to provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate' (Michie et al., 2015).

Empty text boxes were included throughout the draft to include quotes extracted from forthcoming service user interviews in order to demonstrate the behaviour that is being highlighted in a particular section. There is some evidence that integrating a 'narrative communication' (e.g. 'And I'd feel awful if my kids got sick because I didn't get them vaccinated') within a health intervention can be an active ingredient to encourage a particular behaviour (Brewer, 2016; Hinyard and Kreuter, 2007). This technique has also been used in the context of cancer screening (Bailey et al., 2000; Erwin et al.,

1996, 1999) and is suggested as a step (Chapter E: *Using personal stories*) to follow when developing a patient decision aid (Bekker et al., 2012).

5) Component five: *'Tips for booking your appointment'*

Description of content

In this section, a list of things to ask the receptionist when booking an appointment is provided, further to feedback received from the SUGAR service user group. Examples of items to let the staff know include:

- 'Want to be seen by a female or male member of staff',
- 'Would like to receive a reminder',
- 'Need a double appointment',
- 'Get anxious in waiting rooms. Ask for the first or last appointment of the day'.

Rationale for content

This component addressed the following barriers: additional burden, screening environment aggravates mental health symptoms, staff can be rushed, appointment booking, difficulty remembering appointments.
This component incorporated the following enablers: reminders.

Theory used

Selected BCTs: 3.3 Social support (emotional), 4.1 Instruction on how to perform behaviour, 6.1 Demonstration of the behaviour, 7.1 prompt/cues,

11.3 Conserving mental resources, 12.2 Restructuring the social environment.

Application of a BCT to the development of this component

Behaviour change technique *6.1 Demonstration of the behaviour* is defined as trying 'to change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments)' (Michie et al., 2015). The tips provided in this section of the tool may help change the service user's social environment (e.g. by booking the first appointment of the day), which can reduce the risk of the environment triggering mental health symptoms, such as auditory hallucinations and anxiety.

Component six: *'Getting ready for your appointment'*

Description of content

This section provides a list of tips, based on feedback from the SUGAR group and a consultant nurse working for the *My Body Back*[21] charity. These suggestions may help to improve women's screening experience such as:

- Planning your travel to the appointment (e.g. checking bus times)
- Bringing something comforting or relaxing (e.g. music player)
- Wearing a skirt or dress (thereby avoiding having to fully undress)

[21] Specialist cervical screening clinic for women who have experienced sexual violence.

- Speaking to the nurse beforehand (e.g. if you require a pessary prescription)
- Asking someone to accompany you on the day [this may encourage continuity of care if the woman asks her mental health worker to accompany her to the screening appointment]
- Planning something nice and relaxing after the appointment (e.g. going for a walk in the park with a friend)
- Write down and bring to the appointment a list of things that bother you about the test (e.g. parts of the body to avoid touching, whether you want the door locked or unlocked) as well as words that can trigger a panic attack. Suggestion to list alternative safe words instead.

Rationale for content

This component addressed the following barriers: additional burden, mental health symptoms reduce motivation for self-care, embarrassment, screening environment aggravates mental health symptoms, transport difficulties, difficulty remembering appointments, difficulty leaving the house due to mental health problems.

This component incorporated the following enablers: encouragement, reminders, continuity of care.

Theory used

Selected BCTs: 1.3 Goal setting (outcome), 1.4 Action planning, 3.2 Social support (practical), 3.3 Social support (emotional), 4.1 Instruction on how to perform behaviour, 6.1 Demonstration of the behaviour, 9.3 Comparative imagining of future outcomes, 11.2 Reduce negative emotions, 11.3 Conserving mental resources, 12.6 Body changes, 15.1 Verbal persuasion about capability.

Application of a BCT to the development of this component

Behaviour change technique *3.3 Social support (emotional)* is defined as trying to 'advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour' (Michie et al., 2015). The example given in the taxonomy was identical to the suggestion provided in the tool in relation to cervical screening: 'Ask the patient to take a partner or friend with them to their colonoscopy appointment' (Michie et al., 2015).

Component seven: *'Your appointment day'*

Description of content

This section provides a list of suggestions to help women feel more relaxed and in control during the screening test. The list is based on feedback from the SUGAR group and a consultant nurse working for the *My Body Back* charity. Suggestions include:

- A reminder that you can ask the nurse to stop at anytime
- Ask for sedation from your GP if you think this may be necessary

- Agree with the smear taker on a clear signal to stop if you need to
- Ask for a thinner/narrower speculum and more lubricant if you think it may hurt.

Rationale for content

This component addressed the following barriers: staff can be rushed, lack of understanding of mental illness in screening professionals, traumatising, past negative experience.

This component incorporated the following enablers: past positive experience, good relationship with GP, good relationship with practice nurse, staff being understanding.

Theory used

Selected BCTs: 3.3 Social support (emotional), 5.4 Monitoring of emotional consequences, 11.2 Reduce negative emotions.

Application of a BCT to the development of this component

Behaviour change technique *11.2 Reduce negative emotions* is defined as trying to 'advise on ways of reducing negative emotions to facilitate performance of the behaviour' (Michie et al., 2015). This section of the tool lists several suggestions (e.g. agreeing with the smear taker on a stop signal) to reduce the risk that the smear test elicits painful memories from a traumatic event.

Component eight: '*What happens next?'*

Description of content

This section explains what happens after the test. The contact details of Jo's Cervical Cancer Trust are provided if they need support after the test. A list of the symptoms to be aware of in between cervical screening appointments (e.g. 'bleeding between your periods, after sex, or after the menopause' and 'pain or discomfort during sex') is presented. This section explains what to do if symptoms appear.

Rationale for content

This component addressed the following barriers: not know what to expect or what to do, fear of bad news, unsure of need for screening, additional burden, mental health symptoms reduce motivation for self-care, embarrassment.

This component incorporated the following enablers: wanting to be informed, understanding of benefits of screening, feeling 'health conscious', being anxious to avoid further health problems, physical symptoms.

Theory used

Selected BCTs: 1.3 Goal setting (outcome), 1.4 Action planning, 2.3 Self-monitoring of behaviour, 3.3 Social support (emotional), 4.1 Instruction on how to perform the behaviour, 5.1 Information about health consequences, 7.1 Prompt/cues, 11.2 Reducing negative emotions, 13.2 Framing/reframing.

Application of a BCT to the development of this component

Behaviour change technique *2.3 Self-monitoring of behaviour* is defined as trying to 'establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy' (Michie et al., 2015). Part of this section explains what a woman should do if she has unusual symptoms (e.g. irregular bleeding), which includes being aware of the symptoms, not waiting for the next screening appointment and speaking with a health professional if symptoms appear.

Component nine: '*Additional information'*

Description of content

Considering the high rate of trauma in this group, a review of less-invasive alternatives to cervical screening was conducted, which is reported in Chapter Six (section 6.2.2). This last component includes the option of ordering an HPV 'home testing' kit, if women feel that they cannot go through with cervical screening.

Organisations women can get in touch with if they need someone to talk to are provided; these can provide specialist support or advice on cervical screening. The contact details of Jo's Cervical Cancer Trust are provided if they need support or encouragement to attend their appointment. It also includes the contact details of the 'My Body Back Project' which is a specialist cervical screening clinic in London and Glasgow for women who have experienced sexual violence.

Rationale for content

This component addressed the following barriers: past negative experience, traumatising, fear of bad news, difficulty leaving the house due to mental health symptoms, poor relationship with GP.

This component incorporated the following enabler: encouragement.

Theory used

Selected BCTs: 3.2 Social support (practical), 3.3 Social support (emotional), 5.4 Monitoring of emotional consequences, 6.1 Demonstration of the behaviour, 11.2 Reduce negative emotions, 11.3 Conserving mental resources, 12.1 Restructuring the physical environment, 12.2 Restructuring the social environment, 15.1 Verbal persuasion about capability.

Application of a BCT to the development of this component

Behaviour change technique *12.1 Restructuring the physical environment* is defined as trying to 'change, or advise to change, the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments)' (Michie et al., 2015). For women who have experienced sexual violence and find it hard to attend their cervical screening appointment, a specialist clinic exists to support them (the My Body Back charity, with clinics in London and Glasgow). Including the contact details of the charity may help some women who would otherwise not want to be screened.

Chapter summary

This section has detailed how each component of the tool was theoretically underpinned using the BCTs and barriers and enablers to cancer screening uptake, which are mapped to the TDF. An example of how a BCT was used to develop the content of the draft tool was provided for each component. Use of the barriers and enablers to cervical screening identified in the literature review (reported in section 5.1), as well as the relevant component behaviour change techniques (section 5.2.3), ensured that the development of the tool was theoretically underpinned. This fulfils the first and second key objectives of this PhD research, namely that the tool be developed using identified barriers to cancer screening for this group, and that it be theoretically underpinned. Using these techniques, a draft of the tool (Version 0.1, Appendix 6) was developed.

In the following three chapters, the data collection pertaining to the tool is reported. Verification of the tool's clinical accuracy is reported in the next chapter (Six), followed by testing its acceptability (Chapter Seven) and usability (Chapter Eight) with key stakeholders.

Chapter Six – Conception and design of the tool: Stakeholder involvement

In this chapter, the process of involving stakeholders to refine the tool is described. A list of key stakeholders and the importance of their input in the development of the tool is provided. This step was important for ensuring acceptability and usability of the tool by both women with SMI and health professionals. Stakeholders were involved at every stage of the development of the tool. During the initial phase, they informed the development of a version appropriate for acceptability testing, including ensuring that the content was clinically accurate and unambiguous.

6.1 Stakeholder involvement

As reported in Chapter Five, a first draft of the tool (Version 0.1) was produced. As per recommendations from the systematic review (Chapter Four), stakeholders were to be involved at every step of the development of the tool. For this research, stakeholders include women with SMI and service user groups, health professionals, public health policymakers and third sector organisations, such as cancer and mental health charities. Including these groups was essential to ensure women with SMI had a voice and that the tool was usable and acceptable both to them and their health professionals. In addition, all stakeholders provided useful suggestions on how and where to disseminate the tool. In terms of the relative importance of stakeholder input, feedback from women with SMI was given the most weight, followed

by that from the health professionals (working in primary and secondary care). Women with SMI who access secondary mental health care and health professionals who work in that setting were later recruited to test the acceptability and usability of the tool; this is reported in Chapters Seven and Eight, respectively. The ‘co-production’ model is founded on the principle of equity within the relationship between the researcher and the PPI (Patient and Public Involvement) participant, which is an approach to service design and shared decision-making (Involve, 2012; Slay and Stephens, 2013). This model was not selected for this research, as it would have been difficult to find the necessary resources for one person to put in the considerable amount of time required for such an approach. In addition, the candidate sought to gain experience of having primary responsibility for designing this research, as well as collecting and analysing the data, with the aim of acquiring the necessary skills towards becoming an independent researcher.

A multi-disciplinary expert group of stakeholders – thereafter key informants group – was established at the beginning of the process to inform the development of the tool in an iterative manner. Convenience sampling plus snowball sampling was used to identify stakeholders, namely individual experts and relevant organisations who would likely be knowledgeable about the topic. Initial contact with Jo’s Cervical Cancer Trust, the national cervical cancer charity, was established on social media during Cervical Cancer Prevention Week in January 2018; this resulted in the charity joining the stakeholder group and the candidate being introduced to experts working in specialist cervical screening clinics via the cervical cancer charity.

Representatives from Public Health England (PHE) joined the stakeholder group after being informed about the project. Two service user groups and several health professionals who were contacted for this research had been involved with the candidate for prior research on diabetes care for people with SMI (McBain et al., 2016, 2018; Mulligan et al., 2017, 2018). Having displayed a research interest in the physical health of people living with SMI, they were contacted for the purpose of this project and agreed to give feedback on the tool. Members of the key informants group were clustered into five categories, which are listed below:

- Service user groups (n = 4): a group with lived experience of cervical cancer and mental illness (jointly funded by Mind and MacMillan in Middlesbrough), Ealing Mental Health Forum[22] (funded by the Community and Voluntary Service charity), the National Survivor User Network[23] (NSUN) and the Service User and carer Group Advising on Research[24] (SUGAR) based at City, University of London

- Specialised cervical screening clinics (*n* = 4): East London clinic for women who have experienced FGM[25], My Body Back project[26] (for women who have experienced sexual violence), SHRINE[27] (for

[22] https://www.ealingcvs.org.uk/about/
[23] https://www.nsun.org.uk/
[24] https://blogs.city.ac.uk/sugar/
[25] https://www.bartshealth.nhs.uk/news/helping-women-who-have-suffered-female-genital-mutilation--5400
[26] http://www.mybodybackproject.com
[27] https://www.kingshealthpartners.org/our-work/mind-and-body/our-projects/shrine

women with SMI, drug misuse and learning disabilities) and a Well Woman clinic for patients on an inpatient mental health ward[28]

- Charities (*n* = 2): Healing our Way CIC[29] (specialist training to help professionals improve their understanding of trauma/sexual violence) and Jo's Cervical Cancer Trust[30]
- National public health stakeholders (*n* = 2): Public Health England: different teams within NHS screening programme and UK Department of Health and Social Care: Research Programme Manager
- NHS clinicians/clinical academics with an interest in the physical health of people living with SMI (*n* = 5): a GP working in a mental health setting and a GP with expertise in SMI (Newham CCG), a GP with dual training in psychiatry based in London, a psychiatric nurse with expertise in cancer screening in SMI (Nottingham University Hospitals NHS Trust) and a professor of mental health nursing based in London.

PPI (Patient and Public Involvement) comprised six rounds, which included every stage of the development of the tool (see Figure 6.1 below). Round one consisted of feedback collected on the draft protocol and research materials prior to the submission of the candidate's application to the NHS Research Ethics Committee (REC) to recruit service users and NHS health professionals. The results of round one are reported in Chapter Seven (see section 7.1) as this round involved gathering feedback on the empirical

[28] https://www.ghc.nhs.uk/news/gloucestershire-cervical-screening-project-wins-national-award/
[29] https://healingourway.wixsite.com/howcic
[30] www.jostrust.org.uk

aspects of the research and the fieldwork materials. Round two, previously reported in section 5.1.1, consisted of feedback collected on the barriers and enablers to cancer screening with a service user group (SUGAR). Round three of stakeholder involvement is described in this chapter. Rounds four (Chapter Seven) and five (Chapter Eight) consisted of email feedback from members of the key informants group, as well as service users and health professionals who access and work in secondary care. The final round of stakeholder involvement consisted of feedback from the key organisations involved in the development of the tool (see Chapter Eight, section 8.5).

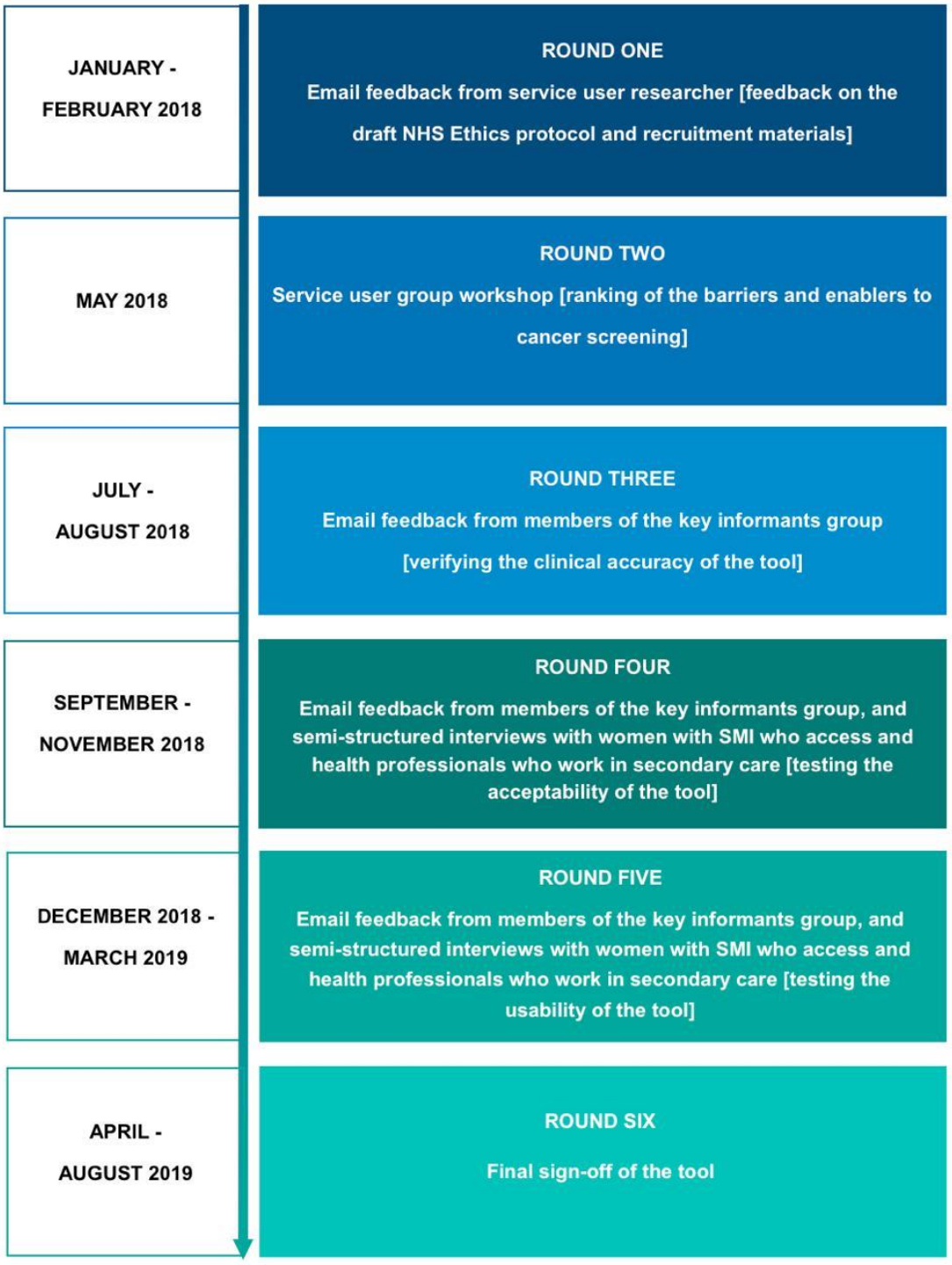


Figure 6.1 Rounds of stakeholder involvement in the development of the tool.

Figure 6.1 lists the different stages of stakeholder involvement in chronological order. 'Round one' is presented in Chapter Seven (see section 7.1.2), which describes service user feedback on the NHS ethics application to recruit service users and health professionals. Chapter Five includes

‘Round two’; section 5.1.1 reports the feedback from a service user group on the initial components of the tool.

6.2 Round three – Verifying the clinical accuracy of the tool

6.2.1 HPV primary testing

Before the tool could be tested with service users, verification that it complied with current NHS cervical screening guidelines was ascertained (NHS, n.d.; PHE Screening, 2019). During this PhD research, a novel method for cervical screening cytology – ‘primary HPV testing’ - was introduced across the NHS. In 2016, it was announced that primary HPV screening would be implemented into the NHS Cervical Screening Programme. From December 2019, primary HPV screening has been fully rolled out and is being offered across England as part of the NHS Cervical Screening Programme (PHE, 2019). To receive this screening, women still need to make an appointment to have a smear test. The difference between the two tests concerns the examination of the collected cells (cytology). While previously cytology identified cellular changes associated with precancerous cervical lesions, primary HPV screening identifies the infection that triggers these cellular changes. Ample evidence has shown that infection with high-risk types of HPV is a requisite step to develop cervical cancer or pre-cancerous lesions (Walboomers et al., 1999).

Increasing evidence has shown that cervical screening with primary HPV testing coupled with cytology triage is more effective than cervical screening with cytology triage at detecting relevant precancerous lesions and

decreases cervical cancer incidence (Bains et al., 2019; Lew et al., 2017; Ogilvie et al., 2013). Over 200 types of HPV have been identified (Burd, 2003); the approach for screening is to use hr (high-risk) HPV testing as a primary screening test, with cytology reserved only for triage of women who test positive for HPV. This change had to be reflected in the tool. Thus, a definition of HPV and its causal link with cervical cancer was included in the draft tool; this triggered a discussion with members of the key informants group, which is discussed below.

6.2.2 Collection and analysis of feedback on the clinical accuracy of the tool

Version 0.1 of the tool was emailed in July 2018 to health professionals who are members of the key informants group (excluding the service user groups to avoid providing them with potentially inaccurate information) to verify the clinical content of the tool. A content analysis of the feedback received (by email) was conducted (Hsieh and Shannon, 2005; Owen, 2012). Content analysis is defined as a research method that seeks valid inferences from qualitative data to the context or environment in which they were produced (Downe-Wambolt, 1992; Krippendorff, 2004). It consists of two steps: first, to quantify and analyse the presence, meanings and relationships of words and concepts, and second, to elicit meaning from the data collected and to draw realistic conclusions from it. Such an analysis can be useful to pre-test and improve an intervention prior to its launch (Abroms et al., 2011).

The clinical content of the tool was reviewed by Jo's Cervical Cancer Trust and Public Health England. In addition, feedback was received from health

professionals working with the population of interest, and/or vulnerable groups where there may be overlap. These include a GP with expertise in SMI, as well as health professionals working in specialist cervical screening clinics for the following groups: women who have experienced sexual violence (feedback from *n* = 1 clinician), women who have survived FGM/C (*n* = 2), women who have SMI and/or a history of substance misuse (*n* = 1) and women on a mental health inpatient ward (*n* = 1).

The fully coded content analysis for this phase is contained in Appendix 7. The rationale for including and rejecting the requested changes and suggestions was discussed with the supervisory team; decisions were guided by current NHS cervical screening guidelines (NHS, n.d.; PHE Screening, 2019). Examples of requested revisions to one section of the tool are reported in Table 6.1 below.

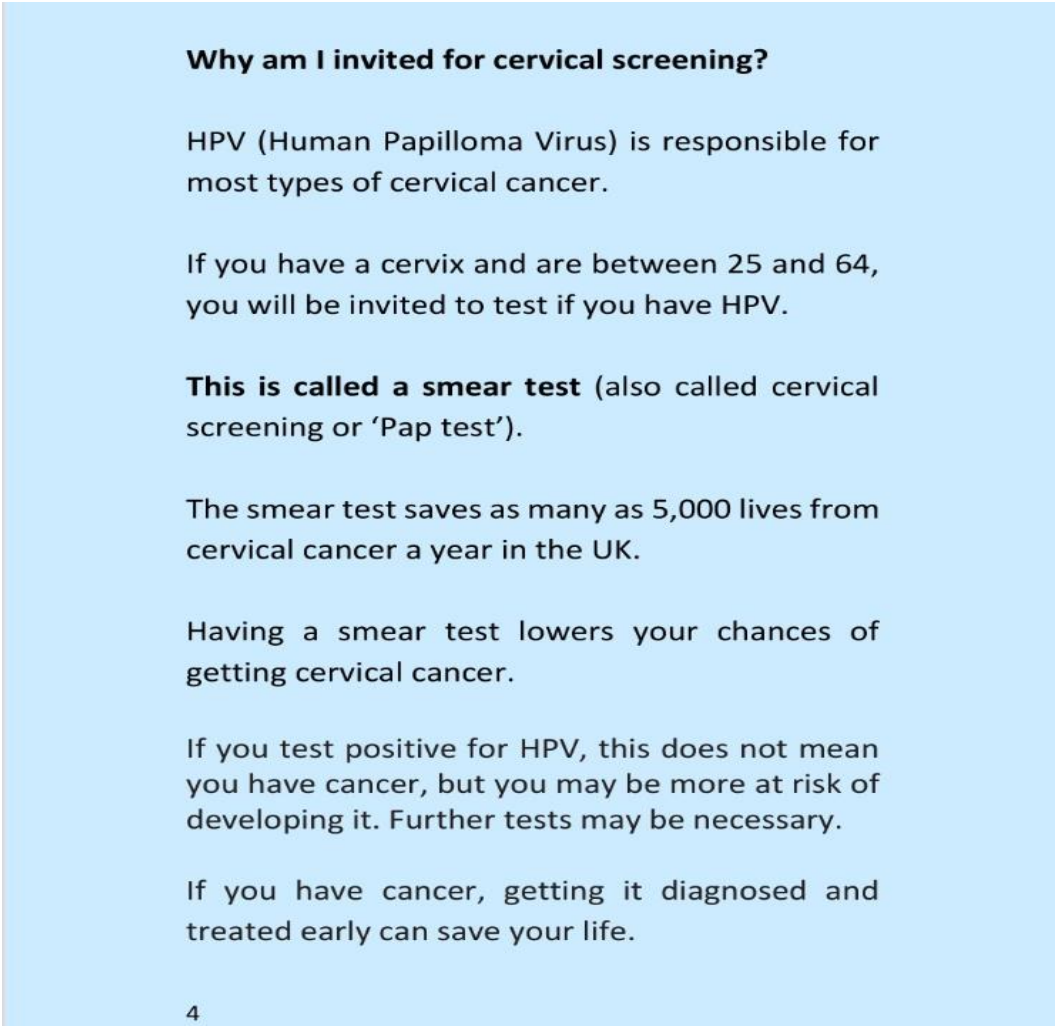


Figure 6.2 'Why am I invited for cervical screening?' (page 4, Version 0.1, Appendix 6).

Table 6.1 Revisions made to the ‘Why am I invited for cervical screening?’ section of the tool by group (Version 0.1, Appendix 6).

Requested revision:	Revision requested by (*n* =)				Decision made:	
	Key informants group				Revision accepted	Revision rejected
	Charities	NHS clinicians	National public health stakeholders	Clinicians working for specialised cervical screening clinics		
I think this section should say, more explicitly, that screening can pick up changes that, if left untreated, might eventually lead to cancer		1			Wording amended to reflect this	
Is it a bit confusing saying they will be invited for a test to see if they have HPV rather than a smear? Also, the smear doesn’t look for cancer it looks for pre-cancerous cells				1	Wording amended to reflect this	
People may not always get their smear done at a GP surgery, so you may want to include alternative arrangements (some sexual health clinics and STI clinics do smears, and so do some gynae clinics, especially for patients who require adjustments)		1			Wording amended to reflect this	
We need to highlight that this is a test for detecting an often-silent cancer		1			The extent to which the risks of non-uptake of cervical screening should be highlighted in the tool will be discussed with health professionals and service users. Results are reported in Round four of stakeholder involvement (section 7.3.2).	

Important to emphasise that women should go for regular screening		1		1	This comment was incorporated into this sentence: ‘Going for cervical screening when invited is the best way to protect yourself against cervical cancer.’	
HPV can be confusing for some people; it has an association with sex and can be confused with HIV – best to avoid mentioning in the tool				1	Wording amended to reflect this	
‘Staying healthy’ message – focus on prevention rather than mentioning ‘cervical cancer’				1	The extent to which the risks of non-uptake of cervical screening should be highlighted in the tool is discussed with health professionals and service users in Round four of stakeholder involvement (section 7.3.2)	
This may read better by putting the sentence ‘It is not a test for cancer’ at the start		1			Wording amended to reflect this	
Why ‘Why am I invited for cervical screening?’ Are they receiving this at the time of a letter? Should it be ‘why have I been…?’	1				This sentence was removed	
Need to include ‘if I am not sexually active now or ever or never do I need the cervical screening test’				1	This sentence was added: ‘If you’re not sure whether you need a test, talk to your GP or nurse.’	

'if you have a cervix and are between 25 and 64' is confusing, reword				1	This section was revised to: 'To be invited for cervical screening you must: - be registered with a GP as female - be between the ages of 24 and 64'	
I would maybe list the places a woman can go to get a cervical smear. It is largely provided by primary care and an explanation about the process may be helpful. Like mentioning that the GP will send you a letter every 3 years to invite you, so making sure your patient details are up to date would be good. Some sexual and reproductive health clinics will opportunistically too but that may get confusing to mention because it is opportunistic				1	This section was revised to: 'Your GP surgery will invite you for cervical screening if your contact details are up to date (…) In some areas, you may be able to arrange your appointment at a sexual health or well woman clinic instead of your GP surgery.'	
Could give more info about HPV; Very positive page – if this leaflet is to help people to decide, should it have the pros and cons? Probably need to say it's not just about checking for cancer as that isn't clear	1				The extent to which the risks of non-uptake of cervical screening should be highlighted in the tool is discussed with health professionals and service users in Round four of stakeholder involvement (section 7.3.2)	
If the focus of this booklet is tips for people with SMI, just do an overview of cervical screening here then signpost out. Getting	1				Wording amended to reflect this	

into HPV will make it very complicated						
Eligibility age for screening: '25-64' rather than '24-64'. It's better to stick with the screening ages here to avoid confusion.	1				Wording amended to reflect this	
Offer alternative sources of information as not everyone has access to a computer or the internet			1			Research shows this group has access to the internet and a computer

Given the high incidence of sexual trauma in people with SMI (see Chapter One, section 1.3.2) and the barriers to their accessing primary care (see Chapter Five, section 5.1), less-invasive alternatives to cervical screening were reviewed (Gravitt et al., 2011; Kitchener and Owens, 2014; Madzima et al., 2017; Pathak et al., 2014; Sancho-Garnier et al., 2013; Szarewski et al., 2011; Virtanen et al., 2011). Alternatives to cervical screening include self-sampling (whereby a kit is sent to your home) or urine sampling. Using a self-sampling HPV test kit (Gravitt et al., 2011) or self-administered urine test (Pathak et al., 2014) were suggested in the tool as alternatives to the current speculum examination of the smear test, which is more invasive and requires a visit to a GP practice or sexual health clinic. However, the option of using urine sampling or self-sampling kits to check for the presence of HPV was removed further to advice received from the Cervical Screening Programme at PHE Screening:

> '*At present, HPV self-sampling is not offered by the NHS Cervical Screening Programme so it would be inappropriate to mention it in a leaflet aimed at women attending for NHS screening. The UK National Screening Committee will be reviewing the evidence on these devices in the near future*'.

6.2.3 Implications for the development of the tool

The clinical content of Version 0.1 of the tool was amended following revisions requested from members of the key informants group. The title and

certain sections were reworded for clarity (see Table 6.2). In addition, Jo's Cervical Cancer Trust provided support with formatting.

Table 6.2 Rewording of the sections of the tool (Round three of stakeholder involvement).

Version 0.1	**Version 0.2**
Title: Thinking about cervical screening (smear test)	Title: Support available for cervical screening (smear test)
Why this leaflet was developed	What is in this leaflet?
Why am I invited for cervical screening?	What is cervical screening?
What happens on the day?	During your appointment
Common questions and anxieties	Content from 'Common questions and anxieties' has been incorporated into other sections
Tick box page	Tick box page
Tips for booking your appointment	Booking your appointment
Getting ready for your appointment	Before your appointment
Your appointment day	Content from 'Your appointment day' has been incorporated into the section 'During your appointment'
What happens next?	After your appointment
Additional information	Getting support

Chapter summary

This chapter described the iterative process of involving stakeholders in the development of the tool. It focused on one particular step of this process, which involved gathering feedback on the clinical accuracy of the tool. The revised[31] version of the tool (Version 0.2) was presented to service users and health professionals to assess its acceptability. This is reported in the following chapter.

[31] A sample page of Version 0.2 of the tool is provided in Appendix 8

Chapter Seven – Tool development: Assessing the acceptability of the tool

This chapter describes Study Three, which consisted of assessing the acceptability of the tool (Version 0.2) with stakeholders, thus dealing with one of the two parts of Objective 3 of the research. This study addresses part of Objective 3 of the research, which is highlighted in Box 2 below. Acceptability testing is defined as assessing the perception among stakeholders that an intervention is agreeable to them (Peters et al., 2013). Service users and health professionals were recruited for this purpose from two NHS Trusts from September to November 2018.

Box 2: Development of the tool (continued)

Objectives of the research that this chapter addresses (in bold):

Objective one: To develop an informed-choice tool for women with SMI which addresses some of the barriers to screening attendance

Objective two: The tool should be theoretically underpinned

Objective three: Acceptability and usability of the tool by stakeholders should be tested

Phases of the MRC guidance

Development: Identifying the evidence base

Development: Identifying/developing theory

Feasibility/Piloting: Testing procedures

Evaluation: Understanding change process

Steps to follow when developing an informed-choice tool for people with SMI

Step one: Identify barriers to decision-making

Step two: Theoretically underpin the intervention

Step three: Involve service users in the development of the tool

Step four: Test usability of the intervention

Step five: Assess readability levels

Stakeholder involvement to develop the tool

Round one (February – March 2018)

Round two (May 2018): covered in Chapter Five

Round three (July – August 2018): covered in Chapter Six

Round four (September – November 2018)

Round five (December 2018 – March 2019)

Round six (April – August 2019)

The acceptability of the tool (Version 0.2) was tested with service users who access secondary care and health professionals who work with them. The method to recruit these participants is described below. This same version of the tool was emailed to members of the key informants group for iterative feedback in September 2018. Data are reported together with results from acceptability testing of the tool (see Chapter Seven, section 7.3).

7.1 Methods

7.1.1 Design and setting

This was a qualitative, individual interview study. There were two study settings: outpatient mental health clinics (CMHT) within the West London NHS Trust (thereafter West London Trust) and Dorset HealthCare University NHS Foundation Trust (thereafter Dorset Trust). Recruiting from two Trusts ensured some variation in population experience (one Trust was urban and the other was mixed rural/urban) and in demographic characteristics of the population, including socioeconomic status, age structure and ethnicities.

7.1.2 Ethical considerations

This research involved a group that is often excluded from research (Bucci et al., 2015; Humphreys et al., 2015). In addition, the selected topic, cervical screening, is both a sensitive subject and one which can trigger the memory of painful experiences, such as childhood abuse or loss of a loved one from cancer. During the interviews, several service users disclosed painful and often traumatic personal experiences; the candidate always ensured that the

participant was able to discuss her experience in a safe and empathetic space and ensured the participant was not in distress when the interview ended. To mitigate the risks of potential distress to participants, a gatekeeping recruitment process with psychiatrists was set up to ensure that only women who were deemed well enough were invited to take part (see Chapter Seven, section 7.1.4). Collecting participant views was both challenging in terms of the complexity of recruiting in mental health services (see Chapter Seven, sections 7.1.3-7.1.5) and rewarding, as participant feedback significantly improved the final output. Though no safeguarding issues were encountered, a safety protocol for the benefit of the candidate was in place during the data collection phase, as detailed in the REC-approved protocol. For example, interviews only took place in community mental health team offices. During PhD supervision, the candidate discussed several difficult cases with her supervisors (two of whom are psychologists and the third a consultant psychiatrist), who were thus able to provide a safe space and offer support and guidance. The candidate allowed herself time to process the painful disclosures in between interviews.

The study received a favourable assessment from the University of West London Ethics Committee on the 7 December 2017 (Reference: UWL/REC/CNMH-00301). Prior to the submission to the National Research Ethics Service, Patient and Public Involvement (PPI) was sought at the design stage of the research proposal. Feedback was given on the draft protocol and research materials by a service user researcher; this was round one of stakeholder involvement (January–February 2018). Feedback led to

changes in the terminology and length of the document, as well as the re-ordering of certain sections of the research materials to improve the accessibility and user-friendly nature of the documents. The full list of feedback is contained in Appendix 9; some of the feedback was removed to preserve anonymity of the service user researcher. One suggestion was to 'invite people's suggestions about the content of the information [to be included in the tool] **before** you put a draft together and present it to them. You will probably get a more genuinely user-centred leaflet in that way'. This suggestion was implemented; round two of stakeholder involvement (see Chapter Five, section 5.1.1) consisted of a workshop with a service user group (SUGAR) that included a general discussion on the content of the tool (barriers and enablers to cervical screening) and the format of the tool prior to acceptability testing (see Appendix 4).

The study received a favourable opinion from the National Research Ethics Service (Ref: 18/SC/0123) on the 16th April 2018. Research and Development letters of access were obtained on the 18th May 2018 for Dorset Trust and the 20th August 2018 for the West London Trust.

7.1.3 Participant recruitment criteria

Eligible women (and trans men) were those who were (a) diagnosed with SMI including: schizophrenia, schizotypal and delusional disorders, bipolar affective disorder, or severe depressive episodes with or without psychotic episodes (NICE, 2016), (b) able to read English and (c) currently receiving adult (aged 18–65 years) outpatient mental health services in either Dorset or West London Trust. Women with SMI were excluded if they were considered

by their clinical team to lack capacity to consent or to be currently too unwell to take part. Eligible health professionals included those who were (a) working in secondary mental healthcare (doctor, clinical psychologist, nurse, social worker or nurse working as a care coordinator), (b) currently working for either Dorset or West London Trust.

Given the uncertainty around mental illness classifications and diagnoses, the frequency of co-morbidity and because the tool is likely to be used across population groups, the focus was on individuals who are currently accessing community mental health services (secondary care) as opposed to people with an SMI diagnosis using only primary care. The aim was to recruit people with a degree of mental illness that is likely to have an impact on their daily lives. Recruiting mental health service users without referring to a specific diagnosis has been a successful recruitment method (Brown et al., 2019; Clifton et al., 2016).

7.1.4 Sampling and recruitment procedure

Sample size justification: Sample sizes of *n* = 10 for each type of participant (women and healthcare professionals) were based on the estimated number required for theoretical saturation informed by previous similar research (Knowles et al., 2016; Roos et al., 2016). For women with SMI, convenience sampling was used. For health professionals, convenience sampling plus snowball sampling was used to identify health professionals who would be likely to be knowledgeable about the topic. That is, participants were asked

to identify further individuals whom they believed would provide useful information (Goodman, 1961).

Recruitment procedure: Women diagnosed with SMI

Recruitment was supervised by consultant psychiatrists and Trust Research Leads. The candidate was invited to attend several Trust team meetings (*n* = 1 in Dorset and *n* = 2 in West London) to present the research study to health professionals and to clarify any questions about the recruitment procedure. Psychiatrists and one clinical psychologist working in community mental health teams (CMHT) acted as gatekeepers for the research study by suggesting participants who were eligible and well enough to take part.

Psychiatrists (or a clinical psychologist) screened eligible participants during their outpatient clinics and notified the candidate when potential participants had expressed an interest to participate in the study. The candidate was contacted by the psychiatrists or the clinical psychologist by email or, if she and the service user were already in the clinic, in person. The candidate was available to speak to each potential participant (either over the telephone or in person) to discuss the study and agree a date and time to meet. In all cases, when the participant spoke in person with the candidate about taking part in the study, they agreed for the interview to take place immediately. Interviews were conducted face-to-face in a private space in community mental health clinics (*n* = 1 site in Dorset, *n* = 4 sites in West London), audiotaped with consent and transcribed verbatim. To preserve

anonymity, an alphabetical letter was attributed to each recruitment site.

Prior to the start of every interview, the candidate referred to an independent source, i.e. a member of the participant's clinical care team (psychiatrist or clinical psychologist), to ensure that the participant had capacity to participate. This was to ensure that the participant was able to give their written consent to participate and able to retain information long enough to make the decision and to make the decision at the point when it needed to be made. The consent form (Appendix 10) was signed by the candidate and the participant. The candidate explained the information sheet (Appendix 11) to the participant prior to the interview. This was to ensure that the participant understood the purpose and nature of the research, what it involves, its risks and burdens and the alternatives to taking part.

Recruitment procedure: Health professionals

Posters about the research study were emailed to the study gatekeepers, to be placed in community mental health team waiting rooms, staff meeting rooms and inpatient wards. The candidate attended several Trust team meetings to present the research study to health professionals. Participant information sheets (Appendix 12) and informed consent forms (Appendix 13) were distributed during the meeting, and members of staff (n = 3) with an interest in physical health recommended colleagues who they thought may want to take part.

7.1.5 Materials

The tool used for this study was Version 0.2 (a sample page is provided in Appendix 8).

Demographic and clinical questionnaire for women with SMI (Appendix 14): Participants were asked to complete a demographic and clinical questionnaire. Information requested included demographic characteristics (gender, year of birth, ethnic group) and clinical information (mental health diagnoses, duration of illness(es), whether participants have been for one or more cervical screening appointment(s) in the past and, if so, when the most recent appointment took place). These data were collected since past screening experience has previously been shown to impact upon future uptake (Clifton et al., 2016; Roncancio et al., 2013).

Health professional demographic and professional questionnaire (Appendix 15): Participants were asked to complete a demographic questionnaire. Information requested included demographic (year of birth, gender and ethnic group) and professional characteristics (profession, length of time in current role, work setting and length of time qualified).

The interview schedule for women with SMI (Appendix 16) includes questions relating to what the participant thinks about the tool, any suggestions about the content of the tool and in what context (both in terms of setting and in collaboration with whom) the participant would use the tool. Interviews lasted up to 45 minutes; they were audio recorded and transcribed verbatim. Participants were given the tool and then given some

time alone to read it. Some women wanted the candidate to talk them through it.

The interview schedule for health professionals (Appendix 17) explores what participants think of the tool, whether there is any content they feel should be included, excluded or changed, and the context in which they think the tool should be introduced. Interviews lasted between 30 and 45 minutes; these were audio recorded and transcribed verbatim by the candidate.

7.2 Analysis

The demographic and health data were summarised using descriptive statistics, such as standard deviations and means. A content analysis of the transcripts was conducted (Hsieh and Shannon, 2005; Owen, 2012). Data from service users and health professionals, alongside iterative feedback from members of the key informants group, represents round four of stakeholder involvement (see Figure 6.1). Data from these three stakeholder groups were combined. Each requested revision was coded line by line into two categories: ‘Modification Accepted’ and ‘Modification Declined’. If a service user feedback contradicted professional feedback, priority was given to suggestions from service users, as they are the primary target group, provided it did not contradict NHS cervical screening guidelines (NHS, n.d.; PHE Screening, 2019). The candidate discussed every action with her principal supervisor (who is a nurse and health psychologist) and, where relevant, with a member of Jo’s Cervical Cancer

Trust to ensure clinical accuracy. Any query requiring further deliberation was discussed with the candidate's second and third supervisors (a consultant psychiatrist and chartered psychologist). The rationale for accepting or declining each action is reported.

7.3 Results

7.3.1 Sample profile

Women with SMI

A total number of *n* = 18 women with SMI were approached by their clinician to take part in this study, 10 of whom took part. A total of *n* = 8 women refused to take part in the study. Several women (*n* = 5) gave a reason for declining to take part: history of trauma which they did not want to discuss: *n* = 2; bad cervical screening experience: *n* = 1 and refusing to go for cervical screening (no reason given): *n* = 2. The majority of participants (*n* = 7) had attended cervical screening more than once in the past (though one had not been for 13 years), one participant had never attended cervical screening, one had attended once but declined further invitations due to a bad cervical screening experience and one was not yet of eligible age (aged 23). Her data were included in the analysis as her perception of what cervical screening entails was highly valuable to the development of the tool.

A summary of the results from the questionnaires are shown in Tables 7.1 and 7.2.

Table 7.1 Demographic characteristics of study participants (service users) (*n* = 10).

Gender *n* (%) Female Other	 10 (100) 0
Age, years: mean (SD)	42 (SD: 7.99)
Recruitment sites	3
Ethnicity (grouped), *n* (%) White – all Black/Black British – all Asian/Asian British – all	 5 (50) 4 (40) 1 (10)
Self-report diagnosis, *n* (%) Schizophrenia spectrum Bipolar disorder Psychotic depression Personality disorders	 4 (40) 2 (20) 1 (10) 3 (30)
Had cervical screening *n* (%) More than once Once Never Not yet eligible	 7 (70) 1 (10) 1 (10) 1 (10)
Last cervical screening *n* (%) In the last 5 years Over 5 years ago Never Not yet eligible	 6 (60) 2 (20) 1 (10) 1 (10)

Table 7.2 Demographic characteristics of study participants (health professionals) (*n* = 10).

Gender *n* (%) Female Male Other	 6 (60) 4 (40) 0
Age, years: mean (SD)	43.5 (SD: 9.12)
Recruitment sites	4
Ethnicity (grouped), *n* (%) White – all Black/Black British – all Asian/Asian British – all	 9 (90) 0 1 (10)
Work setting (grouped), *n* (%) Community mental health team Psychiatric hospital Recovery team Liaison psychiatry	 7 (70) 1 (10) 1 (10) 1 (10)
Profession (grouped), *n* (%) Nurse – all Care coordinator GP Psychiatrist	 4 (40) 2 (20) 1 (10) 3 (30)
Length of time in current role, years: mean (SD)	6.03 (SD: 4.66)
Length of time since initial qualification, years: mean (SD)	12.6 (SD: 7.68)

7.3.1. Overall feedback on the tool

The fully coded content analysis is contained in Appendix 18. Some revisions to the tool were requested (*n* = 8 changes requested from service users and *n* = 35 from health professionals). Overall feedback on the tool from service users and health professionals was positive. Positive feedback (*n* = 28 from health professionals and *n* = 54 from service users) was recorded, displaying acceptability of the tool with key stakeholders. Example quotes of positive feedback are listed below:

'*The leaflet would be helpful to women who don't go [to screening]*' (service user #5),

'*I think it's brilliant (…) you've put everything in the leaflet*' (service user #6).

'*It would be good if* [the tool] *got sent out into the post, you know when you have the letter for the reminder, so they* [women] *can have a look at the leaflet, so it prepares them, it would give them more faith to book this test*' (service user #2).

Similarly, health professionals found it to be of value:

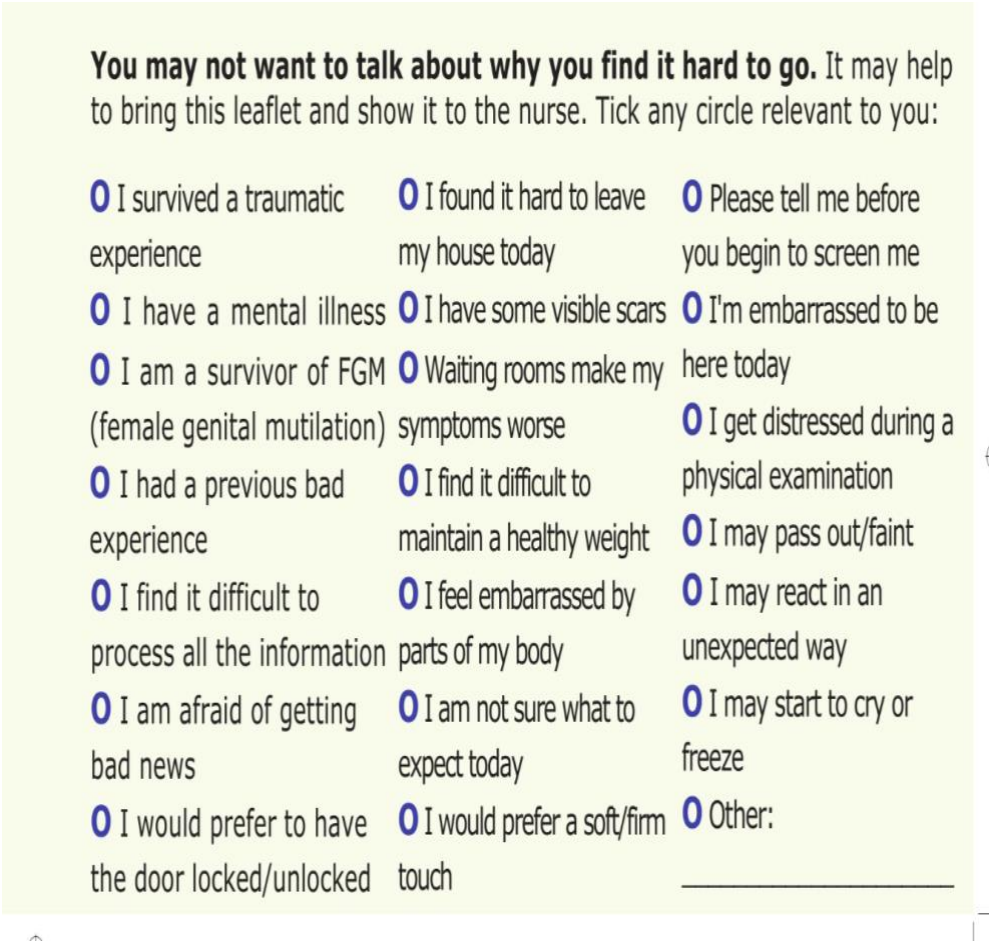
'*I think it's really thoughtful, and really sensitive, you can tell a lot of thought has gone into it, and I think the wording is very good, it captures quite difficult things but in an easy to understand way*' (Psychiatrist, West London Trust), '*I think it's great, really fantastic*' (GP, West London Trust),

'*Very useful to have this leaflet to hand out and then to follow-up with at the next appointment (…) It gives people a tool if they need extra help, it's written in the leaflet what they can ask for (…) leaflet is great, it's one of those things like sexual dysfunction for men on antipsychotics, don't always think to check, so leaflet is useful*' (psychiatric nurse, West London Trust).

An example of a requested revision is provided here. During feedback on the first draft of the tool (Version 0.1), a member of the key informants group suggested including a sentence in the tool 'to ask for a tranquiliser if you are feeling very anxious before the test'. This change was implemented in Version 0.2. During the acceptability testing phase, one of the participants (a

GP working in a mental health setting) felt that benzodiazepine medication (tranquilisers) should not be suggested to participants as a way of reducing their anxiety, as this may lead to adverse reactions for patients on antipsychotic medication. This sentence was therefore removed.

Examples of requested revisions to a component of the tool (the 'Tick box page') are shown in Table 7.3. The rationale (seconded by the supervisory team) for accepting or rejecting each change was included in the table.



You may not want to talk about why you find it hard to go. It may help to bring this leaflet and show it to the nurse. Tick any circle relevant to you:

- O I survived a traumatic experience
- O I have a mental illness
- O I am a survivor of FGM (female genital mutilation)
- O I had a previous bad experience
- O I find it difficult to process all the information
- O I am afraid of getting bad news
- O I would prefer to have the door locked/unlocked
- O I found it hard to leave my house today
- O I have some visible scars
- O Waiting rooms make my symptoms worse
- O I find it difficult to maintain a healthy weight
- O I feel embarrassed by parts of my body
- O I am not sure what to expect today
- O I would prefer a soft/firm touch
- O Please tell me before you begin to screen me
- O I'm embarrassed to be here today
- O I get distressed during a physical examination
- O I may pass out/faint
- O I may react in an unexpected way
- O I may start to cry or freeze
- O Other: _____

Figure 7.1 'Tick box page' (page 9, Version 0.2 of the tool).

Table 7.3 Revisions made to the ‘Tick box page’ section of the tool by group (Version 0.2 of the tool).

Revision:	Revision requested by (*n* =)				Decision made:	
			Key informants group		Revision accepted	Revision rejected
	Service user	Health professional	Member of service user group	Clinician/ member of NHS organisation		
Ensure service users understand that filling out this page is optional	2			1		Women would not have to bring the tool to their appointment, so it is optional by nature
[Participant had a previous bad experience with practice nurse, candidate asked whether it would it be clearer if the tool includes: ‘I had a previous bad smear test experience’ rather than: ‘I had a previous bad experience’]: ‘maybe, it’s clearer’	1				Change made to distinguish any type of trauma from ‘a previous bad smear test experience’, which is more specific	
‘This is good [the tick box page] as long as it’s all kept confidential’	1					It would be confusing and possibly distressing to introduce confidentiality into the tool
You may also want to add points related to people from marginalised communities, e.g. women who identify as lesbian,			1			We had already included ‘I am a survivor of female genital

bisexual or transgender and women from BAME communities with particular cultural issues						mutilation/cutting (FGM/C)'. Jo's Trust are developing a separate tool for LGBTQIA community
'I think it would be useful to suggest having the opportunity (a) to let the nurse know beforehand about these issues and (b) to talk through with him/her beforehand (i) how a particular issue affects your feelings about a smear test and (ii) what would help you'			1			Due to time pressures in primary care, it is not possible for practice nurses to start a conversation about this
All words need to be spelt out fully e.g. examination not exam			1		Wording amended to reflect this	
'I may react in an unexpected way': nurse may ask 'so what are you gonna do?!' in a not very helpful way, so it's better to have a line where the person can write down how they think they may react	1				Change made; the option 'Other: _____' was added	
You could add 'I have an issue with my GP' as a barrier		1				The option was added: 'I have had a bad smear test experience', which includes any negative experience with a health professional
I wonder whether there should be a space for (optionally) writing 'my mental health conditions/diagnoses are...' so that the tool can be shown to the health professional doing the test. The nurse/Dr may not have access to medical records at the				1	'I have a mental illness' was replaced with 'I have a mental health condition: _____'	

time of the test, and it might make it easier for the patient						
Obesity is an issue with this group: could add ‘I am embarrassed by my body shape’		1			The option was added: ‘I am embarrassed by my body’	
‘I am a voices hearer and get distressed during a physical exam’: split into two different categories		1			The options were added: ‘I hear voices’ and ‘I get distressed during a physical examination’	
The option ‘I have other health issues’ isn’t clear, could be replaced by ‘I find it hard to maintain a healthy weight’				1	The option ‘I have other health issues’ was removed. It was replaced by ‘I am embarrassed by my body’	
Instead of just pass out, add ‘faint’				1	The option was added: ‘I may pass out or faint’	

A key consideration that emerged early in the interviews was the importance of supporting women who have experienced trauma. As reported earlier (section 1.3.2), people living with SMI are at substantially increased risk of domestic and sexual violence than those in the general population (Khalifeh et al., 2015). For physical abuse, the prevalence in SMI has been found to be 47% compared with 21% in the general population and 37% in SMI *versus* 23% in the general population for sexual abuse (Mauritz et al., 2013). Including tips and adjustments throughout the tool was noted by most service users and health professionals as relevant, innovative and helpful. Every health professional interviewed acknowledged that having a history of abuse or trauma is likely to be a substantial barrier to any type of cancer screening. Seven out of ten service users interviewed openly disclosed that they were survivors of rape or childhood abuse:

'*There's loads of people that have survived traumatic experiences and don't want to go for smear tests for that reason*' (service user #6),

'*I was raped about 20 years ago, and it [cervical screening] definitely brings it back*' (service user #10).

A member of a service user group also disclosed how her experiences made her feel during a smear test:

'It's not just embarrassment, or bad self-esteem, for crying out loud, it is a vulnerable part of the body and somebody is attacking it, often causing quite

considerable pain and if you complain they have a go at you, making you feel bad because you 'can't relax'. Then other people start telling you you're stupid and a complete 'wuss' if you complain'.

Deciding whether to disclose a history of trauma to the screening professional was discussed with several participants. Other than one health professional (care coordinator #2, West London Trust), no participant was familiar with the My Body Back project (charity offering cervical screening for women who have experienced sexual violence), which is mentioned in the 'Getting Support' section, indicating value to retain it in the tool:
'*ah that's useful*' (service user #10).

The tick box page was commented on by every service user and health professional. Most service users felt that this page would help them to disclose their traumatic event (or other issue) and any reactions (e.g. fainting, freezing up, or crying) they anticipate when being screened:
'*I wish I'd had it* [the tool] *when I had my appointment because I could have ticked the boxes*' (service user #6).

One woman reported avoiding screening due to her fear of the nurse's reaction to the scarring on her legs caused by self-harm. She welcomed the tool's tick box page to help her disclose her history of self-harm:
'*I have deep scars on my legs (…) so I don't like to take my trousers off and show my legs to a doctor*' (service user #7).

Another said the tool gave legitimacy to her worries (hearing voices) '*because it's on your tick box page*' (service user #10).

Service users appreciated the fact that they would not have to discuss their issue with the screening professional, but could simply show them the page to make them aware:

'*it's brilliant, because then you don't have to explain that you have a mental health condition, so if you behave a bit strangely, they're understanding, rather than brush you off or treat you like an idiot*' (service user #1).

One service user admitted she would not use the tick box pages:
'*that would probably make me more anxious than having to say it, and I would assume my nurse would have that information anyway*' (service user #3).

Though the nurse would, in most instances, not have access to this information, it is an interesting finding that someone would believe that to be the case.

All health professionals and members of the key informants group felt that this was an innovative and useful section of the tool:

'*It looks a nice leaflet and we particularly like the part with the tick boxes of why they find it difficult to attend*' (Public Health England),

'In a clinic, asking open-ended questions can sometimes be overwhelming for the patient (e.g. are you anxious about anything?), having the 'tick box' page is helpful' (psychiatric nurse, West London Trust).

7.3.2 Main contentious issues

Two main contentious issues were raised during the interviews, one regarding the terminology around SMI, and the other whether to focus on the benefits of cervical screening or the risks of non-attendance. In line with content analysis, the coding categories were derived directly from the transcribed data. These are discussed in the following section.

1) Terminology

During feedback collected on the first draft of the tool (Version 0.1), one of the members of the key informants group commented on the lack of clarity of who the target audience of the tool is:

'*It's slightly confusing as to who the reader is supposed to be. I would have a sub-heading which reads '*A comprehensive guide to support people with mental health issues' *(not sure what term is being used)*' (Jo's Cervical Cancer Trust).

The charity felt that there was little reference to severe mental illness in the tool. Their preference was for 'SMI' or 'people who are anxious about screening' to be included in the title of the tool, and to explicitly mention the target audience throughout. At the beginning of every interview with service

users and health professionals, the candidate discussed the extent to which references to mental illness should be included in the tool and whether an alternative title to 'Support available for cervical screening (smear test)' should be adopted. The consensus across service users was that making a specific reference to SMI was unnecessary:

'*The title is clear*' (service user #5), '*I like the title*' (service user #6) and

'On p.3 and elsewhere, it would be helpful to avoid using purely medical language for mental distress (e.g. 'a mental health condition' here and on p.10, 'mental health symptoms' (p.6), 'symptoms' (p.10); (…) a problem for considerable numbers of us is the interpretation of mental distress via a clinical model. If people are unhappy with the use of purely medical language in the leaflet, it may well impact on their reactions to the leaflet as a whole' (member of service user group, feedback received by email on 29/11/18). Similarly, health professionals worried that an over-emphasis on 'SMI' might deter women attending, who may either feel that the tool is irrelevant to them, or that they are being stigmatised:

'*One of the beauties of the leaflet is that it doesn't go out of the way to state mental health, it's a really useful leaflet for everybody actually (...) we need to be connecting with them as people (...) it would turn some people off if it became focused on SMI (...) as professionals we categorise them, but the person walking in the street isn't thinking 'I have SMI', so we need to give*

them information in a way that gives them better access to available screening' (Psychiatrist, Dorset Trust).

2) Balancing the risks and benefits of cervical screening in the tool

The second contentious issue that emerged was how to strike a balance between the risks of non-attendance and giving women a choice of whether to attend cervical screening. Several participants and members of the key informants group were in favour of emphasising a 'loss framed' message: *'Don't be afraid to be explicit about the risks involved if they don't go, don't be scared to use the word 'cancer''* (Psychiatric nurse, Dorset Trust),

'In the sentence where you say 'it is not a test for cancer' I think a natural conclusion might be 'why bother then?'. I think it should say, more explicitly, that it can pick up changes that, if left untreated, might eventually lead to cancer' (doctor with dual training as a GP and Psychiatrist, member of the key informants group),

'Need to be factual, don't shy away from using the word 'cancer'' (Nurse prescriber, Dorset Trust),

'We need to highlight that this is a test for detecting an often-silent cancer – I am a bit worried that saying it's up to you (without people knowing the facts that this is a test for cancer) may not emphasise the importance of this test' (GP, member of key informants group).

This preference to focus on the risk of non-attendance contrasts with research which reports that 'gain-framed messages' may be more appropriate (Cooke and French, 2008). To increase cancer screening attendance, authors recommend that screening organisations would be best advised to send people information designed to generate positive attitudes (Cooke and French, 2008). A number of participants and members of the key informants group were in favour of focusing on a 'gain-framed' message: *'It can be scary if you read this list* [of cervical cancer symptoms], *you may think you have cancer but it can be lots of different things like thrush (…) discharge can also be thrush, not cancer (…) so list can be scary, important to explain it can be other things'* (service user #7),

'Reword: 'it is still important to be aware of cervical cancer symptoms' to something like: 'if you experience any of these symptoms it is important to see your doctor straightaway. It might not be cancer, but it is important to have them checked'' (service user group with lived experience of mental illness and cervical cancer),

'Should we be talking about cancer so early on in the leaflet? Could make people more anxious … it is important, but it might put some people off, maybe better to talk about the practical things first, that's what's really important' (Psychiatrist, West London Trust),

'The word 'cancer' appears too much, you might scare people off ... (…) word 'abnormalities' doesn't sit well with me and I guess also for people who have SMI' (Care coordinator (2), West London Trust),

'There is too much mention of the word 'cancer', might worry someone who has paranoia or health anxiety and they might think 'I'd rather not know'' (Care coordinator, West London Trust),

''Staying healthy' message – focus on prevention rather than 'it's a cancer test'' (Consultant nurse, member of the key informants group),
'I don't like the bit about cancer developing, as that would make me very anxious' (Jo's Cervical Cancer Trust).

Following feedback from participants, an effort was made to balance the risks of non-attendance with the benefits of screening throughout the tool. Cancer prevention was highlighted in the 'What is cervical screening?' section (e.g. 'If not monitored or treated, some changes may eventually develop into cervical cancer' (page four). The health promotion message to emphasise the benefits of screening appears in different sections of the tool, e.g. 'Going for cervical screening when invited is the best way to protect yourself against cervical cancer' (page four, 'What is cervical screening?') and 'These symptoms don't mean you have cancer and are often caused by other things, but it's important to get them checked' (page 11, section 'Looking after your health').

Changes were incorporated to ensure acceptability of the tool with key stakeholders; this became Version 0.3 (a sample page is provided in Appendix 19).

Chapter summary

Objective three (reported in Chapter Two, section 2.2) is defined as testing the acceptability and usability of the tool by stakeholders. Acceptability of the tool was demonstrated with key stakeholders and any changes to the content were incorporated in Version 0.3. This version was then used to test the usability of the tool with stakeholders (service users, health professionals and members of the key informants group). This step is reported in the following chapter.

Chapter Eight – Tool development: Usability testing of the tool

This chapter describes Study Four, which was conducted to test the usability of the tool. Work to this point had ensured that the tool was acceptable to stakeholders. It was now important to test whether the tool could be used by its intended users to fulfil the third objective of this research (see Box 3 below). The think-aloud method (van Someren et al., 1994) was used for the purpose of usability testing. The readability of the tool (Versions 0.2 and 0.3) was assessed and final changes were made to obtain ‘sign-off’ of the tool from stakeholders (see Figure 6.1).

Box 3: Development of the tool (continued)

Objectives of the research that this Chapter addresses (in bold):

Objective one: To develop an informed-choice tool for people with SMI which addresses some of the barriers to screening attendance

Objective two: The tool should be theoretically underpinned

Objective three: Acceptability and usability of the tool by stakeholders should be tested

Phases of the MRC guidance

Development: Identifying the evidence base

Development: Identifying/developing theory

Feasibility/Piloting: Testing procedures

Evaluation: Understanding change process

Steps to follow when developing an informed-choice tool for people with SMI

Step one: Identify barriers to decision-making

Step two: Theoretically underpin the intervention

Step three: Involve service users in the development of the tool

Step four: Test usability of the intervention

Step five: Assess readability levels

Stakeholder involvement to develop the tool

Round one (February – March 2018)

Round two (May 2018)

Round three (July – August 2018)

Round four (September – November 2018)

Round five (December 2018 – March 2019)

Round six (April – August 2019)

The usability of the tool Version 0.3 was tested with service users who access NHS mental health services and health professionals who work there. The method to recruit these participants is described below. In addition, this version of the tool was emailed to members of the key informants group for iterative feedback in December 2018. These data are reported in section 8.3 together with results from usability testing of the tool.

8.1 Methods

Some of the study's methodological elements (ethical considerations, participant recruitment criteria and recruitment procedure), are identical to those used in Study Three and have been reported in detail (see Chapter Seven, section 7.1). Thus, only the methodological elements that are specific to this study are described below.

8.1.1 Design and setting

The think-aloud method was used to collect feedback on the design and layout of the tool (Version 0.3). The rationale for using the think-aloud method stems from findings from the systematic review (Study Two, Chapter Four), suggesting using this method to test the usability of an intervention. The think-aloud method is a validated method of qualitative inquiry (van Someren et al., 1994) that is used to assess user experience and usability of interventions and allows observation of the actual reactions of the participant taking part in an intervention/using a particular tool (McDonald et al., 2016). This method has been used successfully to test smoking cessation interventions with participants with SMI (Ferron et al.,

2011; Vilardaga et al., 2016). The Ferron (2011) study used the think-aloud method to develop the smoking cessation tool described in Chapter Four, whereas the Vilardaga et al. (2016) study reported the results of a user experience evaluation of a National (US) Cancer Institute smoking cessation app, QuitPal, and provided user-centred design data (e.g. using large buttons on the interfaces, breaking down the smoking cessation behaviour into smaller steps, maximising the consistency of the design) that researchers can use to tailor smoking cessation interventions for this population.

Participants were instructed to ‘think aloud’, that is, they were encouraged to communicate any thoughts, comments or suggestions they had about the design or layout of the tool while they interacted with it. If the participant paused while going through the tool, the candidate would ask what they are thinking, and would respond to comments about the design elements of the tool, for instance by asking participants to elaborate and by making suggestions for changes on which participants could comment.

The settings (West London NHS Trust and Dorset Healthcare University NHS Foundation Trust), sampling technique and recruitment criteria and procedure are identical to those used for Study Three and described in section 7.1.

8.1.2 Participant recruitment criteria

The recruitment criteria are identical to those reported in section 7.1.

8.1.3 Sampling and recruitment procedure

Sample size justification: Studies testing the usability of an intervention usually suggest a minimum of five participants to ensure the identification of usability issues (Macefield, 2009). Studies reporting usability testing using the think-aloud method with adults who have SMI used similar numbers of participants: *n* = 5 (Vilardaga et al., 2016), two cycles of *n* = 5 to test and verify usability of an app (Whiteman et al., 2017). Sample sizes of *n* = 8 for service users and *n* = 6 for health professionals were selected, based on the estimated number required for theoretical saturation informed by previous similar research (Vilardaga et al., 2016; Whiteman et al., 2017). The sampling technique was identical to the one reported in Chapter Seven (see section 7.1).

The recruitment procedure is identical to that reported in section 7.1.

8.1.4 Materials

Version 0.3 of the tool was used for this study.

The demographic questionnaires for women with SMI and health professionals are identical to the ones reported in 7.1 (Appendices 14 and 15). Sample participant information sheets and consent forms are contained in Appendices 10-13.

The interview schedule for women with SMI includes questions about what the participant thinks of the overall layout and design of the tool, whether

there is anything that should be changed or added or removed, whether the wording is clear and how easy it was to go through the tool. All participants were asked to provide feedback on what health professionals and health services might do that would make it easier for people with SMI to decide whether to go for cancer screening. The interview lasted up to 35 minutes.

The interview schedule for health professionals includes questions on what the participant thinks of the overall layout and design of the tool, whether there is anything that should be changed, added and/or removed, whether the wording is clear and how easy it is to go through the tool. The interview lasted between 30 and 40 minutes.

8.2 Analysis

The same data analysis was conducted as reported in section 7.2: the demographic and health data were summarised using descriptive statistics and a content analysis of the transcripts was conducted (Hsieh and Shannon, 2005; Owen, 2012). In addition to email feedback from members of the key informants group, a service user group (SUGAR, *n* = 12) commented on Version 0.3 of the tool during a workshop at City, University of London in January 2019. This feedback, alongside usability testing with service users and health professionals, consists of round five of stakeholder involvement (see Figure 6.1) and is reported in the following section.

8.3 Results

8.3.1 Sample profile

Women with SMI

A total of 17 women with SMI were approached by their clinician to take part in this study, eight of whom consented. Of the nine women who refused to take part, six gave a reason for declining to take part: history of trauma/abuse: *n* = 2; bad cervical screening experience: *n* = 1 and refuses to go for screening (no reason given): *n* = 3.

Every participant had been for cervical screening more than once (between 2012 and 2018, though one could not remember the last time she went). A summary of the results from the questionnaires are shown in Tables 8.1 and 8.2. Participants are different individuals from those recruited in Study Three. To assess participants' usability of the tool, the think-aloud method was applied to interviews conducted with women with SMI who access (*n* = 8) and health professionals (*n* = 6) who work in secondary mental healthcare.

Table 8.1 Demographic characteristics of study participants (service users) (*n* = 8)

Gender *n* (%) Female Other	 8 (100) 0
Age, years: mean (SD)	47 (SD: 7.98)
Recruitment sites	2
Ethnicity (grouped), *n* (%) White – all Black/Black British – all Asian/Asian British – all	 6 (75) 2 (25) 0
Self-report diagnosis, *n* (%) Schizophrenia spectrum Bipolar disorder Psychotic depression Personality disorders Depression and complex PTSD	 4 (50) 1 (12.5) 1 (12.5) 1 (12.5) 1 (12.5)
Had cervical screening *n* (%) More than once Once Never Not yet eligible	 8 (100) 0 0 0
Last cervical screening *n* (%) In the last 5 years Over 5 years ago Never Not yet eligible	 6 (75) 2 (25) 0 0

Table 8.2 Demographic characteristics of study participants (health professionals) (*n* = 6)

Gender *n* (%) Female Male Other	 4 (66.67) 2 (33.3) 0
Age, years: mean (SD)	42 (SD: 4.36)
Recruitment sites	4
Ethnicity (grouped), *n* (%) White – all Black/Black British – all Asian/Asian British – all	 5 (83.33) 0 1 (16.7)
Work setting (grouped), *n* (%) Community mental health team Recovery team Primary care mental health service	 4 (66.67) 1 (16.67) 1 (16.67)
Profession (grouped), *n* (%) Nurse – all Clinical psychologist Care coordinator Psychiatrist	 2 (33.3) 2 (33.3) 1 (16.67) 1 (16.67)
Length of time in current role, years: mean (SD)	5.83 (SD: 4.74)
Length of time since initial qualification, years: mean (SD)	11.07 (SD: 6.16)

The tool was designed using the Dyslexia Friendly Guide (British Dyslexia Association, 2018). The guide recommends using a dyslexia-friendly font (Arial was selected), avoiding the use of a white background and using a font size of a minimum 12 point (14 was selected based on feedback from SUGAR, one of the service user groups from the key informants group).

8.3.2. Overall feedback on the tool

Overall, feedback on the design of the tool was positive:

'*I think the colours are really good, it's quite friendly and opening, and it is quite informative, and I don't think it makes it too scary, which is nice because obviously when you mention the word cancer or screening, it's like OMG, and then people don't want to go but not the way you've done it (…) it's normally*

one page, or a boring booklet in black and white' (service user #17)

.

Several changes were requested. These are listed in Table 8.3, which categorises the revisions requested from each group and the rationale for accepting/rejecting the change. The rationale (seconded by the supervisory team) for including and rejecting the requested changes and suggestions and is included in the table. Although feedback during this phase pertained to the design/layout of the tool, occasionally participants made suggestions relating to the content of the tool. These revisions were incorporated, provided they did not contradict NHS cervical screening guidelines (NHS, n.d.; PHE Screening, 2019).

Table 8.3 Revisions made to the tool by group (Version 0.3 of the tool).

Section of the tool:	Revision requested by (*n* =)				Decision made:	
	Service user	Health professional	Key informants group		Revision accepted	Revision rejected
			Service user group (SUGAR)	Ealing Mental Health Forum		
GENERAL FEEDBACK						
[On translations of the leaflet] Is there anything you can put at the end [of the leaflet], I don't know if you have the resources, about getting this information in a different language	1					Funding will be sought for translations for subsequent versions of the tool
Increase the font for page numbers	1		1		Change made: font size was increased to 14 like the rest of the tool	
COVER PAGE						
Maybe insert the word 'your' to the [front cover] title: 'Support available for **your** cervical	1				Change made	

screening, I think it makes it slightly clearer and also slightly more personable like it's not an abstract thing that some people have and some people don't, it applies to everyone						
WHAT IS CERVICAL SCREENING						
A picture of the cervix and the different parts of the vagina might be helpful	1		3		Change made; diagram included on page 4. This revision was mentioned during both phases of data collection with service users	
BOOKING YOUR APPOINTMENT						
Change the background colour for this section (too dark)	1				Change made (very pale blue)	
BEFORE YOUR APPOINTMENT						
Make the tips section more like a flashcard/punchy bullet points rather than expanding and going into too much detail		4	2		This section was revised to avoid overwhelming service users with too much text	
ACTION PLANNING PAGE[32]						
Cannot write on the blue sections – issue with colour contrast			3	1	Change made to a much lighter blue	
Doesn't like the action planning page: 'It's important for me to go because … other ideas': sounds a bit like school, would people fill it out?		1				This was not raised by any service user so this change was rejected
Add a space for women to ask questions before their appointment				1	Change made	
TICK BOX PAGE						
This page has a lot of text, it would be better suited on two pages				1	Change made	
Bring this page to the beginning as it's the most useful and clears service user mental blocks		1	1			The tick box pages are most visible in the middle of the leaflet

[32] Three action planning boxes were included in the tool to allow women to write down their thoughts: 'This would help me go to my appointment', 'It's important for me to go because' and 'Other ideas'

Maybe perforate the tick box page so people can rip it out? The printers will just perforate that page, or you can perforate all the pages if you like	1					This is something which might be considered in subsequent versions of the tool
The background colour of the tick box page is too dark, cannot write on it	1		Group feedback	2	The background colour was changed to lilac	
AFTER YOUR APPOINTMENT						
Put in bold: 'Remember, having an abnormal result does not mean that you have cancer', because women do panic and go into complete meltdowns	1				Bold font was used for this sentence	
Use a diagram to describe 'hip bones'			2			There was no space to add a diagram to illustrate hip bones

Three contentious issues were raised during the think-aloud sessions: the length of the tool, the front cover image and the order of certain sections. In line with content analysis, the coding categories were derived directly from the transcribed data. These are discussed in the following section.

8.3.3 Main contentious issues

1) Length of the tool

The main negative feedback on the tool was its length (14 pages), an issue that was raised by several service users and health professionals during both phases of testing:

'*the booklet is too long/wordy*' (*n* = 3 SUGAR members),

'*Concentration is an issue with this group of patients, could we cut it down a little?*' (Psychiatric nurse, West London Trust).

However, several people stated that every page was of value:

'*Perhaps the leaflet is a little long, might be overwhelming for patients who are quite anxious, but having said that there are no sections I would remove and also you don't want to undersell the importance of the test*' (Doctor, West London Trust).

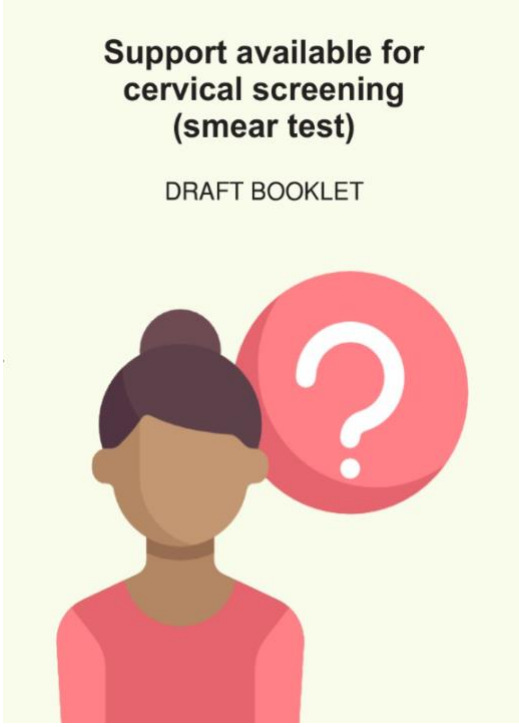
The rationale for not shortening the tool was for readability purposes, to avoid pages displaying too much information:

'*Avoid too much writing – it can be overwhelming*' (service user group funded by Mind/Macmillan),

'*I can't read it* [font was too small], *sorry my eyesight is so bad*' (service user #11),

'*The tick box page would be better suited on two pages*' (participant at Ealing Mental Health Forum).

Following feedback from service users that the tick-box page was too condensed when it was on a single page, it was reformatted onto two pages. This was also to give more prominence to this section, which aroused significant interest with service users, professionals and public health stakeholders.



2) The front cover page

Revisions to the front cover image

Figure 8.1 Front cover of the tool (Version 0.3 of the tool).

The draft front cover image *(shown inset)* was not popular with participants:

‘*Question mark on the first page is to produce some interest in the leaflet? Or is it about questions answered? Purpose of the question mark image is unclear*’ (Psychiatrist, West London Trust).

Some service users made suggestions for a new image:
‘*Face of a young person would be better on the first page*’ (SUGAR member),

‘*Illustrate groups of people most at risk of not attending in order to attract those groups*’ (SUGAR member),

‘*Personally, I’d prefer silhouette of a face, feeling relieved, rather than blank*’ (service user #12),

‘*you can put two people on it* [front cover image]*, and it’s like little* [speech] *bubbles, and they are having a conversation and it’s like (…) ‘no don’t be embarrassed’, like a supportive friend, so there’s two women talking and one is whispering to the other, coz that’s how it starts, it has to be someone really clued on that says ‘come on I’ll take you there*’‘ (service user #18),

‘If I had that leaflet I would share it with another person like a friend, I would say ‘oh look at this it’s got a bit of information and that might help you’, obviously I would share it if someone was coming with me to the appointment, I would show it to them to give them an insight’ (Service user #2).

Based on the suggestions received from service users #2, #18 and a SUGAR member, the front cover image was revised. An illustrator was commissioned to conceptualise the image, which illustrates three women of different ages and ethnicities having a conversation on a couch about going for cervical screening. During a clinic in a CMHT (site C), the candidate asked service users (*n* = 3) and health professionals (*n* = 2) to give feedback on the image. Service users (*n* = 3) requested a larger font size for the speech bubbles in the image. This change was incorporated.

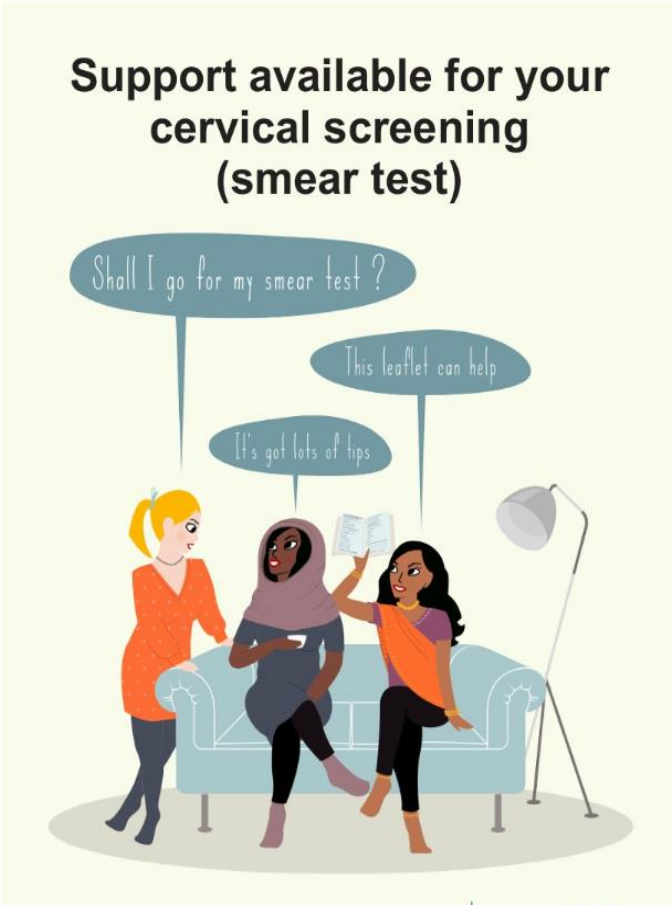


Figure 8.2 Revised cover image (Version 0.4 of the tool).

3) Order of sections of the tool

The order of certain sections in the tool was discussed:

'*I like the bit about getting extra support, appropriately put at the back* [of the tool]' (Psychiatrist, West London Trust),

'*It's relevant for people to know what to get checked between appointments. I'm thinking, though, that this section might be better near the end of the leaflet. As people are likely to be nervous before going for a smear test at all, it's probably not helpful to mention too early on what problems may arise even after one has gone for an appointment*' (member of a service user group).

Based on the feedback received from the member of the National Survivor User Network, the list of cervical cancer symptoms was removed from the '*What is cervical screening'* section and became a separate section entitled *'Looking after your health',* which is the penultimate section of the tool.

Two suggestions were discussed but subsequently rejected as they had not been raised by any service user: 1) one health professional suggested moving the tick box pages to the beginning as they considered them to be the most useful section; 2) another health professional suggested changing the order of every section:

'*Not 100% sure about this, but it seems more logical to describe the appointment and then offer tips, rather than giving tips before knowing what they are for*' (Psychiatrist, West London Trust),

'First give information about what cervical screening entails, then give tips, might work better to capture the interest, set the scene. Once the person knows what the appointment entails, she can then think about what support/tips she needs, and what is obstructing them' (Psychiatrist (2), West London Trust).

The revised tool, which incorporated the revisions, became Version 0.4 (a sample page is provided in Appendix 20).

8.4 Assessing readability of the tool

Assessing and adjusting the readability levels of the tool was identified in the systematic review (Study Two, Chapter Four, section 4.3.4) as a step to follow when developing an informed-choice tool for people with SMI. People living with SMI may periodically face chronic executive function issues, including drowsiness or cognitive blunting (Castillo et al., 2015; Le et al., 2017). In order to ensure accessibility of the tool for this group, who may have lower than average reading levels, the readability of the tool (Versions 0.3 and 0.4) was assessed using the Flesch Reading Ease and Flesch-Kincaid scales (Flesch, 1948; Kincaid et al., 1975). These scales were identified in the systematic review (Chapter Four) as having been used in other studies to assess the readability of a decision aid for people living with SMI (Brohan et al., 2014a). Those authors revised their decision aid to be understood by US 8th or 9th graders (between 13 and 15 years of age). The aim was to ensure that the present tool was readable by this age group.

The Flesch Reading Ease scale generates a score, a number from 0 to 100. A higher score indicates easier reading and lower numbers mark passages that are more difficult to read. The formula for the Flesch reading-ease score test is the following:

206.835 -1.015 (total words/total sentences) – 84.6 (total syllables/total words).

The Flesch–Kincaid Grade scale produces a score as a US grade level, reflecting the number of years of education generally required to understand this text. For example, a score of 8.4 indicates that the text is understood by an average student in 8th grade (13–15 years old). The grade level is calculated using the following formula:

0.39 (total words/total sentences) + 11.8 (total syllables/total words) – 15.59

Scores can be interpreted as shown in the table below.

Table 8.4 Interpretation of Flesch reading ease and Flesch-Kincaid Grade levels scores.

Flesch reading ease score	Flesch–Kincaid Grade level score	US school level	Reader's age	Explanation
100.00–90.00	3–5	5th grade	7–9 year olds	Very easy to read
90.0–80.0	5–6	6th grade	9–11 year olds	Easy to read (conversational English)
80.0–70.0	6–7	7th grade	11–13 year olds	Fairly easy to read
70.0–60.0	7–8	8th and 9th grade	13–15 year olds	Plain English
60.0–50.0	8–10	10th to 12th grade	15–17 year olds	Fairly difficult to read
50.0–30.0	-	College	17–19 year olds	Difficult to read
30.0–10.0	-	College graduate	University graduates	Very difficult to read
10.0–0.0	-	Professional	University graduates	Extremely difficult to read

8.4.1 Assessment of readability of the tool

Readability levels were assessed twice using versions 0.3 and 0.4 of the tool (which includes changes from the usability testing phase). User testing enabled the tool to be revised, including refining use of language to increase readability, such as providing a definition and diagram for the word 'cervix' as described above. The scores from the readability scales of Version 0.3 are reported in Table 8.5 below.

Table 8.5 Initial readability scores using the Flesch Reading Ease and Flesch-Kincaid scales (Version 0.3 of the tool).

Section of the tool:	Initial score (Version 0.3)			
	Flesch Reading Ease score	Flesch-Kincaid Grade Level	Reader's age (in years)	Explanation
Who is this leaflet for?	61.9	7.02	13–15	Plain English
What is cervical screening?	74.3	7	11–13	Fairly easy to read
Booking your appointment	68.02	6.48	13–15	Plain English
Before your appointment	70	7.7	12–14	Plain English
Tick box page(s)	80.31	3.92	8–9	Very easy to read
During your appointment	87.3	3.2	8–9	Very easy to read
After your appointment	72.4	6.6	11–13	Fairly easy to read
Symptoms page	64.84	6.33	13–15	Plain English
Getting support	50	7.84	15–17	Difficult to read

To increase readability, several revisions were made to Version 0.3. The 'Getting Support' page was ranked 'fairly difficult to read' during the initial score (see Table 8.5). This was due to the description of the charities which were listed on this page, which reduced the readability of that section. Each

charity was contacted and the simplified language that was provided was incorporated into the tool e.g. Jo's Cervical Cancer Trust suggested replacing 'eradicating cervical cancer' with 'eliminating cervical cancer'. These changes improved the readability of that section when final scores were calculated for Version 0.4. The reader's age decreased (meaning readability of the tool increased) from 15–17 to 10–11. The scores from the readability scales of Version 0.4 are reported in Table 8.6 below. The sections of the tool with an improved reader's age are highlighted in bold.

Table 8.6 Final readability scores using the Flesch Reading Ease and Flesch-Kincaid scales (Version 0.4 of the tool).

Section of the tool:	Final score (Version 0.4)			
	Flesch Reading Ease score	Flesch-Kincaid Grade Level	Reader's age (in years)	Explanation
Who is this leaflet for?	71.816	6.47	13–15	Plain English
What is cervical screening?	73.7	6	11–13	Fairly easy to read
Booking your appointment	74.1	5.7	10–11	Easy to read
Before your appointment	78.7	5.5	11–13	Fairly easy to read
Tick box page(s)	85.2	2.9	8–9	Very easy to read
During your appointment	83.1	4.4	8–9	Very easy to read
After your appointment	77.7	4.8	10–11	Easy to read
Symptoms page	67	6.5	11–13	Fairly easy to read
Getting support	56.3	6.6	10–11	Easy to read

Final reading capability levels improved from the initial score for another four sections of the tool: *Booking your appointment* (reader's age decreased from 13–15 to 10–11), *Before your appointment* (12–14 to 11–13), *After your appointment* (11–13 to 10–11) and *Looking after your health* (13–15 to 11–13). The following changes were made: the length of sentences was reduced

['What time will you need to get up and leave the house?' was removed] and complicated words [e.g. 'diagnostic'; 'cervix'] were either removed or replaced. The remaining sections maintained the same reader's age (13–15 or below). The changes described, therefore, achieved the original aim (see Chapter Eight, section 8.4) of developing an intervention that was (as a minimum) readable to an age group of 13–15 years.

8.5 Sign-off of the tool

Version 0.4 was emailed in April 2019 to each organisation cited in the tool as a source of support: Jo's Cervical Cancer Trust, My Body Back Project, Samaritans, SANE. In addition, the University of West London (which provided the PhD studentship) and the two Trusts where recruitment took place (West London NHS Trust and Dorset HealthCare University NHS Foundation Trust) were emailed the tool. The University of Surrey was added to the back page of the tool, as the principal supervisor of the candidate moved to that institution during the project.

The West London NHS Trust queried whether translations and/or other formats of the leaflet were planned. The candidate answered that an East London council is looking into funding to translate the leaflet into Arabic. The candidate acknowledged that while no funding is currently available, this will be sought for subsequent versions of the tool. Requested changes are listed below. This feedback represents the final round (six) of stakeholder involvement (see Figure 6.1).

Table 8.7 Changes requested to obtain the sign-off of the tool.

Change requested	Change requested by	Change made
Version control	West London NHS Trust	The following sentence was added to the back cover of the tool: 'This leaflet was printed in 2019. Version 1.0. The information in this leaflet was correct at the time of publication.'
Removal of all logos from the back page (the list of logos was confusing as to which organisation owns the leaflet)	West London NHS Trust	The logos were removed from the back page and were replaced by the name of the organisations
Include the NHS logo on the front cover	West London NHS Trust	The tool was not commissioned by NHS England, so the NHS logo could not be included on the front cover
Include Jo's Cervical Cancer Trust logo on the front cover	Jo's Cervical Cancer Trust	The logo was included on the front cover
Include the 'Creative Commons Non-Commercial licence' image on the back cover	University of West London	The logo was included on the back page
Include the acronym 'HPV' on page 4 to comply with 'Primary HPV screening' which is being introduced across the NHS	Consultant nurse (member of the key informants group)	The following sentence was modified to include HPV: 'Cervical screening is a free health check that looks for HPV or cell changes (abnormal cells) on your cervix'

These changes were incorporated into Version 0.4 of the tool. The amended version was emailed once again to stakeholders in June and final sign-off was approved in August 2019. The completed version of the tool became Version 1.0[33]; a sample page is provided in Appendix 21. The front cover of the tool is provided below (Figure 8.3). Table 8.8 details its final approved content.

[33] The weblink to access a copy of the leaflet is the following: https://www.surrey.ac.uk/sites/default/files/2019-08/cervical-screening-and-SMI-2019-lowres.pdf

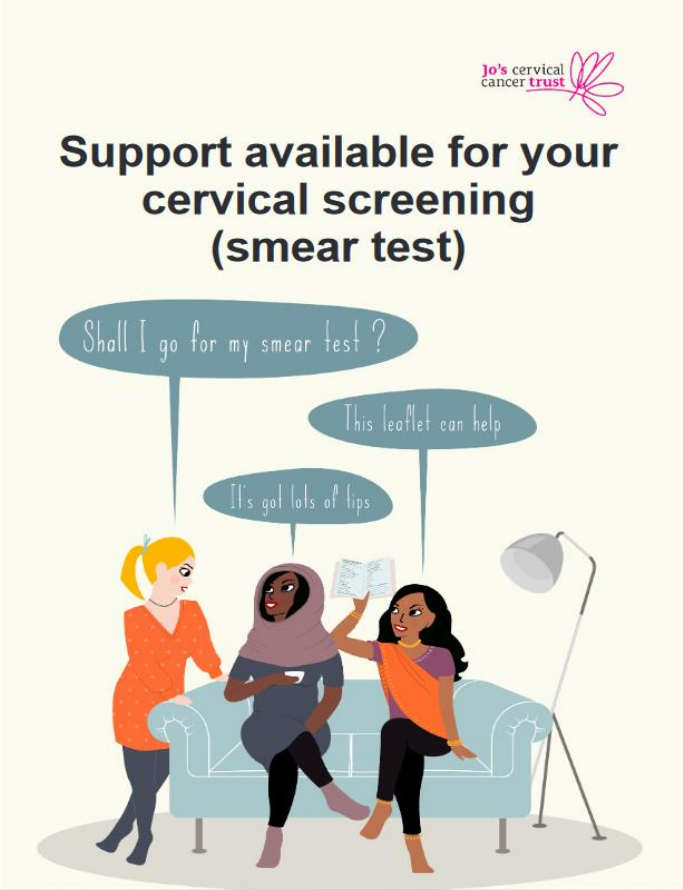


Figure 8.3 Signed-off tool (Version 1.0 of the tool).

Table 8.8 Content of the signed-off version of the tool (Version 1.0 of the tool).

Section (pages)	Content (summary)	Image/text box included	Barrier(s) addressed	Enabler(s) addressed
Title page (1)	Title: Support available for your cervical screening (smear test)	Image of three women discussing whether to go for screening Logo of Jo's Cervical Cancer Trust	-	-
Who is this leaflet for? (2)	Explanation of who the leaflet is for, and how it can help you plan your appointment	-	-	-
What's in this leaflet? (3)	Lists every section and includes page numbers	-	-	-
What is cervical screening? (4-5)	• who is eligible for screening • the different health settings where screening is available • what cervical screening entails • the benefits of attending and risk of not attending • definition of the cervix	Image of the female reproductive system Service user quote	Unsure of need for screening, fear of bad news, poor relationship with GP.	Understanding of benefits of screening, feeling 'health conscious', being anxious to avoid further health problems, familiar location.
Booking your appointment (6)	A list of things to ask the receptionist is provided, including: • chaperone • preference for a female nurse	Action planning text box is provided so women can optionally include the reason(s) why they have decided to book their appointment	Additional burden, screening environment aggravates mental health symptoms, staff can be rushed, appointment booking,	Reminders

	• reminder before your appointment is due • longer appointment • first appointment of the day, if you feel anxious in waiting rooms	Service user quote	difficulty remembering appointments	
Before your appointment (7)	List of tips which may help to improve the screening experience such as: • Planning your travel to the appointment (e.g. checking bus times) • Bringing something comforting or relaxing (e.g. music player) • Wearing a skirt or dress (so you don't need to fully undress) • Speaking to the nurse beforehand (e.g. if you require a pessary prescription) • Asking someone to accompany you on the day	Action planning text box is provided for women to optionally include what would help them go to the appointment and what would they like to ask the nurse	Additional burden, mental health symptoms reduce motivation for self-care, embarrassment, screening environment aggravates mental health symptoms, transport difficulties, difficulty remembering appointments, difficulty leaving the house due to mental health problems	Encouragement, reminders, continuity of care

	• Planning something nice and relaxing after the appointment (e.g. going for a walk in the park with a friend).			
Tick box pages *(8-9)*	Optional list of boxes to tick. Each box represents a service user barrier to cancer screening (Clifton et al., 2016). Developed as a 'disclosure aid' to support women who may find it hard to discuss their issue(s) with the nurse. Aim of this component to show the tool to the nurse before the test, so nurse becomes aware of the issue(s) without having to discuss them. Examples of tick box options include: ☑ I hear voices ☑ My medication makes me shake ☑ I have scars ☑ I am a survivor of sexual violence	-	Difficult to process information, mental health symptoms reduce motivation for self-care, stigma of mental illness, past negative experience, embarrassment, traumatising, lack of understanding of mental illness in screening professionals, screening environment aggravates mental health symptoms, staff can be rushed, staff can be rough, difficulty leaving the house due to mental health problems, made to feel like a burden on the health service	Staff being understanding, good relationship with GP, good relationship with practice nurse.
During your appointment (10–11)	Lists each step of a cervical screen Reminds the reader that they can ask the nurse to stop at any time	Image of someone having a smear test (cervical screen) Service user quote	Not knowing what to expect or what to do, traumatising	Wanting to be informed

After your appointment (12)	Explanation of what happens after the test List of suggestions of who to contact if you need support after the test	Service user quote	Not know what to expect or what to do, fear of bad news	Wanting to be informed, understanding of benefits of screening, feeling 'health conscious'
Looking after your health (13)	List of the symptoms to be aware of in between cervical screening appointments (e.g. unusual bleeding) is presented Explains what to do if symptoms appear	Image of a nurse	Unsure of need for screening, additional burden, mental health symptoms reduce motivation for self-care, embarrassment, fear of bad news	Wanting to be informed, feeling 'health conscious', being anxious to avoid further health problems, physical symptoms
Getting support (14–15)	List of organisations women can get in touch with if they need someone to talk to It also includes the contact details of organisations which can provide specialist support or advice on cervical screening	Logos of Jo's Cervical Cancer Trust, SANE, My Body Back	Past negative experience, traumatising, fear of bad news, difficulty leaving the house due to mental health symptoms, poor relationship with GP	Encouragement
Back cover page (16)	Lists who supported the development of the leaflet and provides links to websites for further information Version control	A Creative Commons Non-Commercial licence image	-	-

Chapter summary

At the end of this work, a theory-informed tool on cervical screening for people living with SMI was created. The tool was produced in collaboration with key stakeholders and met established criteria for readability relevant to the target audience. The tool was guided by several theories and frameworks and developed using the two systematic reviews (Lamontagne-Godwin et al., 2018, 2020) and barriers to cancer screening uptake identified by service users in a qualitative study which was underpinned by the TDF (Clifton et al., 2016). The following chapter (nine) describes a preliminary evaluation of the tool.

Chapter Nine – Evaluation of the tool

This chapter reports Study Five, which consisted of conducting a preliminary evaluation of the tool's impact on cervical screening decision-making with women with SMI. A cervical screening informed-choice tool had been developed which was readable, acceptable and usable to key stakeholders. The next step was to evaluate the proof of concept of the tool. Two validated scales were selected for the evaluation: The Stage of Decision-Making scale (O'Connor, 2000 – updated 2003) and the Decisional Conflict Scale (O'Connor, 1993 – updated 2010). Underpinned by the TPB, the data from this study were used to elaborate on the qualitative data collected as part of studies three and four.

9.1 Methods

Some of the study's methodological elements (ethical considerations, participant recruitment criteria and recruitment procedure) are identical to those used in Study Three and have been reported in detail in Chapter Seven (see section 7.1). Thus, only the methodological elements that are specific to this study are described below.

9.1.1 Design and setting

This was a quantitative, proof-of-concept study (to obtain an initial demonstration of the feasibility of the tool) using a convenience sample of women with SMI (*n* = 25). This study is in line with the 'Evaluation' phase (understanding change process) of the MRC guidance.

9.1.2 Sampling and recruitment procedure

Sample size justification: The selected sample size was based upon previous similar studies, for instance: pre-post intervention study (repeated measure), which evaluated a breast cancer prevention decision aid, recruited 17 higher-risk women (O'Connor et al., 1999; Scariati et al., 2015); a preliminary evaluation of a decision aid to support people with mental illness to reach disclosure decisions enrolled 15 service users (Brohan et al., 2014a), a conservative approach was used and (*n* = 25) women were recruited to test the feasibility and potential effectiveness of the tool. The recruitment procedure is identical to the one reported in section 7.1.

9.1.3 Materials

The demographic questionnaires for women with SMI and health professionals are identical to the ones presented in section 7.1 (Appendices 14 and 15). Sample participant information sheets, and consent forms are contained in Appendices 10-13.

Instruments: As recommended by the Ottawa decision support framework (O'Connor et al., 1999), the validated Decisional Conflict Scale (O'Connor, 1993 – updated 2010) and the Stage of Decision-Making scale (O'Connor, 2000 – updated 2003) were selected to assess decisional conflict and an individual's readiness to engage in decision-making respectively. These are contained in Appendices 22 and 23. These instruments are normally used with decision aids. Though the primary aim of this research is to develop and test an intervention that aims to surmount or reduce the impact of barriers to

cervical screening in women with SMI, these instruments were selected for this proof of concept study as the outcomes they measure are relevant to this research, namely whether the tool has any impact on participants' decision-making to attend screening.

The Decisional Conflict Scale (DCS) (O'Connor, 1993 – updated 2010) exists in four versions. It consists of four or five subscales depending on the version:

- Informed subscale (three items): Do you know which options are available to you, do you know the benefits of each option and do you know the risks and side effects of each option,
- Values clarity subscale (two items): Are you clear about which benefits matter most to you and are you clear about which risks and side effects matter most to you,
- Support (three items): Do you have enough support from others to make a choice, are you choosing without pressure from others and do you have enough advice to make a choice,
- Uncertainty (two items): Are you clear about the best choice for you and do you feel sure about what to choose,
- Effective decision (no items for this version).

The DCS measures an individual's personal perceptions of three factors of their decision-making process:

1. uncertainty in choosing options;
2. modifiable factors contributing to uncertainty (such as feeling uninformed, being unclear about personal values and feeling unsupported in decision-making); and
3. effective decision-making (other than for the 'low literacy' DCS) such as feeling the choice is informed, values-based, likely to be implemented and expressing satisfaction with the choice.

The 'low literacy' version of the Decisional Conflict Scale (DCS-LL) that is recommended for individuals with limited reading or response skills was selected for this study to mitigate any cognitive impairment of participants. The scale has two components: Part A of the scale asks the participant which treatment/screening option they prefer: Option 1/2/3 or Unsure. Part B is composed of four subscales: Informed (three items), Values clarity (two items), Support (three items) and Uncertainty (two items). The response format is yes, no, unsure. The scoring and interpretation for part B is as follows: for each item [e.g. 'Are you clear about the best choice for you?'], the participant responds with either 'No' (four points), 'Unsure' (two points) or 'Yes' (zero points). The mean score of the items is determined for each subscale (feeling uninformed; feeling uncertain, having unclear values; feeling unsupported) and multiplied by 25. The mean score of all items is also determined and multiplied by 25 to create a 'global' score of decisional conflict. A summary score of zero suggests no decisional conflict or an overall good decision process; a score of 100 suggests extremely high

decisional conflict. Improvement is therefore indicated by a reduction in score.

One published study – a cancer screening study with men eligible for prostate cancer screening – has investigated the psychometric properties of this version of the DCS (Linder et al., 2011). In this study, Cronbach's alpha for the total scale was ≥ 0.83, which demonstrated adequate internal consistency (Nunnally, 1978).

In terms of psychometric properties, The DCS-LL has been used (Henderson et al., 2013) and validated (Bunn and O'Connor, 1996) with people diagnosed with schizophrenia. The scale had adequate internal consistency (Cronbach's alpha values ranging between 0.78 and 0.84) and significant discrimination ($p < 0$ to 0.037) between service users who expressed certainty and uncertainty regarding decisions to continue with psychiatric treatment (Bunn and O'Connor, 1996).

The second scale used in this study is the Stage of Decision-Making; this scale (O'Connor, 2000 – updated 2003) measures (1) an individual's readiness to engage in decision-making, (2) progress in making a choice, and (3) receptivity to considering or re-considering options. The scale consists of four statements indicating increasing levels of readiness (I have not yet thought about the options; I am considering the options; I am close to choosing one option; I have already made a choice). Participants indicate their agreement with one of the statements by ticking that option. The scale

should be presented to the participant pre- and post-intervention. It can be used to screen out participants who may not benefit from an intervention; it is an important covariate in determining who benefits most from a decision support intervention. In terms of the psychometric properties of the scale, no validity data are available; early stages (statements one and two) correspond to higher decisional conflict (i.e. less readiness to make the decision) and later stages are associated with reduced decisional conflict (O'Connor, 2000; updated 2003).

Procedure

Each participant was asked to fill in the demographic questionnaire and to complete the Decisional Conflict Scale and Stage of Decision Making (O'Connor 1993, 2000). Following this task, the participant engaged with the tool (Version 0.4) and was then asked to complete the scales once more.

9.2 Analysis

Pre- and post-intervention, data from the Decisional Conflict Scale and Stage of Decision-Making Scale (O'Connor 1993, 2000) were analysed using SPSS (Statistical Package for Social Sciences, Version 24). Because scores were not normally distributed, a Wilcoxon signed-rank test, a non-parametric test, was used to compare women's decision-making regarding cervical screening before and after using the tool. It is used to test the null hypothesis that the median of a distribution is equal to some value. The effect size (*r*) of the

change was also calculated, as this is more meaningful for smaller samples and early-stage evidence (Sullivan and Feinn, 2012).

9.3 Results

9.3.1 Impact of the tool on decision-making

Forty women were approached by their clinician to take part in this evaluation study, of these, 15 women refused. Several women (*n* = 9) gave a reason for declining to take part: history of trauma: *n* = 2; bad cervical screening experience: *n* = 3; refuses to go for screening (no reason given): *n* = 3 and does not want to discuss cancer screening: *n* = 1.

A sample of 25 women aged 19–57 who accessed the two community mental health teams agreed to participate in the study between June and September 2019. Most participants (*n* = 17) reported having attended cervical screening more than once in the past (though two had not been for over five years), two participants had been once but had declined further invitations and three participants had refused to attend any cervical screening.

Three participants were aged 23 and 24 (eligible to take part in the study though not yet eligible for screening), though one had very recently received her invitation. The second disclosed she was unlikely to attend once she became eligible due to her history of trauma, while the third disclosed experiencing painful physical symptoms and for this reason was interested to take part in a cancer screening study to find out more about the test. Data

from these three women were included, as each had expressed an interest in taking part in the study and appeared to benefit from the information included in the tool. The demographic and health data were summarised using descriptive statistics such as standard deviations and means. A summary of the results from the demographic and clinical questionnaires is shown in Table 9.1 below.

Table 9.1 Demographic characteristics of study participants (service users) (*n* = 25)

Gender *n* (%) Female Other	 25 (100) 0
Age, years: mean (SD)	42 (11.3)
Ethnicity (grouped), *n* (%) White – all Black/Black British – all Asian/Asian British – all Other	 14 (56) 6 (24) 5 (20) 1 (4)
Self-report diagnosis, *n* (%) Schizophrenia spectrum Bipolar disorder Psychotic depression Depression Personality disorders Depression and PTSD Depression and eating disorder	 6 (24) 6 (24) 2 (8) 4 (16) 4 (16) 2 (8) 1 (4)
Had cervical screening *n* (%) More than once Once Never Not yet eligible	 17 (68) 2 (8) 3 (12) 3 (12)
Last cervical screening *n* (%) In the last 5 years Over 5 years ago Never	 16 (64) 3 (12) 6 (24)

Table 9.2 Decisional Conflict Scale - Difficulty in making this choice [Part A]

Which cervical screening option to you prefer?	Before using the tool *n* %	After using the tool *n* %
Option 1: I will attend my cervical screening appointment	14 56	21 84
Option 2: I will not attend my cervical screening appointment	5 20	3 12
Option 3: Unsure	6 24	1 4

Results from Part A indicated that the direction of change is towards having screening. There was a statistically significant reduction in decisional conflict regarding which cervical screening option participants preferred after using the tool (Z = -2.42, p = 0.016, r = -0.34).

Table 9.3 Decisional Conflict Scale scores (median) pre- and post- use of the tool [Part B]

Category	Median (IQR[34]) before using the tool	Median (IQR) after using the tool	Statistic[a]
Total Decisional Conflict Scale	39 (135)	11 (231)	Z = -2.81, p = 0.005, r = -0.39
Uncertainty subscale (Range)	6 (34)	0 (50)	Z = -1.34, p = 0.18, r = -0.19
Informed subscale	15 (30)	3 (68)	Z = -1.63, p = 0.102, r = -0.23
Values clarity subscale	10 (28)	4 (46)	Z = -1.34, p = 0.180, r = -0.19
Supported subscale	11 (46)	4 (67)	Z = -1.60, p = 0.109, r =-0.23

[a] Wilcoxon Signed-Rank Test

Decisional conflict scores (Table 9.3) improved (reduced) for all subscales post-use of the tool. The global and individual subscale decisional conflict scores were all below 25; scores below 25 are associated with making decisions (O'Connor, 1993 – updated 2010). A statistically significant overall

[34] IQR, interquartile range.

reduction in decisional conflict after using the tool (Z = -2.81, p = 0.005, r = -0.39) was also indicated. The direction of change is positive for each of the decisional conflict subscales: feeling uncertain (*Z* = -1.34, *p* = 0.18, *r* = -0.19), feeling uninformed (*Z* = -1.63, *p* = 0.102, *r* = -0.23), feeling unclear about values (*Z* = -1.34, *p* = 0.18, *r* = -0.19) and feeling unsupported (*Z* = -1.60, *p* = 0.109, *r* =-0.23); however, these reductions are not statistically significant.

Table 9.4 Stage of Decision-Making.

How far along are you with your [cervical screening] decision?	Pre-intervention		Post-intervention	
	n	%	*n*	%
a. I have not yet thought about the options	2	8	0	0
b. I am considering the options	1	4	4	16
c. I am close to choosing one option	1	4	1	4
d. I have already made a choice	21	84	20	80
e. Total	25	100	25	100

Results from the Stage of Decision-Making scale indicated that some women had begun to think about their options and/or consider another choice. The direction of change of participants' overall stage of decision-making on screening attendance after using the tool was positive, though changes were not statistically significant (*Z* = -0.17, *p* = 0.86, *r* = -0.03).

9.4 Preliminary analysis of the broader impact of the tool on participants

In order to obtain a broad understanding of the impact of the tool on women's attitudes towards attending screening, the results of all empirical data were taken into account. The qualitative data collected in studies three and four were used to support the interpretation of the quantitative data. As reported in Chapter Five (see section 5.2.1), some of the constructs of the Theory of

Planned Behaviour (TPB) were used to categorise the different ways the tool may have impacted participants. The first stage of analysis was therefore deductive, as this approach involves beginning with a theory, in this case the Theory of Planned Behaviour; the final level of analysis was therefore interpretive. The analysis was conducted using the quantitative data from this evaluation (*n* = 25) as well as qualitative data from service user groups (*n* = 4) and service user data (*n* = 18) reported in Chapters Seven and Eight.

In order to maximise the trustworthiness of the data, a reflective stance was taken to consider the ways in which the candidate may have influenced what is communicated, e.g. participants may have assumed that I was in favour of cervical screening due to my research interest, which may have led some to state that they were attending screening or that they had no difficulty attending in order to avoid a discussion on why they were declining their invitation. Field notes were also considered. The candidate had no prior involvement with either NHS Trust before commencing the research, so there was no conflict of interest in terms of her role as a researcher to collect the data. A potential risk of bias was that the candidate both developed and collected feedback on the tool. To mitigate this risk, the multidisciplinary supervisory team helped with the analysis.

Four preliminary categories of impact the tool had on participants were identified from the data, all supported by both qualitative and quantitative data. Each one is presented below; some service user feedback appears in more than one category, as each one is not mutually exclusive.

1) Category one: Impact of the tool on participants' knowledge of cervical screening and cervical cancer symptoms

Two subscales from the Decisional Conflict Scale related to knowledge around screening (the *Informed* and *Supported subscales)* and for both, scores had dropped below 25 after using the tool. Scores below 25 are associated with implementing decisions (O'Connor, 1993 – updated 2010). These scores are concordant with the qualitative feedback, in that they both indicated improvement in knowledge of cervical screening and cancer symptoms.

Several women reported that the tool was 'informative' (service users #17 and #9). Some participants reported their knowledge of cervical screening increased after having used the tool:

'Thought it was like a swab? [The candidate asked whether the tool has clarified what cervical screening entails] *yeah it's clarified it'* (service user #7),

'I have enough advice to make a choice, but for my daughter [26 years old], *I feel there isn't enough information out there, so the booklet is good for her'* (service user #14) and,

'That's good [referring to this sentence in the tool: 'having an abnormal result does not mean you have cancer']*, because I thought it did, you know I*

was in such a panic by the time my appointment came through, I was a nervous wreck, coz I thought I had cancer' (service user #6).

Some participants found it helpful to know that they can request certain adjustments:

[after I explained what a chaperone is] *'I would use a chaperone'* (service user #7),
'I didn't know I could ask for a smaller speculum. I have an inverted uterus so it hurts' (service user #13).

Some women commented that although they knew what cervical screening entailed, they felt the tool was useful as it reminded them of the benefits of cervical screening:

'I remember now that it's important to go, even though I really don't like it' (service user #2).

Some participants found the '*Looking after your health*' section of the tool, which describes possible symptoms of cervical cancer, useful:
'*this page* [Looking after your health section] *has clarified what the symptoms of cervical cancer could be. I didn't know that* [these symptoms] *could be cervical cancer. Useful to have in the leaflet'* (service user #17).

Other participants commented on the usefulness of the '*Getting Support*' section, which includes the contact details of several organisations:

'I'm very concerned about my daughter [who displayed a lot of the symptoms described on the page]. *Didn't know Jo's Trust, will contact them. Think it's great to have the charity contact details in the leaflet'* (service user #12) and [on including the cervical screening clinic for survivors of sexual violence – the My Body Back project – in the 'Getting Support' section]: '*ah that's useful*' (service user #10).

2) Category two: Impact of the tool on participants' attitudes towards cervical screening

Changes in three subscales (Values clarity, Supported and Uncertainty) of the Decisional Conflict Scale indicated more positive attitudes towards screening following interaction with the tool. From examination of the qualitative data, it was possible to determine that the tool may improve the cervical screening experience of some women who either already attend or are unsure about attending. It is also evident that some women with SMI may be at increased risk of having a negative screening experience compared to women in the general population. Research has shown that such a screening experience may reduce a woman's inclination to attend in the future (Clifton et al., 2016). Though most participants reported attending cervical screening (and wanted to continue attending), it became apparent during interviews that some women feared the appointment (e.g. that it might trigger

distressing memories and/or worried about the nurse's reaction if they responded in an unexpected way during the test). The tool might therefore be helpful to women who have had a negative *screening* experience in helping to address their anxiety. Some women might have felt judged by the practice nurse or experienced significant pain during the test. One participant disclosed a bad experience with the nurse, which had led the participant to decline cervical screening thereafter. The candidate asked whether the tool had changed her decision:

'Maybe, something that I will probably think slightly differently, this whole leaflet, with me I already feel a little differently about it [going for screening]' (service user #9).

The tool might also improve the experience of women who find it hard to overcome feelings of shame, embarrassment or anxiety. Several participants alluded to how the tool might support them in that way:

[on the tick box pages] '*it's brilliant, because then you don't have to explain that you have a mental health condition, so if you behave a bit strangely, they're understanding, rather than brush you off or treat you like an idiot*' (service user #1),

'I would find the tick box page useful' [to disclose her history of child sexual abuse] (service user #6) and

‘*Waiting, and waiting* [in GP surgery waiting room], *I start shaking, I could easily get panic attacks (...) Definitely would be easier for me [*to go*] if I don’t have to spend time in waiting rooms, if that could be as it says here first appointment, that would help’* (service user #9).

3) Category three: Impact of the tool on participants’ intended behaviour

Results from Part A of the Decisional Conflict Scale [‘*Which cervical screening option do you prefer?*’] showed that for some participants, the tool had a positive impact on their intention to attend screening. All participants who, before the use of the tool, were unsure whether to attend cervical screening (*n* = 6) had decided to attend after using the tool. Of those (*n* = 5) who refused to attend before using the tool, three still refused after viewing the tool, one decided she would attend, and one was now unsure. This suggests that it may be harder to change intention among women who are clear about refusing to attend screening compared with those who are unsure.

For some women who already attend, while their decision to go for screening had not changed, the tool may improve their screening *experience*. The tool may be beneficial to them in various ways, for instance by supporting them to plan their appointment. As reported in Chapter Five (section 5.2.1), an implementation intention would involve a woman outlining the various steps required to perform the cervical screening behaviour. The ‘Booking your appointment’, ‘Before your appointment’ and ‘Getting support’ pages were

considered useful by some women to book and attend their appointment (e.g. tips on what to wear so as not to feel so exposed, whom or what they could bring for support, who they could contact before/after if they needed to discuss their anxiety):

'If I had that leaflet I would share it with another person like a friend, I would say 'oh look at this it's got a bit of information and that might help you', obviously I would share it if someone was coming with me to the appointment, I would show it to them to give them an insight (…) [women] *can have a look at the leaflet, so it prepares them, it would give them more faith to book this test*' (service user #2) and,

'I like the sentence 'treat yourself to something nice', I think that might be good because if you've had an experience that you're not happy with and then you treat yourself, it will help you to forget your bad experience (...) maybe treat myself to some lunch somewhere or something' (service user #4).

Lastly, the 'tick box pages' section, which can act as a disclosure aid, may improve women's intention to attend screening:

'[On using the tick box page during the appointment]: *I would consider going now'* (service user #9),

[following disclosure of trauma]: *'If I had the leaflet, I would make an appointment straight away. I love the tick box page, it gives you a voice, it makes you feel that your fears are legitimate. The test mimics what happened to me, it's something that is there in your body that you don't want. I cry after my appointment'* (service user #11).

4) Category four: When the tool may not help

It was unclear whether the tool enabled some women to make a more informed decision. Results from the Stage of Decision-Making scale indicated that for the majority of participants (*n* = 21 pre- and *n* = 20 post-intervention), the tool did not affect, either way, their intended behaviour regarding cervical screening attendance. Some women reported attending their appointment with no issues. Exploring participants' experience of screening (including any difficulty with attending) was not an aim for any of the studies; however, during the interviews several participants (*n* = 3) explained that they already understood the benefits of screening and did not identify any barriers to going. They indicated that they attended their appointment on a regular basis to avoid putting their health at risk:
'*I do not have shame about my body, I go for my health. I wouldn't use the tick box page*' (service user #8) and,

'*It's a very straightforward appointment, I make my appointment and go*' (service user #12).

Other women, however, reported that while the tool was informative, there was nothing that could make them reverse their decision to decline screening:

'I wouldn't use the leaflet because I don't want to go for screening (...) there is nothing that would make me go' (…) the leaflet hasn't changed my mind about going for screening' (service user #4) and,

'Nothing could make me change my mind' (service user #13).

Some women did not give a reason why this decision was taken. Several participants shared their experience of fluctuating mental illness and disclosed that when their mental health symptoms became worse (for instance, making it hard to leave the house or experiencing delusions), no amount of support could make them attend. Although, in principle, they agreed that it was important to attend cervical screening, they were unwilling to book an appointment during that time and would often forget to do so when they felt better again. One woman explained how being '*bombarded*' (service user #3) with reminder letters during this time was unhelpful. It appeared that a positive screening experience in the past could be overshadowed by the current presentation of their mental illness:

'The nurse was lovely [during her previous cervical screen] *but I don't feel like going'* (service user #17) and,

'Last time I had cervical test I had unpleasant experience and then test hasn't been finished and actually after that I just couldn't bring myself to do it again, that's one of the reasons, the other reason, it is my mental health, I find it difficult to go' (service user #9).

Some feedback suggests that these women's refusal to attend is due to their belief that they will be diagnosed with cancer:

'The nurse will find cancer' (service user #6) and,

'Fear of the unknown can also be a factor which stops women from going: if I do go then it's more likely that I have it [cancer], *so people think if I don't go and I'm alright now, maybe I shouldn't go because if I do go then something might happen'* (service user #4).

For women (*n* = 10) who either reported declining cervical screening or had not been in over five years, the 'anticipated regret' (Rosenbaum et al., 2014) of having missed/delayed a cancer diagnosis due to non-attendance seemed to have little or no influence on their decision. The section on the benefits of attendance and the risks of non-attendance (tool pages 4–5) did not appear to alter their decision.

Some women reported that they did not require additional support during cervical screening; these women were clear that the tool was of little use to them:

‘*Personally I don’t read leaflets even if they are handed to me (…) I find it easier to have a face to face conversation (…)* [on the tick box pages:] *It would probably make me more anxious than having to say it, and I would assume my nurse would have that information anyway*’ (service user #3), *‘I wouldn’t call a mental health professional or a charity* [if the appointment made her feel anxious], *I’m just glad when it’s over and done with’* (service user #5),

‘It [the tick box pages] *would be useful but me personally, I am a mental health person but I am very private person, I don’t like people to know that I have mental health, even my closest friends* [don’t know]*’* (service user #8).

9.5 Discussion

9.5.1 Summary of key findings

The change between pre- and post-utilisation of the tool in decisional conflict was overall in a positive direction. The change between pre- and post-utilisation of the tool in stage of decision-making was in a positive direction (16% of participants were considering the options in comparison to 4% before using the tool). The tool appears to have helped some women make an informed decision to attend, while for others, the tool made them reflect on their decision to refuse screening, also making their choice more informed. For several women, there was no movement in their decision to decline screening; some may need a separate intervention to help them

attend. For the reasons stated above, the preliminary data that were gathered demonstrate that the proof of concept of the tool was achieved. Looking at the various ways the tool could impact upon women's decision-making exemplified that this informed-choice tool can positively influence a woman's intention or attitude towards cervical screening.

The tool appeared to address some of the barriers identified in each of the three categories where the tool had an impact (such as how to disclose a history of trauma, what support is available during the appointment or feeling anxious in waiting rooms). The tool might be beneficial in terms of patient engagement and satisfaction with care, for example by starting a dialogue between the patient and the smear taker. This study has illustrated the complexity of the cervical screening decision-making process for some women with SMI, which goes beyond the dichotomy of whether to attend or decline the invitation. There are several ways to decrease decisional conflict, including becoming informed about choices for screening, feeling supported in the screening decision, knowing personal priorities around the decision and feeling certain about the decision. The positive direction of change from the subscales of the Decisional Conflict Scale and the relevant qualitative data showed that the tool addressed every aspect of the decision-making process.

A determinant of inconsistency between a person's attitude and the uptake of the test may be barriers, objective or perceived, to undergoing a test such as cervical screening (Michie et al., 2004). As discussed in Chapter Five (see

section 5.1), performing any of the steps related to cervical screening uptake can prove prohibitive to women with SMI. Previous studies have found that if an individual has, in the past, engaged in a health behaviour, they are more likely to continue performing that behaviour in the future (Norman and Conner, 1996; Ronis et al., 1989; Sutton, 1994). In addition, research has shown that having had a positive screening experience increases the intention of attending in the future (Roncancio et al., 2013). For some women with SMI, this decision-making process may be more complex. If the screening invitation is sent when the woman is unwell, she may refuse to attend even if she had a positive screening experience in the past. Further research is needed to address the following barriers to screening for women with SMI identified in the Clifton et al. (2016) study: 'My mental health symptoms reduce motivation for self-care' and 'I find it difficult leaving the house due to mental health problems'. The tool may not be appropriate for this group as they may not be in a position to make an informed decision; they may need more support than a leaflet (see Chapter Ten, section 10.5).

Owing to the infrequent and sensitive nature of the test, women may start a new decision-making process every time about whether to be screened. An individual's attitude towards cervical screening uptake is therefore not 'static' and is likely to be influenced by several factors (Clifton et al., 2016). The tool may support some 'lapsed attenders' (i.e. screening categories 'late' and 'very late') to build implementation intentions. While all the participants in the study knew what cervical screening entailed, some were unaware of the adjustments they can request (e.g. asking for a smaller speculum or a

chaperone) or where they can access support. The tool seemed to have increased their knowledge in this regard. Qualitative data illustrated how the tool may provide some reassurance to women who usually attend their appointment but find it difficult to disclose any issue(s) they are struggling with (e.g. how to disclose that they are survivors of sexual trauma). These difficulties may put some women at higher risk of a negative screening experience; the tool may reduce the possibility of such an experience occurring and improve their attitude to screening.

Lastly, fear of cervical screening and/or cervical cancer, indicated by avoiding or not attending, seemed to have played a role in some women's decision-making process. It is unclear to what extent the information provided in the tool was able to reduce their fear, thereby allowing them to make a more informed choice. Further research is therefore warranted to find ways to overcome this barrier, for example by supporting them to reduce their anxiety, either through counselling or other intervention, such as urine sampling (see Chapter Ten, section 10.5).

9.5.2 Strengths and limitations

To our knowledge, this is the first study to evaluate an intervention's impact on cervical screening decision-making for women with SMI (Barley et al., 2016). Initial evidence has been gathered on the complexity of the decision-making process for some women living with SMI. The sample size was not powered to detect a statistically significant difference, as this study was designed to assess proof of concept only, so findings should be interpreted with caution. Nonetheless, though the findings from this study cannot be

generalised due to the small size of this convenience sample, the cohort was diverse in terms of demographics, type of site (both rural and inner city) and screening participation, so findings are likely to be applicable to a wider population. This evaluation study has highlighted the potential impact that the various barriers to cervical screening can have on women's choice whether to attend screening, and how the tool may be able to help.

In terms of the proof of concept, the Decisional Conflict Scale and Stage of Decision-Making Scale (O'Connor, 1993, 2000) were relevant instruments for measuring the immediate post-intervention outcomes. The quantitative study captured changes in participants' decision-making, but the data were unable to illustrate the full impact that the tool may have had on participants. However, this limitation of the quantitative data was offset by including the interview data in the analysis. The qualitative data were able to capture the impact of tool on some participants, such as how it may improve their future experience of screening, or how it has improved their awareness of cervical cancer symptoms. For instance, though some women maintained their decision to attend screening before and after using the tool, they disclosed feeling more confident about attending their appointment, knowing what adjustments they can request. The qualitative data were therefore useful to support the interpretation of the quantitative data and demonstrates that the tool supported informed decision making.

A limitation of this study is the risk of social desirability bias, which refers to the tendency of research subjects to over-report socially desirable attitudes

and behaviours instead of choosing responses that reflect their true feelings (Paulhus, 2002). This effect may have led to an over-reporting of past and/or future intentions regarding cervical screening attendance among participants, possibly to avoid discussing why they refuse to attend cervical screening. Lastly, it was not possible to verify whether those participants who were overdue for cervical screening and disclosed an intention to book an appointment did so following use of the tool; this should be explored in future work.

Chapter summary

This chapter has reported the results of a preliminary evaluation of the tool, which showed a positive direction of change in relation to feeling informed about their decision. The data analysis of the impact of the tool on study participants, using some of the TPB constructs, identified four categories of impact. The tool may have an impact on knowledge and attitudes to screening, as well as improving the experience of women who attend their appointment but who may be at risk of a bad screening experience. Further research is warranted to develop interventions that seek to remove some of the barriers to screening which could not be addressed by this tool. The next and final chapter highlights these areas of future investigation and the contribution of this research to research, policy and practice.

Chapter Ten – Discussion and conclusions, future research and dissemination

This final chapter summarises the main findings from the research. A reflection on its unique contribution to knowledge is presented. The methodological strengths and limitations of developing the tool are also provided here. Lastly, the tool's implications for clinical practice and possible future research directions are considered.

10.1 Summary of the research findings

This research provides specific information on how limited resources could be utilised to improve health outcomes using a population-specific informed-choice tool. The tool was developed following the identification of a knowledge gap which was highlighted by previous research (Barley et al., 2016; Clifton et al., 2016), that is, the lack of any intervention to support women with SMI to attend cervical screening in the face of barriers specific to this group. All three objectives that were set out for this PhD research have been achieved. A theory-informed tool developed in collaboration with key stakeholders that meets established criteria for readability relevant to the target audience has been produced (objective one). The development of the tool was guided by the MRC framework (Craig et al., 2013) and the Theory of Planned Behaviour (Azjen, 1991), and was underpinned by the Theoretical Domains Framework (Cane et al., 2012); the tool's components were developed using behaviour change techniques (Michie et al., 2015). This

fulfils objective two, namely that the informed-choice tool should be theoretically underpinned. Lastly, the acceptability and usability of the tool was tested with key stakeholders (objective three). Stakeholder involvement ensured that the voices of women with SMI were heard, allowing the tool to be developed in line with their preferences, where this did not contradict NHS cervical screening guidelines (NHS, n.d.; PHE Screening, 2019).

PPI participants (including mental health service users, health professionals, as well as members of the key informants group: policy makers, clinicians, clinical academics, service user groups, charity workers) were consulted at every stage of this research (see Figure 6.1). PPI participation ensured the informed-choice tool was relevant and addressed issues of importance to the target group (Ashcroft et al., 2016). PPI feedback was also sought on the dissemination of the tool; this highlighted the importance of it being available in non-clinical settings (e.g. Recovery Colleges), in addition to primary and secondary NHS health care. Recovery colleges offer educational courses that focus on mental health and recovery; courses are ‘co-produced’ and ‘co delivered’, whereby service users, carers and staff collaborate to develop courses. A cancer-screening module within a Recovery College curriculum is currently in the early stages of development (see section 10.4.1).

Results from the preliminary data analysis show that the tool may impact women in several ways. While the tool may not impact women’s decision-making if they already attend screening, some participants reported improved knowledge regarding cervical screening and cervical cancer

symptoms (Category one: Impact of the tool on participants' knowledge of cervical screening and cervical cancer symptoms). Several participants became aware of the kinds of adjustments they can request (such as asking for a chaperone or requesting a smaller speculum), which in turn may improve their experience. In addition, regardless of whether women decided to attend screening, the list of symptoms associated with cervical cancer displayed in the tool was also deemed beneficial by some participants, some of whom appeared to be unaware of them. The tool may thus have the added benefit of acting as a health promotion tool, as it encourages women to speak to their health professional if any of the symptoms appear. Becoming aware of which adjustments they can request and what the symptoms of cervical cancer are two examples of how the tool increased participants' informed choice about screening.

Some participants reported a positive change in attitudes regarding screening (category two: Impact of the tool on participants' attitudes towards cervical screening). These findings highlight the need for an intervention to support women who find it hard to disclose a traumatic event or previous negative screening experience. By sharing their stories, participants highlighted the specific issues needing to be addressed within the tool to increase the likelihood of impact (e.g. how to reduce the risk of re-traumatisation). Several women disclosed such experiences, which were also raised as the reasons for non-participation by other women. The tool – in particular the tick-box pages – has the potential to reduce the burden on women to disclose a painful experience, such as a sexual assault, or relate

some of the symptoms of their mental illness, such as hearing voices or scarring from self-harm. Support with disclosure may in turn reduce the risk of having a negative screening experience. Though the findings are from a relatively small sample, and so should be interpreted with caution, given the significant prevalence of sexual violence in this group, this tool may also be useful for some women without SMI who have experienced trauma.

The results also showed that while some women had already decided that they would attend screening, the tool may improve their screening *experience* (Category three: Impact of the tool on participants' intended behaviour). The tool may assist them with planning their appointment – to build an implementation intention – by listing tips and suggestions to help them feel more comfortable and supported before, during and after their appointment.

It was unclear whether the tool enabled some women to make a more informed decision (category four). Some had already decided to attend (they disclosed having no difficulty with screening), while others had maintained their decision to decline screening, due to prior adverse experiences or their beliefs of what screening entails; this second group may require further support (see section 10.5). For women in this category, although the quantitative data showed no change in their decision pre- and post-use of the tool, the tool may have solidified their informed decision to either refuse or attend cervical screening. Further research would be needed to explore whether the tool had any impact on this group (see section 10.5). Lastly,

some women reported that they did not use leaflets; therefore, another format may help (see section 10.5).

10.2 Reflections on conducting this research

Cervical screening uptake is a personal choice. During the data collection process, although I highlighted the benefits of cervical screening as well as going for a check-up if worrying symptoms appeared, a conscious effort was made to keep an open mind so as not to influence participants' decision-making when the option of non-uptake was discussed during interviews. Some women disclosed gynaecological issues during the three data collection phases, such as having very painful periods, irregular bleeding or pain after sex. In these instances, I encouraged the service user to make an appointment with her GP, or to discuss it with her trusted mental health professional for assistance on seeking medical help.

Upon reflection, I made three assumptions at the outset of the interviews. The first was that women with SMI may need additional support during and/or after the appointment. The feedback received was that often women would benefit from support *before* their appointment. Participants explained that they often felt anxious in the days leading up to or the night before the appointment and would appreciate talking to someone who would motivate or reassure them, like a friend or their mental health worker. The second assumption was that women who have experienced sexual trauma would be likely to reject or delay cervical screening uptake. While this was raised by some participants and given as a reason why others refused to take part in an interview, some of the

women who disclosed a history of trauma chose to attend screening, but often had a negative experience as it caused them distress and anxiety. Becoming aware of their resilience to attend a health check that can cause them significant psychological harm, coupled sometimes with disregard for their own wellbeing was a very humbling experience. Thirdly, I assumed that mentioning the word cancer (or the risk of cancer) in the tool might have a negative effect on their decision to attend screening. This worry was also raised by several members of the key informants group and interviewed health professionals (see Chapter Seven, section 7.3.2). Though the sample does not allow us to generalise whether this would be the case for most women, this concern was not raised by service users; it may reflect the paternalistic or 'overprotective' behaviour of some health professionals towards their patients (Marwaha et al., 2009; Slade, 2009). This research has highlighted the importance of giving these women a voice.

Lastly, collaborating with a variety of different stakeholders from clinical, policy and academic backgrounds, each one with a different agenda, posed both rewards and, at times, challenges. Producing an informed-choice tool that is being used in clinical settings (see Chapter Ten, section 10.4.1) has been a hugely gratifying experience. While the cancer charity supported this project's concept of developing a tool for women with experience of mental illness as part of an academic exercise, there were at times differing views (see Chapter Seven, section 7.3.2), such as the extent to which the tool should explicitly target women with mental illness, or which logo should appear on the front cover. In addition, the charity's agenda to launch this tool

(as soon as possible) was at odds with the PhD timeline, which required developing the tool with academic rigour. This research has increased my skills to collaborate and negotiate with stakeholders with differing interests.

10.3 Limitations of the research

The research has several limitations, which are listed below.

First, the tool may not be applicable to all women with SMI. Certain populations remained inaccessible during the development of the tool, such as service users on forensic and inpatient wards, or homeless people who do not access primary care, so the leaflet may not be acceptable or usable to them. In addition, the literature review of barriers and enablers identified no studies from low and middle-income countries. It is possible that this may have led to certain barriers being overlooked, though this appears unlikely, as the literature review of the barriers to screening was inclusive of any health setting. Furthermore, some study participants had spent time on inpatient wards, and health professionals who took part in this research and members of the key informants group work in multiple settings, so their perspectives may have partly offset this limitation. Second, some of the systemic barriers to accessing cervical screening pertain to the healthcare system, which this tool could not address.

With regards to the intervention, developing a paper colour leaflet has its limitations. Though the tool can be read and downloaded free of charge and is available on several websites and NHS portals, printing costs can be a

barrier to its dissemination and visibility. In addition, some people do not read leaflets. The content is available online and could easily be adapted to another format.

Most theories applied to public health interventions tend to emphasise health as a matter of individual choice and capability and, by implication, a personal responsibility (Davis et al., 2015; Holman et al., 2018). Health behaviour interventions have sometimes been criticised for side-lining the issues of context and social factors (Davis et al., 2015). While use of the TPB is widespread, one of its limitations is the assumption that individuals systematically use the information available to them to make rational decisions about how to behave (de Vries and van der Pligt, 1998; Sandberg and Conner, 2008). Cancer screening is a complex behaviour, which entails personal, social and environmental factors, yet the TPB fails to acknowledge the influence of affective processes (Conner and Armitage, 1998). The TPB does not reflect the extent to which the decision to attend cervical screening is influenced by non-rational factors, such as values, morals and other reasons unrelated to self-interest (Armitage and Conner, 2001; Roncancio et al., 2013).

This research builds on previous studies, which have highlighted that emotional outcomes are taken into consideration during one's decision-making process (Michie et al., 2004; van der Pligt et al., 1998). Affective processes are particularly relevant for this population, who have been estimated to have a lifetime incidence of trauma and abuse of 69%

(Anderson et al., 2016). Last, while there has been interest in anticipated regret in recent years (Rosenbaum et al., 2014), none of the leading theories of health behaviour, including the TPB, yet incorporate this important construct (Brewer et al., 2016).

The TDF is widely considered to be the most comprehensive framework for designing implementation interventions, as it provides a broader coverage of potential change pathways than any single theory (French et al., 2012). It provided a number of benefits to the development of the tool, as it highlighted the relevant domains that can either hinder or enhance the screening behaviour for this group. The behaviour change techniques were selected in accordance with the relevant TDF domains, thus enabling the tool to be theoretically underpinned. However, several limitations have been mentioned (Francis et al., 2012). In the context of interview studies when the TDF is used as a coding framework, inter-coder agreement can be low; this may be due to the difficulty within some research teams to clarify the boundaries between domains (Francis et al., 2009, 2012). The second limitation relates to the fact that interview-collected data may reflect what participants perceive to be influencing their behaviours, rather than ‘actual’ causes (Weiner, 1985). Third, an interview topic guide based on the TDF may be considered too constricting, which may cause participants to respond to questions on the topic in ways that fit into the framework, thereby missing valuable nuances (Francis et al., 2012). However, a study on the barriers and enablers to hand hygiene, which compared results when methods were based on the TDF versus atheoretical methods, concluded that using a

theoretical framework may elicit barriers that may not ordinarily be identified, but which can have an important impact on behaviour (Dyson et al., 2011). Lastly, critics of the TDF have reported that the full range of meaning of the domains may not be evident to researchers without training or experience in behavioural sciences, so the TDF may be poorly or superficially applied; thus, including a health psychologist within the research team is advised (Francis et al., 2012). A health psychologist and a chartered psychologist (who is a full member of the UK Division of Health Psychology) were supervisors to the candidate to ensure the TDF was correctly utilised in the context of this research.

10.4 Implications for practice

The principal implication for practice is that the tool may help people make an informed choice whether to attend cervical screening. Since cervical screening is beneficial and the tool addresses barriers to attendance, the tool may also translate into more women attending, thus saving lives and reducing the burden of needing cancer treatment.

This research has other specific implications for practice at different points of the cervical screening journey. Prior to the test appointment, the tool may impact on the way in which clinicians discuss screening uptake with their patients, for example it might facilitate a discussion of why the patient is struggling to attend. The tool may also act as a reminder/trigger to the health professional to discuss screening during a consultation. During the cervical screening appointment, if the patient shares the ‘tick box pages’ with the

smear taker, this may have an impact on the way staff view screening through the lens of someone who has mental illness and/or had a traumatic experience. Having a better understanding of a patient's set of circumstances might in turn modify their behaviour towards other patients. The tool might have an impact on how patients and smear takers interact during the screening appointment, for example any words to avoid using or asking for a narrower speculum. Following the appointment, patients may feel more comfortable discussing their screening appointment with a member of their mental health support team. Service users may also feel more confident to ask their trusted mental health professional to accompany them to the appointment. These implications for practice require further investigation (see section 10.5).

10.4.1 Dissemination of the tool and outreach

Considerable effort has been made to disseminate the tool; uptake has been achieved by so many services and across different settings, indicating its perceived value by health professionals. In April 2019, funding was received from the University of Surrey to develop a webpage on this project where the tool could be hosted. In addition to details about this research, information was collated on other resources and specialist clinics throughout the UK, which aim to support people who find it hard to go for screening. The weblink was added to the back page of the tool.[35]

[35] www.surrey.ac.uk/mental-health-friendly-health-checks

The leaflet is available on SystmOne, a clinical computer system currently used in GP practices, community services, prisons, hospitals, social care and mental health. It is also available on Jo's Cervical Cancer Trust[36] website, NHS Trust physical health portals and some local EMIS (Egton Medical Information Systems) Health[37] portals, NHS websites such as the Northern Cancer Alliance[38] or third sector organisations such as HealthWatch Ealing.[39] The leaflet is being downloaded by CCGs and secondary care Trusts and distributed in community mental health teams, trauma and forensic services, primary care and sexual health clinics, as well as specialist clinics and charities working with women who have experience of mental illness and/or trauma. A print-run of the tool was funded by the West London Trust (*n* = 500) and the University of West London (*n* = 500) following a press release.[40] Distribution is currently under way in specialist cervical screening clinics and community mental health teams, following a temporary pause due to the COVID-19 pandemic in spring 2020. Imperial College Health Partners have written a blog about this research, which is hosted on their website.[41] In addition, the tool continues to be downloaded by universities, charities and businesses.

[36] www.jostrust.org.uk/smeartestsupport
[37] EMIS Health supplies electronic patient record systems and software used in primary care, acute care and community pharmacy in the United Kingdom
[38]https://www.northerncanceralliance.nhs.uk/pathway/prevention-awareness-and-screening/cancer-screening/
[39]https://healthwatchealing.org.uk/news/west-london-nhs-trust-involved-in-life-changing-smear-test-research/
[40] https://www.uwl.ac.uk/news-events/news/support-smear-tests-set-save-hundreds-lives
[41] https://imperialcollegehealthpartners.com/project/improving-cervical-screening-women-mental-health-conditions/

The tool is being used as part of two separate training packages on cancer screening in two mental health Trusts and as part of a module that is currently being developed on cancer screening for a Recovery College. Funding was received from the West London NHS Trust, the University of West London and Dorset Healthcare University NHS Foundation Trust to develop a 90-second animated video, created by Sci Ani (Science Animated),[42] which illustrates the key points of the tool. The video is available on Jo's Cervical Cancer Trust,[43] YouTube[44] and the project website hosted by the University of Surrey.[45] It was included alongside the tool in the December 2019 Newsletter of the Faculty for Homeless and Inclusion Health.[46]

Oral and poster presentations of various stages of this research were given at the Annual Division of Health Psychology Conference in 2018, the Annual Public Health Conference in 2019, the Behavioural Science and Public Health Network Annual Conferences in 2018 and 2019 (poster was runner-up in 2018[47]) and the Annual Doctoral Conference at the University of West London every year from 2017–2020 (first prize awarded for the oral presentation in May 2019). The candidate was invited to present her research findings at the West London Trust Research Day (June 2019) and Physical Healthcare Steering Group Meeting (January 2020), UCL (July 2019) and the University of Surrey (September 2019). An accepted abstract

[42] Sciani.com
[43] https://www.jostrust.org.uk/video/support-your-cervical-screening-smear-test
[44] https://www.youtube.com/watch?v=75MUQVwv908
[45] www.surrey.ac.uk/mental-health-friendly-health-checks
[46] https://mailchi.mp/260decbff36c/news-jobs-meetings-research?e=464b82308a
[47] https://twitter.com/bsphnetwork/status/968853668840857600

of a presentation is contained in Appendix 24. An article[48] entitled '*Cervical cancer screening resources aimed at addressing mental health disparities'* appeared in the Journal of Mental Health Practice (Jones-Berry, 2020) to highlight the tool and animated video and showcase its benefits and use in an NHS trauma service. The journal is distributed to all mental health nurses who are affiliated with the Royal College of Nursing.

Requests have been made to adapt the tool to different settings and populations. Funding permitting, the tool may be used as a prototype to develop another tool for women with anxiety in collaboration with Public Health England. A Clinical Commissioning Group has enquired about adapting the tool to their local services. Funding to translate the tool into Arabic and/or Somali is being sought by an East London council. The tool has had international reach. Lastly, following a presentation at the French National Cancer Institute[49] in October 2019, the national public health agency is currently seeking funds to translate and adapt the tool to its healthcare system for use in clinical settings.

10.5 Future research directions

As reported above, the tool is being disseminated in settings accessed by women who may not have a mental illness diagnosis, such as homeless populations and specialist cervical screening clinics for women who have survived FGM or sexual violence. The tool is also available in some GP

[48]https://rcni.com/cancer-nursing-practice/features/cervical-cancer-screening-resources-aimed-addressing-mental-health-disparities-157561
[49] https://www.e-cancer.fr/

practices and sexual health clinics for the public. There is a need to evaluate its use in these other groups. The ‘tick box pages’ were acceptable to women with SMI to act as a ‘disclosure aid’; these could be adapted to other physical health checks such as dental appointments or hearing/eyesight tests. Whether the information contained in the leaflet in other format, such as a mobile app, would increase its benefits could also be tested. Similar interventions for this population may be useful for breast, bowel and prostate screening. Though there is currently no national screening programme for lung cancer in the UK, the NHS has been offering ‘Lung Health Checks’ in some parts of England since Autumn 2019 (NHS England – National Cancer Programme, 2019). Given the high rate of smoking within this population, such an intervention may warrant further investigation.

It was unclear whether the tool enabled some women to make a more informed decision (category four); more research may be needed to ascertain whether the information provided in the tool improved their informed choice to attend or refuse screening. The risk of reliving the trauma by going for screening was deemed too great by some participants, so further research with this group on the acceptability of alternatives to a cervical swab, such as self-testing or urine sampling (possibly collected in community mental health teams during a physical health clinic) is worth consideration. For some women, the fear of receiving a cancer diagnosis was a factor in refusing to be screened; this group may need additional support to manage their anxiety. The leaflet only addresses one aspect of the screening journey – additional interventions may be required. Some

women with SMI who require further tests (for example if a positive HPV result is received), or oncological treatment following a cancer diagnosis, may need further support. High mortality rates from cancer in this group, as reported in Chapter One, warrant exploring which interventions might be of value since none specific to people with SMI are currently available. Lastly, some women receive the letter when they are mentally unwell. They may need a separate intervention to help them attend; coordinating screening and mental health services would help to ensure that the invitation to screening is not sent out when women are unwell.

There are systemic barriers to accessing cervical screening pertaining to the healthcare system, which this tool could not address, such as being excluded from a GP practice or not receiving the invitation for screening if admitted to forensic services. How to overcome these barriers warrants further research. Training of health professionals (e.g. nurses working in primary care and sexual health clinics) on barriers to screening in this group to reduce some of the stigmatising attitude women with SMI may experience should be investigated. A separate intervention using secondary care records to ensure women are not invited when they are unwell, e.g. if they are in hospital, should also be explored.

An external scoping review of the tool's pathways for dissemination across NHS services was conducted by Imperial College Health Partners in September and October 2019. All stakeholders interviewed 'felt that a quantitative evaluation was unnecessary for this type of intervention, given

that it is low cost, likely to be of some benefit, and the fact that other innovations of a similar type do not undergo this level of evaluative rigour'. Instead, some qualitative feedback on acceptability at the point of use from service users and health workers delivering the tool was suggested as a more appropriate route. This could be the subject of a future research project focused on implementation.

The potential impact of the shift to HPV primary testing on the tool should also be highlighted. In addition, HPV vaccinations may in the long-term reduce the need for the number of cervical screening appointments; however, these will still be required, as well as regular follow-ups, if a woman tests positive. HPV self-testing is being trialled in two London sites (Pike, 2019), and the sensitivity of urine sampling to detect CIN2+ (moderately abnormal cells found on the surface of the cervix) is being compared to vaginal and cervical samples (Sargent et al., 2019). Any adoption by Public Health England of an alternative to cervical screening would require the tool to be updated, for example if women are offered the opportunity to provide a urine sample in a mental health setting in lieu of cervical screening in primary care.

Lastly, the psychological impact on women with SMI of testing positive for HPV deserves further investigation. Even though HPV may have been acquired many years prior to screening, and HPV is qualitatively different from other sexually acquired infections due to its high prevalence and long latency, relaying of 'positive' results will create significant challenges both for

health professionals and for patients (Ogilvie et al., 2013). Research has been conducted on the potential for anxiety and distress for women in the general population following receipt of results from routine HPV primary testing; health professionals will need to explain the context for HPV infections and manage emotional responses to positive results (McBride et al., 2020). While some qualitative research (*n* = 27) has found the emotional impact of HPV testing to be modest, with the primary concern relating to abnormal results (O'Connor et al., 2014), other work has reported that the sexually transmitted nature of HPV infection can cause psychological distress (McCaffery et al., 2006; Waller et al., 2004). Women also report concern about communicating positive test results to sexual partners, stigma and shame associated with having a sexually transmitted infection and anxiety that it might be misinterpreted as infidelity as well as the impact of positive HPV results on relationships with partners (McCaffery et al., 2003). The shift of cervical screening from an oncological to a communicable disease paradigm may create a novel barrier to cervical screening uptake for women with SMI. How this population of interest will react to receiving cervical screening results in the context of a positive or negative HPV test warrants further investigation.

10.6 Contribution to knowledge

This is the first cervical screening informed-choice tool for women with SMI that has been developed to address some of the specific barriers faced by women with SMI. Findings from this research contribute to the scientific literature as previous community-based research identified low cervical

screening rates in this population. This project has highlighted how women with SMI might use a cervical screening informed-choice tool and what information they would like included. To our knowledge, this is the first literature review that has been conducted on the barriers and enablers to all types of cancer screening in people with SMI. The systematic reviews have been published and the protocols are included on the PROSPERO website, so updates to the reviews can be conducted by other researchers, thereby building on the existing body of knowledge. The review on the design and development of informed-choice tools for this population has synthesised a list of steps that researchers might apply when developing an informed-choice tool for people with SMI. While some steps overlap with the MRC guidance (e.g. both recommend identifying barriers as a first step), this list nonetheless contributes to the evidence base on developing interventions specifically for people with SMI (such as assessing readability of the tool).

This research has developed and evaluated a novel intervention with the input of a population often excluded from research (Bucci et al., 2015; Humphreys et al., 2015). Very few interventions for people with SMI have been tested using the think-aloud method; this research adds to the literature on methods that can be used for this group to assess the usability of an intervention. The publication (Lamontagne-Godwin et al., 2018) based on the realist review of interventions to increase uptake of or access to screening for people with SMI, has already been cited in the academic literature (*n* = 13 citations as of October 2020) and generated concerted interest on social media. A final publication on the development and preliminary evaluation of

the tool is in preparation. Looking beyond the PhD, I would like to continue developing interventions that aim to improve the physical health of people with SMI. Potential future areas of investigation include screening for other types of cancer and metabolic syndrome, given my prior research interest of working on improving diabetes care in people with SMI (Jones et al., 2016; McBain et al., 2016, 2018; Mulligan et al., 2017, 2018).

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Appendix 1. Completed PRISMA checklist (Moher et al., 2009)

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

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A
Section/topic	**#**	**Checklist item**	**Reported on page #**
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1 PRISMA Diagram
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 1 and 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Tables 1 and 2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Tables 1 and 2
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	10-12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12

Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	12-13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Appendix 2. Full electronic search strategy for one database (MEDLINE)

The following terms will be used in all data sources: (cardiovascular OR vascular OR CVD OR ‘chronic heart disease’ OR ‘coronary heart disease’ OR CHD OR diabetes OR metabolic OR aneurysm) OR cancer OR neoplasm OR carcinoma OR maligna* OR *tumour OR tumor OR breast OR mammogra* OR bowel OR cervical OR pap*) OR (dental OR dentist OR tooth OR teeth) OR (eye OR retinopathy) AND (‘mass screening’ OR surveillance*) OR “Screening Test” OR ((cholesterol OR fecal OR faecal OR blood OR HIV OR sig¬moid OR tuberculosis) AND test*) OR “health check*” AND (letter OR mail* OR phone OR telephone OR ‘reminder system*’ OR ‘videotape recording*’ OR ‘audiotape recording*’ OR questionnaire* OR strateg* OR alert* OR hotline OR community OR media) AND (intervention* OR goal OR ‘behav* change’ OR ‘implementation intention*’ OR plans OR planned OR planning OR plan OR educat* OR campaign* OR barriers OR intention* OR ‘behav* outcome’ OR outcome OR ‘lifestyle change’ OR longitudinal OR ‘follow up’ OR motivation*) AND (satisf* OR dropout* OR ‘drop out’ OR attrition OR uptak* OR adher* OR compliance OR complie* OR comply* OR ‘patient acceptance of health care’ OR encourag* OR improve* OR improving OR increas* OR promot* OR particip* OR nonattend* OR ‘non attend’ OR accept* OR attend* OR attitud* OR utilisation OR utilization OR refus* OR respond* OR respons* OR reluctan* OR nonrespon* OR ‘non respon*’ OR incidence OR prevalence OR prevalence OR satisfaction OR cooperat* OR ‘co operat*’) AND (‘severe mental illness’ OR ‘mental illness’ OR schizophrenia OR catatonic OR paranoid OR disorganized OR disorganised OR bipolar OR manic OR psychosis OR psychotic OR psychiatric OR schizophrenic OR SMI)

Appendix 3. Completed PRISMA checklist (Moher et al., 2009)

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Additional file 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7

Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8
Section/topic	**#**	**Checklist item**	**Reported on page #**
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8 and Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 1 and 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 1 and 2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	9
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	17-19
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	19
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	19-20
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	20

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097.

Appendix 4. Service user group feedback on the draft content of the tool (Round two of stakeholder involvement)

Feedback received on the draft contents of the tool during a workshop with a service user group (May 2018):

• Request first appointment of the day (20 minutes maximum is helpful in the waiting area)

• Let people know about the “My Body Back” charity (screening clinic in London and Glasgow for women who have experienced sexual violence) although they are inundated with referrals!

• Question yourself why you may not want to attend the appointment and try to overcome this [this was developed into an action planning text box]

• Nurse could be informed previously (about history of trauma/abuse)

• Bringing music may help you relax before the procedure, not during the procedure: “If I was the practitioner I would want the person to hear me (be able to communicate)”

• Language/non-verbal communication used by health professionals is important

• Do not be afraid to ask the nurse what is going to happen during the procedure

• Some people might need an interpreter/translator

• Need visual aids/diagrams of equipment used, genitals and position used for the procedure

• Offer a pre-visit clinic to talk about what happens

• All staff involved say “hello my name is…” and introduce themselves clearly

• Explain why I need a smear if I am not diagnosed with cervical cancer

• Explain how long you need to wait for the result

• Explains what happens if you get a positive/negative result

• Are there any side effects to having a smear? These need to be explained

• Do you need to give a reason if you ask for a double (i.e. longer) appointment?

• If you feel comfortable with your GP, can you ask him/her to perform the smear?

• Suggestion for non-verbal disclosure: use a paper card [to show the nurse] to disclose something they do not want to discuss. Something interactive within the tool would be ideal – space for people to write down/think about own barriers, then take it to the GP.

• Be specific in mentioning people can request a female nurse

• Explain why some people may need more frequent smears (e.g. if they have a STD (sexually transmitted disease))

• One person said it is important to bring the carer to the appointment but not in the room during the test

• Resource should acknowledge that access to screening is not just an issue for people with SMI – general problem

• Important to explain importance of cervical screening

• Make it clear that cervical screening is a choice and acknowledge people may not feel up to it on the day

• Staff need to respect people's wishes about whether or not they want to talk about their mental illness/experiences

• Emphasise importance of cervical cancer: but might explanation of risks put people off?

• Need to be clear that being asked to go for cervical screening does not mean you have cancer

• Receiving too many reminders (letters, texting) is stressful.

Appendix 5. Coding of barriers and enablers to component behaviour change techniques (Michie et al., 2015)

Barrier to cancer screening uptake	**Related TDF Domain**	**Component behaviour change techniques (BCT) coded by Reviewer #1 [the candidate]**	**Component behaviour change techniques (BCT) coded by Reviewer #2 [psychologist with expertise in health psychology]**	**Coding verification by Reviewer #3 [health psychologist]**	**Section(s) of the tool that address(es) the barrier**
Not knowing what to expect or what to do	Knowledge [of condition]	5.1 Information about health consequences [REJECTED following discussion with Reviewer #2] 4.1 Information on how to perform the behaviour	4.1 Information on how to perform the behaviour	Agreement	*During your appointment* *After your appointment*
Unsure of need for screening	[Procedural] Knowledge	13.2 Framing/reframing		Agreement	*What is cervical screening?*
Difficult to process information	Memory, attention and decision processes [Cognitive overload, tiredness, attention control]	Agreed to include 11.3 Conserving mental resources	11.3 Conserving mental resources	Agreement	Every page *Tick box pages*
Additional burden	Goals [goal priority]	1.3 Goal setting (outcome) 1.4 Action planning 9.3 Comparative imagining of future outcomes		Agreement	*Booking your appointment*

					Before your appointment
Mental health symptoms reduce motivation for self-care	Goals	1.3 Goal setting (outcome) 1.4 Action planning 15.4 Self-talk: [REJECTED following discussion with Reviewer #2] 3.3 Social support (emotional)		Feedback from Reviewer #3: Are we asking them to set a goal (e.g. smart goal with date and time etc.) or is attending screening an assumed goal? Make 15.4 (Self-talk) clearer	*Before your appointment* *Tick box pages*
Stigma of mental illness	Emotion	3.3 social support (emotional) 11.3 Conserving mental resources		Feedback from Reviewer #3: Not quite clear how these specifically fit with the next column [Following feedback from Reviewer #3, the decision by Reviewers #1 and #2 was made to keep 3.3 and 11.3.]	*Tick box pages*
Past negative experience	Emotion	5.4 Monitoring of emotional consequences [REJECTED following discussion with Reviewer #2] 9.3 Comparative imagining of future	5.4 Monitoring of emotional consequences [REJECTED following discussion with Reviewer #1] 9.3 Comparative imagining of future outcomes [REJECTED following	Feedback from Reviewer #3: Not quite clear how these specifically fit with the next column [5.4 and 9.3 were removed further to feedback from	*Tick box pages* *Getting support*

		outcomes [REJECTED following discussion with Reviewer #2] 3.3 Social support (emotional)	discussion with Reviewer #1]	Reviewer #3 and a discussion between Reviewers #1 and #2]	
Embarrassment	Emotion	3.3 Social support (emotional) 12.6 Body changes		Agreement	*Tick box pages* *Before your appointment*
Traumatising	Emotion	3.3 Social support (emotional) 5.4 Monitoring of emotional consequences 11.2 Reduce negative emotions		Agreement	*Tick box pages* *During your appointment* *Getting support*
Fear of bad news	Emotion	3.3 Social support (emotional) 11.2 Reducing negative emotions 13.2 Framing/ reframing		Agreement	*What is cervical screening* *After your appointment* *Getting support*
Lack of understanding of mental illness in screening professionals	Behavioural regulation	No BCT identified		Agreement	*Tick box pages*
Screening environment aggravates mental health symptoms	Behavioural regulation	3.3 Social support (emotional) 5.4 Monitoring of emotional consequences	3.3 Social support (emotional) 5.4 Monitoring of emotional consequences 6.1 Demonstration of the behaviour	Feedback from Reviewer #3: Perhaps the rationale for 12.2	*Booking your appointment* *Before your appointment* *Tick box pages*

		6.1 Demonstration of the behaviour 11.2 Reduce negative emotions 12.2 Restructuring the social environment 12.5 Adding objects to the environment [REJECTED following discussion with Reviewer #2]	11.2 Reduce negative emotions 12.2 Restructuring the social environment	needs to be stronger	
Staff can be rushed	Behavioural regulation	3.3 Social support (emotional) 12.2 Restructuring the social environment		Feedback from Reviewer #3: Perhaps the rationale for 3.3 needs to be stronger	*Booking your appointment* *Tick box pages*
Staff can be rough	Behavioural regulation	3.3 social support (emotional)		Agreement	*Tick box pages*
Exclusion from GP registers	Behavioural regulation	12.1 Restructuring the physical environment [REJECTED following discussion with Reviewers #2 and #3]		Feedback from Reviewer #3: Not sure this is how I would interpret this barrier [Following feedback from Reviewers #2 and 3#, BCT 12.1 was removed].	-

Appointment booking	Environmental context and resources	4.1 Instruction on how to perform behaviour 11.3 Conserving mental resources		Agreement	*Booking your appointment*
Transport difficulties	Environmental context and resources	4.1 Instruction on how to perform behaviour 11.3 Conserving mental resources		Agreement	*Before for your appointment*
Difficulty remembering appointments	Environmental context and resources	4.1 Instruction on how to perform behaviour [REJECTED following discussion with Reviewer #2] 6.1 Demonstration of the behaviour 11.3 Conserving mental resources	6.1 Demonstration of the behaviour 11.3 Conserving mental resources	Agreement	*Booking your appointment* *Before your appointment*
Difficulty leaving the house due to mental health problems	Environmental context and resources	3.3 Social support (emotional) 11.2 Reduce negative emotions		Agreement	*Before your appointment* *Tick box pages* *Getting support*
Taking time off	Environmental context and resources	No BCT was identified		Agreement	-
Made to feel like a burden on health service	Emotion	3.3 Social support (emotional)		Feedback from Reviewer #3: Perhaps explain the value of 3.3 in the final column	*Tick box pages*

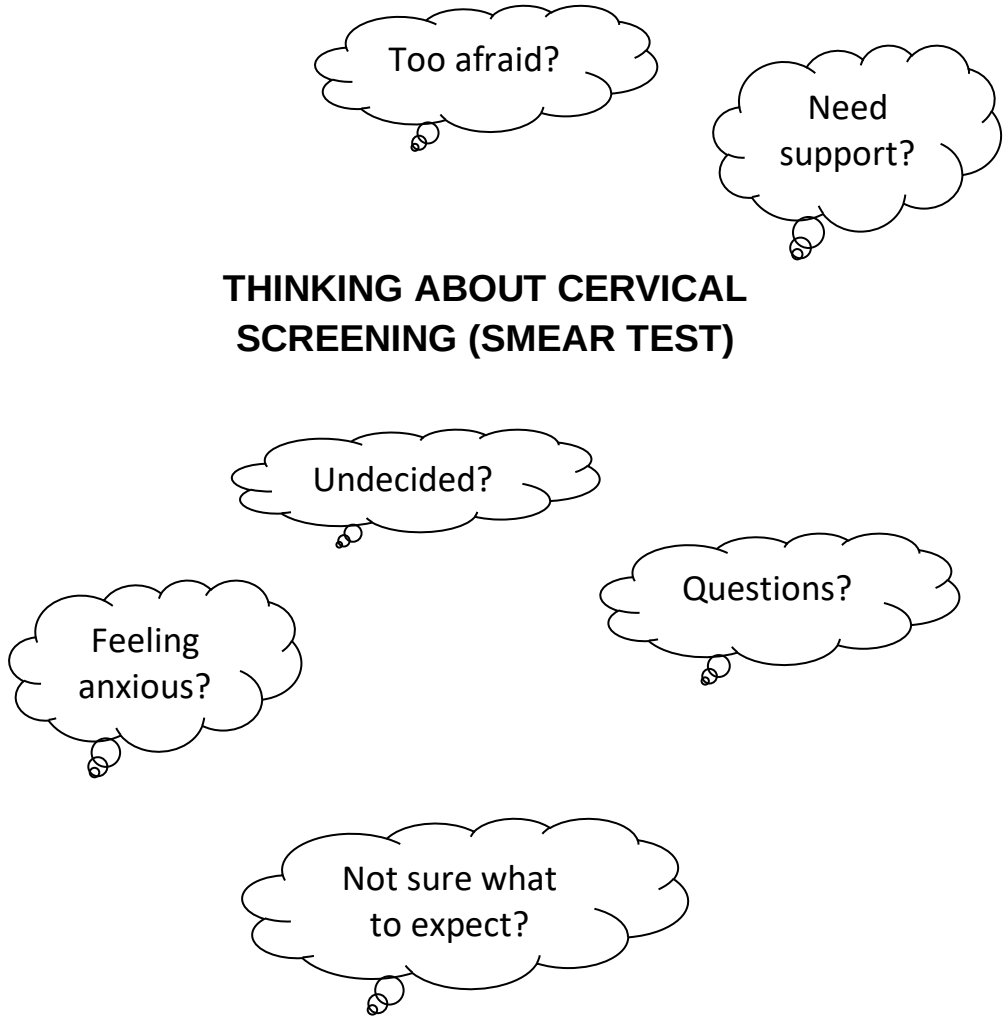
Poor relationship with GP	Emotion	12.2 Restructuring the social environment		Agreement	*What is cervical screening* *Getting Support*
Diagnostic overshadowing	Emotion	No BCT was identified		Agreement	-
Enabler to cancer screening uptake	Related TDF Domain	Component behaviour change techniques (BCT) coded by Reviewer #1 [the candidate]	Component behaviour change techniques (BCT) coded by Reviewer #2 [psychologist with expertise in health psychology]	Coding verification by Reviewer #3 [health psychologist]	Section(s) of the tool that address(es) the barrier
Wanting to be informed	Knowledge	4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences		Feedback from Reviewer #3: Is BCT 5.1 more about the information provided regarding prevention of cancer and risks if screening not attended? As below	*During your appointment* *After your appointment* *Looking after your health*
Understanding of benefits of screening	Knowledge	5.1 Information about health consequences		Agreement	*What is cervical screening* *After your appointment*
Encouragement	Social influences	3.2 Social support (practical) 3.3 Social support (emotional) 6.1 Demonstration of the behaviour	3.2 Social support (practical) 3.3 Social support (emotional) 6.1 Demonstration of the behaviour	Agreement	*Before your appointment* *Getting Support*

		15.1 Verbal persuasion about capability	11.3 Conserving mental resources [INCLUDED following a discussion with Reviewer #1] 15.1 Verbal persuasion about capability		
Feeling 'health conscious'	Goals	1.3 Goal setting (outcome) 1.4 Action planning 5.1 Information about health consequences 5.6 Information about emotional consequences [REJECTED following a discussion with Reviewer #2] 10.7 Self-incentive [REJECTED following a discussion with Reviewer #2]	1.3 Goal setting (outcome) 1.4 Action planning [REJECTED following a discussion with Reviewers #1 and #3] 5.1 Information about health consequences [INCLUDED following a discussion with Reviewer #1]	Feedback from Reviewer #3: Not sure "Feeling 'health conscious'" is really goal setting or action planning	*What is cervical screening* *After your appointment* *Looking after your health*
Being anxious to avoid further health problems	Goals	1.1 Goal setting (behaviour) 1.3 Goal setting (outcome)	1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 2.4 Self-monitoring of outcome of behaviour [INCLUDED following a discussion with Reviewer #1]	Agreement	*What is cervical screening* *Looking after your health*

Physical symptoms	Goals	1.3 Goal setting (outcome) 5.1 Information about health consequences	1.3 Goal setting (outcome) 4.1 Action planning [INCLUDED following a discussion with Reviewer #1] 5.1 Information about health consequences 7.1 Prompt/cues [INCLUDED following a discussion with Reviewer #1]	Agreement	*Looking after your health*
Past positive experience	Emotion	15.3 Focus on past success		Agreement	-
Staff being understanding	Behavioural regulation	3.3 Social support (emotional)		Feedback from Reviewer #3: The tick box pages aim to increase staff empathy/understanding so you could perhaps include 3.3.	*Tick box pages*
Staff knowledge of mental illness	Behavioural regulation	No BCT was identified		Agreement	-
Familiar location	Environmental context and resources	No BCT was identified	12.1 Restructuring the physical environment [INCLUDED following a discussion with Reviewer #1]	Agreement	*What is cervical screening*
Reminders	Environmental context and resources	No BCT was identified	6.1 Demonstration of the behaviour [INCLUDED following a discussion with Reviewer #1]	Agreement	*Booking your appointment* *Before your appointment*

			7.1 prompt/cues [INCLUDED following a discussion with Reviewer #1]		
Good relationship with GP	Emotion	3.3 Social support (emotional)		Feedback from Reviewer #3: The tick box pages aim to increase staff empathy/understanding so you could perhaps include.	*Tick box pages*
Good relationship with Practice Nurse	Emotion	3.3 Social support (emotional)		Feedback from Reviewer #3: The tick box page aims to increase staff empathy/understanding so you could perhaps include 3.3.	*Tick box pages*
Continuity of care	Emotion	3.2 Social support (practical) 3.3 Social support (emotional)		Feedback from Reviewer #3: Suggestion to go to the appointment with a health professional/social worker may help with this barrier.	*Before your appointment*

Appendix 6. Version 0.1 of the tool



Page

Why this leaflet was developed

It is up to you to decide whether to attend your smear test or not.

There are lots of reasons why this decision might be difficult to make.

This leaflet provides clear information and addresses common questions and anxieties.

This leaflet was based on experiences of people who found it difficult to attend their appointment.

The leaflet isn't designed to persuade you either way. It's here to help you make a decision and let you know what help and support is available.

You can use this leaflet to plan your appointment. You can bring it on the day.

Why am I invited for cervical screening?

HPV (Human Papilloma Virus) is responsible for most types of cervical cancer.

If you have a cervix and are between 25 and 64, you will be invited to test if you have HPV.

This is called a smear test (also called cervical screening or ‘Pap test’).

The smear test saves as many as 5,000 lives from cervical cancer a year in the UK.

Having a smear test lowers your chances of getting cervical cancer.

If you test positive for HPV, this does not mean you have cancer, but you may be more at risk of developing it. Further tests may be necessary.

If you have cancer, getting it diagnosed and treated early can save your life.

What happens on the day

The nurse or doctor will ask you to undress from your waist down and lie on a bed with your knees bent and apart.

A device - called a speculum - will be put into your vagina and then used to open it gently.

This allows the nurse or doctor to see your cervix.

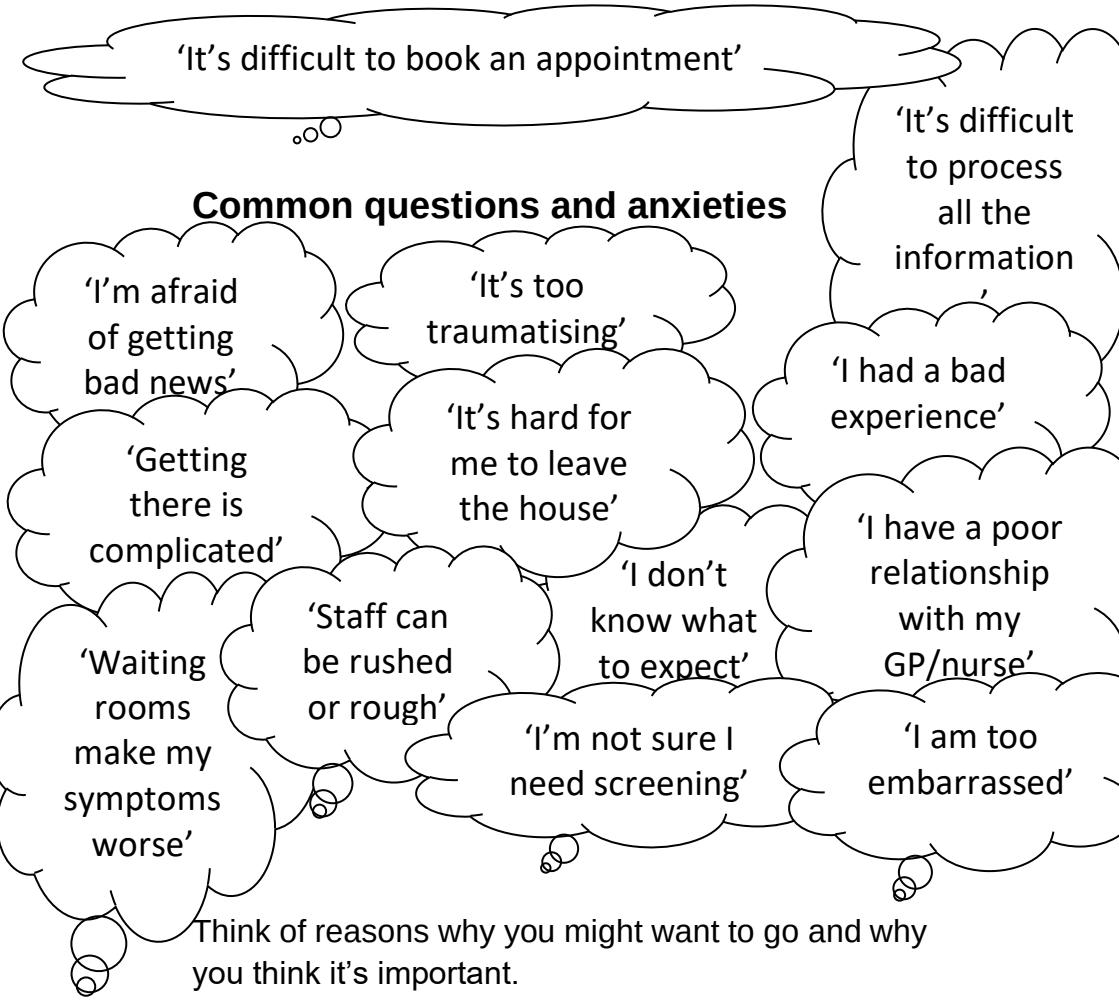
A small brush (like a long cotton bud) will be used to take a sample from the surface of your cervix.

The sample is sent to a laboratory to see if you test positive for HPV.

This leaflet supports the NHS leaflet *Cervical Screening: Helping you decide* and *Cervical Screening: Easy Guide*.

This website has lots of videos to explain what happens on the day: www.jostrust.org.uk/video-page

Common questions and anxieties



Think of reasons why you might want to go and why you think it’s important.

Write down what would help you attend your appointment:

FFFFFFFFDDD

Below are some issues that have been raised:

Tick all boxes that apply to you	I can talk about this	I don't want to talk about this today
I survived a traumatic experience – sexual/domestic violence – abuse		
I have a mental illness		
I am a survivor of FGM		
I have visible cutting scars		
I am afraid I may pass out or react in an unexpected way		
I am a voices hearer and get distressed during a physical exam		
I have other health issues		
I am embarrassed by parts of my body		
My medication makes me shake		
I had a traumatic birth and find the smear test uncomfortable		
I am a female to man/trans man and I am feeling anxious		
Other: _____ _____		

Tips for booking your appointment

Let the staff know if you:

A) Get anxious in waiting rooms. Ask for the first or last appointment of the day.

B) Want to be seen by a female or male member of staff.

C) Want to be seen by your GP.

D) Would like to receive a reminder for your appointment (text-message, postal or telephone reminder).

E) Need a double appointment.

F) You may feel more comfortable having a first appointment to discuss what is important to you.

Tips on getting ready for your appointment

A) Things to pack that you might find comforting:

- Something from home to cover yourself (like a blanket or shawl)

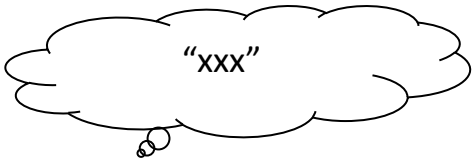
- A music device and earphones to help you relax before your appointment

B) Wear a loose-fitting skirt on the day

C) Ask a trusted person to accompany you on the day – ask them to take the morning or afternoon off

D) Organise transport to and from your appointment in advance

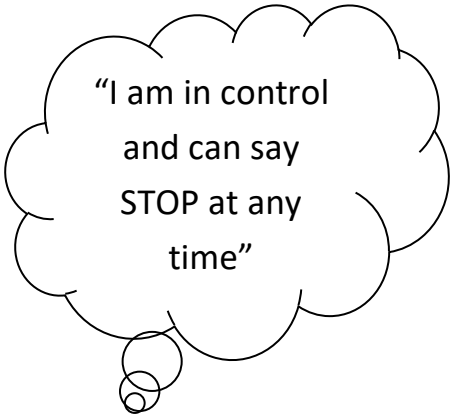
E) Plan something nice after your appointment, like going to the cinema, or going for tea and cake with a friend.



F) There may be things that bother you about the smear test. Write them down if it's easier. This could be:

- parts of your body not to touch
- whether you prefer a soft or firm touch,
- whether you want the door locked or unlocked,
- any reactions that you may predict that you would prefer the health professional to know about in advance.

G) There may be words which could trigger anxiety or flashbacks. List alternative 'safe' words to replace these. Bring the list to your appointment.



Your appointment day

A) You can have an impartial observer (a ‘chaperone’) if you would like one. A chaperone can be a friend, family member or a trained healthcare professional such as a practice nurse. You do not have to accept the person who is offered to you as a chaperone. If you have asked for one but there is no-one immediately available you can reschedule your appointment.

B) The smear test is a collaboration between you and the nurse/doctor. Agree on a signal to stop if you need to do so at any stage.

C) Ask the nurse/doctor to warn you before they touch you and to explain what they will be doing.

D) Speak to your doctor about sedation or medication to reduce your anxiety on the day if you think it would help.

E) You can ask for a smaller instrument and more lubrication.

What happens next?

You should receive a letter explaining your results within two weeks of your appointment.

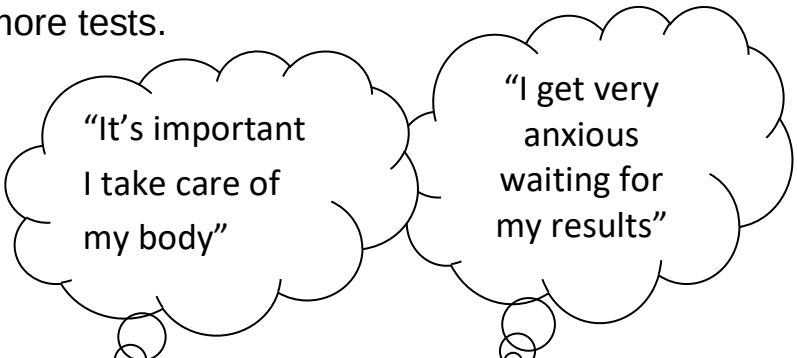
If your results, or waiting for your results, makes you anxious, you can contact Jo's Cervical Cancer Trust (www.jostrust.org.uk) by calling:

0808 802 8000

The majority of people with a cervix will test negative for HPV. **This means you have a very low risk of developing cervical cancer before your next smear test**.

You will receive another invitation in 3 or 5 years (depending on your age).

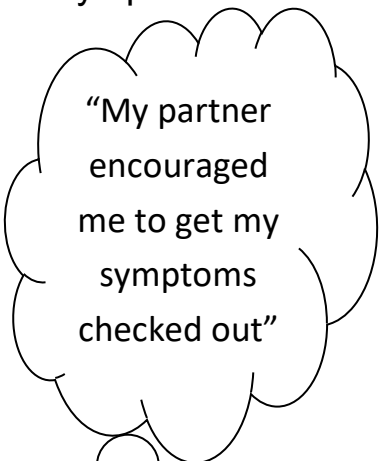
If you test positive for HPV, you will need to do more tests.



Cancer can, very rarely, develop between regular smear tests. If you have symptoms such as:

- Pain or discomfort during sex,
- Bleeding between your periods, after sex, or after the menopause,
- Unusual and/or unpleasant vaginal discharge
- Lower back pain

Don't wait for your next smear test. Make an appointment with your nurse or doctor. Usually these symptoms won't mean you have cancer. It's best to have your symptoms checked out.



Additional information

Order a ‘self-testing’ kit

Buy your kit online. It’s not available on the NHS. It costs between £50 and £100. The sample is collected by putting a swab (it looks like a tampon) into the vagina. The sample is then put into a test tube to be sent off to a laboratory. Discuss your results with your nurse or doctor.

Organisations that can support you:

Jo’s Cervical Cancer Trust
Telephone: 0808 802 8000
www.jostrust.org.uk

My Body Back (London and Glasgow)
Cervical screening clinics for women in the UK who have experienced sexual violence
www.mybodybackproject.com

Ask your GP or nurse about local support services.

This leaflet was developed to make sure that everyone with a cervix who is invited for a smear test has access to information to help you decide whether you want to attend.

We would like to thank all the patients, service user groups, professionals and frontline staff who helped in the making of this leaflet.

This leaflet is available in English, Arabic, French and Somalian.

This work was funded by the University of West London.

UWL / King's logos
Dorset and WLMHT Logos
Jo's Cervical Cancer Trust logo

Appendix 7. Fully coded content analysis of the clinical accuracy testing phase (Round three of stakeholder involvement)

	Revision requested by (*n* =)				Decision made:	
Requested revision:	Key informants group				Revision accepted	Revision rejected
	Charities	NHS clinicians	National public health stakeholders	Clinicians working for specialised cervical screening clinics		
"Title page"						
It's slightly confusing as to who the reader is supposed to be. I would have a sub-heading which reads…a comprehensive guide for people with…, or to support people with mental health issues (not sure what term is being used)	1					Service users (and most mental health professionals) would not want to use such a label for this group. It's our role to ensure the leaflet is tailored to their needs, and available in the services they access in primary and secondary care
I would take out the thought bubbles as they are slightly confusing and potentially insensitive	1					The format of the cover page was not the focus of this feedback session. The cover page was changed (image and title)

						according to service user preference
Do we need to make it clear up front that this is a specialised resource for people with SMI? Just wondering if a) it lets people know it's for them and b) it helps HCPs who are looking for a particular resource. Just adding a tag-line like 'A guide for people with severe mental illness'. However, I don't know if this a label people would want to see or think it applies to them	1					Service users (and most mental health professionals) would not want to use such a label for this group. It's our role to ensure the leaflet is tailored to their needs, and available in the services they access in primary and secondary care
[Discussion around what to call the test: smear test? Pap test? Cervical screening?]: Suggest cervical screening (smear test)				1	This suggestion has been incorporated into the title (following approval from Jo's Cervical Cancer Trust)	
"Why this leaflet was developed"						
Prefers the expression "found it difficult to attend" to "feeling anxious about attending"				1		Both sentences were included, because anxiety is a real issue service users can relate to: "This leaflet is for women who find it hard to go for cervical screening

						(a smear test). Some women feel anxious because…"
Add “What’s in this booklet?" as a title for the page	1				Wording amended to reflect this	
Would replace "What's in this booklet?" with "What’s in this leaflet?"			1		Wording amended to reflect this	
You may want to add that people find it difficult to go “because they are feeling anxious about going for a smear test”, rather than just "because you have a mental illness or have had a traumatic experience"			1		Wording amended to reflect this	
I would take out the word ‘anxieties’ of the 4th heading, that seems like pre-empting an anxiety with doesn’t seem very reassuring	1					This word was not removed and was tested with service users during the acceptability phase
This section seems a bit long and repetitive. It’s an ideal place to say who the target reader is and why…so what evidence has led to its development? what do we mean by mental health? how the leaflet can be used etc.	1				Wording amended to reflect this	
I’d also probably add something like, many people who go for screening feel anxious and it’s ok to feel that					Wording amended to reflect this	

way, however the information should help to reduce/manage anxiety and/or prepare you for a screening appointment						
I like that it covers informed choice, but wording could probably change to make it slightly less daunting and confusing. It might be easier to have one sentence along the lines of…it's important to under/know about the process to help you decide if you want to attend - but in saying that…is that the purpose of the booklet? Or is it to reduce anxiety?	1					The purpose of the leaflet is to support women make an informed choice. Reducing anxiety is one of the barriers the leaflet aims to address
I wonder if you can make more of the work you've done with people with SMI here – that is the really special thing about it. Something like: 'We worked closely with people with severe mental illness to develop this leaflet. Some felt anxious about cervical screening because of their mental illness, a previous traumatic experience, or for another reason. You will see some of their stories and tips throughout the leaflet.'	1				Wording amended to reflect this	
"What does this leaflet cover?" As a header for the contents list	1				Wording amended to reflect this	

“Why am I invited for screening?”						
I think this section should say, more explicitly, that screening can pick up changes that, if left untreated, might eventually lead to cancer		1			Wording amended to reflect this	
Is it a bit confusing saying they will be invited for a test to see if they have HPV rather than a smear? Also the smear doesn’t look for cancer it looks for pre-cancerous cells				1	Wording amended to reflect this	
People may not always get their smear done at a GP surgery, so you may want to generalise it slightly (some sexual health clinics and STI clinics do smears, and so do some gynae clinics, especially for patients who require adjustments)		1			Wording amended to reflect this	
People may not always get their smear done at a GP surgery, so you may want to include alternative arrangements (some sexual health clinics and STI clinics do smears, and so do some gynae clinics, especially for patients who require adjustments)		1			Wording amended to reflect this	

We need to highlight that this is a test for detecting an often silent cancer		1			The extent to which the risks of non-uptake of cervical screening should be highlighted in the tool will be discussed with health professionals and service users. Results are reported in Round four of stakeholder involvement (section 7.3.2).	
Important to emphasise that women should go for regular screening		1		1	This comment was incorporated into this sentence: "Going for cervical screening when invited is the best way to protect yourself against cervical cancer."	
HPV can be confusing for some people, it has an association with sex and can be confused with HIV – best to avoid mentioning in the tool				1	Wording amended to reflect this	
''staying healthy'' message - focus on prevention rather than mentioning "cervical cancer"				1	The extent to which the risks of non-uptake of cervical screening should be highlighted in the tool is discussed with health professionals and service users in Round four of stakeholder	

					involvement (section 7.3.2)	
This may read better by putting the sentence "It is not a test for cancer" at the start		1			Wording amended to reflect this	
Why "Why am I invited for cervical screening?" Are they receiving this at the time of a letter? Should it be "why have I been…?"	1				This sentence was removed	
Need to include “if I am not sexually active now or ever or never do I need the cervical screening test”				1	This sentence was added: “If you’re not sure whether you need a test, talk to your GP or nurse.”	
“if you have a cervix and are between 25 and 64” is confusing, reword				1	This section was revised to: “To be invited for cervical screening you must: - be registered with a GP as female - be between the ages of 24 and 64”	
I would maybe list the places a woman can go to get a cervical smear. It is largely provided by primary care and an explanation about the process may be helpful. Like mentioning that the GP will send you a letter every 3 years to invite you, so making sure				1	This section was revised to: “Your GP surgery will invite you for cervical screening if your contact details are up to date (…) In some areas, you may be	

your patient details are up to date would be good. Some sexual and reproductive health clinics will opportunistically too but that may get confusing to mention because it is opportunistic					able to arrange your appointment at a sexual health or well woman clinic instead of your GP surgery.”	
Could give more info about HPV; Very positive page – if this leaflet is to help people to decide, should it have the pros and cons? Probably need to say it’s not just about checking for cancer as that isn’t clear	1				The extent to which the risks of non-uptake of cervical screening should be highlighted in the tool is discussed with health professionals and service users in Round four of stakeholder involvement (section 7.3.2)	
If the focus of this booklet is tips for people with SMI, just do an overview of cervical screening here then signpost out. Getting into HPV will make it very complicated	1				Wording amended to reflect this	
Eligibility age for screening: ‘25-64’ rather than ‘24-64’. It’s better to stick with the screening ages here to avoid confusion.	1				Wording amended to reflect this	

Offer alternative sources of information as not everyone has access to a computer or the internet			1			Research shows this group has access to the internet and a computer
I think this whole section needs to be rewritten to make it a bit clearer and in a more logical order - see other attachment. It might be working a bit too hard - if the focus of this booklet is tips for people with SMI, just do an overview of cervical screening here then signpost out. Getting into HPV will make it very complicated	1				Wording amended to reflect this	
"What happens on the day"						
The Easy Guide hasn't been updated since 2013! I am biased, but can I suggest our EasyRead guide which was updated in June 2018? It's also more comprehensive	1				Wording amended to reflect this	
Could what happens on the day be a cartoon and show pictorially?	1				An image of the examination was later introduced in the leaflet	An Easy Guide already exists
Is it worth having some pictures? Eg of the speculum - some people may not know what it is	1				An image of the examination was later introduced in the leaflet	An Easy Guide already exists

'Point 3': Is it worth mentioning that "they would remain covered at all times, not exposed when undressed"				1	Wording amended to reflect this	
Might be an idea to change the wording slightly to make it a bit softer for someone who may be anxious about the process – could talk about different sizes of the speculum…that they can ask for a different size, that the Nurse/GP is trained in doing them and understands that is can be a difficult process for some people for a variety of reasons					Wording amended to reflect this	
It will usually be a nurse doing smear test! [rather than GP]				1	Wording amended to reflect this	
I actually like this section, it's clear and factual, this should probably come up a lot earlier in the leaflet	1					Usability testing of the leaflet will determine if this section should be moved
It might be an idea to explain what a cervix is if it's going to be mentioned	1				An image of the female reproductive system was introduced in a later version of the leaflet	
"Common questions and anxieties"						
I think you could add a few more interactive tools like [One column asking the person to write down what they are				1	Wording amended to reflect this	

concerned about, what would help and then why they will go/why it's important], then this leaflet becomes a tool professionals can use to assist someone to weigh up the pros/cons and potential suggestions to take to an appointment that will make their visit more comfortable. It would feel, hopefully, to the patient like they have been consulted with, they have co-produced the way their consultation will go and they feel respected and valued						
'Common questions and worries' [barriers] can be merged to "Support for people who are anxious about the smear test" table, also I think a different format is needed here spelling myths and answers				1	These two sections have been merged	
There is a lot on this page, it's actually slightly overwhelming, may need to think about layout. Could thought bubbles just be bullet points instead?	1				This page has been merged with the tick box page	
I love this way of presenting people's concerns. Perhaps it can be a little cleaner - see attached	1				Formatting amended to reflect this	
"Tick box page"						
[we can talk about this/I don't want to talk about this]: rather				1		The various sections of the

than these, I would be happier if it is one column saying what are the corresponding solutions of their problem						leaflet offer tips, but these are not included on this page
There is some repetition in the "tick box" page and the page before which has suggestions for women who have experienced sexual violence. Some of the suggestions on this page (e.g. "do you prefer a soft/firm touch, do you want the door un/locked") could be moved to the "tick box" page			1		These two sections have been merged to avoid repetition	
I am a female to man/trans man and I am feeling anxious: Just saying 'trans man' is better	1					This sentence has been removed as was out of the scope of this project
Instead of just pass out, add "faint"			1		Wording amended to reflect this	
The option "I have other health issues" isn't clear, could be replaced by "I find it hard to maintain a healthy weight"			1		Wording amended to reflect this	
I'm not sure about this, but I wonder whether there should be a space for (optionally) writing 'my mental health conditions/diagnoses are...' so that the leaflet can be shown to the health professional doing the test. The nurse/doctor may not have		1			This suggestion was included and will be tested with service users during the acceptability phase	

access to medical records at the time of the test, and it might make it easier for the patient. Or not. Something to ask the service users, I guess						
Is it worth saying it is optional to fill this [tick box page] out?				1		The leaflet would only be used if the individual chose to bring the leaflet to the appointment
I'm confused by page 7, is the idea to show this to the person doing the smear? If so I think that's a whole other project in terms of supporting HCP's to manage and support those with specific mental health issues having this process within the time and professional constraints they have. I'd be keen to lose this page actually	1					This page will be tested with service users and health professionals during the acceptability phase
"Tips for booking your appointment"						
I would remove the option to be seen by your GP- nearly all practices have nurses doing the smears and it may be disappointing for patients to ask for something that the practice cannot provide- GPs are not best placed to do smears these days and some are not up to date with training!		1			Wording amended to reflect this	
The last appointment may be result in a longer wait if the			1		Wording amended to reflect this	

clinician has run over in their previous appointments. Is there evidence that supports the last appointment having sorter wait times?						
It would be a bad idea to book the last appointment of the day as these are very often late		1			Wording amended to reflect this	
The patient may not get a double appointment on request, this would be up to the nurse to rebook if the patient was anxious- by setting out incorrect patient expectations we may lose trust		1			Wording amended to reflect this	
With regard to chaperones - a family friend is not a chaperone - CQC define a chaperone as a neutral party who has knowledge of the practical intimate procedure occurring to protect both patient and clinician- the patient can bring a friend or relative but they are not acting as a chaperone		1			Wording amended to reflect this	
“Book a double appointment”: what does this mean?	1				Have revised to "a longer appointment"	
“if you get anxious sitting in waiting rooms”: say the symptoms rather than label of anxious	1					This will be tested with service users during the acceptability phase
May have to manage expectation, there may not be	1				Wording amended to reflect this	

staff of required genders and/or they may not have policy for double appointments for screening, or ability to send a text message as a reminder – maybe need line to say "this may not be available in all GP surgeries"						
"Let the receptionist know if you would like to have a chaperone. This is a person working at the clinic, like another nurse, who can be there during the screening": It doesn't have to be – it could be someone they bring and trust.	1				Wording amended to reflect this	
"Tips on getting ready for your appointment"						
The way we talk about some of these things should be softened slightly - for example, rather than 'do this', we can say "You may feel more comfortable wearing a skirt or dress, as you will not have to undress from the waist down"	1				Wording amended to reflect this	
I'd refrain from telling the reader to do something 'nice' afterwards…also if the person is socially isolated this may cause concern	1					Will let service users determine whether they would like this sentence amended during acceptability testing phase

"Make plans to treat yourself to something nice and relaxing after your appointment": this perpetuates the idea that cervical screening is something scary/draining – I think it's just the wording. Maybe 'If you will need support after the appointment, make plans that focus on self-care.'	1					Will let service users determine whether they would like this sentence amended during acceptability testing phase
Section A could be helpful. It might be an idea to have a range of things the reader may find comforting, or to reduce text just ask the reader to think about doing/taking something that helps them most in anxious situations	1				Wording amended to reflect this	
These words can trigger an anxiety attack or flashbacks: Should we be asking people to list words that trigger them? Or should we be asking what words they would prefer to be used?	1					This section will be tested with service users and health professionals during the acceptability phase
In the section "things to pack that you may find comforting", in terms of suggesting "something from home to cover yourself (like your own blanket)", the clinic will always provide a blanket/sheet				1	Wording amended to reflect this	
I'd refrain from asking someone to take time off work	1				Wording amended to reflect this	

It might be worth something along the lines of “some people who attended screening said they felt less anxious about the process if they were able to…”	1					We have focused on "what you find comforting" rather than "what makes you less anxious"
Who is section F for? [There may be things that bother you about the smear test. Write them down if it’s easier] Does this go to the health professionals? May cause anxiety to start writing this down, could just suggest telling the health professional in a way that’s most comfortable for them	1				This section has been merged with the “tick box page”	
Sections C-E make the whole process sound like something that will be time consuming and traumatising.	1					This section will be tested with service users and health professionals during the acceptability phase
Not sure I would suggest the safe words as there is a reliance on the health professional to read this prior to the appointment.						We will keep a box where people can write down any words they don't want used - the tick box page can be brought to the appointment so the nurse will read them during the appointment
“Your appointment day”						

With regards to asking for medication from the doctor if you are feeling anxious: sometimes the person may feel that the [skin] tissues are a bit harder [in the context of FGM] and it is painful and uncomfortable in that case I think GP can give them some medication to use to make tissues softer and that is helpful for releasing physical discomfort				1	Wording amended to reflect this	
"speak to your GP about medication if you are feeling very anxious": some GPs won't prescribe "benzos" [benzodiazepines, anxiety medication] and some GPs are very cautious about giving them, particularly to patients on strong antipsychotic medication: would remove this option, you wouldn't normally prescribe it to the general population		1			This section has been removed	
Remove "impartial observer" as an explanation of "chaperone" and replace with an example "like a healthcare assistant"			1		Wording amended to reflect this	
Needs to make clear that if a chaperone is wanted then this should be mentioned at the		1			Wording amended to reflect this	

time of booking the appointment						
“What happens next”						
Again a nice clear section. I would probably also say they can speak to their GP or someone else they trust along with the charity	1				Wording amended to reflect this	
You "may" need to have more tests, not "you will need to"					Wording amended to reflect this	
“You should receive a letter explaining your results within two weeks of your appointment” add: 'Sometimes it can take less time or longer.' Just in light of the massive delays across England…	1				Wording amended to reflect this	
Maybe worth changing ‘negative’ to ‘not found to have’, I’d shy away from ‘normal’	1				Wording amended to reflect this	
I’d probably change the 3rd paragraph to say ‘the majority of people who go for screening’ as opposed to ‘with a cervix’ as it sounds a bit odd	1				The moniker “people with a cervix” was used to be inclusive of transmen who may not identify with the title ‘woman’ but was removed to avoid confusion	
[You will be invited in three to five years] Given that we may change the screening intervals this could date the leaflet. It			1		Wording amended to reflect this	

may be better to advise you will receive another invitation when your next test is due?						
“**Symptoms” page**						
Would be great to have something about feeling confident to go to the GP in the screening interim if they spot anything unusual – I don’t like the bit about cancer developing as that would make me very anxious, the last line also contradicts that sentence	1				Wording amended to reflect this	
“Cancer can, very rarely, develop between regular smear tests. If you have symptoms such as …” : Can just say 'It is important to be aware of cervical cancer symptoms, including…	1				Wording amended to reflect this	
Instead of “if you have any” suggest “if you have any symptoms”			1		Wording amended to reflect this	
“Bleeding between your periods, after sex, or after the menopause”: Separate these: 'bleeding that is unusual for you (abnormal bleeding) - this may be between periods or after sex' 'bleeding after the menopause'	1				Wording amended to reflect this	
Before "It is important to be aware of these symptoms",			1		Wording amended to reflect this	

you could add "Even if your cervical screening results are normal, it is still important..."						
'You don't have to wait for your next cervical screening invitation': This should read that cervical screening is not a diagnostic test			1			"diagnostic test" complicates this sentence unnecessarily
"Unusual and/or unpleasant vaginal discharge" replace with 'Vaginal discharge that is unusual for you - for example, a different or bad smell'	1				Wording amended to reflect this	
Jo's Cervical Cancer Trust are changing "lower back pain" to "'unexplained lower back pain that lasts a long time"	1				Wording amended to reflect this	
"Don't wait for your next smear test. Make an appointment with your nurse or doctor. Usually these symptoms won't mean you have cancer. It's best to have your symptoms checked out": replace with "If you have any symptoms, see your doctor straight away. You do not have to wait for your next smear test"	1				Wording amended to reflect this	
'Looking after your health': suggested title for this page	1				Wording amended to reflect this	
"Additional information"						
Could we add more [support] organisations? I'm sure there	**1**				Wording amended to reflect this	

are for this group, even if not cervical screening specific!						
Add Samaritans, MIND, charities don't need to know much about physical health, it's more about getting emotional support if they are feeling anxious or a bit upset after their appointment		1			These charities will be contacted in view of including them in the leaflet	
At present, HPV self-sampling is not offered by the NHS cervical screening programme so it would be inappropriate to mention it in a leaflet aimed at women attending for NHS screening. The UK National Screening Committee will be reviewing the evidence on these devices in the near future			**1**		This section has been deleted	
I hesitate around self-testing where there is a cost, as not everyone can afford it and it may cause anxiety if they can't, however it's about informed decisions, so it would be their choice based on the information	**1**				This section was removed further to feedback received from the cervical screening programme at Public Health England	
I was interested in self-sampling kits, I was going to look it up		**1**				This section was removed further to feedback received from the cervical screening programme at

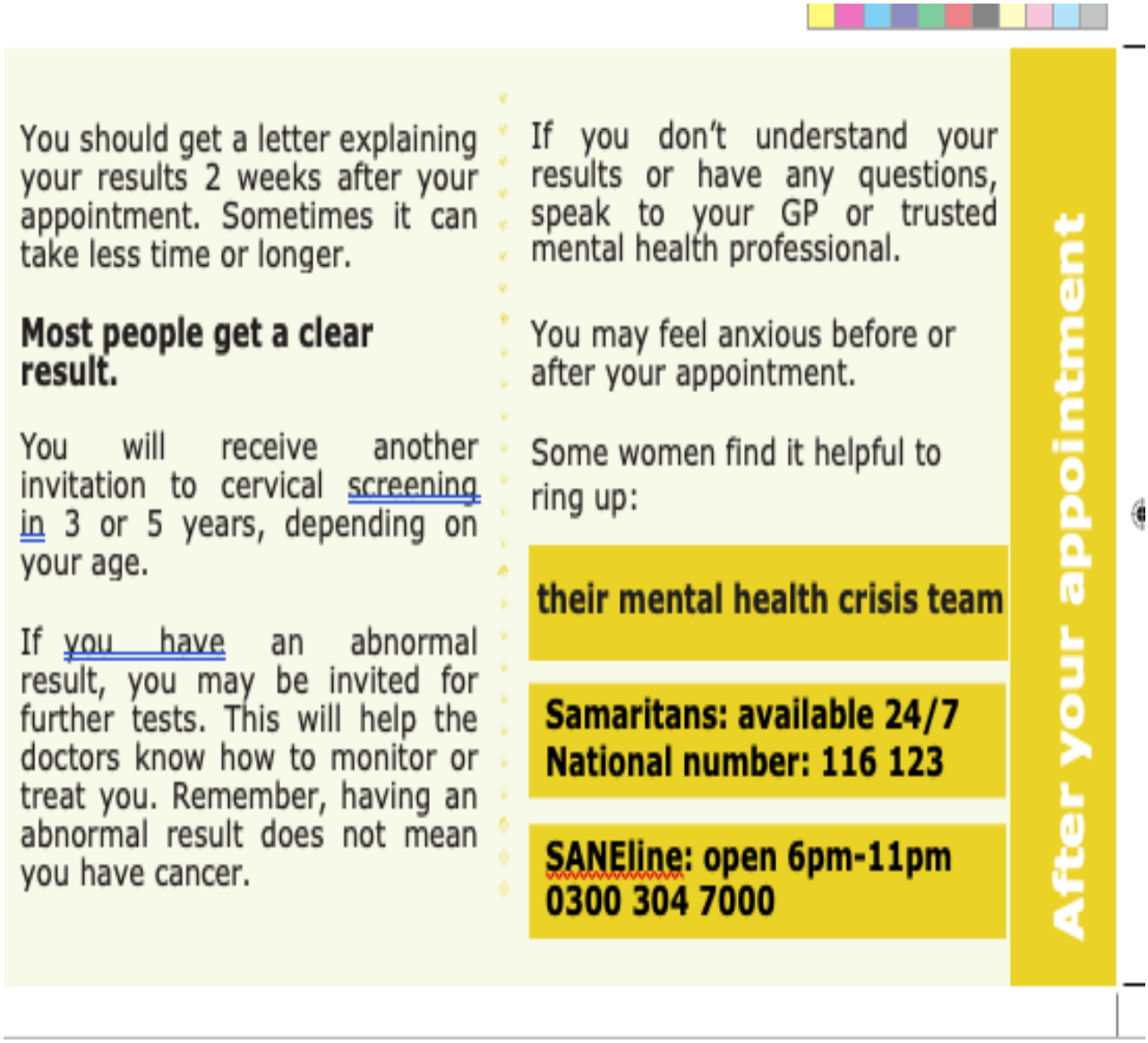
						Public Health England
The cost of self-sampling kits might be a barrier for this group		**1**			This section was removed further to feedback received from the cervical screening programme at Public Health England	
The cost of self-testing kits is high		**1**			This section was removed further to feedback received from the cervical screening programme at Public Health England	
Cautious about this [self-testing kits] - we can't recommend and the NHS doesn't officially endorse either (as far as I'm aware!). So maybe just need to be careful about wording	**1**				This section was removed further to feedback received from the cervical screening programme at Public Health England	
Would suggest taking out self-testing as less effective than cervical screening				**1**	Ibid. as above	
I would be wary of highlighting the ability to order self-sampling kits online. It might be worth picking the brains of the national cervical screening programme manager and			**1**		PHE cervical screening programme was contacted and following their feedback this	

advisory group for their stance on the evidence for those sort of kits first					section has been deleted	
Suggestions to the whole leaflet						
Is there a reason for not including any pictures? because it is limiting to English speaking community…				1		Focus of first draft was not design/layout, images have subsequently been added to the leaflet
Maybe a good video can be linked to the flyer for them to see if they want to				1	An animated video was commissioned to illustrate the key findings from the leaflet	
Images/illustrations should be included			1			Ibid. as above
I think there is a lot, a lot of text and that using pictures would break this up. It seems quite intimidating with all the text even though the language is simple and well-spaced				1		Ibid. as above
To me at the moment it is not giving clarity as which BCT we are using to bring the behaviour change. I don't know what the phase of your PhD is but I would suggest analysing this flyer to identify the Behaviour change techniques (BCTs) according				1		The leaflet was theoretically underpinned: the Theoretical Domains Framework was used, and each barrier/facilitator was coded to a

to the taxonomy. Following that you can develop/ screen the content in this e.g. it is inhibitive or initiative behaviour and what can facilitate that e.g. we want problem solving so this section is listing the problem “Support for people who are anxious about the smear test” and the column next to it should give the solution/answer to it. Otherwise listing problems is not a BCT. Same is do we need Goal setting? or want to change their belief regarding consequences etc						relevant BCT whenever possible
I wonder if the info would sit better in chronological order - for example, start with the explanation of what cervical screening is > before your appointment (tips for booking) > at your appointment > after your appointment etc. It makes it easier to navigate	1				The order of the sections was revised and this was tested during the usability phase	
Perhaps it should be aimed more at professionals/carers rather than just the people with SMI						The leaflet can be used with a health professional but it is aimed at improving decision-making for the individual

Before, during and after need to be more summarised (…) It's very long flyer and to me it is assuming low health literacy of the reader while internet impact is there				1		The length of the leaflet will be tested with service users during the usability phase

Appendix 8. Sample page from Version 0.2 of the tool



After your appointment

You should get a letter explaining your results 2 weeks after your appointment. Sometimes it can take less time or longer.

Most people get a clear result.

You will receive another invitation to cervical screening in 3 or 5 years, depending on your age.

If you have an abnormal result, you may be invited for further tests. This will help the doctors know how to monitor or treat you. Remember, having an abnormal result does not mean you have cancer.

If you don't understand your results or have any questions, speak to your GP or trusted mental health professional.

You may feel anxious before or after your appointment.

Some women find it helpful to ring up:

their mental health crisis team

Samaritans: available 24/7
National number: 116 123

SANEline: open 6pm-11pm
0300 304 7000

Appendix 9. Feedback from service user researcher on the draft research materials and protocol

Some thoughts about your draft research study protocol and revised questionnaire

The draft protocol

Introductory information on patient and public involvement

It is interesting to see your plans for the involvement of women with lived experience in commenting on your research documents and great that you want to have this involvement. A couple of points:

• Because organisation [xxx] as a whole has not been involved and because you have used some of my suggestions, but not others – your total prerogative as a researcher – I think that the extent of xxx's involvement needs putting more cautiously, for example changing the sentence starting 'Members of this group ...' to 'One or two members of this group ...' and then adding at the end of the information about xxxx 'and some changes made as a result of feedback given'.

Background

I thought that this contains some very useful and informative material. Additional suggestions from a lived experience perspective would be:

• Citing some material from women with a serious mental health diagnosis. If you would like to cite the comment in the email which I have sent to you with this

attachment, let me know and I will ask the woman's permission. There is also a relevant quote in my […] Project report, which I can forward to you if you would like

• It was good to see that one or two of the articles which you reference come from co-produced studies. I think it would also be helpful to include studies by people with lived experience and to mention the importance of these (i.e. because the latter know from the inside what their experiences actually are and what approaches they and their peers find beneficial). I am not personally aware of a study about cancer experiences directly from people with serious mental illness diagnoses, but could send you references about user-led research and its value if this would be helpful

• In the final paragraph on p.4, you mention some very relevant barriers to cervical screening for women with a serious mental illness diagnosis. You might want to include as well the sheer impact of mental distress? In the xxx Project, participants named this as a particularly high obstacle to their looking after their physical health. (This is different from the mental capacity issue that you mention on p.5.)

Rationale

The reason for undertaking this study came across to me as well evidenced.

Theoretical Framework

I found it clear that you have worked hard to ensure an adequate theoretical underpinning for your study. You may also want to take account of the fact that people with lived experience can find established frameworks unsatisfactory from their perspectives, because they stem from studies undertaken by researchers without lived experience (or studies in which people with lived experience had some role, but not a co-equal one)

Research questionnaires

Just one suggestion: I wonder whether the sentence starting ‘At the end of the research, we will understand what women diagnosed with a serious mental illness require ...’ should be put a little less strongly? As this is a single study and a comparatively small one, should the sentence read more along the lines of: ‘At the end of the research, we will have an improved understanding of what women diagnosed with a serious mental illness require ...’?

Phase Four: Testing the usability of the tool

Think-aloud testing (Study 3) A couple of questions:

• Validated methodology is clearly important. However, for people with lived experience, there can be a tension between validated scales/questionnaires and material which they find ‘valid’ in their own experience because it is user-led. Would you want to make any mention of recognising the latter too?

• You speak of taking some informal notes on participant behaviour. Will participants be informed that you would like to do this and will it be subject to their consent?

Measures

Demographic and clinical questionnaire

Would it be helpful also to ask healthcare professionals about relevant health issues for them? Some professionals also experience mental distress and may have used mental health services themselves. In addition, it may be relevant to know which of them have undergone cervical screening themselves.

Draft interview schedule for women diagnosed with a serious mental illness

It is good to see the further increase in accessible wording. A few suggestions as well:

• It is encouraging that you have decided to ask people at the UK charity dedicated to cervical cancer/cervical abnormality issues for suggestions about supporting

women who have experienced sexual violence with cervical screening. Will any of the contributors from this charity have lived experience of a serious mental illness diagnosis and will views be sought from women with lived experience about other aspects of cervical screening which are relevant to the leaflet, before a first draft is produced? As I mentioned previously, not asking women with lived experience for their ideas about the information leaflet before an initial draft is collated limits the amount of influence which women will be able to have over it and could have a negative effect on its quality. Otherwise, might it be useful to explain your reasons for not obtaining ideas for the leaflet from women with lived experience before the first draft of it?

• In the 4th question, you may want to invite 3 main reasons for using/not using the leaflet, rather than 3 main benefits: to pre-empt any bias in the question

• I would suggest not limiting the final question to people from BAME and LB and T communities –these were just examples from me. There are issues for other marginalised groups as well, e.g. young people (under 25s) and people who have physical or sensory disabilities/physical health conditions in addition to their mental distress. You may also want to use the terminology ‘people from BAME or LB and T communities’ rather than ‘the BAME/LBT community’? There are a whole host of different communities within BAME and LB and T populations

• I was a little unclear about the difference between the next to last question in the main set and the 3rd question under the heading of ‘finally’. Data analysis I like the emphasis on also looking at ‘deviant cases and disconfirming evidence’ and at dissonance between findings. I think this will be particularly important during analysis of data from people with lived experience who face further marginalisation because

e.g. they belong to a BAME, or LB and T community, are under 25, or have physical or sensory disabilities/health conditions too.

Inclusion and exclusion criteria

I found these very clear. A couple of points:

• I am very aware that many research studies exclude people who cannot read English rather than using translators. It does also concern me, however; exclusion from research studies further marginalises people who already tend to be seriously marginalised

• Although there are unfortunately many precedents for a clinical team making decisions about the capability of someone with lived experience to give informed consent to participation in a study, this approach is unpopular with many people who have lived experience. The latter see it as a rather ‘top down’ approach and one which fails to recognise that they know themselves best. There are also precedents for taking an alternative approach; for example, I had REC approval for doing so when I undertook a study about the Care Programme Approach and recovery. Might you want to reconsider your approach to the issue? Sampling strategy for women diagnosed with a serious mental illness It is helpful that you are aiming to recruit as wide a demographic mix of participants as possible. One thought: people from BAME and LB or T communities and young people are very frequently under-represented amongst research participants, may particularly lack confidence in their views being heard, for instance. If you want to be sure of a good demographic mix, I think you may well need to do something more active than relying on the demographic areas in which recruitment is due to occur.

Recruitment procedure for women diagnosed with a serious mental illness

One thought: there can be considerable tensions between people with lived experience and psychiatrists, which can affect recruitment – mean that there is a bias because the people approached/the people who come forward do not include those who are unhappy with their psychiatrist. Had you thought of recruiting more widely? (Again, there are precedents for doing so.)

Consent from people with lived experience

Some really useful points are covered. In this paragraph, it might also be helpful to include the following issues:

• Sending the information sheet and consent form to participants ahead of an interview: to add to their ability to give informed consent

• Covering confidentiality issues during verbal explanations about the study

• Explaining that choosing not to take part in the study/withdrawing from it will not affect any care which they receive

• Explaining how the researchers will ensure that they are sensitive if they postpone an interview; people with lived experience often have painful experiences of rejection and, if the situation is not handled with considerable sensitivity, could go away feeling further rejected.

Ethical and regulatory considerations

You have some clear information about the health researchers and clinicians who make up the research team. It would have been good to have some service user researchers as well, to bring in a co-production element for the data collection. Service user researchers can sometimes also elicit data which researchers without lived experience do not, because people with lived experience may talk more freely with their peers. Is this something you would consider and would you have a budget

for it? If not, I think it would be helpful if you acknowledged that research team members will not have lived experience expertise

Risks and burdens

Because women with lived experience may have been sexually abused and may have had bad experiences with cervical screening for that and other reasons, I think it would be good if you said a little more here about risks arising from these sorts of factors.(re-traumatisation because of such memories).

Peer review

For the reasons given below (for sub-section 8.4), I think it would be helpful to add at the end of the 2nd sentence in sub-section 8.3 ‘and some changes made as a result of feedback given’.

Societal impact

Would it be worth adding the Healthy London Partnership to your dissemination list? The Partnership has a current focus on physical health experiences for people diagnosed with serious mental illnesses and has itself produced some reports related to cancer and people with these diagnoses.

The revised questionnaire

It is helpful to see some further changes to this. A couple of additional suggestions:

• In gender terms, the following questions are now recommended for equality reasons: ‘At birth, were you described as Female? Male? Intersex?’ and: ‘Which of the following options describes how you think of yourself now: Female? Male? In another way .....?’ (with tick boxes for the various options, of course)

• Would it be worth using one of the standardised sets of wording for the ethnicity part of the questionnaire?

• It would be good to add ‘please’ before the question ‘Tell us about your past experience of ...’

• When I suggested exploring experiences of people with serious mental illness diagnoses who belong to LB and T, or BAME communities etc, I partly had in mind the demographic section of the questionnaire. In this, you are already asking participants about their ethnicity. If you decide to include the gender questions I have suggested, that will cover trans issues. If you invite people to say whether they are heterosexual, bisexual or lesbian, you will also know how many participants you have from these communities. In the data analysis, you might then be able to see whether there are any significantly different experiences of cervical screening for women with lived experience who belong to further marginalised communities/groups

• If you also use the questionnaire to ask specifically about experiences for women with serious mental illness diagnoses who face additional marginalisation, I think what would be helpful is one broad question and one with some re-wording, for example: ‘If you think that your experiences of cervical screening have been affected by factors such as your ethnicity, age, sexual orientation, physical health condition or physical disabilities, please share it here’ (with space underneath to do so).

Hoping that these points are of some help

02/02/18

Appendix 10. Sample consent form (women with SMI)

Rec ref: 18/SC/0123
IRAS Project ID: 233934

[Insert UWL and Trust logos]

Participant Identification Number: _____

Short study title: Cervical screening informed choice tool for women with mental illness
Name of researcher: Frederique Lamontagne-Godwin

CONSENT FORM #1

Women diagnosed with a serious mental illness

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

Please initials in the boxes next to the statements you agree with after you have read the Information Sheet and/or listened to an explanation about the research.

		Please initial
1)	I confirm that I have read and understood the Information Sheet version 0.3 dated 08/03/2018 for the above study and have had the opportunity to ask questions. All questions have been answered to my satisfaction.	☐
2)	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care, work or legal rights being affected.	☐
3)	I understand that I will be interviewed about my views and feedback on a smear test information leaflet.	☐

4) I agree to take part in the above study. ☐

5) I consent to my interview being audio recorded. ☐

6) I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

7) I understand that I may be quoted anonymously (no name or identifying information) in reports of the results of the study. I give my permission for this. ☐

8) I understand that, if I wish, my interview can be excluded from the study if requested prior to 31 July 2019 (after which the final analysis will be conducted). ☐

9) I understand that some parts of the data collected for the study may be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality under the Data Protection Act 1998. ☐

11) I agree to make my anonymised data available with the UK Data Service, which is funded by the Economic and Social Research Council (ESRC). We will use this free UK data service to store the qualitative data and quantitative data as open data. Yes / No

12) I agree to be contacted about the next phase in this study. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of person taking consent (Interviewer)	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 11. Sample participant information sheet (women with SMI)

Rec ref: 18/SC/0123
IRAS Project ID: 233934

[Insert NHS Trust and UWL logos]

INFORMATION SHEET #3

Women diagnosed with a serious mental illness

Short study title: Cervical screening informed choice tool for women with mental illness

This research forms part of a University of West London PhD Studentship (2017-2020)

PhD student/researcher: Frederique Lamontagne-Godwin, University of West London

Principal Supervisor: Professor Elizabeth Barley, University of Surrey

Second Supervisor: Dr Claire Henderson, King's College London

Third Supervisor: Dr Caroline Lafarge, University of West London

Invitation paragraph
We would like to invite you to take part in our research study. Before you decide whether you would like to participate, it is important for you to understand why the research is being carried out and what taking part would involve for you. You do not have to take part. If you don't want to participate it will not impact upon the care you receive in any way. Please take time to read the following information carefully and ask the research team any questions you may have.

Part 1

Why are we carrying out this research?

Screening people for some cancers can be helpful in detecting early cancer and this may help improve health. For this reason, in the UK there are national screening programmes for three types of cancer (breast, bowel and cervical). This research is about the decision to attend a smear test (cervical cancer screening) for women aged 25 to 64. Evidence suggests that people diagnosed with a serious mental illness may be less likely to have cancer screening. One reason is the difficulty to make a decision on whether to attend the appointment. Decision-making can be hard because of factors such as: how mentally distressed people feel, past experiences of physical health care, difficulty remembering appointments and sexual abuse. There has been little research in this area.

What is the purpose of the research?

The aim of the research is to develop an **information leaflet to help women diagnosed with a serious mental illness to decide whether to attend a smear test.** The research will explore the experience of participants (women diagnosed with a serious mental illness and health professionals) when using the leaflet. Our aim is to make the leaflet appealing and user friendly. Your participation will help us achieve this goal.

Why have I been invited?

You receive care from the *xxx NHS Trust*.

Do I have to take part?

No, participation is entirely voluntary. It is entirely up to you to decide whether or not to take part. If you don't want to take part it will not affect the care you receive in any way. If you decide to take part you are free to withdraw at any time, without giving a reason. If you withdraw from the study, this will not affect the care you receive in any way.

What will happen to me if I take part?

You will be asked to provide some details about yourself (gender, diagnosis, duration of illness/es, year of birth, ethnic group, whether you have ever attended a smear test and approximate date when it took place). You will then take part in a short interview with the researcher to provide any feedback you might have on the content and design of the leaflet. Below are example questions you will be presented with:

- **Layout:** what do you think of the overall layout? Is there anything you would change? If so, what?
- **Clarity:** was anything unclear? If so, how would you reword it?
- **Start to finish:** how easy was it to go through the information leaflet? Would you change anything?
- **Look and feel**: what did you think of the design of the information leaflet?
- **Information**: Do you think there is too much/not enough information?
- **Overall**: is there anything you would change/add/remove from the information leaflet? If so, what?
- Is there anything else you would like to say about what health professionals and health services might do that would make it easier for people diagnosed with a serious mental illness to decide whether or not to go for cancer screening?
- What could be done to make the experience of cancer screening better for people diagnosed with a serious mental illness?

Before and after you provide feedback on the leaflet, we will ask you to fill out two short questionnaires on how you would feel about attending a smear test. We want to know if the leaflet has an impact on your decision to attend a smear test in the future. Interviews will be recorded and last up to forty-five minutes. They will be conducted face-to-face in your clinic. The interview will be scheduled at a convenient time for you, either after your planned standard clinical care visit or, if you prefer, on another day. If you have incurred travel expenses that you would not have done without taking part in the study, we will reimburse these. You will be able to take breaks if you need to. You can choose to skip questions you do not want to answer or leave the session at any point if you are not enjoying it, without explaining why.

Who can take part?

We are looking for:

- Women aged between 18 and 64

All participants need to have:

- A diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder or psychotic depression.

You don't need to have had cancer screening (smear test) to take part. We are interested in talking to a wide range of people including those who have missed or declined their smear test appointments, as well as those who have been screened.

What do I do if I am interested in taking part?

If you are interested in taking part please either:

- Phone or email the research team using the contact details at the end of this sheet. To save expense, we will call you straight back OR
- Ask another person, such as a health care worker, friend or relative to pass your details on to us and we will contact you.

Expenses and payments

You will not receive any payment for participating in the study. Neither your health professional nor the hospital are being paid to participate in this study. If you have incurred travel expenses that you would not have done without taking part in the study, we will reimburse these.

What are the possible risks of taking part?

The main disadvantage to you is giving up your time to take part in the research study. Talking to the researcher about cancer screening may remind you of difficult feelings or unpleasant experiences and could cause you to feel distressed. If you find the interview distressing, you can take a break.

What are the possible benefits of taking part?

In similar studies some participants have told us that they found it interesting talking to a researcher about the interview topics. You will be involved in research which will help to increase understanding about uptake of cancer screening in people diagnosed with a serious mental illness diagnosis. The study might not help you directly, but your involvement may help improve attendance of smear tests by women diagnosed with a serious mental illness.

What will happen if I don't want to carry on with the study?

If you change your mind and decide that you do not want to participate in the study, you can withdraw at any time by asking us to stop recording. You do not need to give a reason and your legal rights will not be affected. If you withdraw from the study, we will completely remove your collected information from our records.

Will my taking part in this study be kept confidential?

Your identity and all the information about your participation will be kept confidential. We will choose a unique code number for you and use that instead of your name in all future documents. Recording and transcriptions will be encoded and stored on our secure University of West London server and protected with a password. Any document with your identifiable information (e.g. consent sheets) will be kept in a locked filing cabinet in the researcher's office at the University of West London. The only circumstances in which a researcher would not maintain confidentiality is if you told a member of the research team something which made us believe there was a serious risk to your or someone else's safety. In those circumstances, we would discuss our concerns with your care coordinator or speak to the duty clinician on the team, who would decide whether any further action was required.

We will register the study with the UK Data Service to store our anonymous interview data and numerical data as accessible data. We will make all data available in this way within three months of acceptance by a scientific journal of the main study publications. If you do not wish to have your anonymised data registered on this platform, you can opt out on your Informed Consent Form.

PART 2

Who is organising and funding the research?

This study is funded by a University of West London PhD Studentship (2017-2020) and sponsored by the University of West London.

Who has reviewed this study?

This study was reviewed and approved by the South Central - Hampshire B Research Ethics Committee on the 16/04/2018. This study has been reviewed and given favourable opinion by the University of West London Ethics Committee on the 07/12/2017.

What if there is a problem?

You can contact the researcher who will do her best to answer your questions. You can also contact the Chief Investigator, Professor Elizabeth Barley, at the University of West London (Elizabeth.barley@uwl.ac.uk or 020 8209 4117). If you remain concerned and wish to complain formally, you can do this through the NHS complaints procedure. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. You can contact the Patient Advice and Liaison Service (PALS) at the xxx NHS Trust in the following way:

	XXX NHS Trust
Telephone:	
Email:	
In person:	

Withdrawal

You do not have to take part in this study. If you do take part you are free to withdraw at any time without giving a reason. You may withdraw any interview data already collected if you tell the researcher before 31/08/2019. After that, your data will have been analysed.

Harm

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence, you may have grounds for a legal action for compensation against the School of Human and Social Sciences at the University of West London, but you may have to pay legal costs.

Independent Contact Point

You can contact INVOLVE, a national advisory group which supports active public involvement in the NHS, if you seek general advice about taking part in research.

Contact details can be found below:

Telephone number	**Address**	**Email**
023 8059 5628	Alpha House, University of Southampton Science Park, Chilworth, Southampton, SO16 7NS	involve@nihr.ac.uk

Who will have access to my personal data?

Only the research team have access to your personal data. Trust staff of the Research and Development Office may need to check data in the course of their monitoring and auditing work.

What will happen to the results of the research study?

The results of this study may be published in scientific journals or presented at scientific conferences, but there will be no way of knowing who has taken part. Our results will be accessible by browsing the registry on this database: www.researchregistry.com using the study Research Registry Unique Identifying Number: researchregistry3816.

Research Team Contact Details

If you would like any further information about this study or would like to participate please contact:

	Professor Elizabeth Barley Principal supervisor	**Frederique Lamontagne-Godwin** PhD student
Email:	Elizabeth.barley@uwl.ac.uk	Frederique.lamontagne-godwin@nhs.net
Address:	University of West London School of Human and Social Sciences Paragon House Boston Manor road, Brentford, Middlesex, TW8 9GA	
Telephone:	020 8209 4117	[project mobile number]

The researcher will call you back to avoid expense.

What now?

If you decide to participate in this study, we will ask you to sign a consent form. We will keep one copy, and give you another copy to keep. Thank you very much for taking time to consider being in this study.

Appendix 12. Participant information sheet (health professionals)

Rec ref: 18/SC/0123
IRAS Project ID: 233934

[Insert UWL and Trust logos]

INFORMATION SHEET #1 - Healthcare Professional

Short study title: Cervical screening informed choice tool for women with mental illness

This research forms part of a University of West London PhD Studentship (2017-2020).

PhD student: Frederique Lamontagne-Godwin, University of West London

Principle Supervisor: Professor Elizabeth Barley, University of West London

Second Supervisor: Dr Claire Henderson, King's College London

Third Supervisor: Dr Caroline Lafarge, University of West London

Invitation paragraph
We would like to invite you to take part in our research study. Before you decide whether you would like to take part, it is important for you to understand why the research is being carried out and what taking part would involve for you. This should take about 10 minutes. Please take time to read the following information carefully, and ask the research team any questions you may have.

Part 1

Why are we carrying out this study?

Screening people for some cancers can be helpful in detecting early cancer and this may help improve health. For this reason in the UK there are national screening programmes for three types of cancer (breast, bowel and cervical). This research is about cervical screening for women aged 25 to 64. Evidence suggests that people diagnosed with a serious mental illness, such as bipolar disorder, schizophrenia, other psychoses, may be less likely to have cancer screening. One reason is the difficulty to make a decision on whether to attend a screening appointment. There has been very little research in this area. **Our study aims to improve the decision-making process of whether to attend cervical screening by developing and testing a paper leaflet for women diagnosed with a serious mental illness.** The research is being conducted by a team of researchers led by the University of West London.

We are interviewing women diagnosed with a serious mental illness and their health professionals for their views and feedback on the content of the leaflet. Our goal is to make it appealing, intuitive and user friendly. Your participation will help us achieve this goal.

What is the purpose of the research?

The primary aim is, through use of an informed choice tool, to improve the ability of women diagnosed with a serious mental illness to come to a decision of whether to attend cervical screening. The research will develop an informed choice tool for women diagnosed with a

serious mental illness and explore participants' experience of using the leaflet and feedback from health professionals.

Why have I been invited?

You have been invited because you are an NHS professional and are involved in delivering or promoting physical health in people diagnosed with a serious mental illness. We are conducting our study in the clinic where you work, so we are seeking your agreement to take part.

Do I have to take part?

No, participation is entirely voluntary. It is entirely up to you to decide whether or not to take part. If you decide to take part you are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?

You will be asked to provide feedback on the tool in a single feedback session. This involves filling out a short demographic questionnaire and taking part in a single interview with the researcher (also see below). You do not have to take part in a feedback session in the next and final phase (phase 4). Interviews will last between thirty and forty-five minutes and will be conducted face-to-face in your clinic. The interview will be scheduled at a convenient time for you. If you would like to have a break at any stage, then please tell the researcher. During the interview you do not have to answer anything that you don't want to and if you are not enjoying taking part then you can decide to leave at any stage, without having to tell the researcher why. Interviews will be audio-recorded. Below are example questions you will be presented with:

- What do you think of the tool?
- Are there any experiences/information which you feel are missing and should be included?
- Are there any changes which we should make to the tool?
- How likely would you be to use it with a mental health service user to assist them in their decision-making on whether to attend screening? Why?
- What do you think might be the best setting to introduce the tool to your patients?
- Do you have any experience of using such tools? What was their experience like?

Who can take part?

We are looking for nurses and psychiatrists working in secondary care mental health services.

What do I do if I am interested in taking part?

If you are interested in taking part please phone, email or write to the research team using the contact details at the end of this sheet.

Expenses and payments

You will not receive any payment for participating in the study. If you have incurred travel expenses that you would not have done without taking part in the study, we will reimburse these.

What are the possible risks of taking part?

There are no foreseen risks in participating in the study. The main disadvantage to you is giving up your time to take part in the research study. It is possible that you might find

answering some of the questions difficult. If this were to occur, you can take a break or terminate the interview at any time.

What are the possible benefits of taking part?

In similar studies some participants have told us that they found it interesting talking to a researcher about the interview topics. You will be involved in research which will help to increase understanding about uptake of cancer screening in people diagnosed with a serious mental illness.

Will my taking part in this study be kept confidential?

Your identity and all the information about your participation will be kept confidential. We will choose a unique code number for you and use that instead of your name in all future documents. Recording and transcriptions will also be stored on a secure server and will be password protected. Any paper data with your identifiable information (e.g. consent sheets) will be kept in a locked filing cabinet in the researcher's office at the University of West London.

We will register the study with the UK Data Service to store our qualitative data and quantitative data as open data. We will make all data available in this way within three months of acceptance by a peer reviewed journal of the main study publications. If you do not wish to have your anonymised data registered on this platform, you can opt out on your Informed Consent Form.

PART 2

Who is organising and funding the research?

This study is funded by a University of West London PhD Studentship (2017-2020) and sponsored by the University of West London.

Who has reviewed this study?

This study was reviewed and approved by the South Central - Hampshire B Research Ethics Committee on the 16/04/2018. This study has been reviewed and given favourable opinion by the University of West London Ethics Committee on the 07/12/2017.

What if there is a problem?

You can contact the PhD student Frederique Lamontagne-Godwin, who will do her best to answer your questions. You can also contact the Chief Investigator, Professor Elizabeth Barley, at the University of West London by email: Elizabeth.barley@uwl.ac.uk or telephone: 020 8209 4117. If you remain concerned and wish to complain formally, you can do this through the NHS complaints procedure.

Withdrawal

You do not have to take part in this study. If you do take part you are free to withdraw at any time without giving a reason and your legal rights will not be affected. You may withdraw any data already collected if you wish if you tell the researcher before 31/07/2019, at which time your data will have been analysed.

Harm

In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence, you may have grounds for a legal action for compensation

against the School of Human and Social Sciences at the University of West London, but you may have to pay legal costs.

Independent Contact Point

You can contact INVOLVE, a national advisory group which supports active public involvement in the NHS, if you seek general advice about taking part in research:

Telephone number	Address	Email
023 8059 5628	Alpha House, University of Southampton Science Park, Chilworth, Southampton, SO16 7NS	involve@nihr.ac.uk

Who will have access to my personal data?

Only the research team have access to your personal data. Trust staff of the Research and Development Office may need to check data in the course of their work monitoring and auditing research.

What will happen to the results of the research study?

The results of this study may be published in scientific journals or presented at scientific conferences, but there will be no way of knowing who has taken part. Our results will be accessible by browsing the registry on this database: www.researchregistry.com using the study Research Registry Unique Identifying Number: researchregistry3816.

Research Team Contact Details

If you would like any further information about this study or would like to participate please contact:

	Professor Elizabeth Barley Principal supervisor	**Frederique Lamontagne-Godwin** PhD student
Email:	Elizabeth.barley@uwl.ac.uk	frederique.lamontagne-godwin@nhs.net
Address:	University of West London School of Human and Social Sciences Paragon House Boston Manor road, Brentford, Middlesex, TW8 9GA	
Telephone:	020 8209 4117	[project mobile number]

What now?

If you decide to participate in this study, we will ask you to sign a consent form. We will keep one copy, and give you another copy to keep. Thank you very much for taking time to consider being in this study.

Appendix 13. Consent form (health professionals)

Rec ref: 18/SC/0123
IRAS Project ID: 233934

[Insert Trust and UWL logos]

Participant Identification Number: _____

Short study title: Cervical screening informed choice tool for women with mental illness
Name of researcher: Frederique Lamontagne-Godwin

CONSENT FORM #1

Healthcare Professional

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

Please initials in the boxes next to the statements you agree with after you have read the Information Sheet and/or listened to an explanation about the research.

		Please initial
1)	I confirm that I have read and understood the information sheet version 0.3 dated 08/03/2018 for the above study and have had the opportunity to ask questions. All questions have been answered to my satisfaction.	☐
2)	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my work or legal rights being affected.	☐
3)	I understand that I will be interviewed about my views and feedback on an informed choice tool to facilitate cervical screening decision-making for women diagnosed with a serious mental illness.	☐
		☐

4) I agree to take part in the above study.

5) I consent to my interview being audio recorded. ☐

6) I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

7) I understand that I may be quoted anonymously (no name or identifying information) in reports of the results of the study. I give my permission for this. ☐

8) I understand that, if I wish, my interview can be excluded from the study if requested prior to 31st July 2019 (after which the final analysis will be conducted). ☐

9) I understand that some parts of the data collected for the study may be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality under the data protection act 1998. ☐

10) I agree to make my anonymised data available with the UK Data Service, which is funded by the Economic and Social Research Council (ESRC). We will use this free UK data service to store the qualitative data and quantitative data as open data. Yes / No

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of person taking consent (Interviewer)	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 14. Demographic questionnaire for women with SMI

Participant Identification Number: _____

Rec ref: 18/SC/0123
IRAS Project ID: 233934

[NHS Trust and UWL logos]

Short study title: Cervical screening informed choice tool for women with mental illness
Name of researcher: Frederique Lamontagne-Godwin

Questionnaire for women diagnosed with a serious mental illness

Gender
At birth, were you described as: Female ☐ Male ☐ Intersex ☐ Would rather not say ☐ Which of the following options describes how you think of yourself now: Female ☐ Male ☐ In another way..... Would rather not say ☐
Year of birth
Ethnic group (Choose one option that best describes your ethnic group or background)

White		11. Bangladeshi	
1. English/Welsh/Scottish/Northern Irish/British		12. Chinese	

2. Irish		13. Any other Asian background, please describe ……	
3. Gypsy or Irish Traveller		**Black/ African/Caribbean/Black British**	
4. Any other White background, please describe ……		14. African	
Mixed/Multiple ethnic group		15. Caribbean	
5. White and Black Caribbean		16. Any other Black/African/Caribbean background, please describe ……	
6. White and Black African		**Other ethnic group**	
7. White and Asian		17. Arab	
8. Any other Mixed/Multiple ethnic background, please describe ……		18. Any other ethnic group, please describe: ……	
Asian/Asian British			
9. Indian			
10. Pakistani			

Mental illness diagnoses (please state all current or previous diagnoses) **and duration of illness**

Smear test

Have you ever had a smear test?

Never ☐

Once ☐

More than once ☐

When was the last one? ……

Appendix 15. Healthcare professional questionnaire

Rec ref: 18/SC/0123

IRAS Project ID: 233934

[Insert Trust and UWL logos]

Participant Identification Number: _____

Short study title: Cervical screening informed choice tool for women with mental illness
Name of researcher: Frederique Lamontagne-Godwin

Healthcare Professional Questionnaire

Gender
At birth, were you described as: Female ☐ Male ☐ Intersex ☐ Would rather not say ☐ Which of the following options describes how you think of yourself now: Female ☐ Male ☐ In another way..... Would rather not say ☐
Year of birth

Ethnic group (Choose one option that best describes your ethnic group or background)			
White		11. Bangladeshi	
11. English/Welsh/Scottish/Northern Irish/British		12. Chinese	
12. Irish		13. Any other Asian background, please describe ……	
13. Gypsy or Irish Traveller		**Black/ African/Caribbean/Black British**	
14. Any other White background, please describe ……		14. African	

Mixed/Multiple ethnic group		15. Caribbean	
15. White and Black Caribbean		16. Any other Black/African/Caribbean background, please describe ……	
16. White and Black African		**Other ethnic group**	
17. White and Asian		17. Arab	
18. Any other Mixed/Multiple ethnic background, please describe ……		18. Any other ethnic group, please describe: ……	
Asian/Asian British			
19. Indian			
20. Pakistani			
Profession			
Length of time in current role			
Work setting			
Length of time since your initial qualification			

Appendix 16. Interview schedule (women with SMI)

Rec ref: 18/SC/0123
IRAS Project ID: 233934

Interview Schedule #1

Women diagnosed with a serious mental illness
Feedback on the content of the smear test information leaflet

The interview items are a guide for the discussion and the follow-up questions and prompts can be added as necessary. The order and content of the items do not need to be adhered to precisely. It may be useful or necessary to adjust the wording of some questions for individual participants or to follow up some items using questions that appear elsewhere in the schedule.

Before starting the interview: obtain signed consent to participate in the study and ask participant to complete a brief questionnaire.

Introduction

Thank you for agreeing to take part in our study. We are interested in exploring views of women diagnosed with a serious mental illness on this draft smear test information leaflet, which aims to improve the decision-making process of women to attend a smear test. I just want to ask you a few questions about your thoughts on the content. All information will be kept completely confidential.

Are there any questions you would like to ask me before we start?

Inform participant you are turning on recorder

- What do you think of the information leaflet?
- What suggestions do you have about the content? [Prompt: What information do you feel should be in/excluded?]
- Would the information leaflet have been useful to you in making the decision to attend a smear test in the past? If not, why not?
- Would you use this information leaflet in thinking about attending a smear test in the future? If not, why not? If yes, why (perhaps 3 main benefits)
- Would the information leaflet be useful in making other screening decisions e.g. breast screening? If not, why not? If yes why?
- Would you recommend a friend with a mental health condition to use this information leaflet to reach a screening decision? If not, why not?
- Would you recommend clinicians to use the information leaflet in assisting mental health service users with a screening decision? If not, why not?
- Would you prefer to go through the information leaflet alone or with someone else, and if so, who?

Finally...

- Is there anything else you would like to say about what health professionals and health services might do that would make it easier for people diagnosed with a serious mental illness to decide whether or not to go for cancer screening?
- And what could be done to make the experience of cancer screening better for people diagnosed with a serious mental illness?

.....

Thank the participant for their time and contribution.

Reiterate that the audio-recording will be transcribed for analysis, then deleted with just the transcribed data to be used for analysis.

Check if the participant has any questions for clarification.

Appendix 17. Interview schedule (health professionals)

Rec ref: 18/SC/0123

IRAS Project ID: 233934

Interview Schedule #1

Healthcare Professional

Feedback on cervical screening informed choice tool for women diagnosed with a serious mental illness

The interview items are a guide for the discussion and the follow-up questions and prompts can be added as necessary. The order and content of the items do not need to be adhered to precisely. It may be useful or necessary to adjust the wording of some questions for individual participants or to follow up some items using questions that appear elsewhere in the schedule.

Before starting the interview

Obtain signed consent to participate in the study and ask participant to complete a brief demographic questionnaire. Remind participant of rights to withdraw at any time, before, during or after the study.

Introduction

Thank you for agreeing to take part in our study. We are interested in exploring healthcare professional views of this draft informed choice tool, which aims to facilitate the decision-making process of whether to attend cervical screening for women diagnosed with a serious mental illness. I just want to ask you a few questions about your thoughts on the content – please answer as honestly as possible. All information will be kept completely confidential.

Are there any questions you would like to ask me before we start?

Inform participant you are turning on recorder

- What do you think of the tool?
- Are there any experiences/information which you feel are missing and should be included?
- What information, if any, should be removed?

- Are there any changes which we should make to the tool?
- Any other comments/suggestions about the content?
- How likely would you be to use it with a mental health service user to assist them in their decision-making on whether to attend screening? Why?
- What do you think might be the best setting to introduce the tool to your patients?
- Lastly, do you have any experience of using such tools? What was their experience like? How does this one compare?

.....

Thank the participant for their time and contribution.

Reiterate that the audio-recording will be transcribed for analysis, then deleted with just the transcribed data to be used for analysis.

Check if the participant has any questions for clarification.

Appendix 18. Fully coded content analysis (acceptability testing)

		Revision requested by (*n* =)				Decision made:	
Revision:				Key informants group		Revision accepted	Revision rejected
		Service user	Health professional	Member of service user group	Clinician/ member of NHS organisation		
"Title page"							
Should we mention the leaflet is aimed at women with SMI? Perhaps we don't need to be so explicit…						Service users (and most mental health professionals) would not want to use such a label for this group. It's our role to ensure the leaflet is tailored to their needs, and available in the services they access in primary and secondary care	
[Image of ladies]: add text in bubbles (e.g. can I bring a friend?, I need more information, I'm feeling anxious...).						A professional illustrator was commissioned to design the front page cover based on service user feedback	
"What is in this leaflet"							
On p.3, are the sub-headings of 'What is cervical screening?' etc meant to be a contents				1		Wording amended to reflect this	

list? If so, could this be clarified?						
“What is cervical screening”						
“Going for cervical screening is the best way to protect against cervical cancer”: this contradicts above that it is not a test for cancer. The general perception is that's what it is. So maybe you better off giving details as what it is instead				1	Wording amended to reflect this	
Need to be more specific about the description of cervical cancer symptom "lower back pain": fears too many people will come to the surgery with this symptom and feel anxious that they have cancer		1			Wording amended to reflect this	
Could replace "these symptoms can all be caused by things other than cancer" to "these symptoms can all be caused by lots of different things" - maybe find another word for "things"; be consistent and replace "smear test" with "cervical screening"		1			Wording amended to reflect this	
This may read better by putting the sentence "It is not a test for cancer" at the start			1			This sentence was deleted as may be confusing for service users
In the sentence where you say 'it is not a test for cancer' I think a natural conclusion				1	Wording amended to reflect this	

might be 'why bother then?'. I think it should say, more explicitly, that it can pick up changes that, if left untreated, might eventually lead to cancer						
Word "cancer" appears too much, you might scare people off... (…) word "abnormalities" doesn't sit well with participant and guesses also for people who have SMI		1				This was not raised by any service user
There is too much mention of the word "cancer", might worry someone who has paranoia or health anxiety and they might think "I'd rather not know"		1				This was not raised by any service user
Should we be talking about cancer so early on in the leaflet? Could make people more anxious…it is important, but it might put some people off, maybe better to talk about the practical things first, that's what's really important		1				This was not raised by any service user
Perhaps remove one mention of "cancer" by saying: "it's a preventative check that can prevent some serious illnesses like cancer"; when we describe cervical cancer symptoms, we can say "these things can be caused by things other than cancer"; avoid having the word "cancer" on its own		1			Wording amended to that effect	

Don't be afraid to be explicit about the risks involved if they don't go, don't be scared to use the word "cancer"		1				Have tried to strike a balance between health promotion and cancer prevention
Need to be factual, don't shy away from using the word "cancer"		1				Have tried to strike a balance between health promotion and cancer prevention
You could add: "if you catch it [cervical cancer] in time you'll be alright"		1			Wording amended to reflect this	
Offer alternative sources of information as not everyone has access to a computer or the internet			1			Research shows this group has access to internet and a computer. The leaflet will be available as a paper version in clinics
Is there an option for women younger than 24 to have the test if they are worried?	1					Leaflet is designed to provide information to women on the NHS cervical screening programme
This sentence "If you've never had any sexual contact, your risk of developing cervical cancer is very low. If you're not sure if you need a test, talk to your GP or practice nurse." feels a bit out of place. I would take it out – we don't want to				1	Wording amended to reflect this	

actively discourage people from going, especially as we can't link all cervical cancers to HPV at the moment. Saying 'If you're not sure if you need a test…' is a good enough prompt to talk/ask questions.						
It's relevant for people to know what to get checked between appointments (p.5). I'm thinking, though, that this section might be better near the end of the leaflet. As people are likely to be nervous before going for a smear test at all, it's probably not helpful to mention too early on what problems may arise even after one has gone for an appointment			1		A new section (Looking after your health) towards the end of the leaflet was included which includes information on cervical cancer symptoms	
I didn't know that smear tests wouldn't be able to detect cancer	1				Sentence was removed to avoid confusion	
"Booking your appointment"						
"If your mental health symptoms get worse in waiting rooms, ask to book the first appointment of the day, so you aren't waiting long": This phrase assumes the person does have mental illness, but I didn't get the sense from the start of the booklet that all people reading this would. Think it either needs to be				1		The leaflet should be tailored to their needs without having to be too explicit that this is for people with SMI

definite throughout, or more vague here. Would prefer it definite throughout (see suggestion at start).						
Double appointments are an issue in some practices…		1			Have revised to: "Ask the receptionist if you can book a longer appointment."	
A lot of GPs don't have the licence to do smear tests because they do so few and in some practices it's so hard to get a GP appointment, so it might be worth removing and just stating 'make an appointment with your practice nurse'		1			Wording amended to reflect this	
Patient may not get it, but they could "ask for" a double appointment		1			Wording amended to reflect this	
Could also suggest going to your GUM clinic, more of a female environment	1	1			Wording amended to reflect this	
Asking for the 1st appointment of the day (p.6) sounds a helpful idea for some people who find it hard to wait. However, for others of us, the morning is a particularly difficult time of day. What about an alternative suggestion to fit this, e.g. asking for the first appointment after a surgery's lunch break?			1			We cannot make it so specific as some surgeries don't have afternoon clinics etc.

An appointment reminder (p.6) can be helpful and many surgeries now do this automatically, of course. However, not everyone will feel a need for it, so you might like to add the words: 'If you would find this helpful'?			1		Wording amended to reflect this	
You may want to clarify in what circumstances people would want a longer appointment? Many of us would just like to get in and out as quickly as possible!			1		Wording amended to reflect this	
[Regarding people who might be feeling anxious in a waiting room before their smear test] that's a confusing one, what does that mean, they wouldn't know that you're going [for a smear test]? [I explain that some people get anxious/paranoid sitting in waiting rooms, they don't get anxious because they think other people know they are going for a smear. She then replies:] oh that is me [I get anxious in waiting rooms]	1				Wording amended to reflect this	
"Before your appointment"						
"Ask someone you trust to go to the appointment with you. See if they can be free in the morning or afternoon off work, to stay with you": I think people			1		Wording amended to reflect this	

may not know re health attendants or chaperones and we can introduce that here						
The section "Before your appointment" could come a bit earlier		1				This was not raised by any service user
"book a double appointment/organise transport in advance" sounds quite prescriptive, perhaps replace with "you can book…		1			Wording amended to reflect this	
Instead of "book your transport in advance" you could reword: “If it reduces your anxiety, you can plan your travel the day before, what time do you need to get up, what time do you need to leave the house, what time are the trains etc”	1				Wording amended to reflect this	
Bring a friend, relative "or your mental health professional"		1			Wording amended to reflect this	
"Bringing nicotine chewing gum in case you have a cigarette craving while you’re in the waiting room": Very specific! Has this come up a lot in the SMI interviews?				1		There is a very high prevalence rate of smoking in this group
I'm not sure I'd find it helpful to list for myself why it's important to go (p.8) - for me, the issue is getting oneself there rather than being unaware of the reasons for going. However, everyone is different of course			1			It may be useful as goal setting. Some service users found it useful

[box which allows you to think about why you find it hard to go, what would help you to go...] After point 1 – think about reasons - add lines for the thoughts or add point 2 into the first one. Is point 2 a separate question? This bit is confusing. It seems to be asking two different things with one only one space to write in			1		The formatting of this section has been revised to avoid confusion	
For some people with mental health problems it is very difficult for them to ring and make appointments and ask for the support they need. Could there be a sentence saying something like: if you find making an appointment difficult, ask a trusted relative, friend or your mental health worker to help you			1			There is a box where service users can fill out this section: "This would help me go to my appointment"
"tick box page"						
Ensure service users understand that filling out this page is optional [Is it optional [the tick box exercise]? Do I get given that [leaflet] at the GP or?]	2			1		Women can choose whether to bring the leaflet to their appointment, so it is optional by nature
You may also want to add points related to people from marginalised communities, e.g. women who identify as lesbian, bisexual or transgender and			1			Out of scope for this project, though FGM is mentioned

women from BAME communities with particular cultural issues						
[Service user had a previous bad experience with practice nurse, I asked whether it would be clearer if I put 'I had a previous bad smear test experience' rather than 'I had a previous bad experience'] maybe, it's clearer	1				Wording amended to reflect this	
The language used on this page seems traumatising - it makes the test sound like a big thing to go through. Be careful of using words like 'anxiety', mentioning anxiety could trigger it (…) Could the list of things that might bother you be worded differently – is there another way to describe 'stress responses'?			1			This was not raised during any service user interview
The idea of being able to show the nurse points you may want her/him to understand seems potentially helpful. I think it would be useful also to suggest having the opportunity (a) to let the nurse know beforehand about these and (b) to talk through with him/her beforehand (i) how a particular issue affects your feelings			1			With time pressures in primary care, it is not possible for practice nurses to start a conversation about this

about a smear test and (ii) what would help you						
[participant had a previous bad experience with practice nurse, candidate asked whether it would it be clearer if the tool includes: 'I had a previous bad smear test experience' rather than: 'I had a previous bad experience']: "maybe, it's clearer"	1				Change made to distinguish any type of trauma from "a previous bad smear test experience" which is more specific	
"This is good [the tick box page] as long as it's all kept confidential"	1					It would be confusing and possibly distressing to introduce confidentiality in the tool
You may also want to add points related to people from marginalised communities, e.g. women who identify as lesbian, bisexual or transgender and women from BAME communities with particular cultural issues			1			We had already included "I am a survivor of female genital mutilation/cutting (FGM/C)". Jo's Trust are developing a separate tool for LGBTQIA community
"I think it would be useful to suggest having the opportunity (a) to let the nurse know beforehand about these issues and (b) to talk through with him/her beforehand (i) how a			1			Due to time pressures in primary care, it is not possible for practice nurses to start a

particular issue affects your feelings about a smear test and (ii) what would help you"						conversation about this.
All words need to be spelt out fully e.g. examination not exam			1		Wording amended to reflect this	
"I may react in an unexpected way": nurse may ask "so what are you gonna do?!" in a not very helpful way, so it's better to have a line where the person can write down how they think they may react	1				Change made; the option "Other:……" was added	
You could add "I have an issue with my GP" as a barrier		1				The option was added: "I have had a bad smear test experience" which includes any negative experience with a health professional
I wonder whether there should be a space for (optionally) writing 'my mental health conditions/diagnoses are...' so that the tool can be shown to the health professional doing the test. The nurse/Dr may not have access to medical records at the time of the test, and it might make it easier for the patient.				1	"I have a mental illness" was replaced with "I have a mental health condition: _____"	
Obesity is an issue with this group: could add "I am		1			The option was added: "I am embarrassed by my body"	

embarrassed by my body shape”						
“I am a voices hearer and get distressed during a physical exam”: split into two different categories		1			The options were added: “I hear voices” and “I get distressed during a physical examination”	
The option “I have other health issues” isn’t clear, could be replaced by “I find it hard to maintain a healthy weight”				1	The option “I have other health issues” was removed. It was replaced by “I am embarrassed by my body”	
Instead of just pass out, add “faint”				1	The option was added: “I may pass out or faint”	
“During your appointment”						
Words like cervix can be difficult to understand – may need further explanation and /or diagram	1				An image of female anatomy has been included (copyright jo’s Trust)	
Should there be diagrams to complement the description?					An image of female anatomy has been included (copyright jo’s Trust)	An Easy Guide already exists
It’s silly but…point three…maybe it should say “lie back on a bed"		1			Wording amended to reflect this	
Be careful about making suggestions of nice things to do. Some people may not enjoy what you suggest or be able to afford it			1			This was not raised by any service user (several commented that they appreciated the suggestion, e.g.:

						aaah "treat yourself to something nice after your appointment" [likes that sentence, mention there has been a discussion about whether it's necessary to give specific examples, everyone will have a different idea] I think it's ok for her to leave it like that, for me it would be: "have a bubble bath")
There is not enough emphasis on how quick the test is / minimal level of discomfort / the experience of staff doing the test			1		This sentence was added: "The test only takes a few minutes. It might feel uncomfortable but should not be painful."	
Could mention that the "smear test can be sore/uncomfortable but it will be over quickly" - however that might put people off!		1			This sentence was added: "The test only takes a few minutes. It might feel uncomfortable but should not be painful."	
"If it's uncomfortable ask for a smaller speculum": can we avoid changing the size during the procedure and ask for a smaller size at the outset? they might otherwise be put off and					This sentence was removed. In the 'Booking your appointment' section the following is included: "If you think	

feel traumatised if they have experienced pain					the test may be uncomfortable, speak with the nurse beforehand. They can offer support."	
I'd like to know if the examination is at all painful, or if it's not painful at all (...) it may be handy to put it in the leaflet that it's not painful at all, that it may be uncomfortable but it's not painful (…) just to be constantly reassured that it's not going to be painful (…) Thinks more women would go [to smear test or other medical appointments] if they were reassured that it's not painful and if it hurts, how much does it hurt. It's uncomfortable especially if you're not in a sexual relationship and they might think their vagina is very small, they might think oh god is it gonna hurt (…) Pain is a factor that stops people from going	1				This sentence was added: "The test only takes a few minutes. It might feel uncomfortable but should not be painful."	
Perhaps reword 'tea and cake' to something more generic like 'treat yourself': such an issue with obesity in this group…		1			Was revised to: "Make plans after your appointment. You could treat yourself to something nice and relaxing."	
[queried whether we should take out the "tea and cake"		1				Was revised to: "Make plans after

suggestion] Doesn't have an issue with leaving in "treat yourself to something nice like tea and cake"!						your appointment. You could treat yourself to something nice and relaxing."
Instead of "go out for tea and cake" you could say "make sure you allow yourself time for a pleasurable activity", something that they feel happy with (e.g. going for a walk, shopping, seeing a friend)		1			Was revised to: "Make plans after your appointment. You could treat yourself to something nice and relaxing."	
“After your appointment”						
Could the word ‘worried’ be used instead of anxious?			1			This was not raised by any service user
Could add "share your concerns with your mental health professional"		1			Wording amended to reflect this	
Speak to your mental health professional (not nurse - teams are multidisciplinary) to get emotional support/do a debrief		1			Have included "mental health worker" (more inclusive in terms of roles)	
If the patient needs emotional support, you could add: "speak to your mental health nurse"		1			Have included "mental health worker" (more inclusive in terms of roles)	
Instead of "speak to your doctor" on the "Getting support" page, would add "or nurse"		1			Have included "mental health worker" (more inclusive in terms of roles)	
Instead of "speak to your mental health crisis team" [generally the mental health crisis team is for people who are at the point of admission],		1			Have included "mental health worker" (more inclusive in terms of roles)	

speak to your "community mental health worker/mental health professional"						
Would suggest adding "relative" [if you need support]	1				Wording amended to reflect this	
If I was feeling anxious I would probably talk to one of my support workers, maybe go to CAPE [Community Activities Projects Ealing: http://c-a-p-e.co.uk]. it would have to be someone I trust, and mainly at the moment the only people I think I could trust is the people in authorities so like Dr [psychiatrist] maybe or the nurse if she's alright if she's the same nurse but I wouldn't talk to a friend about it because I don't feel, some of these people, women, that I speak to they're just like oh it's one of them things, but i don't want to hear that, I want positivity I don't want negativity (...) I'd talk to a professional to be honest	1				Have added "trust": "Talk to a trusted friend, relative or health professional"	
Some people may have better relationships with primary care so take out "mental" in sentence "if you don't understand your results or have any questions, speak to your mental health professional"				1	Have added: "Talk to a trusted friend, relative or health professional"	

“Getting support”						
It's good to see the list of support agencies on pp. 13 and 14. Many of us are not so keen on SANEline, though, because SANE is felt to be particularly medical model in ethos. You may want to balance this by mentioning another helpline with a wider approach? You may also want to add helplines for people from BAME communities? There can be particular issues related to institutional racism within the NHS, or some particular sensitivities, e.g. for some Asian women?			1		Samaritans was added (not NHS related)	No issue with SANEline was raised during service user interviews
Add "local" to the sentence "Ask about support services in your [local] area"		1				The leaflet can be adapted to local services; the leaflet must suggest organisations and charities that are accessible nationally
Could there be space here for local areas to add in information about other places to access cervical screening? For example, sexual health clinics offer this service in our area and we have GP practices signed up to be ‘No			1			The leaflet can be adapted to local services; the leaflet must suggest organisations and charities that are accessible nationally

Fear' practices which offer additional support to women						
You could add MIND as a suggestion for contacting someone for emotional support, or "speak to your mental health professional" if you are anxious about results		1			Have included "mental health worker" (more inclusive in terms of roles)	Mind does not have a line for emotional support
Suggest taking out "these charities were suggested" and replace with "some women found it helpful to contact"				1	Have revised to: "You may prefer to speak to someone you don't know. Pages 14 and 15 list helplines you can call."	
Have the use of these phone numbers been sanctioned by the charities?				1	We have approval from every organisation included in the leaflet	
Think having SANEline is a good idea [described what they do, help with distress, anxiety] coz normally it's the day before [that you get anxious], could be the evening before people say oh do I go [to the appointment], what should I do! (…) Samaritans is more if you need to chat to a friend, if you're lonely, so MIND is better, they can help you with your anxiety or stress of something	1				Based on this feedback, we have modified the support page to ensure it's clear that women feel they can ask for support before and/or after their appointment	
Suggestions to the overall document						
Are you able to attach first names to quotes? It can help				1	Will use pseudonyms	

make it a bit more personal for the reader						
Reduce the amount of text in the leaflet/shorten the leaflet		1	1		Have tried to reduce wording in every section	
Perhaps the leaflet is a little long, might be overwhelming for patients who are quite anxious, but having said that there are no sections I would remove and also you don't want to undersell importance of the test		1			Have tried to reduce wording in every section	
Concentration is an issue with this group of patients, could we cut it down a little?		1			Have tried to reduce wording in every section	
You could run a scenario through people's minds [so and so is a teacher, and this is how she went about booking her apt etc.]: service users look at professionals for guidance		1				Not feasible for the leaflet but this idea was suggested for the animated video

Appendix 19. Sample page from Version 0.3 of the tool

Is there anything you think the nurse should know?
If you like, take this leaflet and show this page to the nurse.
Tick any box that is relevant to you:

- ☐ I have experienced trauma
- ☐ I am a survivor of female genital mutilation/cutting (FGM/C)
- ☐ I am a survivor of sexual violence
- ☐ I am embarrassed by my body
- ☐ My medication makes me shake
- ☐ It is hard to process information
- ☐ I don't like to feel exposed or naked
- ☐ Please warn me before you touch me
- ☐ I find it hard to leave my house
- ☐ I am afraid it will be painful
- ☐ I feel like I'm a burden
- ☐ I have a mental health condition:

  -
- ☐ These words can trigger anxiety attacks or flashbacks:

  -
- ☐ I hear voices
- ☐ I get distressed during a physical examination
- ☐ I feel judged
- ☐ I may start to cry or freeze
- ☐ I have scars
- ☐ I may pass out or faint
- ☐ I've had a bad smear test experience
- ☐ Waiting rooms make my symptoms worse
- ☐ Other: - - - - - - - - - - - - -

I want the door:

- locked ☐
- unlocked ☐

I would prefer a:

- soft touch ☐
- firm touch ☐

Appendix 20. Sample page from Version 0.4 of the tool

Booking your appointment

- **If you get anxious sitting in waiting rooms, let the receptionist know.** You can ask to book the first appointment of the day, so you aren't waiting long.
- **If you would prefer to be seen by a woman, ask for a female nurse.**
- **If it's helpful, ask for an appointment reminder.** This could be by text, post or telephone.
- **Tell the receptionist if you would like a chaperone.** This is a person, like another nurse, who can be there during the test.
- **You may feel you need more time for your cervical screening.** Ask the receptionist if you can book a longer appointment.

I have decided to book an appointment because:

- -

- -

"I put everything in my diary and important things have alarms on them as well."
Tracy

Appendix 21. Sample page from Version 1.0 of the tool

Getting support

Jo's Cervical Cancer Trust A national charity dedicated to eliminating cervical cancer. Has information and support about cervical screening, cell changes (abnormal cells) and cervical cancer – no question is too big or small. **www.jostrust.org.uk**

Helpline: 0808 802 8000
(For opening hours, visit www.jostrust.org.uk/helpline)
Ask the Expert: www.jostrust.org.uk/ask-expert

My Body Back (London and Glasgow)

Offers support to women to reclaim control of their body after sexual violence. Runs specialist clinics offering cervical screening and STI testing in London and Glasgow for women and trans men who have experienced sexual violence.
www.mybodybackproject.com Email: info@mybodybackproject.com

Samaritans

Samaritans is available round the clock, every single day of the year. You can talk to them any time you like, in your own way, about whatever's getting to you.
Call free any time on 116 123
Email jo@samaritans.org
Find your nearest branch at www.samaritans.org

SANE

National mental health helpline offering specialist emotional support to anyone affected by mental llness. **www.sane.org.uk**
SANEline: 0300 304 7000
(Every day, 4.30pm to 10.30pm)

Appendix 22. Decisional Conflict Scale (O'Connor, 1993)

Rec ref: 18/SC/0123
IRAS Project ID: 233934

[Add Trust and UWL logos]

BEFORE

My difficulty in making this choice

A. Which smear test option to you prefer? Please check ☑ one.

a. □ Option 1: I will attend my cervical screening appointment
b. □ Option 2: I will not attend my cervical screening appointment
c. □ Option 3: Unsure

B. Considering the option you prefer, please answer the following questions:

	Yes	Unsure	No
1. Do you know which options are available to you?			
2. Do you know the benefits of each option?			
3. Do you know the risks and side effects of each option?			
4. Are you clear about which benefits matter most to you?			
5. Are you clear about which risks and side effects matter most to you?			
6. Do you have enough support from others to make a choice?			
7. Are you choosing without pressure from others?			
8. Do you have enough advice to make a choice?			
9. Are you clear about the best choice for you?			
10. Do you feel sure about what to choose?			

AFTER

My difficulty in making this choice

C. Which smear test option to you prefer? Please check ☑ one.

a. □ Option 1: I will attend my cervical screening appointment
b. □ Option 2: I will not attend my cervical screening appointment
c. □ Option 3: Unsure

D. Considering the option you prefer, please answer the following questions:

	Yes	Unsure	No
11. Do you know which options are available to you?			
12. Do you know the benefits of each option?			
13. Do you know the risks and side effects of each option?			
14. Are you clear about which benefits matter most to you?			
15. Are you clear about which risks and side effects matter most to you?			
16. Do you have enough support from others to make a choice?			
17. Are you choosing without pressure from others?			
18. Do you have enough advice to make a choice?			
19. Are you clear about the best choice for you?			
20. Do you feel sure about what to choose?			

Appendix 23. Stage of Decision Making (O'Connor, 2000)

Rec ref: 18/SC/0123

IRAS Project ID: 233934

[Add Trust and UWL logos]

Stage of Decision Making

How far along are you with your decision?

(Check ☑ the box that applies to you and put the date at the top of the column).

	First time	Second time
Date (day/month/year)		
a. I have not yet thought about the options.		
b. I am considering the options.		
c. I am close to choosing one option.		
d. I have already made a choice.		

Appendix 24. Abstract for the West London NHS Trust R&D Conference (April 2019)

Oral Presentation

Title of presentation: The development, usability and acceptability of a cervical screening informed choice tool for women living with a severe mental illness and/or women who have experienced trauma

Author: Frédérique Lamontagne-Godwin

University of West London

Supervisors:

Professor Elizabeth Barley, University of Surrey

Dr Claire Henderson, King's College London

Professor Caroline Lafarge, University of West London

Abstract

Purpose/Objective: People with severe mental illness (SMI) die on average 10-20 years sooner than the general population, including from cancer. People with SMI face barriers to screening uptake and have poorer survival rates following diagnosis of cancer. The aim of this PhD research is to develop a cervical screening informed choice tool for women with SMI.

Research Questions: What are, if any, the specific design(s) and theoretical underpinning(s) of informed choice tools developed for people with SMI? What are service users' and clinicians' experiences of using the tool? Does the tool have any impact on service users' decisional conflict to attend screening?

Methods: A realist review of interventions to increase access to or uptake of physical health screening for people with SMI and a systematic review of informed choice tools for this

population have been conducted. A mixed-methods research design was used to develop the tool informed by these reviews. The usability and acceptability of the tool (paper leaflet) was tested by service users and clinicians in the West London NHS Trust and Dorset Healthcare University NHS foundation Trust, using semi-structured interviews and the think-aloud method. In May-June 2019, a preliminary evaluation of the tool's impact on decision-making to attend cervical screening will be conducted with service users.

Main findings: Feedback from a national Key Reference Group, service users, service user groups and clinicians demonstrates acceptability and usability of the tool. A dissemination strategy has been planned involving CCGs, Public Health England, NHS Trusts and cancer and mental health charities. An animated video to illustrate key information from the leaflet is currently being developed.

Significance for research and practice: The tool is designed to help women with SMI to make an informed decision about whether to attend cervical screening. It can be used by women themselves or as a tool for clinicians to help their clients. This may impact on screening uptake and mortality rates.